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**PRE-HACCP PROGRAMS FOR FOOD PROCESSORS:**

*Good Manufacturing Practices (GMPs),  
Sanitation Standard Operating Procedures (SSOPs) and  
Good Agricultural Practices (GAPs)*

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E X T E N S I O N

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## **PURPOSE OF THIS PUBLICATION**

Several factors are involved in the processing of sanitary, consumer-safe foods. Sanitation involves all activities and responsibilities for preventing product adulteration, as well as the implementation of actions to prevent the occurrence of some hazards that can harm consumers. Providing a clean and sanitized environment and equipment for food processing is essential for producing safe foods, but that is not the limit of responsibility. Personnel practices, plant facilities, equipment and operations designed to prevent contamination, pest control and warehousing practices are all equally important. It is imperative that all of these considerations be addressed in the design of a comprehensive sanitation program and a subsequent HACCP system.

There are three major basic programs that need to be implemented by commercial food processors to achieve food safety: Current Good Manufacturing Practices (cGMPs), Sanitation Standard Operating Procedures (SSOPs) and Good Agricultural Practices (GAPs). These programs act as guidelines for food processors and should be viewed as essential prerequisites for the development and implementation of a HACCP system.

Current Good Manufacturing Practices (cGMPs) were promulgated by the U.S. Food and Drug Administration (FDA). They are intended to provide criteria for complying with the provisions of the Federal Food, Drug and Cosmetic Act requiring that all human foods be free from adulteration. The requirements of the cGMPs included in this publication have some direct or indirect influence on the biological, chemical or physical safety of the finished products.

Sanitation Standard Operating Procedures (SSOPs) are also of importance to the FDA and the USDA. This program institutes the practice of maintaining a sanitary environment for producing safe and unadulterated food products. Sanitation promotes hygiene for the prevention of foodborne illness.

Good Agricultural Practices (GAPs) are of importance to the FDA and the U.S Department of Agriculture (USDA). They focus on preventing microbial contamination of fresh produce rather than relying on corrective actions once contamination has occurred. This program allows for accountability at all levels of the agricultural and packing environment. By incorporating GAPs, all parties in the supply chain contributes to food safety.

Production of safe foods can be achieved by close attention to the details set forth in all these programs. It is the responsibility of all parties involved to ensure that practices and processes fall within these guidelines.

**1. CURRENT GOOD MANUFACTURING PRACTICES (cGMPs)**

**FEDERAL REGISTER**

**DEPARTMENT OF HEALTH, EDUCATION AND WELFARE  
Food and Drug Administration**

**21 CFR, Part 110**

**PART 110-CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING,  
PACKING OR HOLDING HUMAN FOOD**

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- Sec.  
110.110 Natural or unavoidable defects in food for human use that present no health hazard.

AUTHORITY: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

SOURCE: 51 FR 24475, June 19, 1986, unless otherwise noted.

**Subpart A — General Provisions**

**§ 110.3 Definitions.**

The definitions and interpretations of terms in section 201 of the Federal Food, Drug and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- (a) “Acid foods or acidified foods” means foods that have an equilibrium pH of 4.6 or below.
- (b) “Adequate” means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (c) “Batter” means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- (d) “Blanching,” except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- (e) “Critical control point” means a point in a food process where there is a high probability that improper

control may cause, allow or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) “Food” means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) “Food-contact surfaces” are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

(h) “Lot” means the food produced during a period of time indicated by a specific code.

(i) “Microorganisms” means yeasts, molds, bacteria and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective “microbial” instead of using an adjectival phrase containing the word microorganism.

(j) “Pest” refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies and larvae.

(k) “Plant” means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling or holding of human food.

(l) “Quality control operation” means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) “Rework” means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) “Safe-moisture level” is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage and distribution. The maximum safe moisture level for a food is based on its water activity ( $a_w$ ). An  $a_w$  will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given  $a_w$  will not support the growth of undesirable microorganisms.

