Selected Sections of a Food Safety Plan

Teaching Example

Food Safety Plan

for

Mature Green Round Tomatoes

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This food safety plan teaching example was developed by a group of industry, academic, and government subject matter experts assembled by the United Fresh Produce Association, who worked from draft models originally developed by the Southern Training, Education, Extension, Outreach, and Technical Assistance Center to Enhance Produce Safety based at the University of Florida.

The information in this example is for training purposes only and does not represent any specific operation. Processing steps may have been omitted or combined to facilitate its use for class exercises. **It is not complete and contains both required and optional information.** Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.



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## Company Overview

This multi-source year-round tomato packinghouse was built in 1975 and has about 50 employees. It has 48,000 sq. ft. of ambient packing space and refrigerated holding space. The packinghouse, located in Alexandria NC, is owned by Grimes’ Farms (Sunnyside NJ), who supplies some but less than a majority of tomatoes. Additional tomatoes are sourced from Glen’s Farms (Exmore VA), Carol Dixon’s Farms (Groveton GA), Greenes Growers (Fort Hunt GA), Michonnes Inc. (Annadale FL), and are occasionally imported from The Governors Superior Tomatoes (Woodbury Greenland). All non-produce materials (wash and wax chemicals, ethylene, corrugated boxes) are sourced from approved suppliers. At this facility we pack round tomatoes on one dedicated line. Product is produced up to 6 days a week, with one production shift, plus a daily sanitation shift. Well water sources are tested annually to verify compliance with EPA requirements for drinking water. Temperature controlled rooms are non-ammonia based. All tomato suppliers are demonstrated compliant with the Produce Safety Rule by an annual audit to the USDA Produce GAPs Harmonized Audit.

|  |
| --- |
| Product Description, Distribution, Consumers and Intended Use |
| **Product Name** | Mature green round tomatoes |
| **Product Description, including Important Food Safety Characteristics** | Mature whole green round tomatoes, ready-to-eat |
| **Ingredients** | Mature green round tomatoes |
| **Packaging Used** | Single use boxes of various configurations, e.g., 10, 20, 25 lb |
| **Intended Use** | Foodservice, retail and fresh-cut processing |
| **Intended Consumers** | General public |
| **Allergens** | No allergens are used in this facility |
| **Labeling Instructions** | Keep refrigerated (50-60°F, for quality) |
| **Other Labeling (as applicable)** | Lot Code |
| **Storage and Distribution** | Temperature controlled (50-68°F) storage and distribution |

**Flow Diagram**

Receive packaging

Receive wash and wax chemicals, ethylene

Receive tomatoes

Dump & flume tank

Dry Storage

Well water

Brush Wash

Size sorting

Waxing

Culling

Culls diverted to non-human food use

Dry Storage and Form

Packing

Metal detection

Ripening Room

Case/Code Palletize

Shipping

Cold Storage

**Process Description**

**Receive tomatoes.** Mature whole green round tomatoes, such as varieties Florida 471, Sebring, Amelia, HM 8849CR, Quincy Redline, and Sanibel, arrive in washed and sanitized, well-maintained field bins. Tomatoes are held on trucks until they are processed. Tomatoes are inspected for integrity, specifications, and dryness, prior to lot number assignment. Pulp temperature is measured just prior to dumping.

**Receive packaging, Dry Storage** **and Form.** Food grade packaging materials are received from approved suppliers, inspected on receipt and stored in dry materials storeroom in the packinghouse. Boxes are formed just prior to use.

**Receive wash and wax chemicals, ethylene,** **Dry Storage.** Food grade sodium hypochlorite solution and citric acid are purchased from approved suppliers, mixed with well water, stored in a secured bulk tank outside the packinghouse, and piped directly to point of use. Food grade wax is purchased from approved suppliers and stored in a secured area until use. Tanks of ethylene gas are received from approved suppliers, stored in a secured area, and piped to the ripening rooms using an automated manifold and flowmeter.

**Well water.** Well water is tested at least annually to meet EPA *E. coli* standard for drinking water.

**Dump & flume tank.** Bins of tomatoes are inverted/dumped into heated (≥10°F above pulp temperature), chlorinated (≥15 ppm free chlorine2, pH 6.0-7.02) water. Leaves, stems, and extraneous materials are removed. Product contact time is typically about 30 seconds and is monitored so that it does not exceed 2 minutes2.

**Brush wash.** Tomatoes, on brush rollers, go under a spray bar with chlorinated water (≥15 ppm free chlorine2, pH 6.0-7.02), followed with a potable single pass water rinse. There is no temperature control since tomatoes are not immersed.

