# Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Tomatoes; Draft Guidance

*Contains Nonbinding Recommendations*

July 2009

***DRAFT GUIDANCE***

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-1700.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Food Safety and Applied Nutrition**
**July 2009**

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*Contains Nonbinding Recommendations*
*Draft - Not for implementation*

# Guidance for Industry[1]
# Guide to Minimize Microbial Food Safety Hazards of Tomatoes

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

## I. Introduction

This guidance is intended to assist domestic firms and foreign firms exporting tomatoes to the United States (U.S.) by recommending practices to minimize the microbial food safety hazards of their products throughout the entire tomato supply chain. It identifies some, but not all, of the preventive measures that these firms may take to minimize these food safety hazards. This guidance document is not intended to serve as an action plan for any specific operation but should be viewed as a starting point. We encourage each firm from the farm level through the retail or foodservice level to assess the recommendations in this guidance and tailor its food safety practices to its particular operations by developing its own food safety program based on an assessment of the potential hazards that may be associated with its operations.

In addition, effective management of food safety requires that responsibility be clearly established among the many parties involved in the production of fresh produce. There may be many different permutations of ownership and business arrangements during the growing, harvesting packing, processing, and distribution of fresh and fresh-cut tomatoes. For this reason, it is important to identify which responsibilities rest with which parties, and to ensure that these responsibilities are clearly defined. For example, growers commonly contract with third parties to harvest their crops. Also, it is important that growers clearly identify which party is responsible for each applicable provision of this guidance, such as providing adequate toilet and handwashing facilities and worker training. Approaches to addressing responsibilities include delegating them to individuals within the firm and formally addressing them in contractual agreements when third parties are involved. Each party should be aware of its responsibilities to ensure microbial food safety hazards for tomatoes are minimized at each stage of the supply chain.

This guidance is intended to supplement existing FDA guidances, including the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (October 1998) (Good Agricultural Practices or GAPs Guide), which applies to fresh produce commodities, and the "Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables" (February 2008) (Fresh-cut Guide), which applies to fresh-cut produce. The

GAPs Guide provides recommendations for growers, packers, and shippers to use good agricultural practices in those areas over which they have control to prevent or minimize microbial food safety hazards in fresh produce. The Fresh-cut Guide provides recommendations to fresh-cut produce processing firms to enhance the safety of fresh-cut produce by minimizing the microbial food safety hazards relative to fresh-cut processing operations. The information included in this tomato-specific guidance is consistent with recommendations provided in the GAPs Guide and the Fresh-cut Guide.

FDA will continue to evaluate how best to measure the extent to which the recommendations in this and other federal guidance documents, as well as industry standards and practices, are effective in reducing microbial contamination in tomatoes. In particular, we are considering the extent to which more specific measures, such as metrics, should be utilized to help verify the implementation and efficacy of the federal recommendations and industry practices.

This guidance also specifically refers to FDA's regulations in 21 CFR part 1, subpart J on the establishment, maintenance, and availability of records and 21 CFR part 110 on current good manufacturing practices in manufacturing, packing, or holding human food. The recommendations in this guidance complement, but do not supersede, the requirements in those regulations and any associated recommendations. Further, the recommendations in this guidance do not affect the applicability of any other Federal and State requirements and your responsibility to comply with them.

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

## II. Background

From 1996 to 2008, eighty-two foodborne illness outbreaks were associated with the consumption of fresh produce. Of these produce-related outbreaks, 14 (17.1%) were linked to tomatoes: fresh-cut tomatoes were associated with 5 of the 14 tomato outbreaks (Ref. 1). During this time period, tomato-associated outbreaks accounted for 1,927 illnesses and 3 deaths. All of the tomato-associated outbreaks were due to bacterial agents. Many factors may play a role in the increased incidence and reporting of foodborne illness outbreaks that implicate fresh produce, such as an aging population that is susceptible to foodborne illness, an increase in global trade, a more complex supply chain, improved surveillance and detection of foodborne illness, improvements in epidemiological investigation, and increasingly better methods to detect pathogens (Refs. 2-8).

In 1998, to improve the safety of fresh produce, FDA issued its GAPs Guide. The GAPs Guide provides general food safety guidance on the production and packing of fresh produce for critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing, and storage of fresh produce. More specifically, the GAPs Guide alerts fruit and vegetable growers, packers and shippers to the potential microbiological hazards associated with various aspects of the production chain including land history, near-by land use, water quality, worker health and hygiene, pesticide and fertilizer use, equipment sanitation, and product transportation. Since its issuance, the GAPs Guide has been widely accepted.

In 2004, FDA issued the Produce Safety Action Plan (Action Plan) to minimize further foodborne illnesses associated with the consumption of fresh produce. This Action Plan incorporates "lessons learned" in implementing the GAPs Guide and expands upon other existing produce safety efforts. There are four general objectives set out in the Action Plan: (1) prevent contamination of fresh produce; (2) minimize the public health impact when contamination occurs; (3) improve communication between all parties; and (4) facilitate research relevant to the contamination of fresh produce. For each objective, the Action Plan identifies steps or actions that could contribute to the achievement of the objectives.

One of FDA's activities to implement the Action Plan is a multi-year Tomato Safety Initiative which began in 2007. This Initiative is a collaborative effort between the FDA and the state health and agriculture departments in Virginia and Florida, in cooperation with several universities and members of the produce industry. FDA and state collaborators developed the Tomato Safety Initiative in response to recurring *Salmonella* outbreaks associated with fresh and fresh-cut tomatoes. The Initiative is part of a risk-based strategy to reduce foodborne illnesses by focusing food safety efforts on specific products, practices, and growing areas that have been identified in past outbreak investigations. As the multi-year initiative continues, findings will be used to direct education, outreach, policy decisions, and research efforts. Findings will also be incorporated into future editions of this guidance, as appropriate.

In addition, there have been various other federal, state, and industry activities to minimize foodborne illness associated with tomato consumption. Some examples include:

- In 2006 and 2007, two forums on tomato safety were organized by academia. The first forum was sponsored by the University of Florida/Institute of Food and Agricultural Sciences and the Florida Tomato Exchange to bring together interested parties from industry, academia, and federal and state agencies in major tomato producing states. The second forum was sponsored by the University of Maryland Joint Institute of Food Safety and Nutrition (JIFSAN) and the University of Florida specifically to identify and prioritize research needs.
- In 2007, FDA held two public hearings on produce safety to seek comments and to discuss safer practices for growing, harvesting, packing, cooling, and shipping of fresh produce, including tomatoes (72 FR 8750, February 27, 2007).

Many of the steps set out in the Action Plan are relevant to the goal of reducing foodborne illness associated with tomatoes. One such step was to provide technical assistance to the industry in their efforts to develop commodity specific guidelines. In May 2006, the tomato and fresh produce industries issued the first edition of the "Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain" (Tomato Supply Chain Guidelines). The industries' Tomato Supply Chain Guidelines provide voluntary recommendations on food safety practices that are intended to minimize the microbiological hazards associated with fresh and fresh-cut tomato products. The 2006 Tomato Supply Chain Guidelines were subsequently reopened to incorporate enhancements, which resulted in the second edition of the "Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain" (Ref. 9) issued in July 2008. Subsequently, an industry-led workgroup reconvened to develop "Tomato Metrics," based on the 2008 Tomato Supply Chain Guidelines and programs in Florida and California. The Tomato Metrics are intended to assist auditors and operators along the supply chain in evaluating application of the Tomato Supply Chain Guidelines and other programs and in identifying corrective action options, if needed.

The agency is issuing this commodity-specific supply chain draft guidance for tomatoes, which is drawn primarily from the industry's second edition of the 2008 Tomato Supply Chain Guidelines, along with agency experience and information from other recent public and private programs. This FDA guidance supplements existing, but broader, recommendations in FDA's GAPs Guide and Fresh-cut Guide. Providing the recommendations in this guidance is one step among many that the agency is taking to minimize the microbiological hazards associated with fresh and fresh-cut tomato products. Lessons learned from foodborne illness outbreak investigations, information obtained from the various federal, state, and industry initiatives, and comments in response to this guidance will be used in finalizing this document.

## III. Scope and Use

This guidance covers the growing, harvesting, packing, processing, and distribution of tomatoes along with retail and food service preparation. Tomatoes may be grown and harvested either from an open field, shade house or a greenhouse; they may be packed or repacked either for the fresh market or for "fresh-cut/value-added processing" (i.e., minimally processed, such as by slicing or dicing, and then bagged or prepackaged); and then shipped either to foodservice operations or retail establishments where they are offered for sale to the consumer. The use of the term "tomatoes" in this document includes raw agricultural commodities and fresh-cut/value-added products unless otherwise specified.

This guidance addresses microbiological hazards that may be associated with tomatoes and potential control measures for such hazards; it does not specifically address chemical hazards. Consistent with the GAPs Guide and the Fresh-cut Guide, this guidance also emphasizes the importance of employing prevention rather than elimination strategies to address microbiological hazards. Once fresh produce has been contaminated, removing or killing the microbial pathogens while maintaining the fresh attribute of the produce is very difficult. Prevention of microbial contamination at all steps in the field-to-fork continuum is preferable to treatment to eliminate contamination after it has occurred.

Although this guidance to industry does not include a section specifically for consumers, it is critical that consumers also handle fresh produce safely and not contaminate it. Interested parties may refer to "Safe Handling of Raw Produce and Fresh-Squeezed Fruit and Vegetable Juices."

In the sections that follow, the tomato "field-to-fork" continuum has been broken down into the following operations: (1) open field production, (2) harvest practices, (3) field packing, (4) greenhouse production, (5) packinghouse, (6) repacking and other distribution operations, (7) fresh-cut/value-added processing, and (8) foodservice and retail. A diagram of the supply flow through these unit operations is provided in Figure 1. Within each operation, general recommendations regarding issues relevant to that operation are made to raise awareness and allow individuals and firms involved in the field-to-fork continuum to consider actions that are appropriate to their operations. The identified issues in each section focus only on tomatoes, as defined above, and may or may not apply to other specialty crops. Firms are encouraged to use this document to evaluate their operations and develop their own individual company food safety programs.

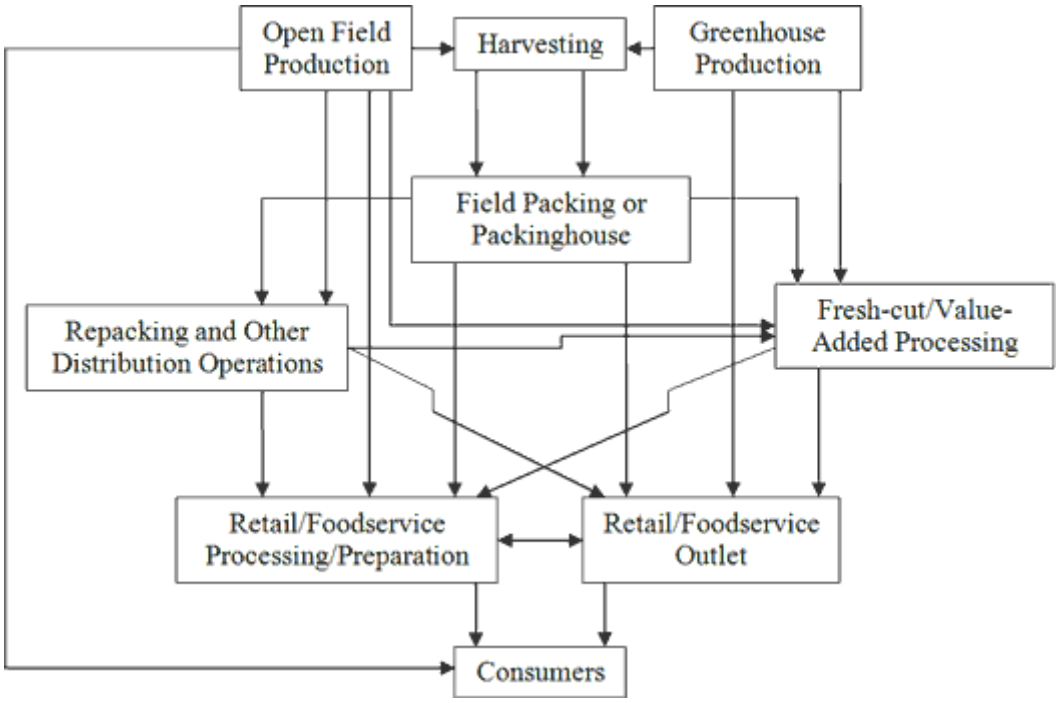


**Figure 1. General Supply Chain Flow for Tomatoes**

The supply flow diagram above provides an overview of the many paths a fresh tomato may take prior to reaching the end user. For any production lot of tomatoes, the supply chain may be simple, very complex, or somewhere in between. For example, in some instances tomatoes may go from open field production and harvest directly to the consumer. Alternatively, tomatoes may be handled by a number of entities, beginning with open field or greenhouse production, harvesting, packing, multiple repackers and distributors, and finally to a retail outlet (or fresh-cut/value added processing then retail) before being offered to the consumer. Note: Figure 1 is reprinted from the "Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain." July 2008 (Ref. 9). (Reprinted with permission).

