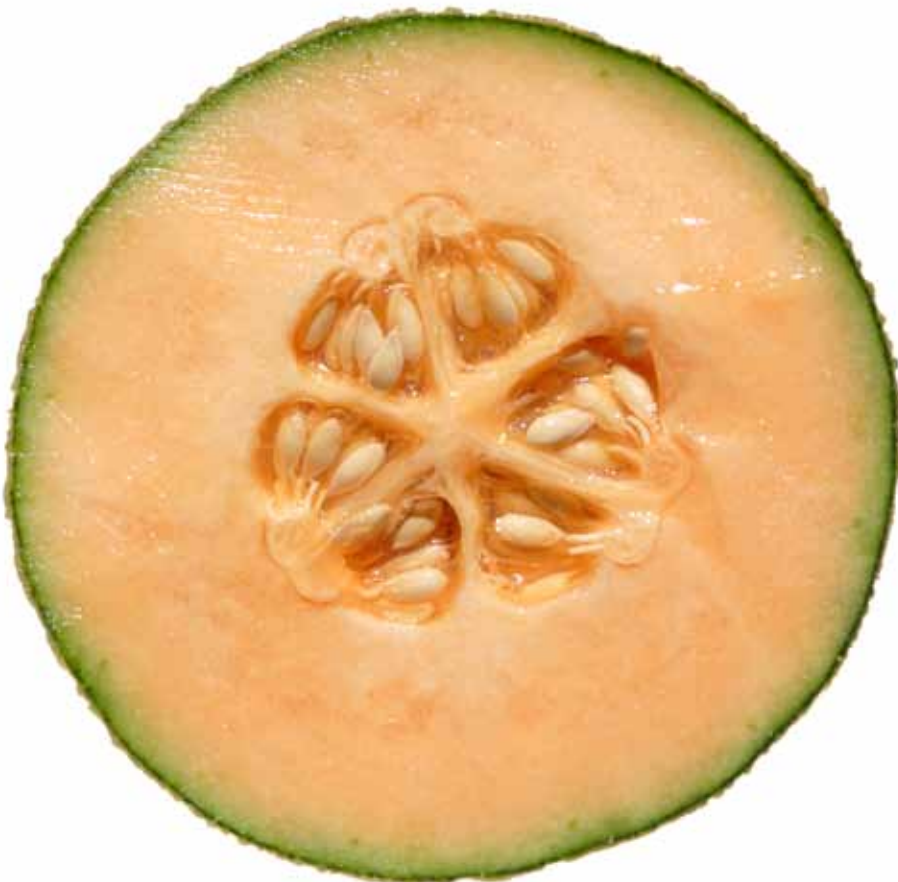


NATIONAL

Commodity-Specific Food Safety Guidelines for

Cantaloupes and Netted Melons



February 8, 2013
Version 1

DISCLAIMER

These guidelines are intended only to convey the best practices associated with the industry as research and practice advance; however, guidelines may change. For this reason, it is recommended that readers periodically evaluate the applicability of any recommendations in light of particular situations and changing standards. The authors, contributors and reviewers make no claims or warranties about any specific actions contained herein.

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Terms used in this document, have been defined as follows:

Agricultural inputs	any incoming material (e.g. seeds, fertilizers, water, agricultural chemicals, plant support) used for the primary production of cantaloupes.
Biosolids	sanitized sludge and other residues from permitted sewage treatment plants.
Cantaloupes (in this document)	refers to whole, organic and conventional, uncut cantaloupes (also known as muskmelons and rockmelons) and all varieties of netted melons.
Compost	organic matter that has been actively decomposed in a closely monitored process including time, temperature and testing (including for human pathogens prior to use on food crops) using measured inputs of water, air and carbon.
Cross-contamination	transfer of a microbial hazard, such as disease-causing bacteria and viruses, a chemical hazard, or any unintended substance from a contaminated item, surface or media to a previously uncontaminated item, surface or media.
Cull	to remove any product from the food stream that shows signs of physical damage or defect (such as skin breaks, decay or market imperfection).
Cultivation	any agricultural action or practice used by growers to allow and improve the growing conditions of fresh fruits or vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses).
Environmental assessment	an evaluation of the growing environment taking into consideration factors, including: topography, hydrology, geographical features, climatic conditions, land history, adjacent land use, agricultural water, and local animal populations as well as human activities to evaluate any safety risks that may increase the potential for cantaloupe to be contaminated. Environmental assessments should be conducted prior to planting, during production, and immediately prior to harvest.
Facilities	any permanent or temporary establishment, structure or structures used in the production, packing, cooling, storage and shipping of cantaloupes. This includes storage facilities for packing materials, chemicals and equipment, but for the purposes of this guidance document, does not include processing or fresh-cut establishments.

Farm	any premise or establishment in which fresh cantaloupes are grown and harvested and the surroundings are under the control of the same management.
Ground spot	an area on the surface of cantaloupes characterized by a lighter color, thin or no netting and which may be soft, typically caused by prolonged contact with the ground (soil, mulch, tray, cup etc.).
Grower	the person responsible for the management of the primary production of cantaloupes.
Hazard	a biological, chemical, or physical agent or undeclared allergen in, or condition of, food with the potential to cause an adverse health effect.
Hydroponics	a general term for the production of plants in a water medium.
Manure	raw and untreated animal excrement including incomplete or improperly composted or treated animal excrement.
Microbial standards for drinking water	Code of Federal Regulations (CFR) Title 40 Part 141.52 “Maximum contaminant level goals for microbiological contaminants” (Total coliform = zero).
Microorganisms	include yeasts, molds, bacteria, viruses and parasites. When used as an adjective, the term “microbial” is used.
Mitigation strategies	includes preventive controls and corrective actions.
Nonsynthetic fertilizer	any agricultural input that contains animal manure, parts, products, and/or by-products or food or green waste that has not been appropriately treated to ensure it does not introduce human pathogens to the production environment.
Packing	the physical process or action of putting fresh cantaloupes in a package. This may take place in a field or in a facility.
Packing facility	any indoor, covered or partially enclosed area with food contact surfaces in which fresh cantaloupes receive post-harvest treatment and/or are packaged.
Pathogen	an infectious microorganism such as a virus, bacterium, prion, or fungus that causes disease in humans.
Potable water	water which meets quality standards of drinking water such as described in the US EPA Clean Water Act and WHO’s Guidelines for Drinking Water Quality.

Primary production	those steps involved in the growing (e.g., planting, irrigation, application of fertilizers, application of agricultural chemicals) and harvesting of cantaloupes.
Standard Operating Procedure (SOP)	a company document which describes a specific food safety or production practice and includes the goal/objective of the procedure, version date and author, requisite equipment and steps to accomplish the objective
Standard Sanitation Operating Procedure (SSOP)	a company document which describes a specific sanitation process or practice and includes the goal/objective of the process, version date and author, requisite equipment and steps to accomplish the objective and verification measures
Visitor	A visitor is any person (other than personnel) who enters your covered farm with your permission.
Worker	includes the permit holder, person in charge, employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working on a farm or in a packing facility. ¹

¹ Food Code 2009 <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/ucm186464.htm>

AFDO: Association of Food and Drug Officials

ATP: adenosine triphosphate

CAC: Codex Alimentarius Commission

FSMA: Food Safety Modernization Act of 2011

GAPs: Good Agricultural Practices

GMPs: Good Manufacturing Practices

HACCP: Hazard Analysis and Critical Control Point

HARPC: Hazard Analysis and Risk-Based Preventive Controls

ISO: International Organization for Standards

MRL: Maximum Residue Limit/Level

MSDS: Material Safety Data Sheet

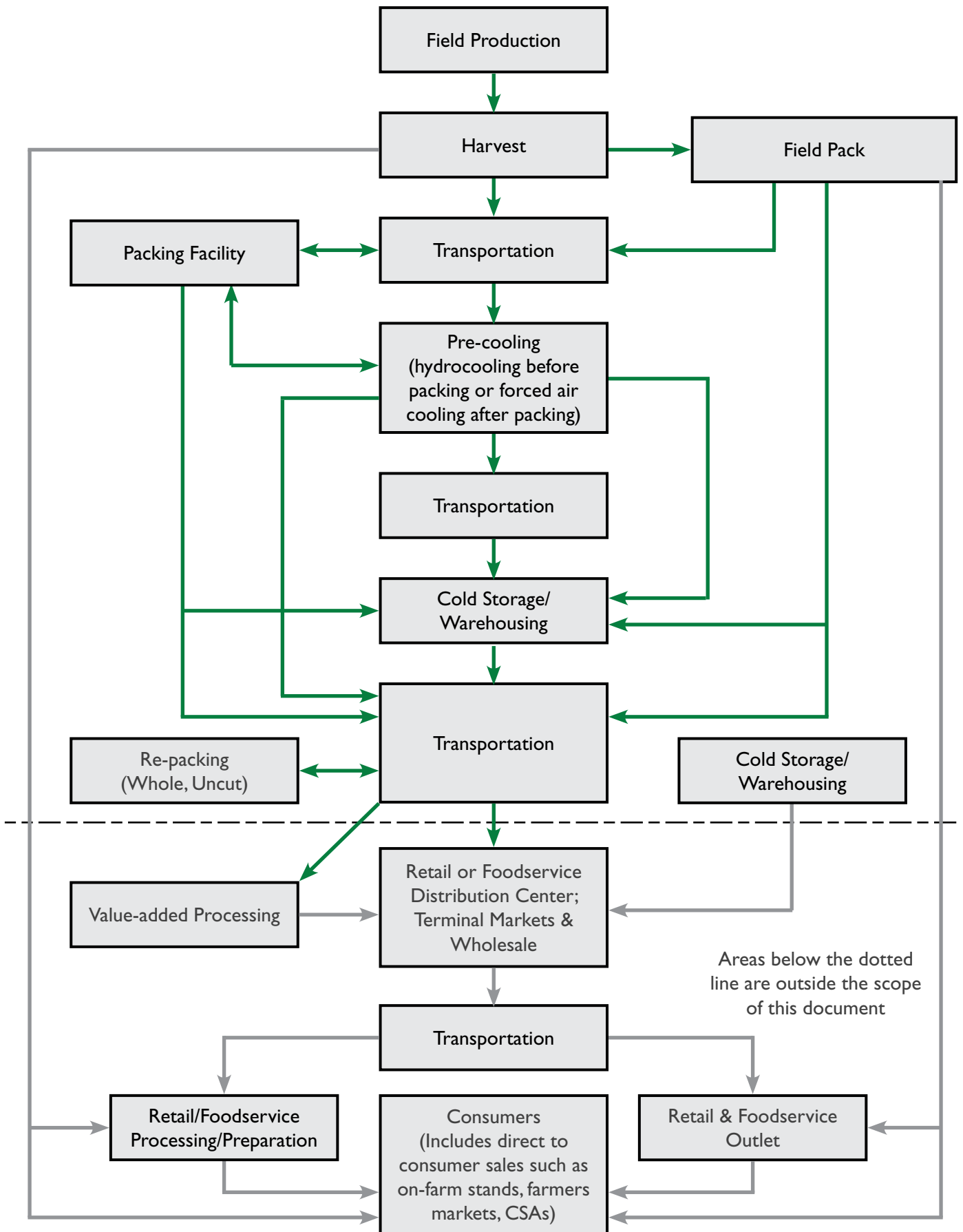
RMBP: Resistance Management Best Practices Program

SOP: Standard Operating Procedure

SSOP: Standard Sanitary Operating Procedures



Figure 1. General Supply Chain Flow for Cantaloupes and Netted Melons



1.0 Introduction

Cantaloupes (also known as muskmelons and rockmelons) are often consumed alone, mixed with other foods in salads and other dishes and as garnishes. They are popular in meals and as snacks and in some countries cantaloupes are a regular part of the diet. Cantaloupes are sliced, diced, and may be blended into smoothies and tropical drinks. The popularity of cantaloupes has remained high as they are readily available in many countries all year round. In recent years, there has been a focus on marketing not only whole cantaloupes, but pre-cut products, convenience products in packages, or in salad bars. To satisfy consumer taste and demand for cantaloupes, new hybrid varieties have been developed with improved nutrient density, higher sugar content and other consumer traits. In addition, new hybrids allow for expanded cantaloupe production in new geographic and climatic areas.

