

## **Appendix B**

### **TITLE 21, Code of Federal Regulations**

#### **Chapter 229. Food and Drug**

##### **SUBCHAPTER N. CURRENT GOOD MANUFACTURING PRACTICE AND GOOD WAREHOUSING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD**

###### **229.211. Definitions**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Those definitions and interpretations of terms of the Federal Food, Drug, and Cosmetic Act (the Act), §201, are also applicable when used in this subchapter.

- (1) Acid foods or acidified foods--Foods that have an equilibrium pH of 4.6 or below.
- (2) Act--Federal Food, Drug, and Cosmetic Act.
- (3) Adequate--That which is needed to accomplish the intended purpose in keeping with good public health practice.
- (4) Approved source--A supplier of food that complies with applicable state and federal laws and is licensed, if required, and inspected by the regulatory authority having jurisdiction over the processing and distribution of food.
- (5) Batter--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.
- (6) Blanching (except for tree nuts and peanuts)--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.
- (7) Control point--Any point, step, or procedure at which biological, physical, or chemical factors can be controlled.
- (8) Food--Articles used for food or drink for human consumption; chewing gum; and articles used for components of any such article.
- (9) Food-contact surfaces--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.

(10) Lot--Food produced during a period of time indicated by a specific code.

(11) Microorganisms--Yeasts, molds, bacteria, and viruses which include, but are 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, the adjective "microbial" is used instead of using an adjectival phrase containing the word microorganism.

(12) Pests--Any objectionable animal or insect including, but not limited to, birds, rodents, flies, and larvae.

(13) Plant--The building or facility, or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(14) Potentially hazardous food--A food that is natural or synthetic and requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms; the growth and toxin production of *Clostridium botulinum*; or in raw shell eggs, the growth of *Salmonella enteritidis*.

(A) The term includes a food of animal origin that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic and oil mixtures that are not acidified or otherwise modified at a food processing plant in a way that results in mixtures that do not support growth as specified in this definition.

(B) The term does not include an air-cooled hard-boiled egg with shell intact; a food with a water activity ( $a_w$ ) value of 0.85 or less; a food with a pH level of 4.6 or below when measured at 24 degrees Celsius (75 degrees Fahrenheit); and a food, in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution. The term also does not include a food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of *S. enteritidis* in eggs or *C. botulinum* cannot occur, such as a food that has an ( $a_w$ ) and a pH that are above the levels specified above and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms. The term also does not include a food that may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness, but that does not support the growth of microorganisms as specified in the definition of a potentially hazardous food.

(15) Quality control operation--A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the Act.

(16) Raw agricultural commodity--Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(17) Rework--Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(18) Safe-moisture level--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.

(19) Sanitization--The application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, yield a reduction of 5 logs, which is equal to a 99.999% reduction of representative disease microorganisms of public health importance.

(20) Shall--Term to state mandatory requirements.

(21) Should--Term to state recommended or advisory procedures or identify recommended equipment.

(22) Water activity ( $a_w$ )--A measure of the free moisture in a food. The quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

## **229.212. Current Good Manufacturing Practice**

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated within the meaning of Texas Health and Safety Code, Chapter 431, Texas Food, Drug, and Cosmetic Act, §431.081(a)(3) in that the food has been manufactured under such conditions that it is unfit for food; or within the meaning of §431.081(a)(4) of the Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(b) Food subject to the requirements of these sections may also be subject to specific current good manufacturing practice regulation found in the Code of Federal Regulations or in other sections of this title (25 Texas Administrative Code).

## **229.213. Personnel**

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

(1) 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.

(2) 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:

(A) wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials;

(B) maintaining adequate personal cleanliness;

(C) washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in a hand-washing facility that meets the provisions of §229.217(e) of this title (relating to Sanitary Facilities and Control), before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated;

(D) 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;

(E) maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material;

(F) wearing, where appropriate and in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints;

(G) storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed;

(H) 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; and

(I) 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.

(3) 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 insanitary practices.