(o) “Sanitize” means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing numbers of other undesirable microorganisms but without adversely affecting the product or its safety for the consumer.

(p) “Shall” is used to state mandatory requirements.

(q) “Should” is used to state recommended or advisory procedures or identify recommended equipment.

(r) “Water activity” ( $a_w$ ) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

### **§ 110.5 Current Good Manufacturing Practice.**

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

### **§ 110.10 Personnel.**

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion — including boils, sores, or infected wounds — or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces or food packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

- (1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces or food packaging materials.
- (2) Maintaining adequate personal cleanliness.
- (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station and at any other time when the hands may have become soiled or contaminated.
- (4) Removing all unsecured jewelry and other objects that might fall into food, equipment or containers and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces or food-packaging materials.
- (5) Maintaining gloves, if they are used in food handling, in an intact, clean and sanitary condition. The gloves should be of an impermeable material.
- (6) Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers or other effective hair restraints.
- (7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
- (8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages or using tobacco.
- (9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475. June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

#### **§ 110.19 Exclusions.**

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

#### **Subpart B — Buildings and Facilities**

##### **§ 110.20 Plant and Grounds.**

(a) *Grounds.* The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

- (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant breeding place, or harborage for pests.

- (2) Maintaining roads, yards and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a)(1) through (3) of this section, care shall be exercised in the plant by inspection, extermination or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces or food-packaging materials with microorganisms, chemicals, filth or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

- (i) Using protective coverings.
- (ii) Controlling areas over and around the vessels to eliminate harborage for pests.
- (iii) Checking on a regular basis for pests and pest infestation.
- (iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not

contaminate food, food-contact surfaces or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials and food contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

### **§ 110.35 Sanitary Operations.**

(a) *General maintenance.* Buildings, fixtures and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials.*

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic

materials may be used or stored in a plant where food is processed or exposed:

- (i) Those required to maintain clean and sanitary conditions;
- (ii) Those necessary for use in laboratory testing procedures;
- (iii) Those necessary for plant and equipment maintenance and operation; and
- (iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents and pesticide chemicals shall be identified, held and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other federal, state and local government agencies for the application, use or holding of these products should be followed.

(c) *Pest control.* No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces.* All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and

food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for onetime use, paper cups and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) *Storage and handling of cleaned portable equipment and utensils.* Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

### **§ 110.37 Sanitary Facilities and Controls.**

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing.* Plumbing shall be of adequate size and design and adequately installed and maintained to:

- (1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal.* Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities.* Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

(e) *Hand-washing facilities.* Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected

food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal.* Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies and ground surfaces.

## **Subpart C — Equipment**

### **§ 110.40 Equipment and Utensils.**

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with

food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying and manufacturing systems, including gravimetric, pneumatic, closed and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating or recording temperatures, pH, acidity, water activity or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

#### **Subpart D [Reserved]**

#### **Subpart E — Production and Process Controls**

##### **§ 110.80 Processes and Controls.**

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial or extraneous-

material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

##### **(a) *Raw materials and other ingredients.***

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification or examination of these materials for contamination.

(5) Raw materials, other ingredients and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations.*

(1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity,  $a_w$ , pH, pressure, flow rate and manufacturing operations such as freezing, dehydration, heat processing, acidification and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act.

Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 F (7.2 C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 F (60 C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling  $a_w$  that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold or store raw materials, work-in-process, rework or food shall be constructed, handled and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors or other suitable effective means.

(9) Food, raw materials and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breadings, sauces, gravies, dressings and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

- (i) Using ingredients free of contamination.
- (ii) Employing adequate heat processes where applicable.
- (iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging and other operations shall be performed in such a way that the food is protected against contamination.

Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in §130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food and dehydrated food, that relies on the control of  $a_w$  for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the  $a_w$  of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the  $a_w$  of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

### **§ 110.93 Warehousing and Distribution.**

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical and microbial contamination as well as against deterioration of the food and the container.