Like other fresh fruits and vegetables that are eaten raw, the safety of cantaloupe products depends on the identification, management and reduction of potential biological, chemical, physical and undeclared-allergen contamination risks. Maintaining strong preventive food safety programs throughout the food chain during primary production, packing, processing, retail, and at the point of consumption is critical. Outbreaks, both domestic and international, related to cantaloupes raise concerns regarding the safety of this fruit. There have been a number of outbreaks associated with cantaloupe consumption with a large percentage being caused by *Salmonella* spp. and more recently, *Listeria monocytogenes*.¹ Major identified risk factors contributing to foodborne illness outbreaks that have been attributed to cantaloupes include: water quality and use (both pre and postharvest), residual surface moisture, and equipment and packing facility sanitation. As whole and pre-cut cantaloupe products move through the food chain, there is also the potential for the introduction, growth and survival of pathogens. Factors contributing to pathogen survival and growth on cantaloupes include pH, temperature, presence of inhibitors (e.g. antagonistic bacteria and/or fungi) and the availability of moisture and nutrients. Moreover, morphological characteristics of cantaloupes, for instance the “netted” rind, make cantaloupes particularly susceptible to bacterial attachment and provide a good medium for growth of bacteria including those that promote spoilage as well as pathogens that cause illness in humans. Cantaloupes are a low acid food, making cantaloupe meat a natural breeding ground for bacteria including pathogens if they are introduced. Fresh cantaloupes are typically consumed without further processing or treatment that would eliminate or inactivate pathogens, if present. Thus, all parts of the food chain where cantaloupes are present need to be ever mindful of the need to reduce risks.

2.0 Objective

The primary purpose of this document is to provide general guidance on how to minimize microbial hazards during primary production through

¹ Report of the FAO to the Codex Committee on Food Hygiene Working Group on the development of an Annex on cantaloupes for the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RPC 53-2003)

Maintaining strong preventive food safety programs throughout the food chain during primary production, packing, processing, retail, and at the point of consumption is critical.

packing and transport of fresh cantaloupes. However, physical and chemical risks are also covered. All individuals in the cantaloupe supply chain are strongly encouraged to use this guidance to then develop very specific food safety programs and practices to ensure microbial hazards are minimized and to address risks posed by both physical and chemical hazards. This document incorporates key elements of the Draft Annex on Melons (2011) to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (2003) developed by the FAO Codex Committee on Food Hygiene for the Codex Alimentarius Commission (CAC) as well as the *Produce GAPs Harmonized Food Safety Standard* (UFPA, 2011) and the *Commodity Specific Food Safety Guidelines for the Production, Harvest, Cooling, Packing, Storage, and Transporting of Cantaloupes and other Netted Melons* (2013). Recommendations for the primary production of fresh fruits are covered in general by other food safety guidance documents (these resources are available in Section 10.0 *Additional Resources*), and include the CAC's *Code of Hygienic Practice for Fresh Fruits and Vegetables* (2003), CanadaGAP's *On-Farm Food Safety Manual for the Production, Packing and Storage of Fruits and Vegetables* (2012), the FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* (1998) and SENASICA's *General Requirements to Recognize and Certify Systems Aimed at Reducing Contamination Risks during the Production of Agricultural Products*.

3.0 Scope

This document provides guidance related to the production, harvesting, packing, cooling, storage, and transporting of fresh, uncut cantaloupes. This document is intended as “guidance” only and the use of the term “should” throughout is intended to encourage individual

operators to tailor their discreet programs to promote high levels of prevention and protective practices where feasible. The term “shall” is used deliberately to reflect regulatory requirements. Strong preventive programs, based on GAP, GMP and commodity specific guidelines such as these also include food safety plans, documented Standard Operating Procedures (SOPs) and Standard Sanitation Operating Procedures (SSOPs), record keeping, training and committed food safety personnel or teams. Strong preventive programs should integrate with any new legislative requirements and rules promulgated in conjunction with the Food Safety Modernization Act of 2011 (FSMA), but users are encouraged to review all FSMA rules and regulations to ensure their programs are compliant with the law. For the purposes of this document the term “cantaloupe” is used to refer to whole, uncut cantaloupes (also known as muskmelons and rockmelons) and all varieties of melon with a netted exterior. This guidance is applicable to both organic and conventional cantaloupes grown in the field (with or without cover). It focuses on preventive controls of microbial hazards, but also addresses physical and chemical hazards only in so far as these relate to Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs). Although important to food safety, requirements for physical, chemical and biological hazards are addressed by other federal and state regulation, and these guidelines do not supersede those requirements or/and any associated recommendations. The document does not provide recommendations for cantaloupe processing (e.g., trimmed, sliced and/or diced cantaloupes), retail outlets, foodservice or consumers. Resources for handling cantaloupes in these settings are provided in Section 10.0 *Additional Resources* at the end of the document.

4.0 Worker Health and Hygiene Training and Practices

Companies should establish policies for worker hygiene and monitor worker health to minimize the risk of contamination from ill or injured workers who come directly into contact with cantaloupes or food contact surfaces during production, harvesting, and post-harvest activities. Visitors to cantaloupe production and handling areas should also adhere to the personal hygiene provisions in this section and, where appropriate, wear protective clothing. The following practices are recommended:

- Each primary production operation should have written SOPs that relate to health, hygiene and sanitary facilities. The SOPs should address worker training, facilities, and supplies, to enable workers to practice proper hygiene. Company policies relating to worker hygiene as well as illness-reporting are critical to reducing risk.
- Before handling cantaloupes workers should wash their hands properly using soap and potable water (i.e., meets the microbial standards of drinking water). Workers should be trained in proper techniques for hand washing (e.g., washing and drying). Workers should be monitored for compliance with company hand cleaning policies.
- If gloves are used, hands must be washed prior to use. A SOP for glove use should be written and followed, and should address such issues as appropriate handling of gloves when using a field toilet. If the gloves are reusable, they should be made of materials that are easily cleaned and sanitized, and they should be cleaned regularly and stored in a clean area. That glove cleaning process should be documented and logged. If disposable gloves are used, they should be discarded when they become torn or contaminated.
- All workers and supervisors in cantaloupe production areas, including contract workers and visitors, should adhere to the company's SOP for personal hygiene.

4.1 Personal Hygiene

Workers who have direct contact with cantaloupes during production, harvesting and post-harvest activities should maintain personal cleanliness. To reduce the risk of pathogen contamination via humans, the following practices are recommended:

- Workers should begin the work day in appropriate, clean clothing or protective outer garments.
- If a company provides or requires workers to wear protective clothing, a policy regarding use, storage and cleaning of the protective clothing should be established along with appropriate log sheets.
- Workers should be prohibited from tobacco use, spitting, chewing gum (or similar) and eating or drinking (other than water) in the production and handling areas.
- Workers should refrain from actions that could result in the contamination of cantaloupes (e.g., unprotected sneezing or coughing over cantaloupes or food contact surfaces).

4.2 Sanitary Facilities

In order to ensure that adequate personal hygiene can be maintained, sanitary facilities should be readily accessible to workers and visitors and, where required, shall be located in accordance with regulations. The following practices are recommended:

- Provide areas away from any field and packing operations for workers to take breaks and eat. These areas should provide access to toilet and hand-washing facilities.
- All workers should be trained in proper use of sanitary facilities. Training should include toilet use, proper disposal of toilet paper, and proper hand washing and drying procedures.
- Sanitary facilities should be provided and located so as to be readily accessible and in accordance with prevailing regulation.

- Sanitary facilities should be located in a manner to encourage their use and reduce the likelihood that workers will relieve themselves outside the sanitary facility. Facilities should be present in sufficient number to accommodate personnel and be appropriate for both genders if the workforce contains males and females.
- Portable facilities should not be located or cleaned in cultivation and product handling areas or near irrigation water sources or conveyance systems. Growers should identify the areas where it is safe to put portable facilities to prevent spread of contamination by traffic in case of a spill, during use, cleaning or transport.
- Sanitary facilities should be cleaned and maintained on a regular basis according to a SSOP so as not to be a source of contamination. Those cleanings should be logged.
- Facilities should include potable water, unscented soap, toilet paper, and single use paper towels or an equivalent sanitary hand drying method. Multiple use cloth drying towels should not be used or even in the toilet facilities. Hand sanitizers should not replace hand washing and should be used only after hands have been properly washed with soap and potable water.

4.3 Health Status

People with a food-transmissible, infectious disease or infected with a pathogen without exhibiting symptoms, can transmit the pathogens to cantaloupes, food contact surfaces and/or other workers. To reduce the risk of pathogen contamination via human transmission, the following practices are recommended:

- Cuts, wounds and other injuries should be properly cleaned and disinfected, then protected by water proof dressings. Injuries should be immediately reported to management to allow them to decide whether a worker or manager can continue to work in proximity to cantaloupes or food-contact surfaces.
- People exhibiting symptoms or suspected to be a carrier of an infectious disease or illness should not be allowed to enter production and handling areas. Any person so affected should immediately report illness or symptoms of illness to management.
- Companies should keep records of workers' observed and reported symptoms of unhealthy conditions such as respiratory or gastrointestinal distress (e.g. head cold, sinus infection, bronchial or lung disorders, diarrhea, etc.)
- Workers should be trained to notice and report symptoms of diarrheal or food-transmissible, infectious diseases in themselves and others.