## IV. Definitions

**Adequate** means that which is needed to accomplish the intended purpose in keeping with good practice.

**Clean** means that food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.

**Control** means to manage the conditions of an operation to be consistent with established criteria, and to follow correct procedures.

**Control Measure** is any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.

**Current Good Manufacturing Practices (CGMPs)** refers to the CGMP regulations that are found in 21 CFR 110 **(**Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding Human Food).

**Culling** means to remove any product that shows signs of physical damage (such as skin breaks or decay).

**Environmental Assessment** means an evaluation of the growing environment, taking into consideration factors including topography, hydrology and geographical features, climatic conditions, land history, near-by land use, agricultural water, and domestic animal and wildlife presence to evaluate any safety risks that may affect the potential for the tomatoes to be contaminated. Environmental assessments may be conducted prior to planting, during production, and immediately prior to harvest.

**Facilities** are the buildings and other physical structures used for, or in connection with, the harvesting, washing, sorting, storing, packing, processing, labeling, holding, or transporting of fresh produce.

**Food-contact surfaces** are those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. "Food-contact surfaces" include equipment, such as containers and conveyor belts, which contact fresh produce, whether used in harvesting, postharvesting, or packaging operations. "Food-contact surfaces" do not include items such as tractors, forklifts, hand trucks, and pallets that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.

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

For different commodities, the fresh-cut form may vary. For example, the form of fresh-cut tomatoes may be sliced or diced, while the fresh-cut form of carrots may be peeled and cut into julienned sticks or baby carrots.

**GAPs Guide** refers to the guidelines set forth in the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," which was issued by FDA in 1998.

**Hazard** means a biological, chemical, or physical agent that is reasonably likely to cause human illness or injury in the absence of its control.

**Human Pathogen** means a microorganism capable of causing disease or injury to people. This is different from a plant pathogen which may cause disease to plants.

**Nontransporter** means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

**Operator** means the person or persons who have day-to-day responsibility for the production, harvesting, washing, sorting, cooling, packing, processing, shipping, or transportation of tomatoes, and responsibility for management of all employees who are involved in each of these activities.

**Packinghouse** means a facility where raw agricultural commodities are washed, waxed, or sorted and packed in commercial containers, e.g., boxes, totes, or consumer packages.

**Pest** means any animal or insect of public health importance including birds, rodents, cockroaches, flies, and larvae that may carry pathogens that can contaminate food.

**Raw Agricultural Commodity (RAC)** means any food in its raw or natural state, including all fruits and vegetables that are washed, colored, or otherwise treated in the unpeeled natural form prior to marketing.

**Ready-to-eat (RTE)** describes foods that need no further preparation (e.g., washing or cutting) before eating.

**Risk** is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Sanitary Survey** is an inspection of the entire water system, including water source, facilities, and equipment, for the purpose of identifying conditions that may result in microbial contamination.

## V. Open Field Production

The development of good agricultural practices for field tomato production involves many elements of the field production system, such as assessing the field site, near-by land use, agricultural inputs (e.g., irrigation water and fertilizers), worker health and hygiene, and production practices. Microbial contamination associated with tomatoes can occur from any number of sources. The evaluation of these risks and their management are important to proper food safety procedures in the production of fresh tomatoes.

### 1. Environmental Assessments and Risk Reduction Practices

An environmental assessment is intended to identify any food safety issues in the environment in and around the produce field that may increase the risk of contaminating the crop with pathogens. An environmental assessment evaluates topography, hydrology, geographical features, climatic conditions, land history, near-by land use, agricultural water, and domestic and wildlife presence.

FDA recommends:

- Determining the previous usage of land. Assessing and mitigating conditions that may pose a food safety risk in and near production fields.
- Conducting an environmental assessment (e.g., considering topography, land history, near-by land use, and domestic animal and wildlife presence) including a consideration of the potential for flooding to create conditions that may pose a food safety risk. Flooding is the uncontrolled introduction of large amounts of water into the production area, which is different from flood irrigation.
- Locating tomato fields away from any area that may receive run-off or drainage from an animal operation or any other source of contamination that may pose a food safety risk.
- Avoiding, preventing, or minimizing run-off into the tomato field from any animal operation or other conditions that may pose a food safety risk.

- Avoiding the harvest of tomatoes in areas that have been contaminated by run-off from an animal operation or other potential source of contamination.
- Documenting procedures used to mitigate risks.

**2. Animal Exclusion**

FDA recommends:

- Excluding domestic animals and livestock from tomato fields.
- Taking measures to minimize wildlife presence such as using barriers or other deterrents, minimizing wildlife attractants and opportunities for harborage, redirecting wildlife to non-sensitive areas, and employing other methods identified by wildlife experts.
- Taking measures to remove, or prevent the harvest of, any potentially contaminated tomato product if animal intrusion into a production area is detected.

**3. Near-by Land Use**

FDA recommends:

- Assessing near-by land for activities or conditions that may pose a food safety risk for tomatoes such as livestock, wildlife, landfills, sewage treatment facilities, and chemical plants.
- Taking appropriate measures to mitigate any identified food safety hazards such as establishing berms, fences, ditches, or buffer zones.

**4. Water Use in the Field**

Water used in production and harvest operations may contaminate tomatoes if it contains human pathogens and contacts edible portions of tomatoes or by means of water-to-soil and soil-to-tomato contact.

<u>Water Sources</u>

FDA recommends:

- Identifying the source(s) of water for each field and agricultural use (e.g., irrigation and crop protection spray).
- Preparing a description of the irrigation water system. Using maps, photographs, drawings, or other means to communicate the location of permanent fixtures and the flow of the water system (including any water captured for re-use). Documenting permanent fixtures, including wells, gates reservoirs, valves, returns, and other above ground features that make up a complete irrigation system so as to enable location on the field. Documenting water sources and the production sites they may serve.
- Performing a sanitary survey prior to the use of water in agricultural operations to determine if the quality of water meets applicable State and local requirements.
- Identifying potential sources of contamination of agricultural water at its source and during distribution and holding.
- Ensuring that any well used is properly designed, located, constructed, and maintained in such a way as to prevent potential contamination of the water.

- Utilizing appropriate water treatment methods and identifying alternate water sources, if necessary, to ensure water quality is sufficient for its intended use.
- Recognizing the potential for facilities and equipment used for holding and distributing agricultural water to be a source of contamination.

Water Use

FDA recommends:

- Ensuring any water used for agricultural purposes (e.g., irrigation, frost control, or crop protection spray) is not contaminated with animal or human feces and is of sufficient microbial quality for its intended purpose.
- Ensuring that water used for application to edible portions of tomato crops, such as foliar applications, is of appropriate microbial quality for its intended use, particularly for water applications close to the time of harvest or during harvesting. Obtaining water that is of appropriate microbial quality at the source or treating and testing the water as needed to ensure appropriate quality.
- Evaluating risks of using reclaimed (primary or secondary) water, including use in operations such as road dust abatement. Reclaimed water may be subject to State and local requirements.

Microbial Monitoring

FDA recommends:

- Maintaining records for sampling and testing protocol, and test results, if testing for microbial quality of agricultural water is conducted.
- Establishing a monitoring frequency for water appropriate to the source and other relevant factors.
- Establishing and following corrective actions if testing indicates a potential problem.

**5. Hygienic Practices in Tomato Fields**

FDA recommends that firms ensure production crews, visitors, and other field personnel are aware of and follow food safety risk reduction principles.

Policies and Employee Training

FDA recommends:

- Developing and implementing employee hygiene practices consistent with GAPs.
- Educating all employees about safe product handling and personal hygiene at the time of hire and at periodic intervals for reinforcement.
- Documenting training sessions, with records of topics covered, dates, names, and signatures of those in attendance.
- Routinely checking (e.g., daily, weekly, monthly, or quarterly, as appropriate to the practice) to verify and document compliance with the firm's worker hygiene and sanitation policies and practices.

Handwashing and Toilet Facilities

FDA recommends:

- Providing sanitary facilities (i.e., toilet and hand washing facilities) for all field workers and visitors during planting, harvesting, and other field activities. Providing a minimum of one toilet facility per twenty employees and making the facilities readily accessible (i.e., located not more than ¼ (0.25) mile from all employees).
- Designing, locating, operating, and servicing toilet facilities in a manner that does not create a risk of contamination to tomatoes or the production field.
- Providing appropriate hand washing stations, including collection of handwashing water, with toilet and handwashing facilities.
- Maintaining toilet and handwashing facilities in a clean and sanitary condition and properly stocking with soap, water for handwashing that is of sufficient microbial quality, single-use towels, and toilet paper. Keeping a record of cleaning and servicing of such facilities.
- Labeling and segregating toilet facility cleaning equipment so these items do not pose a risk of contamination.
- Implementing policies that encourage hand washing with soap and water at the appropriate time, such as before starting work, after breaks, using the toilet, sneezing, or coughing.

Health

FDA recommends:

- Restricting employees, visitors, and other field personnel with symptoms of potentially infectious illness such as diarrhea, fever, or vomiting from working with or being in the vicinity of tomatoes or food-contact surfaces.
- Establishing a policy that employees, visitors, and other field personnel with open sores, cuts, burns, boils, and similar conditions report the conditions to a supervisor before working or entering the tomato field. The supervisor should determine whether the employee should be allowed to work with or in the vicinity of tomatoes or food-contact surfaces.

Hygiene

FDA recommends:

- Designating areas for eating, drinking, smoking, breaks, and storing personal effects, for employees, visitors, and other field personnel.
- Establishing a policy prohibiting eating, drinking, chewing gum, and using tobacco in tomato fields except in clearly designated areas.
- Providing drinking water with either fountains or single-use containers. Handling drinking water containers in a manner that prevents them from becoming sources of contamination.
- Establishing a policy appropriate to the operation regarding employees wearing jewelry in the field.
- Ensuring that employees, visitors, and other field personnel wear clean and suitable outer garments. Considering, as appropriate to the operation, using hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and requiring empty pockets above the waist.

- Developing other good food handling techniques, as appropriate to the specific tomato operation, to prevent cross-contamination.

**6. Gloves**

If tomatoes are handled with bare hands, hand washing procedures should be documented. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for hand contact with tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

Reusable Gloves

If reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.
- Issuing appropriately cleaned and sanitized gloves regularly and as necessary. For example, cleaning and sanitizing or changing reusable gloves after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

**7. Tomato Production Practices**

FDA recommends assessing the risk of all production inputs to reduce contamination risk.

Chemical or Other Non-organic Fertilizers

FDA recommends:

- Following manufacturer's instructions for usage and storage.
- Properly storing and labeling all fertilizers.
- Ensuring that fertilizer mixing areas are not a contamination hazard to tomatoes.

Soil Amendments Containing Manure, Composts, or Biosolids

Soil amendments may be incorporated into agricultural soils to add organic and inorganic nutrients to the soil as well as to reduce soil compaction. Soil amendments can contain animal

manure or can be composed primarily of plant materials. Soil amendments that contain animal manure are of concern because human pathogens may persist in animal manure (particularly aged manure or inadequately composted soil amendments) for weeks or months (Refs. 10, 11), and even longer under certain conditions (Refs. 12-14). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival. However, the persistence of human pathogens in agricultural soils depends on many factors such as pH, temperature, soil type, and native microflora and continues to be under extensive investigation (Refs. 15-18). Tomatoes may be contaminated through contact with contaminated soil amendments if soil amendments containing human pathogens are applied after plant emergence. Field soil contaminated with human pathogens may also provide a means of tomato contamination. Therefore, establishing suitably conservative pre-plant application intervals, appropriate for specific regional and field conditions, is an effective step towards minimizing risk.

FDA recommends:

- Refraining from use of raw animal manure.
- Verifying that any soil amendment that does not contain animal manure has documentation (e.g., ingredient list, statement of identity, or letter of guaranty) from the producer or seller stating that it is manure free.
- Implementing management plans that ensure that the use of soil amendments does not pose a significant potential human pathogens hazard (e.g., timing of applications, storage location, source and quality, and transport).
- Verifying the time and temperature process used during the composting process to ensure that the potential of human pathogens being carried in the composted materials is reduced, controlled, or eliminated.
- Maximizing the time interval between the soil amendment application and time to harvest.
- Implementing practices that reduce, control, or eliminate likely contamination of tomato fields that may be in close proximity to on-farm stacking of manure.
- Using soil amendment application techniques that reduce, control, or eliminate the likely contamination of surface water or edible crops being grown in adjacent fields.
- Segregating equipment used for soil amendment applications such as compost or using effective means of equipment cleaning and sanitation before subsequent use.
- Minimizing the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing tomatoes or adjacent edible crops.
- Obtaining documentation from compost suppliers including composition, dates of treatment, methods utilized (e.g., time/temperature management, turning, and steps to minimize cross-contamination of finished compost by raw or in-process product), and any test results or process verification data demonstrating that any compost, manure or biosolids applied to tomato fields have been sufficiently treated to reduce pathogens that may be present.