### **Subpart F [Reserved]**

### **Subpart G — Defect Action Levels**

#### **§ 110.110 Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard**

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug

Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW, Washington, DC 20204.

## 2. SANITATION STANDARD OPERATING PROCEDURES (SSOPs)

### 2.1 Introduction

FDA and USDA are pursuing a broad and long-term science-based strategy to improve the safety of foods to better protect public health. They are undertaking steps to improve the safety of foods throughout the production, processing, distribution and marketing chain. The Agency's goal is to reduce the risk to public health of consuming foods by reducing pathogenic microbial contamination. Their strategy relies heavily on building the principle of prevention into production processes.

Sanitation Guidelines require that rooms, compartments, equipment and utensils used for processing or handling foods in an establishment must be kept clean and in a sanitary condition. Establishments are responsible for sanitation of facilities, equipment and utensils.

Sanitation maintains or restores a state of cleanliness and promotes hygiene for the prevention of foodborne illness. Sanitation encompasses many areas and functions of an establishment, even when not in production. However, there are certain sanitary procedures that must be addressed and maintained on a daily basis to prevent direct product contamination or adulteration. Good sanitation is essential in these areas to maintaining a safe food production process.

FDA and USDA are requiring meat, poultry and seafood establishments to develop and implement written Standard Operating Procedures for sanitation (Sanitation SOPs) which address these areas. An establishment's adherence to its written Sanitation SOPs will demonstrate knowledge and commitment to sanitation and production of safe foods.

A written Sanitation SOP contains established procedures to be followed routinely to maintain a sanitary environment for producing safe and unadulterated food products. Plant management must develop Sanitation SOPs that describes daily sanitation procedures to be performed by the establishment. A designated establishment employee(s) must monitor the Sanitation SOPs and document adherence to the SOPs and any corrective action to prevent direct product contamination or adulteration.

The following guidelines should help food companies develop, implement and monitor written Sanitation SOPs.

The Sanitation SOPs developed by the establishment must detail daily sanitation procedures it will use before (preoperational sanitation) and during (operational sanitation) operation to prevent direct product contamination or adulteration. Company's auditors would verify an establishment's adherence to its Sanitation SOPs and will take appropriate action when there is noncompliance.

These guidelines, where applicable, include:

- Field operations
- Packing areas
- Processing areas
- Cooling rooms
- Refrigerated trucks

The establishment should update the Sanitation SOPs to reflect changes in equipment and facilities, processes, new technology, or designated establishment employees.

### 2.2 Preoperational Sanitation

Established procedures of preoperational sanitation must result in clean facilities, equipment and utensils prior to starting production. Clean facilities, equipment and utensils are free of any soil, chemical or other injurious substance that contaminates foods.

Preoperational sanitation established procedures shall describe the daily, routine sanitary procedures to prevent direct product contamination or adulteration. The sanitary procedures must include the cleaning of product contact surfaces of facilities, equipment and utensils to prevent direct product contamination or adulteration.

The following additional sanitary procedures for preoperational sanitation might include: Descriptions of equipment disassembly, reassembly after cleaning, use of acceptable chemicals according to label directions and cleaning techniques.

The application of sanitizers to product contact surfaces after cleaning. Sanitizers are used to reduce or destroy bacteria that may have survived the cleaning process.

### **2.3 Operational Sanitation**

The establishment must describe daily, routine sanitary procedures that the establishment will conduct during operations to prevent direct product contamination or adulteration. Established procedures for operational sanitation must result in a sanitary environment for preparing, storing or handling any food product.

Established procedures during operations might include, where applicable: Equipment and utensil cleaning-sanitizing-disinfecting during, as appropriate, at breaks, between shifts, and at midnight cleanup. Employee hygiene: includes personal hygiene, cleanliness of outer garments and gloves, hair restraints, hand washing, health, etc.

The established sanitary procedures for operational sanitation will vary with the establishment. Establishments with complex processing need additional sanitary procedures to ensure a sanitary environment and to prevent cross contamination.