5.0 Primary Production

Cantaloupes may be grown out-of-doors, in protected or semi-protected structures (e.g. greenhouses or shade houses), harvested, and packed in the field or a facility by operations of varying sizes under a wide range of climatic and geographical conditions using various agricultural inputs and technologies. Biological, chemical and physical hazards may therefore vary significantly from one type of production and packing operation to another. In each production area, it is critical to consider site-specific growing practices that promote the safe production of cantaloupes. The production environment and production practices used for cantaloupes should be evaluated for food safety hazards and preventive controls should be adopted where necessary.

The primary production of cantaloupe (i.e., production and harvest) should be managed to ensure a product free of contamination and/or adulteration. Special consideration should be given to practices specific to cantaloupe production because of the unique characteristics of the cantaloupe rind and because cantaloupes frequently have direct contact with soil, media, equipment, personnel, and other potential sources for cross-contamination. The netted rind surfaces of cantaloupes provide an environment where pathogens may adhere and survive with limited

possibility of elimination during post-harvest practices. Potential sources of contamination include the environment, agricultural water, soil amendments, agricultural chemicals, equipment, workers, and product transportation.

5.1 Environmental Risk Assessment

An environmental risk assessment is an evaluation of the growing environment. This assessment is intended to identify hazards (i.e., potential sources of contamination) prior to and during production and harvesting activities so that they can be proactively managed. This is important because contamination that occurs during production and harvesting may not be removed in subsequent steps. For example, pathogenic bacteria deposited on a cantaloupe in the field from animal feces may not be removed or killed by a sanitizing rinse. Because each production site is unique, potential hazards will vary from site to site and each unique site should be assessed individually. Environmental hazards that potentially present a contamination risk to cantaloupe production sites may be related to topographical, hydrological and geographical features of the field and surrounding area, historical land use, adjacent land use, climate, agricultural water, and local animal populations as well as human activities. Particular attention should be given to potential sources of fecal contamination in the cantaloupe production and handling areas (e.g., humans and domestic and wild animals), which may introduce fecal contamination to those areas. In addition, fecal contamination of the production area may occur indirectly from contaminated water, aerosols, tools and/or equipment. Appropriate measures should be taken to mitigate risks from hazards identified in the environmental assessment, and measures taken to address each hazard should be documented.

5.1.1. Assessment of the Production Environment

Prior to the first planting of the season, production site location, prior use and adjacent land use should be assessed for potential risk factors including, but not limited to:

- Topographical and geographical features – the slope and the potential for runoff from nearby fields. This includes flood risk as well as hydrological features of nearby sites in relation to the production site.
- Adjacent land use – the proximity of land and waterways and any factors that may present a contamination risk (e.g., animal production facilities, hazardous waste sites, waste treatment facilities, compost operations, industrial activities and housing.).
- Historical land use – any previous use of the production site that may impact food safety (e.g., hazardous waste sites, landfills, concentrated animal operations, industrial activities)
- Climate – climatic conditions can affect risk in the growing environment. Examples of climatic conditions that might be considered, include, but are not limited to:
 - Frequent or heavy rainfall that might result in flooding or

This [environmental risk] assessment is intended to identify hazards (i.e., potential sources of contamination) prior to and during production and harvesting activities so that they can be proactively managed.

persistent standing water, which may attract animals or increase the potential for pathogen survival in the soil or on non-soil surfaces.

- Prevailing or high winds that might transport pathogens from sources outside the cantaloupe field.

5.1.2 Assessment of Wildlife and Domestic Animal Activity

Any animal, including humans, present in or near the production environment can be a potential pathogen carrier. Animals are also a potential source of contamination of surface water that may be used on cantaloupes. Numerous factors such as presence, types, numbers, habits and habitats may influence the risk animals pose to a cantaloupe production area. It is important that a thorough site-specific evaluation be conducted prior to planting and prior to harvest. To manage these risk factors, the following practices are recommended:

- The grower, a designated food safety manager, or other trained personnel should evaluate the potential for pathogen contamination from animals in the production environment. A risk assessment should be performed to determine the risk level as well as to evaluate potential strategies to control or reduce the introduction of pathogens by animals.
- An evaluation of the potential for pathogen contamination from animals should be included as part of the environmental assessments for cantaloupe production sites conducted prior to the first seasonal planting, prior to and during harvest.
- Production areas should be protected against wildlife, livestock, and domestic animal intrusion in areas where a risk assessment identifies such risks. Mitigation strategies should comply with local, state, and federal regulations.
- Cantaloupe production sites and handling areas should be monitored for evidence of crop contamination (e.g. fecal matter, animal intrusion). Where such evidence is found, the risk should be evaluated by a food safety professional and appropriate action should be determined and documented. This may include buffers around affected areas, destruction of affected crop, or other corrective actions to ensure contaminated cantaloupes are not harvested. Strategies to mitigate animal intrusion may also need to be re-evaluated.
- Cantaloupe production and handling areas should be properly maintained to reduce the likelihood of animal attraction (e.g., minimize standing water, restrict access to water sources, keep production sites and handling areas free of waste and clutter that can provide shelter for animals).
- Growers are encouraged to contact the relevant agencies (e.g., state and federal fish and wildlife agencies, departments of health and agriculture) to develop and document strategies to mitigate animal intrusion. Caution needs to be taken as some of the “pests” (e.g., birds) could be endangered species, and thus it is important to understand how to manage them within the law.

5.2 Ground Spot Reduction Measures

Cantaloupe rind “ground spots,” where the cantaloupe is in direct contact with the soil, ground cover or growth media, have been demonstrated by laboratory analysis to have significantly greater microbial populations than non-ground spot areas and, therefore, may be more susceptible to pathogen contamination. Growers may use various measures to reduce ground spot formation. These measures should be evaluated to ensure that they do not increase the risk of contamination through ground spots or other parts of the cantaloupe surface.

If physical barriers are used underneath cantaloupes, the following are recommended:

- Barriers should be clean and sanitary before being placed under the cantaloupes.
- Barriers should be used in the field in a manner that does not increase the risk of contaminating cantaloupes.

If workers have direct contact with cantaloupes, the following is recommended:

- Ensure that workers follow the personal hygienic practices outlined in Section 4.1 *Personal hygiene* when handling or turning cantaloupes during production and harvest.

5.3 Microbiological Testing

When sampling plans and methodology are properly designed and performed, microbiological testing can be a useful tool to evaluate water quality, verify the effectiveness of composting methods and sanitation practices, and in general, provide information about a production area. The intended use of information obtained (e.g., evaluating the risk posed by a particular hazard) can aid in designing an appropriate sampling plan and determining the most appropriate microorganisms for which to test. In selecting a testing third-party laboratory, growers should ensure that:

- The laboratory is accredited by either US or international accreditation bodies (such as ISO 17025 or equivalent) and uses test methods that have been validated for the intended use.
- The laboratory has experience in conducting the type of testing needed for the particular type of sample matrix.

In addition, each operation should have a corrective action plan in place before a positive and actionable sample is found so that, if one does occur, corrective actions can be taken quickly.

5.4 Water for Primary Production

Growers should identify the sources of water used during production and harvesting activities (e.g., municipality, re-used irrigation water, reclaimed wastewater, discharge water from aquaculture/aquaponics, hydroponics, well, open canal, reservoir, rivers, lakes, roof top catchment, farm ponds). It is recommended that growers assess and manage the risk posed by these waters as follows:

- Assess the potential for pathogen contamination (e.g., from livestock, human habitation, sewage treatment, manure and composting operations) and the water's suitability for its intended use. Reassess the potential for pathogen contamination if events, environmental conditions (e.g., temperature fluctuations, heavy rainfall, flooding) or other conditions indicate that water quality may have changed from baseline measurements.
- Based on the risk assessment, identify, implement, and document corrective actions to prevent, minimize or remediate the risk of contamination. Possible corrective actions may include fencing to prevent large animal intrusion, proper maintenance of wells, filtering water, not stirring the sediment when drawing water, building settling or holding ponds, and water treatment systems or facilities. Settling or holding ponds that are used for irrigation or other production uses may be microbiologically safe, but may attract animals or in other ways increase the microbial risks associated with water that is used in the production area. If water treatment is needed, consult with water safety experts and regulatory authorities.
- Determine how and when sampling and microbiological testing should be done to document and evaluate the quality of water for each intended use. Testing may be necessary after a change in water source, flooding or a heavy rainfall when water is at a higher risk of contamination. When testing, determine and document:
 - What tests need to be performed, (e.g., which pathogens and/or fecal indicators)
 - Parameters pertinent to assessing water quality (e.g., temperature of water sample, water source location, concentration of antimicrobial chemicals, water pH, weather description)
 - Frequency of testing
 - Location and manner of sample collection and handling
 - What the test outcomes indicate
 - How test results will be used to define corrective actions

- Water should be tested at least annually but the frequency of testing should depend on the source of the water (less for adequately maintained deep wells, more for surface water), intended use of the water (degree of contact with the cantaloupe and time until harvest), and the risks of environmental contamination, including intermittent or temporary contamination (e.g., heavy rain, flooding) of the water source or its distribution system. Frequent water tests may be useful to establish the baseline assessment of water quality.
- If the water source is found to have levels of indicator organisms that suggest the potential for contamination with pathogen or is contaminated with pathogens, corrective actions should be taken and documented to ensure that the water is not a source of contamination. When the likely cause of unacceptable microbial levels can be determined, corrective actions should be appropriate to the cause. These may include:
 - Eliminating potential sources of contamination in the water source or in the water distribution system,
 - Using a different water source until the contamination source is corrected, and/or
 - Treating the water to eliminate pathogens in a manner that is acceptable for contact with food. Testing frequency should be increased until consecutive results are within the acceptable range.
- When an environment assessment of historical and adjacent land use indicates a potential chemical hazard (e.g., heavy metals), water sources used in cantaloupe production should be tested for the identified chemical hazard prior to use.

5.4.1 Water Quality for Pre-blossom Irrigation and Dust Abatement

The quality of irrigation water and type of irrigation method used is important when assessing risk of pathogen contamination. Growers should use irrigation methods and practices to minimize contact with cantaloupes and to minimize the soil moisture content where cantaloupes contact the soil or growth medium.

To reduce the risk of pathogen contamination, growers should:

- Use water of known quality that does not increase the risk of cantaloupe contamination when:
 - Irrigating pre-blossom (before plants start to flower).
 - Using water for dust abatement and to maintain roads, yards, and parking lots in areas within or near cantaloupe production sites.
- Avoid creating persistent pools of water that may come into contact with cantaloupe rinds.