**Size sorting.** Tomatoes continue on conveyors to where they are mechanically sorted for size. Rejected tomatoes are diverted by waste conveyor to cull storage bins.

**Waxing.** Tomatoes continue on conveyors to spray wax application, brushing and drying.

**Culling.** Tomatoes are manually inspected, culls moved by waste conveyor to cull storage bins.

**Packing.** Tomatoes are manually packed in preprinted, single use corrugated vented boxes with separate lids.

**Metal detection.** Boxes continue on conveyor through metal detector.

**Case/Code/Palletize.** Boxes are ink-jet coded with USDA Positive Lot Identification stamp, house number, lot number, Julian date code. Boxes are palletized and pallet tag affixed.

**Ripening room/Cold storage.** Pallets are transferred to warehouse for storage (50-60°F) until ready for shipping or stored in ripening room (approximately 68°F) as per customer specifications. Product is stored in ripening room under ethylene gas to increase color change.

**Shipping.** Product is shipped to the customer in visually clean, well maintained refrigerated (50-60°F, for quality) trucks (customer or third party).

1 Commercial names used in this document are for illustrative purposes only.

2 Specific values are used for illustrative purposes only. Actual values may vary depending on commodity, regional differences, process conditions and equipment.

**Hazard Analysis**

Hazard identification (column 2) considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical hazards, including radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