Crop Protection Sprays (Pesticides)

It is important to be familiar with and follow all applicable requirements for crop protection sprays. Note that certain chemicals that are not required to be registered with EPA as pesticides may be regulated by FDA as food-contact substances.

FDA recommends:

- Ensuring that water used for spray applications of pesticides, particularly if used close to the time of harvesting, is not contaminated and is of sufficient microbial quality for this purpose. Note that many chemicals in crop protection sprays do not reduce or eliminate any pathogens present in the water used to mix the sprays.
- To ensure that water is of appropriate quality for its intended use, obtaining water from an appropriate source, or treating and testing water on a regular basis and as needed to ensure appropriate quality.
- Having crop protection sprays applied by trained and, where applicable, licensed personnel.
- Developing Standard Operating Procedures (SOPs) for crop protection spray applicators, application equipment, storage, and usage (including handling, mixing, and diluting).
- Ensuring that the use of pesticides complies with all EPA requirements and any other federal, state or local requirements, including following approved directions for use on labeling.
- Maintaining and keeping current records of use of crop protection sprays.
- Storing crop protection sprays properly and securely. Disposing of empty pesticide containers according to the labeling and regulatory requirements.
- Ensuring that loading, diluting, and mixing of crop protection sprays is done in a manner that will not contaminate the water source or tomatoes.
- Ensuring that the cleaning of crop protection spray equipment is done in a manner that will not contaminate the water source or tomatoes.
- Following precautions to protect against contamination of tomatoes, food-contact surfaces, and packaging materials when mixing or applying crop protection sprays.

**8. Equipment and Containers**

FDA recommends:

- Cleaning and sanitizing any containers and food contact surfaces of other equipment at a frequency sufficient to prevent the surfaces from becoming a source of contamination.
- Constructing reusable containers and food-contact equipment, and utensils of materials that can be easily cleaned and sanitized.
- Cleaning and sanitizing containers, bins, food-contact equipment, and utensils at regularly scheduled intervals during use (e.g., daily), or more often as needed, to remove sand, grit, dirt, and other residue.
- Establishing routine cleaning and sanitizing procedures (i.e., sanitation standard operating procedures (SSOPs)).
- Maintaining all equipment and surfaces in such a way as to minimize contamination of, and injury to, tomatoes.
- Removing broken or damaged containers that are not easily cleanable from food contact use. Clearly marking containers if they are retained for other uses (e.g., trash).

**9. Documentation and Records**

As a general practice, it is important that firms that produce and harvest tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping

requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; field, facility and vehicle sanitation; and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and times; name of person(s) who completed the record; the location of the field and the location in the field, if applicable; and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations" (issued on April 2001 and updated on June 2006) (Guide to Traceback Investigations) to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## VI. Harvest Practices

Tomatoes for fresh and fresh-cut markets should be produced according to the GAPs Guide and the recommendations described in the prior section on Open Field Production.

## 1. Preharvest Environmental Assessment

A preharvest environmental assessment provides an important opportunity to evaluate any safety risks that may have an impact on the potential for the tomatoes to be contaminated. The manager or other responsible person should ensure that an assessment is performed as close as practicable to the beginning of harvest (e.g., not more than 5 days prior to the beginning of harvest).

FDA recommends:

- Conducting an environmental assessment (e.g., considering topography, land history, near-by land use, agricultural water, domestic animal and wildlife presence) and reviewing field environments, records of assessments, and corrective actions.
- Verifying that tomato fields are located away from any area that can receive runoff or drainage from an animal operation or any other source of contamination that may pose a food safety risk.
- Verifying that domestic animals and livestock have been excluded from tomato fields.
- Verifying that wildlife presence has been minimized to the extent practicable.
- Taking measures to remove, or prevent the harvest of, any potentially contaminated product if animal intrusion is detected.
- Verifying that run-off from any animal operation or any other source of contamination that may pose a food safety risk has been prevented.
- Verifying that the source of water for irrigation for tomatoes is documented and is of sufficient quality.
- Following procedures to identify risks and mitigating those risks, and ensuring that these procedures have been documented, followed, and reviewed.
- Assessing tomato fields to ensure that new risk factors have not emerged (e.g., when tomatoes are harvested multiple times).

## 2. Hygienic Practices in Tomato Fields

FDA recommends that harvest contractors and crews are trained in and follow food safety risk reduction principles. This includes recognizing and reporting any food safety risks or potential contamination observed during the tomato harvest operation.

<u>Policies and Employee Training</u>

FDA recommends:

- Developing and implementing employee hygiene practices consistent with GAPs.
- Educating all employees regarding safe product handling and personal hygiene education at time of hire with reinforcement at periodic intervals.
- Documenting training sessions, with records kept of topics covered, dates, names and signatures of those in attendance.
- Routinely checking (e.g., daily, weekly, monthly, quarterly, or as appropriate to the practice) to verify and document compliance with the firm's worker hygiene and sanitation policies and practices.

<u>Handwashing and Toilet Facilities</u>

FDA recommends:

- Providing sanitary facilities (i.e., toilet and handwashing facilities) for all field workers and visitors during harvest. Providing a minimum of one toilet facility per twenty employees and making the facilities readily accessible, located not more than ¼ (0.25) mile from all employees.
- Locating and servicing toilet facilities in a manner that does not create a risk of contamination in the tomato field.
- Providing appropriate hand washing stations in or near toilet facilities.
- Maintaining toilet facilities in a clean and sanitary condition and adequately stocking with soap, water for handwashing that is of sufficient microbial quality, single-use towels, and toilet paper. Keeping a record of cleaning and servicing.
- Labeling and segregating restroom cleaning equipment so these items do not to pose a risk of contamination.
- Implementing policies that encourage hand washing with soap and water at the appropriate time such as before starting work, after breaks, using the toilet, sneezing, or coughing.

Health

FDA recommends:

- Restricting employees, visitors, and other field personnel with symptoms of potentially infectious illness such as diarrhea, fever, or vomiting from working with or being in the vicinity of tomatoes or food-contact surfaces.
- Establishing a policy that employees, visitors, and other field personnel with open sores, cuts, burns, boils, and similar conditions report the conditions to a supervisor before working or entering the tomato field. The supervisor should determine whether the employee should be allowed to work with or in the vicinity of tomatoes or food-contact surfaces.

Hygiene

FDA recommends:

- Designating areas for eating, drinking, smoking, breaks, and storing personal effects for employees, visitors, and other field personnel.
- Establishing a policy prohibiting eating, drinking, chewing gum, and using tobacco in tomato fields except in clearly designated areas.
- Providing drinking water with either fountains or single-use containers. Handling drinking water containers in a manner that prevents them from becoming a source of contamination.
- Establishing a policy, appropriate to the operation, regarding wearing jewelry in the field.
- Ensuring that employees, visitors, and other field personnel wear clean and suitable outer garments. Considering, as appropriate to the operation, using hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and requiring empty pockets above the waist.
- Developing other good food handling techniques as appropriate to the specific tomato operation to prevent cross-contamination.

**3. Gloves**

If tomatoes are handled with bare hands, hand washing procedures should be documented. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for harvesting of tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

Reusable Gloves

If reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.
- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing, or changing reusable gloves after meals, smoking, using toilet facilities, or any process involving handling of materials other than tomatoes where the gloves may become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

**4. Equipment and Containers**

FDA recommends:

- Cleaning and sanitizing any surface or equipment intended to contact fresh tomatoes (i.e., any food-contact surface), at a frequency sufficient to prevent the surface or equipment from becoming a source of contamination.
- Constructing reusable containers and food-contact equipment, and utensils of impervious materials that can be cleaned and sanitized.
- Checking any tomato containers that are received back from a packing house for cleanliness prior to use.
- Cleaning and sanitizing harvest containers, bins, food-contact equipment, and utensils at regular intervals during use (e.g., daily), or more often as needed, to remove sand, grit, dirt, and other residue.
- Establishing routine cleaning and sanitizing procedures (i.e., standard operating procedures).
- Maintaining all equipment and surfaces in such a way as to minimize the risk of contamination of, and injury to, tomatoes.
- Maintaining records of cleaning procedures and their implementation.

- Removing broken or damaged containers that are not easily cleanable from food contact use. If they are retained for other uses (e.g., trash), clearly marking them for their intended use.

**5. Debris Removal**

FDA recommends that dirt, stems, and leaves be removed from tomatoes to the degree practicable in the field, in a manner that does not pose a risk of contamination.

**6. Exclusion from Harvest**

FDA recommends:

- Ensuring that tomatoes that have fallen from the plant to the ground (i.e., "drops") are not harvested.
- Ensuring that tomatoes that have been in contact with any fecal material are not harvested.
- Removing or preventing the harvest of any potentially contaminated product if animal intrusion is detected.
- Excluding damaged, soft, or decaying tomatoes from the harvest to the degree possible.

**7. Culling, Sorting and Removing of Damaged Tomatoes**

Damaged, soft, or decaying tomatoes provide a potential source of contamination. Thus, FDA recommends removing damaged, soft, or decaying tomatoes, to the degree possible.

**8. Transportation**

FDA recommends:

- Ensuring that transportation vehicles are sufficiently clean so that they do not become a source of contamination.
- Inspecting transportation vehicles for cleanliness, odors, and visible dirt and debris before loading. Cleaning and/or sanitizing the vehicles, if necessary, prior to loading with tomatoes.
- Determining prior loads for non-dedicated vehicles that are used for transporting tomatoes. Cleaning and sanitizing vehicles prior to use if there is any doubt about prior loads transported or if there is risk from microbial contamination, such as from raw animal proteins, garbage, or other refuse.

**9. Documentation and Records**

As a general practice, it is important that firms that produce and harvest tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate

subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination if product implicated in an outbreak is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; field, facility and vehicle sanitation; and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and times; name of person(s) who completed the record; the location of the field and the location in the field, if applicable; and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product from its original source through intermediate sources to its final recipient and tracking product from the final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## VII. Field Packing

Field packing of tomatoes includes any practices to grade, sort, size, clean, pack, or palletize tomatoes into containers for commerce. Field packing is conducted in the tomato field and may not include cleaning or washing. Field-packed tomatoes are not intended to be transferred to a packinghouse for washing or further handling. FDA recommends that care should be taken to ensure that practices and conditions during tomato field packing do not contribute to microbial contamination.

## 1. Prerequisites for Field Packing Tomatoes

FDA recommends that the packing of tomatoes in the field follow recommendations included in this document in Section V, Open Field Production, including hygienic practices, harvesting procedures, and record keeping, in addition to the recommendations further detailed in this section on field packing.

## 2. Field Packing Tomatoes

Hygienic practices for employees of field-packed tomato operations should be established, followed, and verified by supervisors to ensure the safety of the harvested product. If independent operators are packing in the field, either in lieu of or in addition to the employees (such as following a crew harvesting tomatoes destined for a packing facility), these independent operators should follow the same standards for food safety and hygiene as any employee handling tomatoes in the field. Field-packed tomatoes may not undergo any further cleaning or sanitizing. If materials such as cloths are used repeatedly for cleaning the tomatoes, steps should be taken to ensure that these cloths or other materials do not become sources of contamination.

FDA recommends:

- Applying extra care to cull and remove any damaged tomatoes during field packing because such packing of tomatoes generally occurs with mature ripe tomatoes.
- Establishing a policy to ensure hygienic practices for field-packed tomato operations and maintaining records showing compliance with the firm's policy.
- Establishing and maintaining documentation of employee training regarding hygienic procedures for the field packing of tomatoes.

## 3. Gloves

If tomatoes are packed with bare hands, hand washing procedures should be documented as indicated above. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

<u>Disposable Gloves</u>

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for field packing of tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

<u>Reusable Gloves</u>

If reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.

- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing or changing reusable gloves after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

**4. Debris Removal**

FDA recommends that dirt, stems, and leaves be removed from tomatoes to the degree practicable in the field, in a manner that does not pose a risk of contamination.

**5. Exclusion from Harvest**

FDA recommends:

- Ensuring that tomatoes that have fallen from the plant to the ground (i.e., "drops") are not harvested.
- Ensuring that tomatoes that have been in contact with any fecal material are not harvested.
- Removing or preventing the harvest of any potentially contaminated product if animal intrusion is detected.
- Excluding damaged, soft, or decaying tomatoes from the harvest to the degree possible.

**6. Cleaning Procedures**

It is common practice to remove visible dirt and debris from a final packing of tomatoes. The manner in which tomatoes packed in the field are cleaned is important because it may be a source of either direct contamination or cross-contamination with potentially harmful microorganisms.

<u>Cleaning Materials Including Cloths</u>

If materials, such as cloths, are used repeatedly for cleaning tomatoes, steps should be taken to ensure they do not become a source of direct or cross-contamination.