5.4.2 Water for Irrigation, Fertilizers, Pest Control, Harvest Activities and Other Agricultural Uses Where Water Contacts Cantaloupe

Pathogens can survive and grow in water and many agrichemical solutions, including pesticides. To reduce the risk of pathogen contamination, growers should:

- Use water that meets the microbial standards for drinking water during irrigation, the application of aqueous fertilizers and pesticides, prior to and during harvest, and any other time it is likely to contact cantaloupes.

5.5 Soil Amendments – Manure, Biosolids and Other Nonsynthetic Fertilizers

Manure, biosolids and other non-synthetic (non-conventional) fertilizers may contain human or animal waste, animal parts or products. Because of this, foodborne pathogens may be present and may persist for weeks or even months, particularly if treatment of these materials is inadequate. If done properly, composting can be a practical and efficient method to inactivate foodborne pathogens in manure. Therefore, it is recommended that growers:

- Do not use biosolids or human waste in any form.
- Do not use raw, untreated and/or partially treated manure or other non-synthetic fertilizers.

When using composted and/or treated soil amendments, growers should:

- Use only compost that has undergone a validated commercial physical, chemical or biological method to reduce the risk of potential pathogen survival.
- When purchasing compost and other nonsynthetic fertilizers and soil amendments that have been treated to reduce microbial contaminants, obtain documentation from the commercial supplier that identifies the origin, treatment used, laboratory tests performed, and the results thereof.
- Implement management plans that control, reduce or eliminate cross-contamination of cantaloupe production or handling areas in close proximity to on-farm manure or manure-based soil amendment storage, treatment or composting sites.
- Prevent cross-contamination from runoff or leaching by securing areas between treated and untreated soil amendments.
- Minimize risk of contamination from untreated or unknown soil amendments used on adjoining fields. If the potential for contamination from the adjoining fields is identified, preventive actions (e.g., application method, run-off, or aerosol controls such as injection, ditches, berms, barriers) should be implemented to minimize the risk.

5.6 Agricultural Chemicals

The inappropriate use, handling and storage of agricultural chemicals may result in a chemical hazard. When using agricultural chemicals follow the instructions on appropriate use provided on the manufacturer's label. In addition:

- Only agricultural chemicals which have been approved for cantaloupes shall be used and they shall be used in accordance with the manufacturer's label instruction and in accordance with all federal, state, and local laws.
- Pesticide residue "Maximum Residue Limit/Level" (MRL) or "Tolerance" as established by regulatory authorities in the destination market(s), shall not be exceeded.²

² USDA's International Maximum Residue Level database (FASonline): <http://www.mrldatabase.com/>

The inappropriate use, handling and storage of agricultural chemicals may result in a chemical hazard. When using agricultural chemicals follow the instructions on appropriate use provided on the manufacturer's label.

- In order to minimize the genetic enrichment and sharing of transmissible antimicrobial resistance, the use of highly selective antimicrobial compounds of agricultural and human or veterinary medical importance (e.g., antibiotics such as Agrimycin, Tetracycline) should, if used, be managed responsibly within a Resistance Management Best Practices Program (RMBP). Information on RMBP may be found on approved agricultural product labels and associated technical bulletins.
- Workers who apply agricultural chemicals should be trained in proper application procedures and, when necessary, supplied with proper protective gear.
- Growers shall keep records of all agricultural chemical applications. Records should include information on the date of application, the chemical used, the crop sprayed, the pest or disease against which it was used, the concentration, method of application, and records on harvesting to verify that the time between application and harvest is in accordance with Pre-harvest Intervals on the product label.
- Agricultural chemical application equipment, including sprayers should be calibrated, as necessary, to control the accuracy of application. Calibration records should be maintained.
- The mixing of agricultural chemicals should be carried out in such a way as to avoid contamination of water and land in the surrounding areas and to protect employees.
- Application equipment such as sprayers and mixing containers should be thoroughly washed after use, especially when used with different agricultural chemicals on different crops, to avoid spraying a chemical on cantaloupes that has not been approved for use on cantaloupes.
- Agricultural chemicals should be kept in their original containers, labeled with the name of the chemical and the instructions for application. Agricultural chemicals should be stored in a safe, well-ventilated place, away from production areas, living areas and harvested fruits or vegetables, and disposed of in a manner that does not pose a risk of contaminating crops, the inhabitants of the area, or the environment of the primary production.
- Empty containers should be disposed of as indicated by the manufacturer's label. They should not be used for other food-related purposes.

5.7 Equipment Associated with Production, Harvesting, and Field-packing

Equipment used during production and harvest, including tools and containers used to hold harvested cantaloupe, should be constructed and maintained in a manner that minimizes the potential to become a source of contamination.

5.7.1 Equipment Construction, Use and Maintenance

Standard operating procedures (SOPs) should be developed for the use and maintenance of production and harvesting equipment to ensure that it is in an appropriate state of repair and condition that facilitates cleaning and sanitizing. The technical specifications recommended by the equipment manufacturers for their proper use and maintenance should be followed. Equipment should function as intended to prevent contamination of cantaloupes, including making sure that oil and lubricants and broken parts of machinery and other harvesting supplies do not contaminate the fruit. In addition:

- Workers should be trained to follow the SOPs on equipment use and maintenance.
- Specific sanitation and maintenance requirements should be identified and Standard Sanitation Operating Procedures (SSOPs) developed for all equipment that is used.
- Food contact surfaces (e.g., padding, cutting tools, product containers) should be constructed of or covered / sleeved with materials that facilitate cleaning and sanitizing, are non-toxic, and will not harbor pathogens (e.g., non-porous).
- Equipment should be maintained in good order and function according to its intended use without damaging cantaloupes.

- A SOP should be established regarding monitoring of all containers used in harvesting and field-packing for cleanliness and condition prior to use.
- Damaged containers should be repaired before use.
- Reusable containers should be cleaned and sanitized regularly or after potential contamination.
- Containers used for holding cantaloupe should not be used for other purposes (e.g., should not hold personal items, waste).
- Containers for waste, by-products and inedible or dangerous substances, should be segregated or otherwise identified to prevent their use as harvesting containers. Such containers should be suitably constructed and, where appropriate, made of impervious material so as not to leak. Where appropriate, such containers should be secured to prevent intentional or accidental contamination of cantaloupes or agricultural inputs.
- Equipment lubrication should be managed so as to not contaminate cantaloupes. Food-grade lubricants should be used on packing equipment where food contact may occur. Food-grade and non-food-grade lubricants are to be properly labeled and stored separately.
- Equipment that is not in use should be properly stored so as not to pose a risk of contamination to cantaloupes.

5.7.2 Equipment Cleaning and Sanitizing Programs

Cleaning and sanitizing procedures (SSOPs) should be in place to ensure that cleaning and sanitizing is carried out effectively and appropriately. Cleaning and sanitizing programs should be monitored for effectiveness and should be regularly reviewed and adapted to reflect changing circumstances such as new equipment or cleaning agent. The following practices are recommended:

- Production and harvesting equipment, including containers and tools such as knives, scissors, sickles, pruners and machetes, that come into direct contact with cantaloupes should be cleaned and sanitized according to an established, documented schedule and as needed to minimize the risk of contamination.
- Water that meets the microbial standards for drinking water shall be used to clean all equipment directly contacting cantaloupes, including harvesting and transportation equipment, containers and tools.
- Cleaning and sanitizing programs should be carried out in a location where the rinse water will not contaminate cantaloupes or food contact surfaces.
- Waste water discharge shall be disposed in alignment with federal, state and local requirements.

Cleaning and sanitizing programs should be monitored for effectiveness and should be regularly reviewed and adapted to reflect changing circumstances such as new equipment or cleaning agent.

5.7.3 Cleaning and Sanitizing Procedures and Methods

The appropriate cleaning and sanitizing methods and materials will depend on the type of equipment and its construction. The following procedures are recommended:

- Cleaning and sanitizing agents and materials should only be used for their intended purpose according to the instructions on the manufacturer's label.
- Cleaning and sanitizing agents and materials should be properly labeled and kept or stored separately in secure storage facilities. A material safety data sheet (MSDS) should be available at all times.
- Cleaning procedures should include the removal of debris from equipment surfaces, application of a detergent solution, rinsing with potable water, and, where appropriate, sanitizing.
- Equipment should be dried in a manner that does not result in contamination (e.g., air dry, single-use disposable towels).
- The effectiveness of cleaning and sanitizing procedures should be monitored.
- Protective clothing worn by workers during cleaning and sanitizing of equipment should be routinely cleaned and stored in a manner that protects them from biological and chemical contamination.

5.8 Harvest and Field-Packing Operations

Cantaloupes are harvested based on the cantaloupe's stage of maturity in relation to variety traits and market preferences. For some cantaloupe varieties, partial or complete separation of the cantaloupe from the vine results in varying degrees of exposure of the stem scar to contamination. Similarly, but to a lesser degree, cantaloupe varieties that are harvested by cutting the vine at the stem also create exposed tissue with a vascular connection to the edible fruit flesh. If pathogens are present in the harvest and field-packing environment, they can become attached to cantaloupe on the rind or at the stem scar. Therefore, preventive controls to minimize pathogen presence established during pre-harvest production should be continued throughout harvest and field-packing operations. Written SOPs should be developed and implemented to ensure appropriate handling of cantaloupes to minimize exposure to pathogens, subsequent attachment and potential internalization at the rind surface and sub-surface layers through openings at the stem or stem scar.

5.8.1 Pre-harvest Assessment

Prior to harvest, a pre-harvest risk assessment should be conducted to ensure that conditions have not changed that pose chemical, physical, or microbiological hazards. Although the focus of these guidelines is microbiological hazards, it is also important to address chemical and physical hazards in a pre-harvest assessment. Any condition that is non-compliant with the company's food safety plan should be addressed to minimize the potential risk to the harvested cantaloupes. Growers should:

- Establish a pre-harvest environmental assessment process and checklist that describes how and when the assessment is to be performed, and includes an evaluation of conditions that may potentially result in physical, chemical or microbiological contamination of cantaloupes. The assessment should include a review of the pre-planting environmental assessment for any changes in the production area and adjacent land that may increase the risk of contamination (see Section 5.1 *Environmental Risk Assessment* for details on pre-planting assessments).
- Document any corresponding corrective actions taken to address identified hazards.