| (1)Ingredient/ Processing Step | (2)Identify potential food safety hazards introduced, controlled or enhanced at this step | (3) Do any potential food safety hazards require a preventive control? | (4)Justify your decision for column 3*Based on severity and likelihood of occurrence*  | (5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? | (6)Is the preventive control applied at this step? |
| --- | --- | --- | --- | --- | --- |
| Yes | No | Yes | No |
| Receive tomatoes | B | Microbial pathogens such as *Salmonella* and Hepatitis A | X |  | Tomatoes have been associated with contamination with microbial pathogens | Supply chain applied control1 | X |  |
| C | Pesticide residues, radiological hazards, heavy metals |  | X | Radiological hazards are not an issue from the regions we from which we source. Quarterly pesticide testing has indicated that pesticide residues are not hazards requiring a preventive control |  |  |  |
| P | Rocks, lead shot, glass, wood splinters, metal fragments |  | X | Tomatoes pierced with physical hazards will spoil quickly, so not reasonably likely to occur in the absence of control |  |  |  |
| Receive wash and wax chemicals (sodium hypochlorite, citric acid, wax), ethylene | B | Microbial pathogens in wax |  | X | No history of contamination; these chemicals do not support growth |  |  |  |
| C | Wrong, contaminated or mislabeled chemical |  | X | Not reasonably likely to occur in the absence of control |  |  |  |
| P | Foreign objects |  | X | Not reasonably likely for physical hazards to occur in the absence of control |  |  |  |
| \* 1 Note: Because this packinghouse is not a “receiving facility” (manufacturer/processor) but only packs and holds produce, it is not required by FDA to have a supply-chain ‎program. |
| Dry Storage Chemicals | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Receive packaging | B | None  |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Dry Storage and Form Packaging  | B | Human pathogens from insanitary handling or conditions |  | X | Not reasonably likely to occur with GMPs  |  |  |  |
| C | Glue, machine lubricant |  | X |  |  |  |
| P | Metal from forming machine  |  | X |  |  |  |
| Well water | B | Microbial pathogens  | X |  | Well water may contain pathogens | Sanitation Control – Source Water program2 | X |  |
| C | Heavy metals, radiological chemicals, agricultural chemicals |  | X | Historical testing demonstrates not reasonably likely to occur in the absence of control |  |  |  |
| P | None |  |  |  |  |  |  |
| Dump & flume tank | B | Microbial pathogen cross-contamination  | X |  | Potential for cross-contamination is reasonably likely to amplify the hazard in the absence of control | Sanitation Control – Dump tank control program3 | X |  |
| C | Excessive wash chemicals |  | X | Not reasonably likely to occur at levels likely to cause illness or injury |  |  |  |
| P | None |  |  |  |  |  |  |
| 2 Note: Some may choose to control potential contamination in source water as part of their GMPs 3 Note: This can also be treated as a Process Preventive Control |
| Brush Wash | B | Environmental pathogens such as *L. monocytogenes* and *Salmonella* | X |  | Enhanced sanitation warranted in this area | Sanitation control - Packing Environment4 | X |  |
| C | Excess cleaning and sanitation chemicals  |  | X | Not reasonably likely to occur at levels likely to cause illness or injury |  |  |  |
| P | Broken brush pieces |  | X | Pieces large enough to cause injury unlikely to end up in finished product and, if it did, mold and decay will quickly render product inedible |  |  |  |
| Size sorting | B | Environmental pathogens such as *L. monocytogenes* and *Salmonella* | X |  | Enhanced sanitation warranted in this area  | Sanitation control - Packing Environment4 | X |  |
| C | Excess cleaning and sanitation chemicals |   | X | Not reasonably likely to occur at levels likely to cause illness or injury |  |  |  |
| P | Machine pieces |  | X | Pieces large enough to cause injury unlikely to end up in finished product |  |  |  |
| Waxing | B | Environmental pathogens such as *L. monocytogenes* and *Salmonella* | X |  | Enhanced sanitation warranted in this area  | Sanitation control- Packing Environment4  | X |  |
| C | Excess cleaning and sanitation chemicals |  | X | Not reasonably likely to occur at levels likely to cause illness or injury |  |  |  |
| P | Machine pieces |  | X | Pieces large enough to cause injury unlikely to end up in finished product |  |  |  |
| 4 Some operations may conclude that GMPs will make contamination with environmental pathogens not reasonably likely to occur, and so not require a Preventive Control. Note that FDA is developing packinghouse guidance which should be consulted for FDA’s current thinking regarding environmental monitoring in a packinghouse |
| Culling | B | Human pathogens from insanitary handling or conditions | X |  | Insanitary handling is adequately prevented by GMPs. Enhanced sanitation warranted in this area to control environmental contamination | Sanitation control - Packing Environment4 | X |  |
| C | None |  |  |  |  |  |  |
| P | Metal fragments and brittle plastic |  | X | Pieces large enough to cause injury unlikely to end up in finished product  |  |  |  |
| Packing | B | Human and environmental pathogens from insanitary handling or conditions | X |  | Insanitary handling is adequately prevented by GMPs. Enhanced sanitation warranted in this area to control environmental contamination | Sanitation control - Packing Environment4 | X |  |
| C | Excess cleaning and sanitation chemicals, machine lubricant |  | X | Not reasonably likely to occur at levels likely to cause illness or injury |  |  |  |
| P | Machine fragments |  | X | Pieces large enough to cause injury unlikely to end up in finished product  |  |  |  |
| Metal detection | B | None |  |  |  |  |  |  |
| C | None |  |  |  |  |  |  |
| P | Metal |  | X | Metal detection is a customer requirement; no metal hazards have ever been detected |  |  |  |
| Case/Code Palletize | B | None |  |  |  |  |  |  |
| C | None |   |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Ripening Room | B | Environmental pathogens |  | X | Product is largely protected. Not reasonably likely to occur with GMPs |  |  |  |
| C | Excess ethylene |  | X | Not reasonably likely to occur at levels likely to cause illness or injury |  |  |  |
| P | None |  |  |  |  |  |  |
| Cold Storage | B | Environmental pathogens |  | X | Product is largely protected. Not reasonably likely to occur with GMPs |  |  |  |
| B | Pathogen growth if temperature abused  |  | X | Chilling is for quality only; pathogens are unlikely to grow on whole, dry tomatoes |  |  |  |
| C | None |   |  |  |  |  |  |
| P | None |  |  |  |  |  |  |
| Shipping | B | Pathogens from shipping containers |  | X | Product is largely protected. Not reasonably likely to occur with GMPs |  |  |  |
| C | Excess cleaning chemicals from truck cleaning |   | X | Product is largely protected. Not reasonably likely to occur with GMPs |  |  |  |
| P | None |  |  |  |  |  |  |

**Process Preventive Control - Metal Detection**

|  |  |
| --- | --- |
| **Records** | Monitoring and calibration check records. Corrective action reports. Annual calibration reportValidation report. |
| **Verification** | Food Safety/ QA Manager reviews monitoring, corrective action reports and calibration check records within 7 days. Food Safety/ QA Manager observes performance of calibration check, monthly.Annual calibration by metal detector service company |
| **Corrective Action** | Hold and rerun, through functioning metal detector, product to last good check. Repair or calibrate metal detector. |
| **Monitoring** | **Who** | Packing line operator |
| **Frequency** | At start of shift, hourly thereafter and at the end of the production run |
| **How** | Check with calibrated ferrous, non-ferrous and stainless steel cards |
| **What** | Metal detector functioning and calibrated |
| **Parameter/ Value** | In-line metal detector functioning (detection and rejection) and calibrated to detect 2.5 mm ferrous, 3.5 mm nonferrous and 3.5 mm 316 stainless steel |
| **Hazard(s)** | Undetected metal because of non-functioning metal detector |
| **Process Control** |  Metal detection |