FDA recommends:

- Establishing a policy for the use and sanitization of cloths used for cleaning tomatoes during packing in the field.
- Ensuring that water of sufficient microbial quality is used if cloths are moistened to facilitate cleaning. Not moistening cloths by repeated immersion in a bucket.
- Replacing cleaning cloths at suitable intervals to ensure that they do not become a source of contamination.
- Ensuring that cloths are washed and sanitized before reuse, which is the responsibility of the field packing company. Not relying on workers to take cloths home for cleaning and sanitizing, unless by a designated responsible party.
- Training workers in the safe and sanitary use of cloths.

FDA recommends documenting all cleaning procedures.

**7. Containers for Field Packing Tomatoes**

All containers should be stored in a manner to prevent contamination. Special attention should be given to contamination risks from rodents, birds, and other pests.

FDA recommends:

- Inspecting all containers upon arrival and storing in a clean manner.
- Ensuring that containers used for field packing are not stored in the field unless protected from potential contamination.
- Distinguishing picking and packing containers from those serving other purposes.
- Prohibiting the reuse of single-use containers, e.g., corrugated boxes, for the field packing of tomatoes.
- Cleaning and sanitizing reusable containers, such as reusable plastic containers (RPC), by a documented procedure before reuse.
- Protecting containers from direct contact with the ground.
- Properly labeling reusable containers with information on current use sufficient to facilitate product tracing. Removing or otherwise marking inaccurate labels on containers before reuse so that all visible information is accurate and not misleading.

**8. Equipment and Picking Containers in the Field**

FDA recommends:

- Cleaning and sanitizing any surface that touches tomatoes in the field (i.e., a food-contact surface) at a frequency sufficient to prevent the surface from becoming a source of contamination.
- Cleaning and sanitizing harvest containers, food-contact surfaces, and utensils at regular intervals during use (e.g., daily or more often as needed), to remove sand, grit, dirt, and other residue.

**9. Washing or Otherwise Treating Tomatoes in the Field**

Washing produce can reduce but not necessarily eliminate pathogens if they are present. In addition, if such washing is done without sufficient controls (e.g., water quality maintenance), washing and other treatments could inadvertently create food safety hazards. Performing postharvest practices in the field (rather than in an enclosed facility) may also introduce the need for additional controls. If washing or other postharvest treatments are conducted in the field to clean or reduce microbial levels, FDA recommends:

- Ensuring that the water used for washing or otherwise treating tomatoes is of sufficient microbial quality for this purpose and contains sufficient disinfectant to prevent cross-contamination. Monitoring the water disinfectant at a frequency sufficient to maintain sanitary conditions.
- Maintaining water temperature at least 10°F warmer than the pulp temperature of the tomato.
- Ensuring that chemical products used for water disinfectants or otherwise used as pesticides in other postharvest treatments are appropriately registered by EPA for such

use, and are used in accordance with all label or labeling instructions, including those for concentration and contact time.
- Establishing and maintaining a procedure for washing and other postharvest treatments of tomatoes that does not contribute to contamination or cross-contamination. Maintaining records that document implementation of the procedure.

**10. Transportation**

FDA recommends:

- Ensuring that transportation vehicles are sufficiently clean so that they do not become a source of contamination.
- Inspecting transportation vehicles for cleanliness, odors, and visible dirt and debris before loading. Cleaning and/or sanitizing the vehicles, if necessary, prior to loading with tomatoes.
- Determining prior loads for non-dedicated vehicles that are used for transporting tomatoes. Cleaning and sanitizing vehicles prior to use if there is any doubt about prior loads transported or if there is risk from microbial contamination, such as from raw animal proteins, garbage, or other refuse.

**11. Storage**

FDA recommends that any area used to collect or store tomatoes packed in the field should be maintained in a clean and sanitary manner.

**12. Labeling**

FDA recommends:

- Accurately labeling all containers with an adequately descriptive commodity name (e.g., round tomatoes or plum tomatoes), field packer firm name, and information sufficient to facilitate product tracing, including the identification of the grower; ranch and field location; harvest crew; and date of harvest or field pack.
- Removing inaccurate labels prior to packing.
- Labeling market-ready containers to identify when the product has been field packed without washing.

**13. Documentation and Records**

As a general practice, it is important that firms that produce and harvest tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination in the event product implicated in an outbreak investigation is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; field, facility and vehicle sanitation; and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient and tracing product from final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## VIII. Greenhouse Production

For the purposes of this guidance, a greenhouse is presumed to be enclosed. Note that this section does not apply to shade houses or other open structures. Shade houses and other open structures should follow recommendations in Section V, Open Field Production. Harvesting of greenhouse tomatoes should follow the recommendations in Section VI, Harvest Practices.

### 1. Greenhouse

FDA recommends:

- Utilizing a foot dip station at all entrances or other measure to prevent the introduction of harmful microorganisms or agents. Documenting the sanitizer used and monitoring to ensure sanitizers are maintained at effective levels.

- Ensuring that soil or other growth medium used in the greenhouse is suitable for its intended purpose and does not pose a risk of contamination.
- Ensuring that adequate hand washing stations with single-use towels are available. Designing these stations to drain or capture all waste water in a manner that does not pose a contamination hazard to the greenhouse.
- Posting conspicuous signs that communicate food safety policies and food safety principles. Using signs that are multilingual, pictorial, or both, as appropriate to the workforce.
- Maintaining covered trash cans in adequate number and location.
- Labeling, handling, and storing cleaning compounds, sanitizers, pesticides, and all other chemicals in a manner that does not pose a risk of contamination to tomatoes, food-contact surfaces, and packaging materials. Keeping food-grade and non-food grade chemicals separate to minimize the risk of accidentally substituting one for the other. These products must be used in accordance with manufacturers' label instructions and all federal, state, and local requirements.

**2. Grounds**

Operator Controlled Grounds

The grounds about a greenhouse under the control of the operator should be kept in a condition that will protect against contamination of tomatoes.

FDA recommends:

- Properly storing equipment, removing litter and waste, and cutting weeds and grass within the immediate vicinity of the facility because these may constitute an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not present a risk of contamination in areas where tomatoes are exposed.
- Adequately draining areas that may contribute to the risk of contamination of tomatoes by seepage, foot-borne filth, or providing an animal attractant or breeding place for pests.
- Operating systems for waste treatment and disposal in an adequate manner so that these systems do not present a risk of contamination in areas where tomatoes are exposed.

Grounds Outside of Operator Control

If the greenhouse grounds are bordered by land that is not under the operator's control, and those grounds are not maintained in the manner described above, care should be exercised by the greenhouse operator to assess and mitigate the effects of pests, dirt, and filth that may present a risk of contamination. Potential hazards include livestock, wildlife, and landfills. Although hazards may originate from land that is outside of operator control, there are mitigation measures that may be within the control of the operator.

FDA recommends:

- Conducting an environmental assessment (e.g., considering topography, land history, near-by land use, and domestic animal and wildlife presence), as appropriate to the grounds of the operation, the surrounding land use, and the environment.

- Taking appropriate control measures to minimize any potential food safety hazards, which may include using berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards.
- Establishing and maintaining records of the assessment, results, and any mitigation measures used to minimize hazards.

**3. Pest Control**

Rodent, Birds, Amphibians (e.g., Tree Frogs), Reptiles, and Other Facility Pests

FDA recommends:

- Taking effective measures to exclude pests from the greenhouse and protecting against the contamination of tomatoes by pests.
- Ensuring that the use of insecticides or rodenticides is consistent with EPA requirements and that precautions are followed to protect against the contamination of tomatoes, food-contact surfaces, and packaging materials by these insecticides and rodenticides.
- Ensuring that no domestic or other animals are permitted in areas where tomatoes are grown, packed, handled, or stored.

Crop Protection Sprays (Pesticides)

It is important to be familiar with and follow all applicable requirements for crop protection sprays. Note that certain chemicals that are not required to be registered with EPA as pesticides may be regulated by FDA as food-contact substances.

FDA recommends:

- Ensuring that water used for spray applications of pesticides, particularly if used close to the time of harvesting, is not contaminated and is of sufficient microbial quality for this purpose. Note that many chemicals in crop protection sprays do not reduce or eliminate any pathogens present in the water used to mix the sprays.
- To ensure that water is of appropriate quality for its intended use, obtaining water from an appropriate source, or treating and testing water on a regular basis and as needed to ensure appropriate quality.
- Having crop protection sprays applied by trained and, where applicable, licensed personnel.
- Developing Standard Operating Procedures (SOPs) for crop protection spray applicators, application equipment, storage, and usage (including handling, mixing, and diluting).
- Ensuring that the use of pesticides complies with all EPA requirements and any other federal, state and local requirements, including following approved directions for use on labeling.
- Maintaining and keeping current records of use of crop protection sprays.
- Storing crop protection sprays properly and securely. Disposing of empty containers according to the labeling and regulatory requirements.
- Ensuring that loading, diluting, and mixing of crop protection sprays is done in a manner that will not contaminate the water source or tomatoes.
- Ensuring that the cleaning of crop protection spray equipment is done in a manner that will not contaminate the water source or tomatoes.

- Following precautions to protect against contamination of tomatoes, food-contact surfaces, and packaging materials when mixing or applying crop protection sprays.

**4. Pre-harvest Agricultural Water**

It is important to ensure that any water that contacts the edible portion of the crop, especially close to harvest as may happen with tomatoes, is not contaminated. Note that many chemicals in crop protection sprays do not reduce or eliminate pathogens that may already be present in the water used to mix sprays.

Water Sources

FDA recommends:

- Obtaining water that is of appropriate microbial quality at the source or treating and testing the water to as needed to ensure appropriate quality.
- Documenting the source of agricultural water used for tomato production.
- Identifying potential sources of contamination of agricultural water at its source and during distribution and holding.
- Ensuring that any well used is properly designed, constructed, and maintained in such a way as to protect from potential contamination of the water.
- Regularly maintaining and protecting water source(s), storage, and distribution systems from potential sources of contamination. Removing any material that may pose a risk of contamination (such as trash or plant material) from the water source.
- Ensuring the use of appropriate backflow prevention devices (e.g., air gaps or backflow valves) to protect water quality at the source and during distribution and use.
- Ensuring that any water for agricultural use is not contaminated with animal or human feces.
- Ensuring that non-foliar agricultural water is not contaminated and is of sufficient microbial quality for this purpose.
- Ensuring that water is not contaminated and is of sufficient microbial quality for any foliar application to tomatoes.
- Using appropriate water treatment methods, where necessary, to ensure water quality is sufficient for its intended use.
- Protecting water source(s) from cross-contamination from fertilizers, pesticides, and waste water.

Microbial Monitoring

FDA recommends:

- Maintaining records of sampling protocol and test results if testing for microbial quality of agricultural waters.
- Establishing and following corrective actions if testing indicates a potential problem.
- Establishing a monitoring frequency for water that is appropriate given the source.

**5. Fertilizers**

FDA recommends assessing the risk of all production inputs to reduce the potential of contamination.

Chemical or Other Non-organic Fertilizer

FDA recommends:

- Following manufacturer's instructions for usage and storage.
- Properly storing and labeling all fertilizers.
- Ensuring that fertilizer mixing areas are not a contamination hazard to tomatoes.

Fertilizers Containing Manure, Composts, and Biosolids

FDA recommends:

- Ensuring that untreated manure is not used to fertilize tomatoes. If compost, manure, or biosolids are used as a component of greenhouse growth medium, properly treating them.
- Documenting composition, dates of treatment, methods utilized, application dates, and any test results or process verification data if treated compost, manure, or biosolids are used.

Additionally, FDA recommends that inert substrates should be treated in such a way as not to pose a risk of contamination.

**6. Equipment and Containers**

FDA recommends:

- Cleaning and sanitizing any surfaces or equipment intended to touch fresh tomatoes (i.e., a food-contact surface), at a frequency sufficient to prevent the surfaces from becoming a source of contamination.
- Using reusable containers and food-contact equipment, and utensils that are constructed of impervious materials and may be easily cleaned and sanitized.
- Cleaning and sanitizing containers, bins, food-contact equipment, and utensils at regular intervals during use (e.g., daily), or more often as needed, to remove sand, grit, dirt, and other residue.
- Establishing and maintaining written SSOPs for cleaning and sanitizing procedures.
- Maintaining all equipment and food-contact surfaces in such a way as to minimize contamination of, and injury to, tomatoes.
- Removing broken or damaged containers that are not easily cleanable from food contact use. Clearly marking any such containers for their intended use (e.g., trash).

**7. Debris Removal**

FDA recommends that dirt, stems, and leaves be removed from tomatoes to the degree practicable in the field, in a manner that does not pose a risk of contamination.

**8. Employee Hygiene and Training**

FDA recommends:

- Developing and implementing employee hygiene practices consistent with GAPs.

- Providing all employees with safe tomato handling and personal hygiene education at time of hire and periodically reinforcing that education.
- Establishing and maintaining records that document training sessions including topics covered, date, names, and signatures of those in attendance.
- Routinely checking (e.g., daily, weekly, monthly, or quarterly, as appropriate to the practice) to verify and document compliance with the firm's worker hygiene and sanitation policies and practices.