5.8.2 Prevention of Contamination, Cross-contamination and Mechanical Damage

During harvest and field-packing operations, cantaloupes are susceptible to mechanical damage, contamination and cross-contamination. Wounds in damaged cantaloupes provide entry points for pathogens and sites for pathogen survival and multiplication. Specific control measures should be implemented to reduce and minimize the risk of

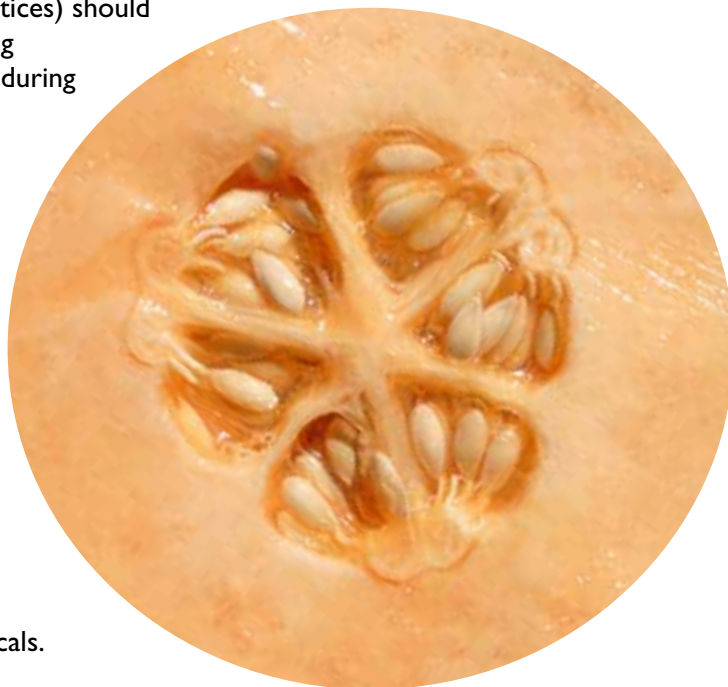
contamination from physical, chemical and biological hazards during harvest and field-packing operations. In order to minimize the risk of contamination, the following practices are recommended:

- Controls should be implemented to ensure that food contact surfaces are in good condition and cleaned and sanitized before use and as necessary. For additional details on equipment maintenance, cleaning and sanitizing, see Section 5.7 *Equipment associated with production, harvesting, and field-packing*.
- Avoid mechanically damaging cantaloupes with rind punctures, cracks, and bruising, as the resulting wounds may provide entry points for pathogens and sites for pathogen survival and multiplication.
- Handle damaged cantaloupes in a manner that does not pose an increased risk of contamination to other cantaloupes.
- Good worker hygiene practices are critical to prevent surface contamination of cantaloupes. For additional details on worker hygienic practices, see Section 4.0 *Worker Health and Hygiene Training and Practices*.
- Identify any procedures that may pose a risk for equipment facilitated cross-contamination of cantaloupe. These include vehicles and farm equipment utilized in the fields, vehicles used to transport workers, vehicles used to haul culls and waste, as well as other possibilities. For such procedures, develop appropriate means of reducing and controlling the possible transfer of pathogens from equipment to cantaloupes or soil, water, concrete and other surfaces that may directly contact cantaloupes.
- Segregate equipment used in high-risk operations or potentially exposed to high levels of contamination (e.g., equipment used to manipulate compost or that travels through animal-related operations, cleaning out waste pits or lagoons), and store in a designated area away from the cantaloupe production and handling areas.
- If equipment was previously used in a high-risk operation, use effective means of equipment cleaning and sanitation before subsequent use in cantaloupe fields.

5.8.3 Harvest

During any operation where cantaloupes are harvested or salvaged, risk factors related to multiple harvests, harvesting tools and direct contact of harvested cantaloupes with soil and humans may pose a contamination risk to cantaloupes. In order to minimize risks related to these factors, the following practices are recommended:

- Prior to harvest, an individual trained in basic food safety practices (e.g., GAPs, Good Handling Practices) should be designated as responsible for harvesting activities. This person should be available during harvesting operations.
- During harvest operations, workers in the field should monitor for physical, chemical, and biological hazards including, but not limited to:
 - Evidence of animal intrusion and fecal contamination.
 - Evidence of debris such as glass, plastic, and metal. Remove the debris or do not harvest cantaloupes in close proximity to the debris if the safety of the cantaloupes is compromised by their presence.
 - Evidence of open and/or unsecured pesticides, fertilizers and other chemicals.



Establish a SOP to ensure that all essential field harvest information is appropriately maintained, transferred and accessible to downstream operations for recordkeeping in the event that contaminated product must be traced to the production site.

- Any other factor that might increase the risk of chemical, physical or biological contamination.
- Document any corresponding corrective actions taken to address identified hazards.
- Include the name and contact information of the party responsible for the harvest crew in the assessment record.
- When a field is to be harvested more than once, identify any additional potential hazards and develop practices and procedures to protect against the introduction of pathogens between harvests.
- As harvest time approaches, schedule irrigation so as to avoid exposing cantaloupes to excessive mud.
- Train workers to recognize and not harvest cantaloupes that have mechanical damage.
- Implement harvest handling practices to minimize the potential for soil-to-cantaloupe contamination.
- Harvesting tools should be properly sharpened, cleaned and sanitized. If improperly used, harvesting tools can wound cantaloupe rinds and provide a point of entry for contaminants. For additional details on equipment use and cleaning, see 5.7 *Equipment associated with production, harvesting, and field-packing*.

5.8.4 Packing Cantaloupes in the Field

Cantaloupes are often packed directly in the field. Field-packing includes any practice that involves grading, sorting, cleaning, and/or packing of cantaloupes into containers for commerce while still in the field. In order to minimize the risk of contamination during field-packing operations, the following practices are recommended:

- Establish a procedure for inspecting and accepting or rejecting cantaloupes.
- Discard foreign objects and debris in an appropriate location so they are not a potential source of contamination.
- Remove loose soil from cantaloupes prior to packing, but avoid using cloth towels or other tools that may potentially cross-contaminate cantaloupes.
- When cantaloupes are cooled, minimize holding time prior to cooling.
- Establish a SOP to ensure that all essential field harvest information is appropriately maintained, transferred and accessible to downstream operations for recordkeeping in the event that contaminated product must be traced to the production site.
- Food contact equipment used in field packing operations and equipment contacting food contact surfaces should be designed, maintained, cleaned and sanitized as described in

Section 5.7 *Equipment associated with production, harvesting, and field-packing*, to minimize the potential for contamination during packing.

5.9 Transport from the Production Site to the Packing and Cooling Facilities or Direct to Market

Conditions under which cantaloupes are transported may provide opportunities for microbial contamination. Harvested cantaloupes should be transported under conditions that minimize the risk of contamination. Recommendations for containers used to hold harvested cantaloupes are located in Section 5.7 *Equipment associated with production, harvesting, and field-packing*. To manage the potential for contamination during transport from the production site, the following practices are recommended:

- Prior to use, shipping containers and transport trailers should be cleaned and made sanitary. Each transporter should have a SOP for shipping containers/trailers for cleaning, sanitizing and maintenance.
- A SOP should be developed for inspecting the shipping container/trailer prior to loading to ensure it is clean, functional, and free of objectionable odors.
- If shipping containers/trailers are used to transport items other than cantaloupes, procedures should be established to ensure that shipping containers/trailers will not potentially contaminate cantaloupes with biological, chemical, physical contaminants or undeclared allergens.
- Fresh cantaloupes should not be transported in shipping containers/trailers previously used to carry potential sources of contamination, such as animals, animal manure or biosolids, trash, chemicals, or non-food grade equipment or tools, unless the containers/trailers are first adequately cleaned and made sanitary.
- Where shipping containers/trailers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there should, where necessary, be effective separation of products.
- If cantaloupes are transported in an open trailer, cantaloupes should be covered. Establish a SOP for use and storage and a SSOP for cleaning of coverings.
- Load and unload cantaloupes in a manner that minimizes damage and contamination.
- When not in use, cleaned shipping containers and transport trailers should be stored in a manner to minimize potential contamination (e.g., from insects, lizards, birds, rodents, dust, water).
- Damaged shipping containers and transport trailers should be repaired or replaced.

6.0 Facilities

A well-designed and managed facility, and its corresponding food safety program, can minimize the risk of contamination. The needs of each facility may vary due to location, environment, local requirements, the volume of cantaloupes handled, and many other variables. Facility design and layout should permit appropriate maintenance, cleaning and sanitation, and minimize airborne contamination. Food contact surfaces and materials should be non-toxic, durable, smooth, non-absorbent, and suitable for cleaning and sanitizing. Facilities (closed, open, canopied), and their pest management programs, should provide effective protection against pest access and harborage. The provisions below apply to facilities that pack, cool, or store cantaloupes.

6.1 Location

When deciding where to locate packing, cooling, and storage facilities, potential sources of contamination that may be present on adjacent land, and/or due to topography, and/or climatic and environmental conditions (e.g., environmentally polluted areas; industrial activities that potentially pose a risk of contamination; adjacent concentrated animal feeding operations; pesticide spray drift from adjacent fields; areas subject to flooding without sufficient safeguards, areas prone to pest infestations, and areas where solid and/or liquid wastes cannot be effectively removed) need to be evaluated.

If facilities are now located in areas that have potential contamination sources, effective protective measures must be taken to address the risk of contamination. Facilities should not be located anywhere where, after implementing protective measures, a threat to food safety clearly remains and is persistent.

6.2 Facility Grounds

- The grounds around the facility should be kept in a condition that will control, reduce, or minimize the risk of contamination to food.
- Store equipment properly, remove litter and waste, minimize standing water, and regularly cut weeds or grass around the buildings or other man-made or natural structures to reduce the chance that they become an attractant, breeding place, or harborage for pests.
- Maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas (fields, packing houses) where cantaloupes are exposed. Roads should be managed to minimize dust prior to harvest or paved.

6.3 Design and Layout

The design and layout for packing, cooling, and storage facilities should permit good handling practices, including protection against cross-contamination between and during operations. Because of the seasonal nature of the cantaloupe harvest, facilities may be used only a few months of the year, leaving them dormant for many months and susceptible to pest infestations and food contact surface and equipment contamination. When dormant, facilities should be appropriately protected from pest infestations. Their design should permit thorough cleaning and sanitizing before the start of the season.

6.3.1 Internal Structures and Fittings

Structures within facilities should be soundly built of durable materials and be designed and constructed so that they can be readily maintained, cleaned and where appropriate, sanitized. In particular the following specific conditions should be satisfied to protect the safety and suitability of food:

- The surfaces of walls/roof supports, partitions, doors, and/or floors should be constructed of materials that minimize the risk of contamination and facilitate cleaning and, where appropriate, sanitizing.
- Ceilings and overhead fixtures should be constructed and maintained to minimize the build-up of dirt, dust, feces, rust, and condensation, and protect cantaloupes, food contact surfaces, and packaging from dripping water and other materials that may drop from the ceiling/fixtures.
- If the facility is closed to protect against external sources of contamination, then windows, vents, fans, and similar features should be adequately protected to minimize entry of pests and other contaminants. If the facility is open, then food contact surfaces should be adequately protected to minimize contamination from pests or other contaminants.
- Food contact surfaces should be in sound condition and durable. They should be constructed of materials that are smooth, non-toxic, non-absorbent, and facilitate cleaning and sanitizing.