### **2.4 Implementing and Monitoring of the Sanitation SOPs**

The Sanitation SOPs shall identify establishment employee(s) (positions rather than specific names of employees) responsible for the implementation and maintenance of the Sanitation SOPs. Employee(s) are to be identified to monitor and evaluate the effectiveness of the Sanitation SOP and make corrections when needed.

The evaluation can be performed by using one or more of the following methods:

- (1) Organoleptic (sensory-e.g., sight, feel, smell);
- (2) Chemical (e.g., checking the chlorine level);
- (3) Microbiological (e.g., microbial swabbing and culturing of product contact surfaces of equipment or utensils).

Establishments might specify the method, frequency and recordkeeping processes associated with monitoring. Preoperational sanitation monitoring

should, at a minimum, evaluate and document the effective cleaning of oil direct product contact facilities, equipment and/or utensils that are to be used at the start of production.

Operational sanitation monitoring should, at a minimum, document adherence to the SOP, including actions that identify and correct instances or circumstances of direct product contamination which occur from environmental sources (facilities, equipment, pests, etc.) or employee practices (personal hygiene, product handling, etc.).

All establishment records of preoperational and operational sanitation monitoring, including corrective actions to prevent direct product contamination or adulteration, may be maintained by the establishment for at least six months, and be made available to auditors if necessary. After 48 hours, they may be maintained off-site.

### **2.5 Corrective Actions**

When deviations occur from the established sanitary procedures within the Sanitation SOP, the establishment must take corrective and preventive actions to prevent direct product contamination or adulteration. Instructions should be provided to employees and management officials for documenting corrective actions. The actions must be recorded.

### **2.6 Model of a Standard Operating Procedure for Sanitation**

The designated manager is responsible for implementing and monitoring of the Sanitation SOPs and recording the findings and any corrective actions. The Sanitation Manager is responsible for training and assigning specific duties to other employees and monitoring their performance within the Sanitation SOPs.

All records, data, checklists and other information pertaining to the Sanitation SOP will be maintained on file and may be available to interested parties. The identification of establishment personnel (positions rather than specific names of employees) responsible for implementing, maintaining, monitoring and records associated with the Sanitation SOP is recommended.

All records pertaining to the Sanitation SOP will be kept on file and may be available to interested parties.

## **Sanitation SOP**

### **I. Preoperational Sanitation — Equipment and Facility Cleaning Objective**

All equipment will be cleaned and sanitized prior to starting production.

#### **A. General Equipment Cleaning.** (Simple equipment and hand tools are cleaned and sanitized in the same manner but they do not require disassembly and reassembly.)

##### **1. Established Sanitary Procedures for Cleaning and Sanitizing Equipment:**

- a. The equipment is disassembled. Parts are placed in the designated tubs, racks, etc.
- b. Product debris is removed.
- c. Equipment parts are rinsed with water to remove remaining debris.
- d. An approved cleaner is applied to parts and they are cleaned according to manufacturers' directions.
- e. Equipment parts are rinsed with potable water.
- f. Equipment is sanitized with an approved sanitizer, and rinsed with potable water if required.
- g. The equipment is reassembled.
- h. The equipment is resanitized with an approved sanitizer, and rinsed with potable water if required.

The established sanitary procedures are daily routine sanitary procedures to prevent direct product contamination or adulteration. Daily routine sanitary procedures to prevent direct product contamination or adulteration are required in the Sanitation SOP; inspection personnel may use them to verify adherence to the Sanitation SOP. The procedures can be as detailed as the establishment wants to make them.

##### **2. Implementing, Monitoring and Recordkeeping.**

The designated manager performs daily organoleptic sanitation inspection after preoperational equipment cleaning and sanitizing. The results of the inspection are recorded on an appropriate form. If everything is acceptable, the report is initialed. If

corrective actions are needed, such actions are to be documented as indicated below.