**9. Handwashing and Toilet Facilities**

Toilet Facilities

FDA recommends:

- Ensuring that restrooms are available to all personnel (at least one toilet for every 20 employees) and located in proximity to the greenhouse. The restrooms should not constitute a risk of contamination. Restrooms should not open directly into greenhouse production areas. Restrooms that do open directly into greenhouse production areas should be equipped with self-closing door mechanisms or have a maze-type entrance/exit.
- Maintaining toilet facilities in a clean and sanitary condition and adequately stocking with soap, water for handwashing that is of sufficient quality for this purpose (including hot water where available), single-use towels, and toilet paper.
- Labeling and segregating toilet facility cleaning equipment so these items do not pose a risk of contamination.
- Keeping a record of restroom cleaning duties, including a record that shows when such cleaning has been completed.
- Posting signs in restrooms that describe appropriate handwashing techniques. Making these signs multilingual, pictorial, or both, as appropriate to the workforce.

Handwashing Facilities

FDA recommends establishing handwashing facilities that are adequate in number and location, and are furnished with running water that is maintained at a suitable temperature.

FDA recommends:

- Establishing handwashing facilities and, where appropriate, hand-sanitizing facilities at each location where good sanitary practices require use of such facilities.
- Providing adequate soap and water for handwashing that is of sufficient quality for this purpose (including hot water where available).
- Providing adequate single-use towels or air drying devices.
- Posting handwashing signs at all stations that describe appropriate handwashing techniques. Using signs that are multilingual, pictorial, or both, as appropriate to the workforce.
- Utilizing refuse receptacles that are constructed and maintained in a manner that protects against the risk of contamination of tomatoes.
- Utilizing methods to ensure that handwashing water is captured, disposed of, or drained in a manner that prevents risk of contamination to the environment.

**10. Handwashing Practices**

FDA recommends:

- Developing policies that encourage hand washing with soap and water at the appropriate time, such as before starting work, after breaks, after visiting locker rooms, after using restrooms, after sneezing, after coughing, after touching any unsanitary surface or material or anytime hands become soiled.
- Using sanitizers only after proper washing of hands.
- Establishing a policy that use of gloves when contacting tomatoes or food-contact surfaces does not a replace good handwashing practices. Replacing single-use gloves and washing and sanitizing reusable gloves whenever they become contaminated or soiled.

**11. Gloves**

If tomatoes are handled with bare hands, hand washing procedures should be documented as indicated above. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for handling tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

Reusable Gloves

If reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.
- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing or changing reusable gloves after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

**12. Health**

FDA recommends:

- Implementing a worker health policy that restricts employees and visitors with symptoms of potentially infectious illness such as diarrhea, fever, or vomiting from working with or being in the vicinity of tomatoes or food-contact surfaces.

- Establishing a policy that employees, visitors, and other field personnel with open sores, cuts, burns, boils, and similar conditions report the conditions to a supervisor before working or entering the tomato field. The supervisor should determine whether the employee should be allowed to work with or in the vicinity of tomatoes or food-contact surfaces.

**13. Other Employee Hygienic Practices**

FDA recommends:

- Designating areas for employee activities, such as eating, drinking, smoking, breaks, and storing personal effects for employees, visitors, and other personnel.
- Establishing a policy prohibiting eating, drinking, chewing gum, and using tobacco in the greenhouses except in clearly designated areas.
- Providing drinking water by either fountains or single-use containers. Handling drinking water containers in a manner that prevents them from becoming a source of contamination.
- Establishing a policy appropriate to the operation regarding wearing jewelry in the workplace.
- Ensuring that employees, visitors, and other personnel wear clean and suitable outer garments. Considering, as appropriate to the operation, hair restraints, plastic aprons and sleeves, restricting nail polish or false nails, and requiring pockets above the waist to be empty.
- Establishing a policy that outer garments and gloves should be changed after cleaning drains, restrooms or other activities that may result in contamination.
- Developing additional good food handling techniques as appropriate to the specific operation to prevent cross-contamination.

**14. Cleaning and Washing Procedures**

When tomatoes are cleaned with cloths or by washing, the manner in which tomatoes packed in the greenhouse are cleaned is of importance since it can be a source of either direct contamination or cross-contamination with potentially harmful microorganisms.

<u>Cleaning Materials Including Cloths</u>

If materials, such as cloths, are used repeatedly for cleaning tomatoes, steps should be taken to ensure they do not become a source of direct or cross-contamination.

FDA recommends:

- Establishing a policy for the use and sanitization of cloths used for cleaning.
- Ensuring that water of sufficient microbial quality is used if cloths are moistened with water to facilitate cleaning. Not moistening cloths by repeated immersion in a bucket of water.
- Replacing cleaning cloths at suitable intervals to ensure that they do not become a source of contamination.
- Ensuring that cloths are adequately washed and sanitized before re-use, which is the responsibility of the greenhouse operator.
- Training workers in the safe and sanitary use of cloths.

Washing Tomatoes

If tomatoes are washed and packed in a green house, ensuring and maintaining the quality of postharvest water that contacts them during flume transport, cleaning, grading, and surface treatment applications is widely recognized as an essential pathogen control point. FDA recommends that a packinghouse operator use water from an adequate source and that the water be of sufficient microbial quality for the particular postharvest processes to be performed. FDA further recommends that greenhouses washing, or applying other post-harvest treatments, to tomatoes follow Current Good Manufacturing Practices (CGMPs) as appropriate to the operation to ensure that all water is of sufficient microbial quality throughout all operations from start-up to end of use. Water used in postharvest operations should be changed as often as necessary and as appropriate for the given operation. For example, water used in the first dump tank may need to be changed more frequently than water used in subsequent processes.

Internalization of bacteria into the stem scar and other openings in the tomato flesh, such as wounds or microabrasions, has been demonstrated with tomatoes submerged in water that is cooler in temperature than the pulp of the tomato. As the tomato cools, a vacuum is created causing water, and potentially pathogens, to be drawn through such openings and into the flesh of the tomato. Therefore, water temperature relative to pulp temperature, and water quality, are critical considerations for maintaining the safety of the product.

FDA recommends:

- Following CGMPs to ensure that all water is of sufficient microbial quality at start-up and throughout all packing operations.
- Establishing and maintaining documentation of microbial test results, water treatment, and water quality monitoring, as appropriate, for the water source.
- Cleaning the dump tank and changing the water daily or more often as needed.
- Ensuring that untreated surface waters are not used in greenhouse for postharvest contact operations where water contacts tomatoes.
- Ensuring that water used in postharvest processes is of sufficient microbial quality for this purpose and contains sufficient disinfectant to prevent cross-contamination.
- Monitoring water disinfectant at a frequency sufficient to maintain sanitary conditions.
- Ensuring that tomatoes are not immersed in cold water as a cooling technique.
- Maintaining water temperature at least 10ºF warmer than the pulp temperature of the tomato. Monitoring water temperature and pulp temperature of tomatoes as needed to reduce potential contamination.
- Ensuring that tomatoes are not submerged in more than one foot of water for more than two minutes total time.
- Where water quality maintenance is based on manually monitoring chlorine levels, establishing a schedule for monitoring and documenting free chlorine and pH as often as needed to ensure that sufficient water quality is maintained. Total chlorine measurements may not accurately represent antimicrobial effectiveness, so it is critical that pH be monitored and maintained in the range of 6.5-7.5 to ensure that chlorine is effective. Measuring devices should have sufficient precision to ensure levels are within established limits and accuracy of such devices should be verified periodically.
- If water quality maintenance is based on Oxidation Reduction Potential (ORP), verifying monitoring oxidant concentrations against a chemical test that measures disinfectant levels (and pH, where applicable) as often as needed to ensure that sufficient water quality is maintained.

- If other water disinfectants are used, ensuring such products are registered with the EPA for their intended use and following manufacturer recommendations for monitoring and limits, as appropriate.
- Calibrating electronic monitoring devices at a frequency sufficient to ensure continuous accuracy of the device.

**15. Trash and Tomato Waste Disposal**

FDA recommends that trash and tomato waste be handled, stored, and disposed of in a manner that 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.

**16. Packing Materials**

FDA recommends that the greenhouse operator minimize the risk of contamination by adopting policies that address the following issues:

- All packaging material should be inspected upon arrival and stored in a clean and sanitary manner.
- Pallets used to keep finished product off the floor should be visibly clean.
- Bins, trays, and pallets should be maintained in clean operational condition according to the firm's SOPs.
- Bins, trays, and pallets should be stored in a secure, clean location.
- Finished produce containers should be distinguished from those serving other purposes.
- Keeping storage locations free of pests and regularly monitoring them for evidence of pest infestation, which includes rodents, birds, or insects.
- Cleaning and sanitizing reusable containers, such as reusable plastic containers (RPC) by a documented procedure before re-use.
- Protecting containers from direct contact with the ground.
- Properly labeling re-usable containers with information on current use sufficient to facilitate product tracing. Re-usable containers should have inaccurate labels removed or otherwise marked before re-use so that all visible information is accurate and not misleading.

**17. Labeling**

If tomatoes are packed in a greenhouse facility, FDA recommends:

- Accurately labeling all containers with an adequately descriptive commodity name (e.g., round tomatoes or plum tomatoes), field packer firm name, and information sufficient to facilitate product tracing, including the identification of the grower, ranch and field location, harvest crew, and date of harvest, or field pack.
- Removing inaccurate labels prior to packing.
- Labeling market-ready containers to identify when the product has been packed without washing.

**18. Transportation**

FDA recommends:

- Ensuring that transportation vehicles are sufficiently clean so that they do not become a source of contamination.
- Inspecting transportation vehicles for cleanliness, odors, and visible dirt and debris before loading. Cleaning and/or sanitizing the vehicles, if necessary, prior to loading with tomatoes.
- Determining prior loads for non-dedicated vehicles that are used for transporting tomatoes. Cleaning and sanitizing vehicles prior to use if there is any doubt about prior loads transported or if there is risk from microbial contamination, such as from raw animal proteins, garbage, or other refuse.

**19. Documentation and Records**

As a general practice, it is important that firms that produce and harvest tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination in the event product implicated in an outbreak investigation is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; water use; grounds, facility and vehicle sanitation; and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of water sources and use; testing water quality; treating water; monitoring for signs of animal intrusion; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and times, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient, and tracking product from the final

recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## IX. Packinghouse

A well designed and managed tomato packinghouse and food safety program can reduce the risk of microbial contamination. However, poor or inconsistent food safety practices can greatly increase this risk. Sanitary conditions and proper food safety practices are important to tomato safety.

The needs of each tomato packinghouse may vary due to location, environment, the volume of tomatoes handled, the type of tomatoes handled, local requirements, and many other variables, but the overall goal of an effective tomato packinghouse food safety program is to minimize risk of contamination. There may be multiple strategies for effectively dealing with individual hazards.

FDA recommends that a facility that packs fresh tomatoes follow the requirements for buildings and grounds, packing, and holding of foods, equipment, and utensils, sanitary facilities and controls, sanitary operations and processes and controls as provided for under 21 CFR Part 110, as appropriate to the facility. This recommendation applies to all aspects of the packinghouse, including ripening and holding rooms.

### 1. Grounds

<u>Operator Controlled Grounds</u>

The grounds around a packinghouse under the control of the operator should be kept in a condition that will protect against contamination of tomatoes. FDA recommends the following:

- Properly storing equipment, removing litter and waste, and cutting weeds and grass within the immediate vicinity of the packing facility because these may constitute an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where tomatoes are exposed.
- Adequately draining areas of water or other liquids that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.
- 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.

<u>Grounds Outside of Operator Control</u>

If the packinghouse grounds are bordered by land that is not under the operator's control and these grounds are not maintained in the manner described above, care should be exercised by the packinghouse operator to assess and mitigate the effects of pests, dirt, and filth that may present a source of potential contamination. Potential hazards include livestock, wildlife, and landfills. While hazards may originate from land that is outside of operator control, there are mitigation measures that may be within the control of the operator.

FDA recommends:

- Conducting an environmental assessment (e.g., considering topography, land history, near-by land use, and domestic animal and wildlife presence), as appropriate to the operation, of the surrounding land use and the environment.
- Taking appropriate control measures to minimize any potential food safety hazards which may include ditches, buffer zones, or other strategies to effectively mitigate any hazards. Keeping records of the measures used.
- Establishing and maintaining records of the assessment, results, and any mitigation measures used to control hazards.

**2. General Maintenance**

Facility Maintenance

FDA recommends:

- Maintaining buildings, fixtures, and other physical facilities of the packinghouse in a clean and sanitary condition and keeping these facilities in sufficient repair to prevent tomatoes from becoming contaminated. Cleaning and sanitizing utensils and equipment in a manner that protects against contamination of tomatoes, food-contact surfaces, and packaging materials.
- Establishing 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 tomatoes. A cleaning schedule should be a part of SSOPs, and an increased volume of tomatoes handled may require more frequent attention to cleaning. Minor surface injuries to tomatoes, 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.
- Labeling, handling, and storing cleaning compounds, sanitizers, pesticides and all other chemicals in a manner that does not pose a risk of contamination to tomatoes, food-contact surfaces, and packaging materials. Keeping food-grade and non-food grade chemicals separate to minimize the risk of accidentally substituting one for the other. These products must be used in accordance with manufacturers' label instructions and all federal, state, and local requirements.