6.3.2 Air Quality and Ventilation

If a facility has a ventilation system, it should be designed, constructed, and maintained so as not to be a source of contamination. For example, ventilation systems should be designed, constructed and maintained to:

- Minimize the entry of dust, dirt, aerosols, and other potential airborne contaminants into the facility.
- Minimize the build-up of dirt, dust, and condensation on the ventilation equipment itself.
- Prevent condensed water, wet solutions, and rust from dripping on product, product packaging or food contact surfaces.

6.3.3 Lighting

- Adequate natural or artificial lighting should be provided to enable good handling practices.
- Lights should be equipped with shatter-proof light bulbs or have similar protective coverings to prevent broken fixtures or light bulbs from contaminating cantaloupes.

6.3.4 Drainage

Adequate drainage is critical to packing, cooling, and storage facilities to minimize the risk of contaminating cantaloupes. To ensure adequate drainage:

- Floors should be kept as dry as possible using appropriate methods.
- The facility should be designed with sloped floors to effectively drain water.
- Workers should have proper training to remove standing water or push standing water to the drains.
- Drains should be designed to facilitate effective cleaning and sanitizing to prevent foodborne pathogens (e.g., *Listeria monocytogenes*) from becoming established in the environment and serving as a source of product contamination.

6.4 HACCP / HARPC plans

Facility operators should control food safety hazards through the use of systems such as Hazard Analysis and Critical Control Point (HACCP) or Hazard Analysis and Risk-Based Preventive Controls (HARPC) built upon foundational programs such as GAPs and GMPs. Facilities should pay special attention to product flow and segregation of incoming and outgoing product to avoid cross-contamination. The following components and practices of food safety hazard control plans are recommended:

- A flow diagram depicting the handling or process steps in the operation.
- Identification of conditions, practices and processes in the operation critical to product safety.
- Implementation of effective control or risk management procedures for identified conditions, practices and processes critical to product safety.
- Monitoring of control or risk management procedures to ensure their continued implementation and effectiveness.
- Documentation of any corrective measures taken.
- Periodical review and update of the control and risk management procedures, especially whenever the operation changes.

6.5 Receiving

When delivered from the field to the facility, it is recommended that controls be developed to ensure that equipment and vehicles do not transfer pathogens cantaloupes directly or into a packing facility. Cantaloupes should undergo an inspection process at the facility and should be accompanied with sufficient information to facilitate traceability (for more details see Section 7.0 *Traceability Program*). The following practices are recommended:

- Ensure cantaloupes are from sources and/or suppliers that are following GAPs outlined in this guidance document.
- Establish a written procedure for inspecting and accepting or rejecting incoming loads of cantaloupes. Avoid accepting whole cantaloupes that have visible signs of decay or damaged rinds (e.g., mechanical damage or cracking) due to the increased risk of the presence of foodborne pathogens in cantaloupes with decay or damage.
- Damaged or decayed cantaloupes should be discarded in a manner that does not serve to attract pests or cross-contaminate other cantaloupes.
- Product staging areas should be kept clean and free of debris.
- Keep harvested cantaloupes as cool as possible during receiving, e.g. use shading or covered receiving areas and minimize the time between receiving and product cooling.
- Reduce the temperature of the cantaloupe as soon as feasible after receiving.
- Cantaloupes should arrive with field information that provides sufficient detail to facilitate product traceability (for more details see Section 7.0 *Traceability Program*). Establish a SOP to appropriately maintain and transfer all documents to downstream operations for their recordkeeping.

6.6 Microbiological and Other Specifications

When sampling plans and methodology are properly designed and performed for facilities and equipment, microbiological testing can be a useful tool to evaluate and verify the effectiveness of safety and sanitation practices, and provide information about an environment, a process, and risk management procedures. The intended use of information obtained (e.g., evaluating the effectiveness of a sanitation practice, evaluating the risk posed by a particular hazard) can aid in designing an appropriate sampling plan and determining what microorganisms are most appropriate to test for. Test methods should be selected that are validated for the intended use. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems. In selecting a third-party testing laboratory, facility operators should ensure that:

- The laboratory is accredited (such as ISO 17025 or equivalent) and uses test methods that have been validated for the intended use.
- The laboratory has experience in conducting the type of testing needed for the particular type of sample.

In addition, each facility should have a corrective action plan in place before a positive sample is found so that, if one is identified in a test, corrective actions can be taken quickly.

6.7 Facility Maintenance

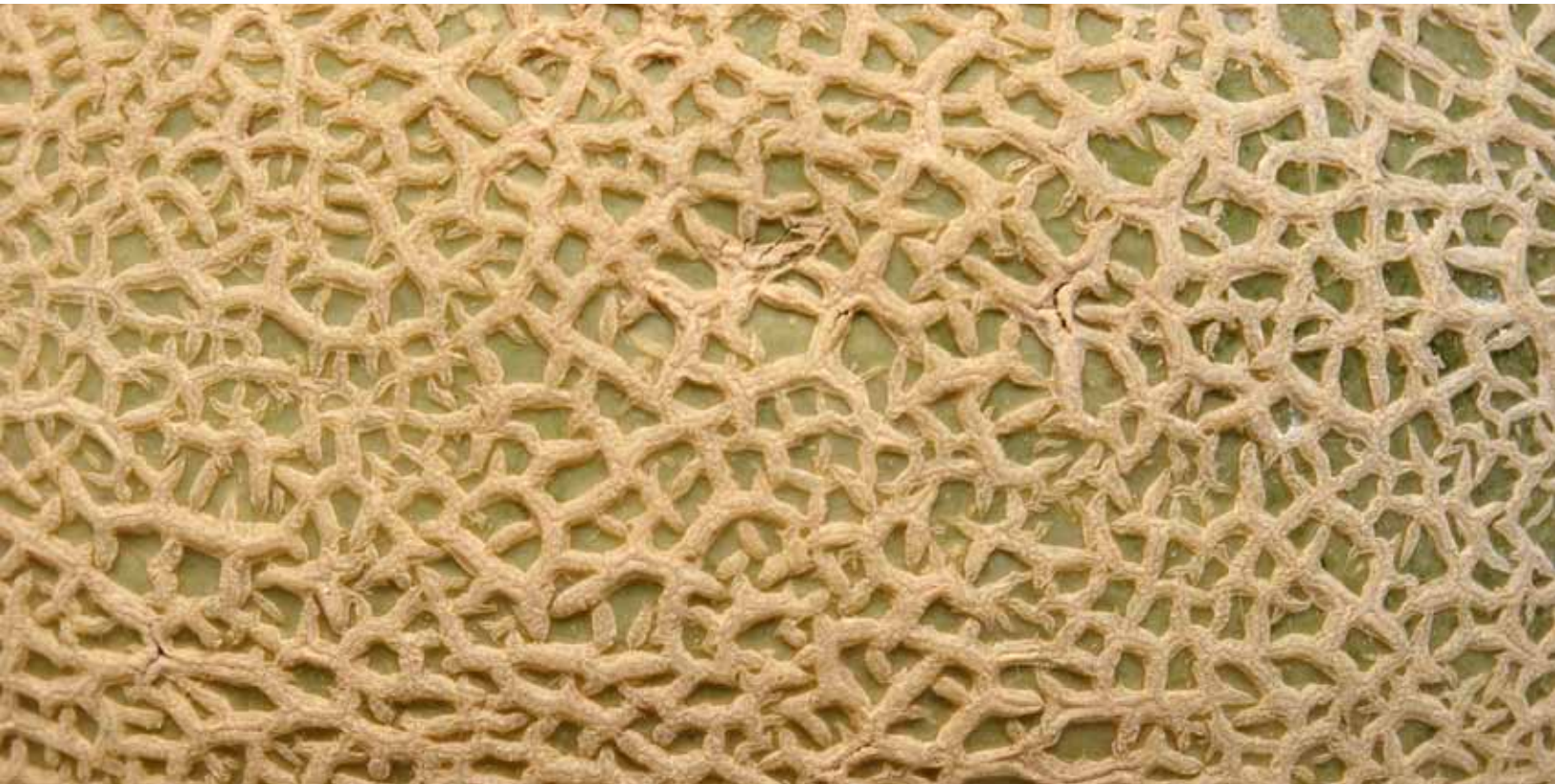
The facility should be kept in an appropriate state of repair and condition to facilitate cleaning and sanitation procedures, function as intended (particularly at critical steps), and prevent contamination of cantaloupes. In addition, the following practices are recommended:

- Establish SOPs for preventive maintenance of the packing, cooling, cold storage and warehouse facilities.
- At the beginning of the packing season, a pre-operative inspection of the facilities should be conducted to ensure it is in an appropriate state of repair.

6.8 Equipment Construction and Maintenance

Various types of equipment used during transport, packing, cooling, and storing operations present an opportunity for contamination of cantaloupes if appropriate practices are not followed. Appropriate equipment design and maintenance measures should be used to reduce and control the potential introduction of human pathogens into the packing, cooling and storage environments. Equipment used in packing cantaloupes should also be engineered and maintained to prevent cantaloupe bruising and damage. The following conditions and practices are recommended:

- Equipment used in packing, cooling, and storing cantaloupes should be engineered and maintained in a condition that allows for effective cleaning and sanitation to prevent the buildup of pathogens.
- Food contact surfaces should be constructed of materials that can be easily cleaned and sanitized. Do not use wood or other porous materials (e.g., carpet) as food contact surfaces as they are difficult to clean and sanitize.
- Where food contact surfaces present a risk of cantaloupe bruising and damage, they should be constructed of materials that minimize such damage, thereby minimizing the potential introduction of human pathogens.
- Protect food contact surfaces from contact with water that does not meet the microbial standards of drinking water and other materials that may be a source of contamination.
- Identify food contact surfaces that should remain dry and implement practices to keep these surfaces as dry as possible (e.g., slant tables).
- Avoid use of hollow structures such as table legs, conveyer rollers, and racks because they may collect water and debris, and thus, harbor pathogens.
- Prepare a SOP for equipment maintenance that addresses the following:



Cleaning and sanitation programs are critical for ensuring that cantaloupes handled in facilities do not become contaminated with pathogens. Pathogenic microorganisms may be found on floors, drains, food contact surfaces, rafters, and equipment surfaces and components.