**Sanitation Preventive Control – Well Water**

|  |  |
| --- | --- |
| **Location** | Source Well |
| **Purpose** | Assess water microbial quality as appropriate for its intended use |
| **Procedure** | Sanitary survey of well and distribution system (check backflow valves; inspect distribution system for dead legs and cross connections to waste water system) |
| **Monitoring** | Visual inspection |
| **Frequency** | Annually for entire survey; monthly (while in operation) checks for any changes to the system |
| **Who** | Maintenance (monthly checks) and Outsourced contractor (annual survey) |
| **Corrections** | Repairs and modifications as needed |
| **Verification** | Microbiological testing for generic *E. coli* (annually) at rotating points of use; PCQI or designee review of records within 7 business days of their creation |
| **Records** | Sanitary survey records; microbiological testing records; repair records |

**Sanitation Preventive Control – Dump Tank**

|  |  |
| --- | --- |
| **Location** | Dump Tank |
| **Purpose** | Minimize potential microbial pathogen cross-contamination |
| **Procedure**  | Maintain adequate levels of sodium hypochlorite and citric acid to maintain free chlorine >15 ppm1 and pH 6.0-7.0. Maintain water temperature >10°F1 above pulp temperature and monitor that product contact time does not exceed 2 minutes to minimize potential for pathogen infiltration. |
| **Monitoring** | Electronic sensing and dosing as needed to maintain free chlorine and pH. Measure pulp temperature on each incoming load; monitor and control water temperature as compared to measured pulp temperature. Monitor water flow rate to ensure tomato dwell time does not exceed 2 minutes. |
| **Frequency** | Electronic sensing of free chlorine and pH, and monitoring of water temperature and water flow rate, are performed continuously during production. Tomato pulp temperature is measured for each load before dumping. |
| **Who** | Designated operations personnel |
| **Corrective Action** | Adjust chlorine or pH level, water temperature, or dwell time. Isolate tomatoes back to last good check and determine disposition of affected tomatoes accordingly. Prepare corrective action record. |
| **Verification** | Hourly titration to verify free chlorine >15 ppm1; PCQI or designee review of monitoring and free chlorine titration records before product shipment. Calibration of free chlorine, pH and temperature sensors according to manufacturer recommendations for frequency; review of calibration and corrective action records within 7 business days. |
| **Records** | Free chlorine sensor logs, pH logs, titration logs, temperature logs and dwell time records. Calibration records for free chlorine sensor and pH sensors and thermometers. Corrective action records. |

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**Sanitation Preventive Control - Packing Environment**

|  |  |
| --- | --- |
| **Location** | Packing Environment (Brush Wash through Packing) |
| **Purpose** | Minimize potential for food contact surfaces to contaminate product |
| **Procedure** | * Check cleaning and sanitation solutions for proper concentration.
* Remove any accumulated debris and produce by dry cleaning.
* Rinse both the upper and lower sides of the transporters. Rinse between the belt line and the supporting framework. Pay special attention to the roller and the belt area, because accumulation of produce is very common here and could be a source of contamination. During this step you can turn on the belts to make the cleaning process easier.
* While running the belt line slowly, apply foam cleaner to machine areas. Let sit for 3 to 5 minutes before rinsing. Then apply sanitizer. Let dry; DO NOT rinse no-rinse sanitizer.
 |
| **Monitoring** | Sanitation Pre-check List, Visual inspection |
| **Frequency** | Daily during production  |
| **Who** | Designated sanitation personnel |
| **Corrections** | If residual soil is observed or ATP test exceeds operational limit pre-start up, re-clean. If cleaning or sanitation solutions are not at correct concentration, per label directions, re-make solutions before use |
| **Verification** | ATP testing (daily by food safety personnel), environmental monitoring (per schedule), PCQI or designee review of records |
| **Records** | Sanitation records, pre-check records, ATP testing and environmental monitoring records |

**ATP and Environmental Monitoring**

Identified testing sites:

|  |  |
| --- | --- |
| ZONE 1 | ZONES 2, 3 AND 4 |
| Aprons | Air blower, filter | Forklifts |
| Belts | Boots | Hoses |
| Brushes | Carts | Legs |
| Conveyors | Ceilings | Lifters |
| Equipment Surfaces | Coat racks | Maintenance tools |
| Equipment Shields | Condensation | Motor housing units |
| Flume inside top edge | Control buttons | Overhead pipes |
| Gloves | Cooling units | Platforms |
| Guiding bars | Doors | Refrigeration units |
| Packaging machines | Drains | Roller bars |
| Product carts | Drop cords | Sinks |
| Racks | Equipment framework | Standing water |
| Scales | Equipment sides | Stands |
| Sealers | Fans | Trash cans |
| Tables | Floor mats | Walls |
| Utensils | Floors | Wheels of carts |