Pest Control

Packinghouse pests include rodents, birds, amphibians (e.g., tree frogs), and reptiles.

FDA recommends:

- Implementing a pest control program to protect the packinghouse from pests.

- Ensuring that the use of insecticides or rodenticides follows precautions to protect against the contamination of tomatoes, food-contact surfaces, and packaging materials. Using only non-toxic traps and pest control devices inside the packinghouse.
- Ensuring that domestic animals and other animals are not in areas where tomatoes are grown, packed, handled, or stored.

Sanitation of Food-Contact Surfaces

FDA recommends:

- Cleaning and sanitizing all food-contact surfaces, including utensils and food-contact surfaces of equipment, in keeping with an established, documented SSOP to protect against contamination of the tomatoes.
- Cleaning and sanitizing non-food-contact surfaces in accordance with the facility's SSOP, or more frequently if necessary, to protect tomatoes from contamination.
- Storing single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) in appropriate containers and handling, dispensing, using, and disposing of these articles in a manner that protects against contamination of tomatoes and food-contact surfaces.
- Ensuring that sanitizing products are registered for their intended use and cleaning and sanitizing products are used according to manufacturers' label instructions and any applicable federal, state, or local law.
- Storing cleaned and sanitized equipment with food-contact surfaces and utensils in a location and manner that protects food-contact surfaces from contamination.

**3. Water Supply and Plumbing**

Water Supply

FDA recommends:

- Ensuring that the water supply is of sufficient quality for the intended operation and is derived from an adequate source. Ensuring that any water that contacts tomatoes or food-contact surfaces, whether intended or unintended, is not contaminated and is of sufficient microbial quality for this purpose.
- Treating and testing the water as needed to ensure appropriate quality.
- Ensuring that running water is available at suitable temperature and at suitable volume where it is needed for packing, cleaning, sanitation, and employee hygiene.

Plumbing

FDA recommends that plumbing should be of adequate size and design and adequately installed and maintained to:

- Supply sufficient quantities of water to required locations throughout the packinghouse.
- 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 otherwise create an unsanitary condition.

- 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.
- 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-contact surfaces. Appropriate backflow prevention devices (e.g., air gaps or backflow valves) should be used to protect water quality at the source and during distribution and use.
- Properly dispose of sewage and wastewater into appropriate sewer, septic, or alternative systems in a manner that does not pose a risk of contamination.

**4. Trash and Tomato Waste Disposal**

FDA recommends that trash and tomato waste be handled, stored, and disposed of 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.

**5. Receiving**

FDA recommends:

- Obtaining tomatoes from suppliers that follow GAPs and the recommendations in this guidance.
- Establishing a procedure for inspecting and accepting or rejecting incoming loads of tomatoes.
- Ensuring that incoming documentation provides sufficient information to facilitate product tracing and establishing a system to maintain that documentation.

**6. Packaging Materials**

FDA recommends:

- Inspecting packaging material upon arrival and ensuring that it is free from contamination. Storing packing materials so as to prevent contamination.
- Keeping storage locations free of rodents, birds, or insects and regularly monitoring such locations for evidence of pest infestation.
- Keeping pallets used to keep finished product off the floor visibly clean.
- Maintaining bins, trays, and pallets in clean operational condition and storing them in a secure, clean location according to established SOPs.
- Distinguishing finished produce containers from those serving other purposes.

**7. Postharvest Water Use**

Adequate water quality, both in the field and at the packinghouse, is critical to achieving and maintaining microbial safety. When tomatoes are washed, ensuring and maintaining the quality of postharvest water that contacts fresh tomatoes during flume transport, cleaning, grading, and surface treatment applications is widely recognized as an essential pathogen control point.

<u>Water Quality</u>

FDA recommends that packinghouses follow Current Good Manufacturing Practices (CGMPs) as appropriate to the operation to ensure that all water is of sufficient microbial quality throughout all operations from start-up to end of use. Water used in postharvest operations should be changed as often as necessary for the given operation. For example, water used in the first dump tank may need to be changed more frequently than water used in subsequent processes.

FDA recommends:

- Following CGMPs to ensure that all water is of sufficient microbial quality at start-up and throughout all packing operations.
- Establishing and maintaining documentation of microbial test results, water treatment, and water quality monitoring, as appropriate, for the water source.
- Cleaning the dump tank and changing the water daily and more often as needed.
- Ensuring that untreated surface waters are not used in packinghouse or other postharvest contact operations.

Water Quality

FDA recommends that a packinghouse operator use water from an adequate source and that the water be of sufficient microbial quality for the particular postharvest processes to be performed. Packinghouses in some states may be subject to additional state or local water quality requirements.

Temperature and Disinfection of Water Supplies Used in Postharvest Applications

Internalization of bacteria into the stem scar and other openings in the tomato flesh, such as wounds or microabrasions, has been demonstrated with tomatoes submerged in water that is cooler in temperature than the pulp of the tomato. As the tomato cools, a vacuum is created causing water, and potentially pathogens, to be drawn through such openings and into the flesh of the tomato. Therefore, water temperature relative to pulp temperature, and water quality, are critical considerations for maintaining the safety of the product.

FDA recommends:

- Ensuring that water used in postharvest processes is of sufficient microbial quality for this purpose and contains sufficient disinfectant to prevent cross-contamination. Monitoring water disinfectant at a frequency sufficient to maintain sanitary conditions.
- Ensuring that tomatoes are not immersed in cold water as a cooling technique.
- Maintaining water temperature at least 10ºF warmer than the pulp temperature of the tomato. Monitoring water temperature and pulp temperature of tomatoes as needed to reduce potential contamination.
- Ensuring that tomatoes are not submerged in more than one foot of water for more than two minutes total time.
- Where water quality maintenance is based on manually monitoring chlorine levels, establishing a schedule for monitoring and documenting free chlorine and pH as often as needed to ensure that sufficient water quality is maintained. Total chlorine measurements may not accurately represent antimicrobial effectiveness so it is critical that pH be monitored and maintained in the range of 6.5-7.5 to ensure that chlorine is effective. Measuring devices should have sufficient precision to ensure levels are within established limits and accuracy of such devices should be verified periodically.

- If water quality maintenance is based on Oxidation Reduction Potential (ORP), verifying monitoring oxidant concentrations against a chemical test that measures disinfectant levels (and pH, where applicable) as often as needed to ensure that sufficient water quality is maintained.
- If other water disinfectants are used, ensuring such products are registered with the EPA for their intended use and following manufacturer recommendations for monitoring and limits, as appropriate.
- Calibrating electronic monitoring devices at a frequency sufficient to ensure continuous accuracy of the device.
- Documenting all wash and water quality maintenance.

Removal of Injured or Damaged Tomatoes

FDA recommends establishing procedures to identify and remove injured (soft or decaying) or damaged tomatoes from dump tanks to reduce microbial contamination. To the degree possible, injured or damaged tomatoes should be removed as soon as possible after detection.

**8. Employee Hygiene and Training**

FDA recommends:

- Developing and implementing employee hygiene practices consistent with CGMPs.
- Providing all employees with safe tomato handling and personal hygiene education at time of hire and periodically reinforcing that education.
- Establishing and maintaining records that document training sessions including topics covered, date of trainings, names, and signatures of those in attendance.
- Routinely checking (e.g., daily, weekly, monthly, or quarterly, as appropriate to the practice) to verify and document compliance with the firm's worker hygiene and sanitation policies and practices.

**9. Handwashing and Toilet Facilities**

Toilet Facilities

FDA recommends:

- Ensuring that restrooms are available to all personnel (at least one toilet for every 20 employees) and located in proximity to food handling areas, but not so close that they constitute a potential source of contamination. As a general practice, restrooms should not open directly into food handling areas. Equipping restrooms that do open directly into food handling areas with self-closing door mechanisms or using a maze-type entrance/exit.
- Maintaining toilet facilities in a clean and sanitary condition and adequately stocking with soap, water for handwashing that is of sufficient microbial quality for this purpose (including hot water where available), single-use towels, and toilet paper.
- Keeping a record of restroom cleaning duties performed and when such cleaning was completed.
- Labeling restroom cleaning equipment and segregating so as not to pose a risk of contamination.
- Posting signs in restrooms that describe appropriate handwashing techniques. Using signs that are multilingual, pictorial, or both, as appropriate to the workforce.

Handwashing Facilities

FDA recommends establishing handwashing facilities that are adequate in number and location, and furnished with running water at a suitable temperature.

FDA recommends:

- Establishing handwashing facilities and, where appropriate, hand-sanitizing facilities at each location where good sanitary practices require use of such facilities.
- Providing adequate soap and water for handwashing that is of sufficient quality for this purpose (including hot water where available).
- Providing adequate single-use towels or air drying devices.
- Posting handwashing signs at all stations that describe appropriate handwashing techniques. Using signs that are multilingual, pictorial, or both, as appropriate to the workforce.
- Utilizing refuse receptacles that are constructed and maintained in a manner that protects against the risk of contamination of tomatoes.
- Utilizing methods to ensure that handwashing water is captured, disposed of, or drained in a manner that prevents risk of contamination of the environment.

**10. Handwashing Practices**

FDA recommends:

- Developing policies that encourage hand washing with soap and water at the appropriate time, such as before starting work, after breaks, after visiting the locker rooms, after using the restrooms, after sneezing, after coughing, after touching any unsanitary surface or material, or anytime hands become soiled.
- Using sanitizers only after proper handwashing.
- Developing policies that clearly communicate that glove use is not a replacement for good handwashing practices if gloves are used when contacting tomatoes or food-contact surfaces. Replacing single-use gloves and washing and sanitizing reusable gloves whenever they become contaminated or soiled.

**11. Health**

FDA recommends:

- Implementing a worker health policy that restricts employees and visitors with symptoms of potentially infectious illness such as diarrhea, fever, or vomiting from working with or being in the vicinity of tomatoes or food-contact surfaces.
- Establishing a policy that employees, visitors, and other field personnel with open sores, cuts, burns, boils, and similar conditions report the conditions to a supervisor before working or entering the tomato field. The supervisor should determine whether the employee should be allowed to work with or in the vicinity of tomatoes or food-contact surfaces.

**12. Other Hygienic Practices**

FDA recommends:

- Designating areas for employee activities such as eating, drinking, smoking, breaks, and storing personal effects.
- Establishing a policy prohibiting eating, drinking, chewing gum, and using tobacco in fields or facilities except in clearly designated areas.
- Providing drinking water by either fountains or single-use containers. Handling drinking water containers in a manner that prevents them from becoming a source of contamination.
- Establishing a policy appropriate to the operation regarding wearing jewelry in the workplace.
- Ensuring that employees wearing clean and suitable outer garments. Considering, as appropriate to the operation, requiring hair restraints, use of plastic aprons and sleeves, restricting nail polish or false nails, and requiring empty pockets above the waist.
- Changing outer garments and gloves after cleaning drains, restrooms, or other activities that may result in contamination.
- Developing additional good food handling techniques as appropriate to the specific operation to prevent cross-contamination.

**13. Gloves**

If tomatoes are handled with bare hands, hand washing procedures should be documented as indicated above. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for packing of tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

Reusable Gloves

If reusable gloves are used for some operations, e.g., waxing tomatoes.

FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized.
- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing or changing reusable gloves after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

**14. Storage, Ripening Rooms and Distribution Facilities**

FDA recommends:

- Maintaining storage ripening rooms and distribution facilities in a clean and sanitary condition, with debris minimized. Systematically and periodically cleaning, and sanitizing all walls, floors, ceilings, and other surfaces to avoid the build-up of mold or other potential contaminants.
- Storing product on pallets to avoid direct contact between the tomatoes and the floor.
- Maintaining a perimeter between pallets and walls to facilitate visual inspection of pest control and sanitation.
- Clearly identifying and segregating rejected product, or product on hold, from other products.
- Excluding trash or waste from the storage or ripening rooms.

**15. Transportation**

FDA recommends:

- Ensuring that transportation vehicles are sufficiently clean so that they do not become a source of contamination.
- Inspecting transportation vehicles for cleanliness, odors, and visible dirt and debris before loading. Cleaning and/or sanitizing the vehicles, if necessary, prior to loading with tomatoes.
- Determining prior loads for non-dedicated vehicles that are used for transporting tomatoes. Cleaning and sanitizing vehicles prior to use if there is any doubt about prior loads transported or if there is risk from microbial contamination, such as from raw animal proteins, garbage, or other refuse.