The designated manager may perform microbial monitoring for Total Plate Counts (TPCs) after preoperational equipment cleaning and sanitizing. The designated manager swabs one square inch of a food contact surface on a piece of equipment or hand tool within one hour prior to production. The samples may be sent to a laboratory or are plated and incubated at 35 degrees C in-house for 48 hours. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Microbial counts are documented on an appropriate record form.

##### **3. Corrective Actions**

a. When the designated manager determines that the equipment or hand tools do not pass organoleptic examination, the cleaning procedure and reinspection are repeated. The sanitation manager monitors the cleaning of the equipment or hand tools and retraining sanitation crew employees, if necessary. Corrective actions are recorded on an appropriate form.

b. If microbial counts exceed \_\_\_\_ CFUs/sq. in., the designated manager notifies the sanitation manager and attempts to determine the cause of the high count (for example, cleaning procedures varied, new people cleaned the equipment, sanitizer not applied). If microbial counts remain high for several days, the QC manager will confer with the sanitation manager. The sanitation manager notifies sanitation crew employees and reviews all cleaning and sanitizing procedures and personal hygiene. Microbial counts are recorded. Corrective actions to prevent direct product contamination or adulteration are also documented.

The establishment may decide to monitor daily routine sanitation activities as described in the Sanitation SOP, the establishment determines the methods and frequency of monitoring. Microbiological sampling is an option, but the company may want to monitor the effectiveness of the cleaning by microbial sampling, in addition to organoleptic monitoring. The set limits established

by the company would enable them to take appropriate action when those limits are exceeded. No specific forms or form numbers are required. However, the establishment will record the daily completion or adherence to its own established procedures in the Sanitation SOP, any deviations from established procedures, and corrective actions.

## **B. Cleaning of Facilities — including floors, walls and ceilings.**

### **1. Cleaning Procedures.**

- a. Debris is swept up and discarded.
- b. Facilities are rinsed with potable water as necessary.
- c. Facilities are cleaned with an approved cleaner, according to manufacturer's directions.
- d. Facilities are rinsed with potable water as necessary.

**2. Cleaning Frequency.** Floors and walls are cleaned at the end of each production day. Ceilings are cleaned as needed, but at least once a week.

There is no specific self-imposed requirement to include facility cleaning in the Sanitation SOP, unless part of the facility could directly contaminate or adulterate product.

### **3. Establishment Monitoring.**

The designated manager may perform daily organoleptic inspection prior to the start of operations. Results are recorded on appropriate form.

### **4. Corrective Actions.**

When the designated manager determines that the facilities do not pass organoleptic inspection, the cleaning procedure and reinspection are repeated. The sanitation manager monitors the cleaning of facilities and retraining sanitation crew employees if necessary. Corrective actions to prevent direct product contamination or adulteration are recorded.

## **II. Operational Sanitation**

**Objective:** Handling of the product and packaging materials will be performed under sanitary conditions and in a manner to prevent contamination of the product.

## **A. Vegetables Handling Operations.**

### **1. Established Methods for Handling Foods.**

- a. Employees will clean hands, arms, gloves, aprons, boots, etc., as often as necessary during the handling procedures.
- b. Employees will clean and then sanitize any equipment as often as necessary during the handling procedures to prevent contamination of foods or packaging materials.

The above methods for handling foods are specific for each company. The establishment considers them to be Good Manufacturing Practices for their type of operation, to prevent direct contamination or adulteration of foods. The company determines the sanitary procedures and any self-imposed requirements they want to detail in their Sanitation SOP.

### **2. Monitoring and Recordkeeping.**

- a. The designated manager is responsible for ensuring that employee hygiene practices, sanitary conditions, and cleaning procedures are maintained during a production shift. The designated manager monitors the sanitation procedures during a production shift. Results are recorded.

- b. A Microbiological Control and Monitoring Program may be used to determine the level of bacteria on product contact surfaces of equipment (e.g., sprayer, sorting, grading etc.) during production. The designated manager may perform microbial monitoring for Total Plate Counts (TPCs). The samples are plated and properly incubated in a selected laboratory or in-house. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Microbial counts are documented.