Routine Sampling Schedule:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Test Site | Zone | ATP testing | *Listeria* spp. and *Salmonella* swabs\* | APC swab |
| 1 | Aprons | 1, 2 | N/A | Quarterly | Weekly |
| 2 | Belts | 1 | After sanitation | Quarterly | Weekly |
| 3 | Brushes | 1 | After sanitation | Quarterly | Weekly |
| 4 | Conveyors | 1 | After sanitation | Quarterly | Weekly |
| [etc.] |
| 37 | Maintenance tools | 2, 3 | After sanitation | Monthly | Monthly |
| 38 | Motor housing units | 2, 3 | After sanitation, if appropriate | Monthly | Monthly |
| 39 | Overhead pipes | 2, 3 | After sanitation | Quarterly | Quarterly |
| 40 | Platforms | 2, 3 | After sanitation, if appropriate | Monthly | Monthly |
| 41 | Refrigeration units | 2, 3 | After sanitation | Monthly | Monthly |
| 42 | Roller bars | 2, 3 | After sanitation | Quarterly | Quarterly |
| [etc.] |
| 46 | Trash cans | 3, 4 | N/A | Quarterly | Quarterly |
| 47 | Walls | 3, 4 | N/A | Monthly | Monthly |
| 48 | Wheels of carts | 3, 4 | N/A | Monthly | Monthly |

\* 1/3 of Quarterly samples are tested monthly on a rotating basis.

Criteria: 1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Microbes | Testing Zones | Target | Acceptable | Unacceptable |
| *Listeria* spp. | 1, 2, 3, 4 | ND | ND | Positive |
| *Salmonella* | 1, 2, 3, 4 | ND | ND | Positive |
| Aerobic Plate Count (APC) | 1, 2, 3, 4 | 0 CFU/cm2 | <100 CFU/cm2 | ≥100 CFU/cm2 |
|  |
| ATP Surface Readings | Testing Zones | Acceptable | Unacceptable |
| Stainless Steel | 1, 2, 3 | ≤1000 RLUs | >1000 RLUs |
| Teflon | 1, 2, 3 | ≤4500 RLUs | >4500 RLUs |
| Plastic | 1, 2, 3 | ≤2500 RLUs | >2500 RLUs |
| Aluminum | 1, 2, 3 | ≤6000 RLUs | >6000 RLUs |
| Rubber | 1, 2, 3 | ≤4500 RLUs | >4500 RLUs |

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**Records:**

Microbiological test records shall include 1) the organisms being tested for; 2) identification of samples tested; 3) identification of the sampling procedure used; 4) the approved laboratory that performed the test; 5) identification of the testing procedure used; 6) actual numerical results or, if reported as non-numerical (e.g., Negative or Not Detectable), the limit of detection; and 7) corrective action taken for any unacceptable test result. Food Safety/QA Manager (PCQI) shall review and initial all microbiological test records within 7 days of creation. Test records shall be retained for at least two years after creation.

**Corrective Actions:**

If testing results are out of acceptable limits, the sample site shall be re-cleaned and sanitized as per the Corrective Action Standard Sanitation Procedure document #105 and then retested. All test sites with repeat positives in 6 months and all Zone 1 *Listeria* or *Salmonella* positives shall be investigated per Repeat Positive Procedure Document # YYY.

**Supply-chain Preventive Control – Tomatoes1**

|  |  |
| --- | --- |
| **Raw material or other ingredient** | Tomatoes (including imports) |
| **Hazard requiring a supply-chain-applied control** | Microbial pathogens such as *Salmonella* and Hepatitis A  |
| **Receiving Procedures** | For each shipment received, the receiving clerk verifies the tomatoes are from an approved supplier and within approval date, and documents the shipment in the incoming goods log |
| **Preventive controls applied by the supplier** | Procedures in accordance with Produce Safety rule and Produce GAPs Combined Harmonized Standards  |
| **Identification of supplier verification procedure(s)** | USDA Produce GAPs Harmonized Audit 2  |
| **Verification procedure** | Copy of third party annual audit by a qualified auditor obtained from supplier to verify control of above hazards. Audit report and any food safety-related corrective actions are reviewed by Food Safety/QA Manager (PCQI). |
| **Records** | Incoming goods log, record of review of the annual audit report and corrective actions |

1 Note: Because this packinghouse is not a “receiving facility” (manufacturer/processor) but only packs and holds produce, it is not required by FDA to have a supply-chain ‎program.

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