- Inspect all equipment prior to use to check for any equipment deficiencies or maintenance requirements.
 - Drip pans (to catch oil or other lubricants) should be in place and tightly secured.
 - Hydraulic hoses, hydraulic motors, and overhead hydraulic fittings should be tight and drip free with no indications of recent leakage.
 - Loose or damaged equipment parts should be removed or appropriately repaired immediately. Temporary remedies, such as string, tape, wire, and / or cardboard, should not be used in equipment repair.
- All equipment maintenance requiring the use of chemicals, oils, greases, and fuels should be conducted away from the production and handling areas
- Equipment that has been repaired should be cleaned and sanitized before returning to the production line.
- Equipment lubrication should be managed so as to not contaminate cantaloupes. Food grade lubricants should be used on equipment where food contact may occur. Food-grade and non-food-grade lubricants are to be stored separately.
- Glass and clear or brittle plastic on equipment should be shatter-proof or covered to prevent broken fixture material from contaminating cantaloupes.
- Establish control procedures for when equipment is not in use, including a policy for removal of equipment from the work area or site and equipment storage.
- Old, unused equipment should be removed from the packing areas and stored in a manner that does not present a food safety hazard.
- All equipment used to control environmental conditions, such as temperature and humidity, should be maintained and calibrated on a routine basis. Calibration activities should be documented and issues addressed and documented immediately.

6.9 Cleaning and Sanitation Programs

Cleaning and sanitation programs are critical for ensuring that cantaloupes handled in facilities do not become contaminated with pathogens. Pathogenic microorganisms may be found on floors, drains, food contact surfaces, rafters, and equipment surfaces and components. Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices including the proper use and handling of cleaning and sanitation chemicals.

Important areas of concern include any surface that comes into contact with cantaloupes, toilet facilities for employees, and control of pests. Without appropriate sanitation practices, equipment and facilities may

harbor pathogens. Cleaning and sanitizing of equipment and facilities should be conducted in a manner that protects against contamination of cantaloupes, cantaloupe-contact surfaces, or packaging materials and should include the following practices:

- Prepare a SSOP for all equipment that describes all aspects of the cleaning and sanitization procedure, as appropriate, for each piece of equipment. Include the frequency with which it is to be cleaned (e.g., daily, weekly, monthly or seasonally), the chemicals to be used and their concentrations and the process to be used for cleaning (e.g., wash, sanitize and rinse if necessary).
- Food contact surfaces (e.g., belts and conveyor systems, packing tables) should be designed and constructed of materials that allow for effective cleaning and sanitation.
- Food contact surfaces should be cleaned and sanitized daily, and more frequently, if needed, such as after moving between different production lots, or if a potential contamination event has occurred. Establish a master sanitation schedule for these areas that clearly identifies cleaning frequency, cleaning agents/sanitizers to be used, precautions, and responsible party. This schedule should clearly identify the equipment with reference to its SSOP.
- Non-food contact surfaces (e.g., harvest equipment and trailers, walls, ceilings, rafters, floors, drains, mezzanines, storage areas, cooler tops or any surface that does not contact cantaloupes) should be cleaned and, if appropriate, sanitized on a routine basis. Establish a master sanitation schedule for these areas that clearly identifies cleaning frequency, cleaning agents/sanitizers to be used, precautions, and responsible party. This schedule should clearly identify the equipment with reference to its SSOP.
- Only water that meets the microbial standards of drinking water should be used in food contact surface and equipment cleaning and sanitizing activities.
- A proper sanitizing solution should be readily available to sanitize and store all hand-held tools that are not in use. Check, adjust (if necessary), and document the sanitizer concentration strength as often as necessary to assure its effectiveness.
- When cleaning and sanitizing equipment, particularly during operations, use techniques and supplies that do not pose a risk of cross-contamination of product or food contact surfaces.
- All chemicals used for cleaning and sanitizing of food contact surfaces including equipment, tools, utensils, and product containers must be approved for that use and used according to the manufacturer's label instructions and all federal, state and local requirements.³ Cleaning and sanitizing chemicals should be stored in a secure, vented storage area located away from areas used for product handling and storage of product packaging materials. A MSDS and the product label for each chemical should be kept on-site or readily available.
- Equipment, utensils and tools used for cleaning or sanitizing, including food contact and non-food contact surfaces, should be identifiable, segregated, and maintained in a manner sufficient to avoid becoming a source of contamination.
- Workers should not walk, step, sit, or lie on food contact surfaces of equipment. If it is necessary to walk on or otherwise contact equipment, such as when cleaning, workers should take proper precautions to prevent contamination (e.g., shoe covers or other protective clothing) and to ensure that surfaces are cleaned and sanitized after work is completed and before production resumes.
- A pre-operative inspection of the equipment and facilities should be conducted daily to verify that cleaning and sanitation procedures have been completed according to the SSOP, the equipment is safe and ready for use, pest control measures are in place and functioning, and all food safety protocols are being followed. Use a checklist and document any corrective actions taken to address deficiencies.
- Verify the efficacy of the facility and equipment cleaning and sanitation methods with routine sanitation

³ Appropriate chemical use can be verified in NSF's White Book™ – Nonfood Compounds Listings Directory available at: <http://www.nsf.org/usda/psnclistings.asp>

verification testing (e.g., adenosine triphosphate (ATP) test). Sanitation verification data should be maintained and be available for inspection. Operations should have a documented environmental sampling and microbial testing program capable of detecting foodborne pathogens of concern based on the operation's risk assessment (e.g., *Listeria* spp.) with testing targeted to areas where moisture, soil or debris may accumulate (e.g., under conveyance belts, drains, forced air tunnels, hydro-cooling equipment).⁴

6.10 Pest Control

Pests pose a risk to the safety of cantaloupes. Cantaloupes have a very high sugar content and are extremely attractive to rodents, flies and other pests that may cross-contaminate cantaloupes. Pest infestations can occur where breeding sites and a food supply are available. Effective measures should be taken to exclude pests from packing, cooling and storage facilities and to minimize the risk of contaminating cantaloupes. Good sanitation, inspection of incoming materials, and active monitoring for pest activity can minimize the likelihood of infestation and thereby limit the need for pesticides. A pest control program should include the following:

- A cantaloupe cull disposal and waste removal program should be implemented to minimize the potential for these materials to serve as an attractant to pests and the potential for pest-to-cantaloupe contamination.
- All pesticides, traps, and bait used in facilities must be acceptable for use in and around a food handling facility and used in accordance with product label and local, state, and federal regulations.
- All pest control chemicals should be properly labeled and stored in a secure separate area.
- If pest control is performed internally or by a third-party pest control company, a copy of the applicator's license, any chemicals used, MSDS, and a schedule of the applicator's activities and actions should be maintained and available for review.
- Permit the use of insecticides or rodenticides inside the facility as per the label and only under precautions and restrictions that will protect against the contamination of cantaloupes, food-contact surfaces, and food-packaging materials.
- If rodent traps are deployed around the inside of the facility and bait stations along the outside perimeter of the facility, detailed maps demonstrating the location of each trap and bait station should be available for review. Traps and bait stations should be inspected routinely and any corrective actions (e.g., cleaning out traps, replacing damaged traps) documented. Traps should have monitoring recording labels inside the trap, not on the outside, to prove that the trap was open and inspected.
- An inspection buffer of 18 inches should be maintained on both the inside and outside perimeters of the physical facility (e.g., between pallets and a wall). Raw product and equipment may not be stored flush against the wall of the facility).

6.11 Waste Disposal

Systems for waste treatment and disposal should operate in a manner so as not to constitute a source of contamination for cantaloupes or the facility. To ensure adequate waste disposal the following practices are recommended:

- Areas for garbage, recyclables, and compostable waste should be located away from produce handling areas and clearly designated for their intended use (e.g., trash, recyclable materials or product that might be re-worked). Weeds and other pest harborage should be minimized around the containers.
- Pest control devices around dumpsites should be used per their labeled directions.

⁴ FDA. 2008. Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-to-Eat Foods; Draft Guidance. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm>

- Waste should be stored in appropriate receptacles that are covered or closed (except for waste collection/cull trailers in active use), removed from the facility on a regularly scheduled basis, and disposed of in a manner to minimize contamination including any controls necessary to ensure that vehicles used to transport waste from the facility do not themselves serve as a source of contamination.

6.12 Post-harvest Water Use

An adequate supply of water that meets the microbial standards of drinking water with appropriate provisions for its storage, distribution and temperature control should be available to ensure the safety and suitability of cantaloupes. Systems carrying water that does not meet the microbial standards of drinking water should be clearly identified, separate, and have appropriate backflow prevention devices installed.

Water is often used in dump tanks or flotation flumes to transport cantaloupes from field containers into the packing facility. Cross-contamination and attachment of pathogens to the outer rind during water contact is a food safety concern. In addition, if the temperature of the water in the dump tank or flume is cold and the internal temperature of the cantaloupes is hot from field heat, the negative water temperature differential may promote infiltration of water and microbial pathogens (if present) into the sub-rind tissue, natural openings, harvest abrasion wounds and, potentially, into the edible portion of the fruit. Focus and consideration should be placed on activities that both maintain water quality and minimize the potential for infiltration, including:

- If water is used in the packing process to wash, cool, or transport cantaloupe, the initial source water should meet the microbial standards of drinking water. Antimicrobials are primarily effective in disinfection of the recycled water. Any pathogens which may be present on the rind surface may be reduced, but are unlikely to be eliminated by washing.
- Netted melons handled in any immersion system or hydrocooler have the potential for pathogen internalization. The melon type, maturity, and duration of contact are important considerations, but infiltration of the stem scar may occur whether water temperature is at a positive or negative differential to fruit pulp temperature.
- Take measures, including controlling product through-put, to minimize the depth of submersion of cantaloupes or netted melons in water. When fully submerged, water is more likely to infiltrate into the cantaloupes.
- If unloading cantaloupe from field containers into dump tanks by immersing containers, measures should be taken to reduce the field soil or road debris that may be present on the outside of containers, wheels, chassis, and sidewalls of vehicles and its potential for significantly interfering with antimicrobial dose management.
- Water pH (where appropriate for oxidizer), sanitizer concentration, soil load, turbidity levels, water hardness, product through-put capacity, and resident or contact time in dump tank water should be controlled and monitored to ensure the efficacy of any antimicrobial water treatment.



6.13 Fungicidal treatments

Fungicides may be applied, per label instructions, to cantaloupes by use of an aqueous spray or immersion to extend the post-harvest shelf-life of the fruit. Maximum Residue Limits/Levels (MRLs) vary among countries, so handlers must be aware of MRLs for the area in which they are growing as well as in the destination market when applying fungicides. The following are recommended:

- Only fungicides that are authorized for use on cantaloupes by the prevailing regulatory authorities in both the country of origin and destination markets shall be used. Fungicides and all pesticides shall be used according to the manufacturer's label instructions. All federal, state, and local laws shall be followed including those regulating MRLs.⁵
- Water that meets the microbial standards of drinking water should be used in water-based chemical treatments to ensure that the water does not contaminate the cantaloupes with pathogens.
- If hot water treatments are used as an alternative to post-harvest chemical fungicide or other pest control treatments, water temperature and time should be evaluated and monitored to ensure that the appropriate water temperature and time is maintained.