### **3. Corrective Actions.**

- a. Any visible contaminants will be removed by cleaning and sanitizing equipment prior to

resume production. The designated manager attempts to determine the cause of the contamination and takes corrective action. This may require adjusting equipment, retraining employees, temporarily stopping or slowing the line speed, etc. Corrective actions are recorded.

b. If microbial counts from equipment swabbing exceed the action level set, the designated manager notifies the sanitation manager. The Supervisor attempts to determine the cause (for example, new people not adequately trained, equipment not adjusted properly) and takes corrective action. If microbial counts remain above established limits for several days, the

designated manager confers with the sanitation manager and all handling operations are reviewed. The sanitation manager notifies the employees and reviews personal hygiene, equipment adjustment, and sanitary handling procedures. Corrective actions to prevent direct product contamination or adulteration are recorded.

The establishment may decide to monitor the daily sanitation activities as described in its Sanitation SOP, but the company determines its own methods for monitoring, the frequency of monitoring and the corrective actions to include in the Sanitation SOP. Records will be kept on daily completion of

### 3. GOOD AGRICULTURAL PRACTICES (GAPs)

#### *An FDA Guide to Minimize Microbial Food Safety Hazards in Agricultural Products*

the established procedures, deviations and corrective actions.

#### Key Facts

**This Guide provides general, broad-based voluntary guidance that may be applied, as appropriate, to individual operations.**

#### The Guide

- Is intended to assist domestic and foreign growers, packers and shippers of unprocessed or minimally processed (raw) fresh fruits and vegetables by increasing awareness of potential hazards and providing suggestions for practices to minimize these hazards
- Covers agricultural and post harvest water uses, manure and bio-solids, worker health and hygiene, field and facility sanitation, transportation, and trace back
- Does not impose any new requirements or supercede existing laws or regulations
- Will be most effective when used to evaluate individual operations and to institute Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) appropriate to the individual operations

#### Basic Principles include

- Prevention of microbial contamination of fresh produce is favored over reliance on corrective actions once contamination has occurred.
- Accountability at all levels of the agricultural and packing environments is important to a successful food safety program.

#### Water

**Wherever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination.**

#### Agricultural Water

- Identify source and distribution of water used.
- Be aware of current and historical use of land.
- Review existing practices and conditions to identify potential sources of contamination. Consider practices that will protect water quality.
- Maintain wells in good working condition.
- Consider practices to minimize contact of the edible portion of fresh produce with contaminated irrigation water. Where water quality is good, risk is low regardless of irrigation method.

### Processing Water

- Follow GMPs to ensure water quality is adequate at the start of and throughout all processes.
- Maintain water quality, such as by periodic testing for microbial contamination, changing water regularly and cleaning and sanitizing water contact surfaces.
- Antimicrobial chemicals may help minimize the potential for microbial contamination to be spread by processing water; levels of antimicrobial chemicals should be routinely monitored and recorded to ensure they are maintained at appropriate levels.
- As organic material and microbial load increase, the effectiveness of many antimicrobial chemicals will decrease. Filtering recirculating water or scooping organic material from tanks may help reduce the build-up of organic materials.

### Cooling Operations

- Maintain temperatures that promote optimum produce quality and minimize pathogen growth.
- Keep air cooling and chilling equipment clean and sanitary.
- Keep water and ice clean and sanitary.
- Manufacture, transport and store ice under sanitary conditions.

## **Manure and Municipal Bio-solids**

*Properly treated manure or bio-solids can be an effective and safe fertilizer.*

- If manure is used as a fertilizer, it should be managed to minimize microbial hazards.
- Federal regulations address the requirements for use of bio-solids in the United States. Some states also have specific requirements for the use of bio-solids. Foreign growers should follow these or similar requirements.