**16. Labeling**

FDA recommends:

- Using new corrugated containers that are accurately labeled with commodity name, (e.g., round tomatoes or plum tomatoes) packinghouse firm name, and lot identification sufficient to permit accurate product tracing.
- Removing or correcting inaccurate labels from previously used containers.

**17. Documentation and Records**

As a general practice, it is important that firms involved in postharvest tomato operations maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an "adequate description" of the food, including brand

name and specific variety, and provides an example of "romaine lettuce, not just lettuce." The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination in the event product implicated in an outbreak investigation is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; water use; grounds, facility and vehicle sanitation; and employee training programs.
- Maintaining records for significant activities performed, such as testing water quality and disinfectant level; monitoring storage temperatures; equipment, container, and vehicle sanitation; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient, and tracking product from the final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## X. Repacking and Other Distribution Operations

All firms involved in the supply chain that handle tomatoes, including repacking facilities, terminal markets and other facilities have an important role in ensuring and maintaining the safety and tracing of tomatoes.

### 1. Prerequisites for Repacking of Tomatoes

In addition to the recommendations described in this Section on repacking, anyone involved in repacking tomatoes should consider the recommendations in this guidance located in

Section IX, Packinghouse, including receiving, water supply and plumbing, trash and tomato waste disposal, general maintenance, packaging material requirements, postharvest washing of fresh tomatoes, employee hygiene, written policies and employee training, handwashing and toilet facilities, handwashing practices, health policies, other hygienic practices, gloves, storage and ripening rooms, product labeling/tracing, and transportation, as appropriate to their operation (e.g., if a repacker washes tomatoes, then the wash recommendations apply).

**2. Product tracing, Lot Identification**

In addition to the recommendations described in Section IX, Packinghouse, FDA recommends:

- Establishing procedures to maintain lot identity of tomatoes throughout the repacking process, such as the following:
    - Maintaining documentation by the repacker for each lot received to include sufficient information about the source (i.e., production location, supplier identification, and lot identification) as well as the recipient of the lot such that appropriate tracing of product may be conducted, if necessary.
    - Ensuring that as the tomatoes move through sorting and repacking to shipping, this source information continues to be associated with the respective tomatoes.
    - It is preferred that incoming lots of tomatoes are not mixed/commingled during repacking. However, if incoming lots are mixed/commingled, then documentation should be maintained to identify all included sources.
    - Ensuring that product tracing records are readily identifiable and available.
    - Evaluating at least annually the effectiveness of these procedures. Creating and maintaining a record of such testing and the results.
- Repacking tomatoes into their original boxes if tomato lots are not commingled. When original containers of a grower or packinghouse supplier are to be reused (i.e., the tomatoes are removed, resorted, and returned to the original clean and sanitary containers), the repacker should label the container as being repacked, indicating the commodity, the repacker, and lot identification.
- Repacking tomatoes into new boxes that are clean and sanitary if tomato lots are commingled, or repacking into the original boxes for those same lots. The tomatoes should be accurately labeled indicating the repacker information and lot identification to maintain the integrity of tracing information for all tomatoes in the comingled lot, back to their sources. Such information about commingling should also be captured in the firm's records and the documentation that moves with the tomatoes through the supply chain. In the event of a recall, all tomatoes in the commingled lot could be affected.
- If boxes are reused as secondary shipping containers, ensuring that the original identification information on the box has been removed or otherwise made clear that it is no longer accurate.

**3. Cleaning Materials Including Cloths**

If materials, such as cloths, are used repeatedly for cleaning tomatoes, certain steps should be taken to ensure they do not become a source of direct or cross-contamination. FDA recommends:

- Establishing a policy for the use and sanitization of cloths used for cleaning tomatoes for firms repacking tomatoes.
- Using water of sufficient microbial quality if cloths are moistened with water to facilitate cleaning. Not moistening cloths by repeated immersion in a bucket.
- Replacing cleaning cloths at suitable intervals to ensure that they do not become a source of contamination.
- Ensuring that cloths are adequately washed and sanitized before re-use, which is the responsibility of the repacker. Not relying on workers to take cloths home for cleaning and sanitizing, unless by a designated responsible party.
- Training workers in the safe and sanitary use of cloths.

**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, should follow the recommendations in this guidance, as appropriate to their specific operation.

**5. Documentation and Records**

As a general practice, it is important that firms involved in distribution operations relating to tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an "adequate description" of the food, including brand name and specific variety, and provides an example of "romaine lettuce, not just lettuce." See § 1.352 in FDA's regulations for information on the types of records transporters must maintain. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination in the event product implicated in an outbreak investigation is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; facility and vehicle sanitation; and employee training programs.

- Maintaining records for significant activities performed, such as testing water quality and disinfectant level; monitoring storage temperatures; equipment, container, and vehicle sanitation; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient, and tracking product from the final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## XI. Fresh-cut/Value-Added Processing

Fresh-cut processors are reminded that FDA's regulations in part 110 establish CGMPs for preparing, packing or holding food. The CGMP regulations include both binding requirements and non-binding recommendations relating to personnel, buildings and facilities, equipment, and production and process controls. Part 110 uses the word "shall" to state mandatory requirements and the word "should" to state recommended or advisory procedures. Fresh-cut fruits and vegetables, including fresh-cut tomatoes, are considered "processed food" as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(gg)). Thus fresh-cut processors of tomatoes are subject to the CGMP regulations. The practices provided in this guidance, including those applicable to fresh-cut processors, are recommendations that complement, but do not supersede, the requirements and recommendations in part 110.

Processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce. 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 in the absence of proper sanitation procedures in the processing environment increases the potential for the tomatoes to be contaminated 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 larger volume of product. In addition to the recommendations in this section, FDA also recommends following the Fresh-cut Guide for enhancing food safety practices.

The transfer of warm tomatoes from ripening rooms directly into an ice water bath to make the tomatoes firm before cutting may lead to water infiltration and, potentially, microbial contamination of the tomatoes. It is essential that processors be familiar with their raw

material suppliers (e.g., whether the tomatoes have been washed) and develop appropriate steps to maintain water quality and minimize the potential for contamination.

**1. Receiving**

FDA recommends:

- Obtaining tomatoes from suppliers following GAPs, as appropriate, and the recommendations in this guidance.
- Establishing a procedure for inspecting and accepting or rejecting incoming loads.
- Ensuring that incoming documentation provides sufficient information to facilitate traceback of the received product to the original source.
- Maintaining records of the inspections of incoming shipments.

**2. Facility Sanitation**

Comprehensive sanitation programs with trained sanitation personnel reduce the risk of microbial contamination from equipment, floors, and drains. Improper use of chemicals may lead to inadequately cleaned equipment or chemical contamination of equipment and thus, contamination of product. A pest control program may reduce the risk of rodent, insect, or bird infestations in and around the facility, which otherwise could lead to product contamination.

FDA recommends:

- Segregating raw, in-process, and finished product by using physical barriers or other adequate control measures to separate these areas.
- Using a foot sanitizing foam/dip at the entrance to processing area.
- Establishing a written sanitation program that satisfies applicable regulatory requirements and ensures the cleanliness of product handing equipment and the facility, including storage, processing, and other rooms.
- Establishing and maintaining a schedule of cleaning activity in a facility, which includes peripherals such as walls, ceilings, light fixtures, and cooling units.
- Ensuring chemicals are registered with EPA and used in accordance with label instructions for time, temperature, concentration, and application.
- Implementing a program that monitors the adequacy of and the facility's compliance with the sanitation program.
- Documenting and monitoring the results of the cleaning and sanitation verification program to identify areas for continuous improvement.
- Maintaining a program (e.g., color coding) to readily identify and segregate food-contact vs. non-food-contact equipment, and utensils used in the sanitation program.
- Cleaning and sanitizing hands prior to handling clean equipment.
- Protecting or removing tomatoes during cleaning and sanitizing operations to reduce the potential for cross-contamination.
- Ensuring that floors or drains are not sprayed with high-pressure hoses (resulting aerosol may contaminate product surfaces) by sanitation personnel.
- Removing excess water from cleaned equipment by sanitation personnel.
- Ensuring that product contact equipment is not placed directly onto the floor by sanitation personnel.
- Identifying and segregating equipment used to clean drains and floors. Facilities should not use equipment aids with wooden or hollow handles.

- Establishing a program that minimizes or eliminates the potential for environmental pathogens. Using environmental swabs to verify the effectiveness of the program.
- Establishing a preventive maintenance program that identifies areas 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 should be placed under motors and bearings which are located over product zones or traffic areas, and equipment should be free of rust).
- Developing and implementing a pest control program that includes a trained pest control technician, adequate monitoring frequencies, and pest control devices to control rodents and insect infestations. Pesticides should be EPA approved for the methods, target pests, and locations where they are used.

**3. Employee Health and Hygiene**

FDA recommends:

- Developing and implementing employee hygiene practices consistent with CGMPs with training for all employees at time of hire and at least annually with periodic refresher training.
- Implementing worker health policies that restrict employees and visitors with symptoms of potentially infectious illness such as diarrhea, fever, or vomiting from working with or being in the vicinity of tomatoes or food-contact surfaces.
- Establishing a policy that employees, visitors, and other field personnel with open sores, cuts, burns, boils, and similar conditions report the conditions to a supervisor before working or entering the tomato field. The supervisor should determine whether the employee should be allowed to work with or in the vicinity of tomatoes or food-contact surfaces.
- Establishing policies that encourage employees working with open products to wear clean outer garments, gloves, and hairnets. Considering use of plastic aprons and sleeves.
- Developing policies to define conditions when outer garments and gloves should be changed, such as after cleaning drains, restrooms, or other similar areas.

**4. Gloves**

If tomatoes are handled with bare hands, hand washing procedures should be documented as indicated above. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

<u>Disposable Gloves</u>

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for handling tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.

<u>Reusable Gloves</u>

single-use, disposable gloves are preferred for most operations within a fresh-cut facility. However, if reusable gloves are used, FDA recommends:

- Using gloves made of materials that can be readily cleaned and sanitized.
- Ensuring that gloves are adequately washed and sanitized. It is the responsibility of the firm to ensure that reusable gloves are properly sanitized. The firm should not rely on workers taking such gloves home for cleaning and sanitizing.
- Issuing appropriately cleaned and sanitized gloves, regularly and as necessary. For example, cleaning and sanitizing or changing reusable gloves after meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled, or otherwise damaged or contaminated.
- Providing a safe and sanitary location (e.g., bin or shelf) to leave gloves when they are not in use by an employee (e.g., during breaks and toilet use).
- Training workers to clean and sanitize or change gloves that have come in contact with the ground or other non-food-contact surfaces.

**5. Raw, Intact Product Storage**

FDA recommends:

- Designing storage containers and storage facilities with the proper materials and construction to facilitate cleaning.
- Storing containers and product in a manner that minimizes the potential for contamination. Protecting stored containers and product with liners or covers as appropriate and ensuring storage areas are clean and devoid of pests.

**6. 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 decaying raw material and to maintain gentle handling practices to reduce the risk of damage or contamination of product.

FDA recommends:

- Maintaining any boxes reused as secondary shipping containers for packing sorted tomatoes in a clean and sanitary condition.
- Culling tomatoes that show signs of physical damage (such as skin breaks or decay) from processing. Properly disposing of culled tomatoes so they do not become a potential source of contamination.
- Ensuring that the sorting process minimizes damage to the tomato.
- Maintaining lot identity throughout the sorting process.
- Implementing preventive measures to remove foreign/extraneous materials.

**7. Whole Tomato Wash**

Internalization of bacteria into the stem scar and other openings in tomato flesh, such as wounds or microabrasions, has been demonstrated with tomatoes submerged in water that is cooler in temperature than the pulp of the tomato. When the tomato cools, a vacuum is created causing water, and potentially pathogens, to be drawn through such openings and into the

flesh of the tomato. Therefore, water temperature relative to pulp temperature, and water quality, are critical considerations for maintaining the safety of the product.

FDA recommends:

- Ensuring that the water used in processing is of sufficient quality for this purpose and contains sufficient disinfectant to prevent cross-contamination. Monitoring the water disinfectant at a frequency sufficient to maintain sanitary conditions.
- Pre-cooling whole tomatoes by air in a cold room prior to processing.
- Ensuring that tomatoes are not immersed in cold water as a cooling technique.
- Maintaining water temperature at least 10ºF warmer than the pulp temperature of the tomato. Monitoring water temperature and pulp temperature of tomatoes as needed to reduce potential contamination.
- Ensuring that water disinfectants are registered with the EPA and used in accordance with manufacturer's label instructions, particularly for concentration and contact time.
- Ensuring that tomatoes are not submerged in more than one foot of water for more than two minutes total time.
- Monitoring and recording free chlorine and pH at least at start-up and every hour thereafter if water quality maintenance is based on manually monitoring chlorine levels. It is critical that pH be maintained in the range of 6.5-7.5 to ensure that chlorine is effective since total chlorine measurements do not accurately represent antimicrobial effectiveness. Measurements should be sufficiently precise to ensure levels are within established limits.
- Maintaining an ORP of at least 650 mV if water quality maintenance is based on ORP.
- Following manufacturer recommendations for monitoring and limits if water quality maintenance is based on other water disinfectant treatments.
- Verifying monitoring oxidant concentrations against a chemical test that measures disinfectant levels (and pH where applicable) at start-up and at least every 2 hours thereafter, and recorded, when monitoring is done electronically.
- Calibrating electronic monitoring devices at a frequency sufficient to ensure continuous accuracy.
- Designing the line so that the entire tomato surface is rinsed if spray systems are utilized in place of whole tomato immersion.