6.14 Cooling Cantaloupes

Cantaloupes are typically cooled by forced-air cooling or by use of a chilled water drench or immersion. Cooling cantaloupes by placing them in cold storage is not an effective means of cooling but this practice is preferable to storing cantaloupes at ambient temperatures. While cooling cantaloupe with water, if done properly, may reduce microbial loads on the outside surface of cantaloupes, it may also substantially increase the risk of contamination if done improperly. Microbial reduction on cantaloupe surfaces is dependent on disinfectant concentration and contact time. However, it is important to remember that human pathogens, once present on the surface of a cantaloupe, cannot be completely eliminated by washing. Soaking cantaloupes in aqueous solutions containing wash water disinfectants for even very long periods of time is not an effective means of eliminating surface microbial contamination of the cantaloupe rind and may actually aid in the infiltration of human pathogens into the edible portions of the cantaloupe by creating an infiltration driving force. Cantaloupe cooling water may also be a significant source of microbial cross contamination if there is insufficient water disinfectant present. Also, because cantaloupe cooling water is colder than the cantaloupes, infiltration of small amounts of cooling water may enter cantaloupes through the stem scar and rind. Forced-air cooling operations present a lower risk, but may also spread product contamination if forced air cooling equipment is not cleaned and sanitized regularly. To manage these risk factors, the following practices are recommended:

- Cooling and cold storing cantaloupes as soon as possible after harvest is recommended to retard multiplication of foodborne pathogens, if present, on or from the rind surface of cantaloupes.
- During forced air cooling, crates/bins should be stacked in a manner that allows for uniform air flow and distribution.
- Water that is used in hydro-coolers should meet the microbial standards of drinking water. Water that is used only once and not recirculated is preferable.
- If water is used for cooling and it is recirculated, it should be evaluated and monitored to ensure that disinfectant levels are sufficient to reduce the potential risk of cross-contaminating cantaloupes.
- Cooling systems including forced-air cooling equipment should be cleaned and sanitized on a regular basis according to the SSOP to ensure that the potential for cross-contamination is minimized.
- Cooling systems' condensation units should drain directly into drainage systems. Emptying of this water into floor drains should be prohibited.
- Cooling cantaloupes by putting ice on the top of cantaloupes should be avoided. This practice poses a

5 USDA's International Maximum Residue Levels database (FASonline): <http://www.mrlatabase.com/>

food safety risk if the ice is contaminated. In addition, ice melts at refrigeration temperatures such that water will drip from one cantaloupe to another, potentially cross-contaminating cantaloupes.

6.15 Cold Storage and Warehousing

Cold storage and warehouse facilities are often the last areas that house cantaloupes before they are shipped to the next point of the supply chain. Increased emphasis on cold chain logistics and management is recommended, in line with advancing knowledge and technologies for both refrigeration and temperature monitoring. The conditions and sanitation programs of these facilities are critical in maintaining the integrity of the finished product before it exits the facility. The following practices are recommended:

- Storage and warehousing of finished cantaloupes should be under conditions that will protect them against physical, chemical, and microbial contamination as well as against deterioration of the product and the container.
- Product placement and storage should not facilitate cross-contamination (e.g., pallets placed on top of bins, iced containers placed above containers with non-iced product).
- Cantaloupes should be stored at appropriate temperatures according to industry standards (ideally between 36° and 41°F and 95% relative humidity).⁶
- Refrigeration units should be inspected on a regular basis and kept in good operating condition.
- Temperature monitoring devices should be placed in the warmest area of the refrigerator unit and calibrated on a regular basis.
- In the event that condensation forms in the facility, develop a management plan to ensure that it does not pose a risk of contamination to cantaloupes and food contact surfaces. Condensation provides conditions optimal for microbial growth and may potentially serve as a source of cross-contamination.
- Condensate/water from evaporator-type refrigeration systems should be contained in catchments designed to assure that it does not become a source of contamination. Water from refrigeration catchments should be drained and disposed of away from product and product contact surfaces.
- The storage area should be included in the facility's master cleaning schedule and pest control program. If finished product is present during cleaning of floors or drains, product should be moved or protected to ensure that water does not splash on product.
- Forklifts and other pallet moving equipment should be included in the master sanitation schedule and should be cleaned on a regular basis.
- Cleaning and sanitation activities should be documented.

6.16 Transportation Between Packing/Cooling Facilities and Retail

Conditions under which cantaloupes are transported to the next stage in the market may provide opportunities for microbial contamination. Temperature control during transportation of cantaloupes should be managed to reduce, control, or eliminate the risk of contamination. For example, if cantaloupes are pre-cooled, refrigerated transport should be used to maintain the temperature of pre-cooled cantaloupes throughout transport. Putting ice on the top of cantaloupes to keep cantaloupes cold during transport creates potentially unsanitary conditions and is not recommended because water will drip from one cantaloupe to another, potentially cross-contaminating other cantaloupes. In addition to the recommendations listed in Section 5.9 *Transport from the production site to the packing/processing facility or direct to market*, the following practices for transport between packing/cooling facilities and retail are recommended:

- Refrigeration equipment should be fully functional and properly maintained.

⁶ USDA and NFSMI – Cantaloupe Information Sheet (<http://nfsmi.org/documentlibraryfiles/PDF/20110822024612.pdf>); University of California, Davis – Cantaloupe: Safe Methods to Store, Preserve, and Enjoy (<http://anrcatalog.ucdavis.edu/pdf/8095.pdf>)

Recall programs are procedures to remove product from commerce when there is reason to believe the product is or may be contaminated. The ability of companies to remove contaminated or potentially contaminated cantaloupes from the marketplace quickly and effectively is vital to both businesses and consumers.

- Prior to loading, the vehicle should be pre-cooled.
- Temperature of cantaloupes should be measured and recorded prior to or during loading and maintained during transit.
- Vehicle cleaned and checked for damage

7.0 Traceability Program

Product traceability refers to the ability to follow the movement of a food through specified stage(s) of production, cooling, packing, processing, and distribution. Tracing information about cantaloupes facilitates tracking the physical movement from their original source through intermediate sources to their final recipient and tracking product from the final recipient back to the source. Though not a preventative measure, effective product tracing systems are an important element of a comprehensive food safety program and should be verified periodically for effectiveness. The following practices are recommended:

- A documented traceability program should be established. Record contents and retention should be consistent with applicable regulations. At a minimum, the following records should be maintained:
 - Records that enable reconciliation of product delivered to recipients (one step forward) should be maintained except for direct-to-consumer sales.
 - Records should be maintained that link product with source of the produce and other supplies and raw materials (one step backward).
 - Records should include the items and date of receipt, lot numbers, quantities, source of the produce, and transporter.
- A trace-back and trace-forward exercise should be conducted at least annually and should achieve accurate traceability within four hours or as required by applicable regulations. The trace exercise should achieve an account of all product one step forward and one step back (100% reconciliation).

8.0 Recall Program

Recall programs are procedures to remove product from commerce when there is reason to believe the product is or may be contaminated. The ability of companies to remove contaminated or potentially contaminated cantaloupes from the marketplace quickly and effectively is vital to both businesses and consumers. The following practices are recommended:

- A documented recall program, including written procedures, should be established.⁷ The documented program should include:
 - A designated recall team with team members' 24-hour, seven-days-a-week contact information.

⁷ FDA's Guidance for Industry: Product recalls, including removals and corrections. <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

- A 24-hour contact list of customer point persons to be called if product requires recall.
- A contact list of key regulatory officials (e.g., federal and state) that may need to be notified if a recall is warranted.
- A contact list of commodity organizations and trade association experts that could be called upon to provide technical help if needed.
- A documented mock recall exercise should be performed at least annually. The mock recall should include the trace back and trace forward exercise (described above in Section 7.0 *Traceability Program*) with 100% reconciliation of product and should be completed as stated in the program and in compliance with applicable regulations.

9.0 Documentation and Records

A comprehensive written food safety plan that includes a description of each of the hazards identified in assessing the conditions, practices and processes at the operation, as well as the steps that will be implemented to address each hazard, should be prepared by the company managing the cantaloupe operation. The description should include, but is not limited to, the following: an evaluation of all facilities, water and distribution system, personnel illness reporting policy, worker hygiene procedures, cleaning and sanitation procedures, monitoring programs, and training programs.

The following are examples of the types of records that should be retained for a minimum of two years or as required by prevailing regulation:

- Microbiological testing results and trend analyses
- Water monitoring and test results
- Worker training records
- Pest control records
- Cleaning and sanitation reports
- Equipment monitoring and maintenance records
- Inspection/audit records
- Corrective actions

10.0 Additional Resources

10.1 Good Agricultural Practice Guidance Documents

- Association of Food and Drug Officials' (AFDO) *Model Code for Produce Safety*. <http://www.producesafetyproject.org/admin/assets/files/AFDO-Model-Code.pdf>
- CanadaGAP. *On-Farm Food Safety for Fresh Fruits and Vegetables*. <http://www.canadagap.ca/en/manuals/off-manualdownloads.aspx>
- Good Agricultural Practices Manual – Improving the safety and quality of fresh fruits and vegetables: A training manual for trainers. College Park: Joint Institute for Food Safety and Applied Nutrition, 2010. <http://www.jifsan.umd.edu/training/gaps.php>
- United Fresh Produce Association. *Harmonized Standards – Field Operations and Harvesting*. http://www.unitedfresh.org/assets/food_safety/Harmonized_Standard_pre-farm_gate_110722.pdf
- U.S. Food and Drug Administration. *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*. <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm>
- Codex Alimentarius Commission. *Code of Hygienic Practice for Fresh Fruits and Vegetables*. http://www.codexalimentarius.org/roster/detail/en/?dyna_fef%5Buid%5D=80352
- SENASICA. *General Requirements to Recognize and Certify Systems Aimed at Reducing Contamination Risks during the Production of Agricultural Products*.

10.2 Good Manufacturing Practices Guidance Documents

- Association of Food and Drug Officials' (AFDO) *Model Code for Produce Safety*. <http://www.producesafetyproject.org/admin/assets/files/AFDO-Model-Code.pdf>
- Good Manufacturing Practices for Harvesting and Handling Fresh Produce – Improving the safety and quality of fresh fruits and vegetables: A training manual for trainers. College Park: Joint Institute for Food Safety and Applied Nutrition, 2010. <http://www.jifsan.umd.edu/training/gaps.php>
- United Fresh Produce Association. *Fresh-cut Produce Handling Guidelines*. <http://www2.unitedfresh.org/forms/store/ProductFormPublic/>
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- FDA's Guidance for Industry: Product recalls, including removals and corrections. <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>
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