### Manure

- Use treatments to reduce pathogens in manure and other organic materials. Treatments may be active (e.g., composting) or passive (e.g., aging).
- Manure treatment and storage sites close to fresh produce fields increase the risk of contamination.
- Consider factors such as slope and rainfall and the likelihood of runoff into fresh produce production areas.
- Use barriers or physical containment to secure storage and treatment sites.
- Protect treated manure from being recontaminated.
- When purchasing treated manure, get information about the method of treatment.
- Maximize the time between application of manure to production areas and harvest.
- Use of raw manure on produce during the growing season is not recommended.

### Animal Feces

**While not possible to exclude all animal life from fresh produce production areas, many field programs include elements to protect crops from animal damage.**

- Domestic animals should be excluded from fields and orchards during the growing and harvesting season.
- Follow GAPs to ensure animal waste from adjacent fields, pastures, or waste storage facilities does not contaminate fresh produce production areas. Where necessary, consider physical barriers such as ditches, mounds, grass/sod waterways, diversion berms and vegetative buffer areas.

- Control of wild animal populations may be difficult or restricted by animal protection requirements. However, to the extent feasible, where high concentrations of wildlife are a concern, consider practices to deter or redirect wildlife to areas where crops are not destined for fresh produce markets.

## **Worker Health and Hygiene**

**Infected employees who work with fresh produce increase the risk of transmitting foodborne illness.**

- Train employees to follow good hygienic practices.
- Establish a training program directed towards health and hygiene — include basics such as proper hand-washing techniques and the importance of using toilet facilities.
- Become familiar with typical signs and symptoms of infectious diseases.
- Offer protection to workers with cuts or lesions on parts of the body that may make contact with fresh produce.
- If employees wear gloves, be sure the gloves are used properly and do not become a vehicle for spreading pathogens.
- Customer-pick and roadside produce operations should promote good hygienic practices with customers — encourage hand washing, provide toilets that are well equipped, clean, and sanitary and encourage washing fresh produce before consumption.

### Sanitary Facilities

- Poor management of human and other wastes in the field or packing facility increases the risk of contaminating fresh produce.
- Be familiar with laws and regulations that apply to field and facility sanitation practices.
- Toilet facilities should be accessible to workers, properly located, and well supplied.
- Keep toilets, hand washing stations, and water containers clean and sanitary.
- Use caution when servicing portable toilets to prevent leakage into a field.
- Have a plan for containment in the event of waste spillage.

## **Field Sanitation**

**Fresh produce may become contaminated during pre-harvest and harvest activities from contact with soil, fertilizers, water, workers and harvesting equipment.**

- Clean harvest storage facilities and containers or bins prior to use.
- Take care not to contaminate fresh produce that is washed, cooled, or packaged.
- Use harvesting and packing equipment appropriately and keep as clean as practicable.
- Assign responsibility for equipment to the person in charge.

## **Packing Facility**

**Maintain packing facilities in good condition to reduce the potential for microbial contamination.**

- Remove as much dirt as practicable outside of packing facility.
- Clean pallets, containers, or bins before use; discard damaged containers.
- Keep packing equipment, packing areas, and storage areas clean.
- Store empty containers in a way that protects them from contamination.

### *Pest Control*

- Establish and maintain a pest control program.
- Block access of pests into enclosed facilities.
- Maintain a pest control log.

### **Transportation**

**Proper transport of fresh produce will help reduce the potential for microbial contamination.**

- Good hygienic and sanitation practices should be used when loading, unloading and inspecting fresh produce.
- Inspect transportation vehicles for cleanliness, odors, obvious dirt and debris before loading.
- Maintain proper transport temperatures.
- Load produce to minimize physical damage.

### **Trace back**

**The ability to identify the source of a product can serve as an important complement to good agricultural and management practices.**

- Develop procedures to track produce containers from the farm, to the packer, distributor, and retailer.
- Documentation should indicate the source of the product and other information, such as date of harvest, farm identification and who handled the produce.
- Growers, packers and shippers should partner with transporters, distributors and retailers to develop technologies to facilitate the trace back process.
- Once good agricultural and management practices are in place, ensure that the process is working correctly. Without accountability, the best efforts to minimize microbial contamination are subject to failure.



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