**8. Cutting**

Blade condition (i.e., 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 the shelf life.

**9. Washing Tomatoes after Cutting**

Antimicrobial chemicals that are appropriately utilized minimize the potential for microbial contamination of the processing water, which reduces the risk of cross-contamination of tomatoes. FDA recommends that processors refer to 21 CFR 173.315 for information about approved wash water chemicals.

FDA recommends:

- Ensuring that the water used in washing is of sufficient quality to comply with applicable federal, state, and local requirements.

- Using sufficient disinfectant with adequate dwell time to prevent microbial build-up over time. Monitoring the disinfectant with a frequency sufficient to maintain sanitary conditions.
- Monitoring wash water temperature to ensure that fresh-cut tomatoes do not exceed refrigerated temperatures (i.e., ≤41ºF).

**10. Packaging**

FDA recommends:

- Maintaining an effective system to prevent the use of contaminated, damaged, or defective cartons, trays and totes to minimize microbial contamination of fresh-cut tomatoes during packaging operations.
- Identifying packaging materials coming into direct contact with the fresh-cut tomatoes, including tracing to the source.
- Ensuring that packaging containers and cartons are used only for their intended purpose.
- Storing packaging materials in a manner that protects them from contamination, such as away from pests, dirt, cleaning chemicals, and water condensation from overhead equipment and structures.
- Labeling primary or secondary finished fresh-cut tomato product containers with recommended storage instructions (e.g., "Keep Refrigerated") and with storage temperature to inform all persons handling the product of the recommended storage conditions.
- Coding primary and secondary packaging to facilitate product tracing.

**11. Storage Rooms and Distribution Facilities**

FDA recommends:

- Storing finished, cut products at refrigerated temperatures not exceeding 41ºF.
- Keeping storage rooms and distribution facilities clean and sanitary, with debris minimized. Systematically and periodically cleaning and sanitizing all walls, floors, ceilings, and other surfaces to avoid the build-up of mold or other potential contaminants.
- Placing product on pallets to avoid direct contact of tomatoes with the floor.
- Maintaining a perimeter between pallets and walls to facilitate visual inspection of pest control and sanitation.
- Clearly identifying and segregating product on hold or rejected from other product.
- Ensuring that trash or waste is not stored in the storage rooms.

**12. Transportation**

Finished products transported in sanitary, refrigerated coolers and vehicles reduce the risk for microbial contamination or growth.

FDA recommends:

- Transporting finished products at refrigerated temperatures not exceeding 41ºF.
- Transporting finished products in pre-cooled vehicles equipped with a calibrated temperature recording device.

- Ensuring that transportation vehicles are sufficiently clean so that they do not become a source of contamination.
- Inspecting transportation vehicles for cleanliness, odors, and visible dirt and debris before loading. Cleaning and/or sanitizing the vehicles, if necessary, prior to loading with tomatoes.
- Verifying records of prior loads if non-dedicated vehicles are used for transportation. Cleaning and sanitizing vehicles prior to use if there is any doubt about prior loads transported or if there is risk from microbial contamination, such as from raw animal proteins, garbage, or other refuse.

**13. Labeling**

FDA recommends:

- Accurately labeling primary and secondary containers with commodity name, processor firm name or identification code, and lot identification sufficient to permit accurate product tracing.
- Correcting or removing inaccurate labels.

**14. Documentation and Records**

As a general practice, it is important that firms handling tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It is also important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an "adequate description" of the food, including brand name and specific variety, and provides an example of "romaine lettuce, not just lettuce." See § 1.352 in FDA's regulations for information on the types of records transporters must maintain. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination in the event product implicated in an outbreak investigation is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices; facility and vehicle sanitation; and employee training programs.

- Maintaining records for significant activities performed, such as testing water quality and disinfectant level; monitoring storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source through intermediate sources to its final recipient, and tracking product from the final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## XII. Foodservice and Retail

Specific procedures for storing or displaying food, for excluding or restricting ill employees, for washing hands, date-marking, and for washing and sanitizing equipment can be found in the FDA Food Code. The FDA Food Code is a model code developed by FDA to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. In addition, FDA provides recommendations specific to cut tomatoes in its Program Information Manual titled "Storage and Handling of Tomatoes."

Further considerations for tomatoes are found below. In addition, handlers of tomatoes should be aware of and follow all Federal, State, and local requirements. Tomatoes may be handled extensively at retail or in food service operations; therefore, it is of particular importance to wash hands thoroughly with soap and water before cutting or handling tomatoes. Rewash as necessary.

### 1. Purchasing

FDA recommends that foodservice and retail operators purchase tomatoes that they use in their operations from suppliers following GAPs, FDA's Fresh-cut Guide, as appropriate, and the recommendations in this guidance. Practices can be verified through documented self-inspections, audits done by qualified government or private sector food safety auditors, or other appropriate mechanisms.

### 2. Receiving - Whole and Fresh-cut Tomatoes

FDA recommends:

- Establishing procedures for inspecting and accepting or rejecting incoming loads. Procedures should include the standards for the condition of transportation vehicles as well as incoming product specifications.
- Ensuring that incoming documentation provides sufficient information to facilitate product tracing to the immediate prior supplier.
- Maintaining records of incoming inspections.
- Ensuring that the temperature of fresh-cut tomatoes (i.e., sliced, diced, or chopped) is at ≤41ºF upon receipt and that there was continuous temperature control during transport.
- Rejecting fresh-cut tomatoes >41ºF at receipt.

**3. Storage - Whole and Fresh-cut Tomatoes**

FDA recommends:

- Maintaining whole tomatoes at the temperature recommended for the variety and the particular stage of ripening.
- Maintaining the temperature of fresh-cut tomatoes at or below 41 degrees Fahrenheit (≤41ºF), in accordance with state and local requirements and recommendations in the most current edition of the FDA Food Code.
- Keeping tomatoes elevated off the floor and stored in a manner to prevent cross-contamination from raw food products, chemicals, or unsanitary conditions.

**4. Facility Sanitation**

FDA recommends that retail and foodservice facilities adhere to state and local requirements for facility sanitation and utilize information in the most current edition of the FDA Food Code.

**5. Employee Health and Hygiene**

FDA recommends that retail and foodservice facilities adhere to state and local requirements for employee health and hygiene and utilize information in the most current edition of the FDA Food Code.

**6. Preparation within Foodservice/Retail Establishments**

Facility

FDA recommends that a facility preparing tomatoes be designed and maintained to be consistent with state and local requirements and the most current edition of the FDA Food Code, including:

- Ensuring that floors, walls, and ceilings can be effectively cleaned and sanitized.
- Closing and/or providing screens for external doors and windows.
- Ensuring that water is of sufficient quality for the intended use and suitable for product and food-contact surfaces.
- Providing sufficient hot water for the intended use.
- Adequately storing cleaning and sanitizing chemicals and supplies to prevent cross-contamination.
- Providing adequate hand-wash facilities.

- Providing adequate resources to wash, sanitize, and dry equipment and utensils.
- Maintaining an effective pest control program with no signs of insect or rodent activity.

Equipment

FDA recommends:

- Following state and local requirements and utilize information in the most current edition of the FDA Food Code regarding facilities and equipment, temperature control, cleaning and sanitizing, and personal hygiene, when preparing or further handling tomatoes at retail.
- Ensuring that equipment and utensils used to hold, cut, dice, or slice tomatoes are designed for that purpose. Equipment should be easily cleaned, free from damage that prevents proper cleaning, and stored in a manner that will not contribute to product contamination. Some examples of equipment include:
    - Cutting boards
    - Thermometers
    - Utensils
    - Disposable gloves
    - Safety gloves
    - Finished product containers

Employees Preparing Tomatoes

Employees preparing tomatoes should adhere to state and local requirements and utilize information in the most current edition of the FDA Food Code. FDA recommends that firms ensure that employees:

- Are adequately trained in safe food handling procedures.
- Aree free from symptoms or diagnosed transmissible diseases as defined in the most current edition of the FDA Food Code.
- Implement and practice good hand washing procedures, such as at the start of the shift, after breaks, after visiting restrooms, after sneezing, after coughing, after handling trash or money, or anytime hands become soiled, or otherwise contaminated.
- Not eat, drink or use tobacco products while in the food preparation or storage areas.
- Wear a clean uniform and/or outer clothing.
- Minimize bare hand contact with tomatoes to be sold as ready-to-eat. Options may include using clean and sanitary utensils or disposable gloves.
- Utilize hair and beard nets when appropriate.
- Practice good retail practices and food handling techniques to prevent cross-contamination.

**7. Gloves**

If tomatoes are handled with bare hands, hand washing procedures should be documented as indicated above. If gloves are utilized, a procedure for glove use should be established, followed, and documented.

Disposable Gloves

If disposable gloves are used, FDA recommends:

- Using single-use disposable gloves for handling tomatoes.
- Washing hands before putting on gloves.
- Using hand sanitizers only after proper washing of hands.
- Changing disposable gloves after returning from meals, smoking, using toilet facilities, any process involving handling of materials other than tomatoes, or when the gloves have become torn, soiled or otherwise damaged or contaminated.

Reusable Gloves

FDA does not recommend the use of reusable gloves for hand contact of tomatoes at food service/retail operations. When gloves are utilized, FDA suggests using single-use disposable gloves.

**8. Tomato Washing and Culling**

To prevent exterior microorganisms from infiltrating the interior of the tomato during washing, FDA recommends that the wash water temperature is at least 10°F warmer than the internal tomato pulp temperature.

FDA recommends:

- Utilizing information in the FDA 2005 Food Code Section 3-302.15, which specifies: "Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form."
- Ensuring that whole tomatoes are free from obvious signs of filth and skin damage, such as punctures, prior to cutting, slicing, or dicing.
- Washing tomatoes before cutting by either:
    - Continuous running water, or
    - If disinfectants are used in the wash water of tomatoes, they should conform to 21 CFR 173.315 and be used according to the manufacturer's label instructions for recommended concentration and contact time.
    - Soaking tomatoes or storing them in standing water is not recommended.

**9. Storing Cut/Sliced/Diced Tomatoes**

FDA recommends:

- Chilling to and maintaining tomatoes at ≤41°F after cutting.
- Storing cut tomatoes in a covered container and above other items that may cause contamination.
- Storing tomatoes off the floor and in a manner to prevent cross-contamination from raw food products or unsanitary conditions.
- Indicating the date, or day, by which food should be consumed on the premises, sold, or discarded for fresh-cut tomatoes that are held longer than 24 hours.

**10. Displaying Cut Tomatoes for the End Consumer**

FDA recommends:

- Maintaining cut tomatoes at ≤41°F during display.
- If time is the control measure used, developing procedures for following this measure. Refer to the current edition of the FDA Food Code for details of displaying cut/sliced/diced tomatoes without temperature control.
- Ensuring that cut tomatoes are not stored in direct contact with ice or water if the cut tomato is subject to the entry of water because of the nature of its packaging, wrapping, container, or its position in the ice or water.

**11. Displaying Whole Tomatoes for the End Consumer**

FDA recommends that whole tomatoes should be free of obvious signs of filth, and skin damage such as punctures, cuts, or breaks.

**12. Documentation and Records**

As a general practice, it is important that end-user firms handling tomatoes maintain documentation and records related to operational information about the product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already impose certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include identifying information regarding the food. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J. Note: Restaurants and certain retail food establishments (as those terms are defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J.

***Operational records*** about products and practices can be helpful to firms. First, such records help ensure consistency of production and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or further employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors for contamination in the event product implicated in an outbreak investigation is traced to a particular farm or facility.

FDA recommends:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, facility and vehicle sanitation, and employee training programs.
- Maintaining records for significant activities performed, such as monitoring of storage temperatures; cleaning and sanitation of equipment, containers, and vehicles; employee training; and corrective actions taken.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity or production station in the documentation.

***Product tracing*** refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about the product facilitates tracking the physical movement of a product between its original source

through intermediate sources to its final recipient, and tracking product from the final recipient back to its source. Effective product tracing systems can serve as important complements to food safety programs intended to prevent microbial contamination.

FDA recommends:

- Utilizing information outlined in the GAPs Guide and the FDA Guide to Traceback Investigations to develop a product tracing system applicable to the tomato supply chain.
- Developing and maintaining standardized, clear records that can be used to enhance the ability to follow the movement of the product. Examples of such records include records with product identifying information (i.e., labels), invoices, inventory records, bills-of-lading, and shipping/receiving records.

## XIII. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm173902.htm

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