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

#### **229.214. Exclusions**

The following operations are not subject to this section: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

#### **229.215. Plant and Grounds**

(a) Grounds. The grounds around 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) 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 a manner so that they do not constitute a source of contamination in areas where food is exposed; and

(5) if the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (1) through (4) of this subsection, 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 which may include the design, separation of operations, 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:

(A) using protective coverings;

(B) controlling areas over and around the vessels to eliminate harborage for pests;

(C) checking on a regular basis for pests and pest infestation; and

(D) 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 sufficient 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 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; and

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

### **229.216. 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 so that food does not become 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. 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:

- (1) those required to maintain clean and sanitary conditions;
- (2) those necessary for use in laboratory testing procedures;
- (3) those necessary for plant and equipment maintenance and operation; and
- (4) those necessary for use in the plant's operations.

(c) 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.

(d) 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.

(e) 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 one-time 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 for sanitization and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(f) 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.

### **229.217. Sanitary Facilities and Controls**

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

(1) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an approved source.

(A) Requirements for approved source. Sources in Texas shall comply with the following requirements.

(i) Public water systems. Sources in Texas which are public water systems shall comply with the Texas Health and Safety Code, Chapter 341, Subchapter C, concerning drinking water standards and rules adopted thereunder by the Texas Natural Resource Conservation Commission, 30 Texas Administrative Code (TAC), §§290.101-290.122 (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Supply Systems), and §§290.38-290.47 (relating to Rules and Regulations for Public Water Systems).

(ii) Other sources. Any other sources in Texas shall comply with 30 TAC, §§290.101-290.122 concerning drinking water standards and 30 TAC, §§290.38-290.43 and §290.46 concerning rules and regulations for public water systems.

(iii) Compliance with these sections is required as if the source were a public water system.

(B) Sampling requirements.

(i) Approved community public water systems as defined by 30 TAC, §290.38(8) and (41) (relating to Definitions). No additional source water sampling is required.

(ii) Source water obtained from other than a community public water system shall be sampled in accordance with 30 TAC, §§290.101-290.122 for transient noncommunity water systems.

(C) Any water that contacts food or food-contact surfaces shall be safe and of sanitary quality for its intended use. 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.

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

(A) carry sufficient quantities of water to required locations throughout the plant;

(B) properly convey sewage and liquid disposable waste from the plant;

(C) avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition;

(D) provide 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; and

(E) provide that there is no 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.

(3) Sewage disposal. Sewage disposal shall be made into an approved sewerage system in accordance with applicable state regulations and local ordinances.

(4) Toilet facilities. Each plant shall provide its employees with readily accessible toilet facilities adequate in number and location. Compliance with this requirement may be accomplished by:

(A) maintaining the toilet facilities in a sanitary condition;

(B) keeping the toilet facilities in good repair at all times;

(C) providing self-closing doors on toilet facilities; and

(D) providing doors on toilet facilities 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 air-flow systems).

(5) Hand-washing facilities. Hand-washing facilities shall be adequate in number and location and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(A) 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;

(B) effective hand-cleaning and sanitizing preparations;

(C) sanitary towel service or suitable drying devices;

(D) devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands;

(E) readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or 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; and

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

(6) 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.

### **229.218. Equipment and Utensils**

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be 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 constructed so that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be designed and constructed so as 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 installed to accurately show the temperature 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 properly maintained, and in sufficient quantity 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 food additives.

## **229.219. Production and Process Controls**

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with good public health and 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. Testing procedures shall be used where necessary to identify sanitation failures or possible food contamination by chemicals, microbes, or extraneous materials. 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.

(1) Raw materials and other ingredients.

(A) 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 sanitary quality for its intended use. 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 contamination or deterioration of food.

(B) 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.

(C) 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.

(D) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or 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.

(E) 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 a temperature and relative humidity and in a manner to prevent the food from becoming adulterated within the meaning of the Act. Material scheduled for rework shall be identified as such.

(F) Frozen raw materials and other frozen 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.

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

(2) Manufacturing operations.

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

(B) 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. Compliance with this requirement may be accomplished by 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.

(C) The internal temperature of potentially hazardous foods during transport and storage shall be maintained at 45 degrees Fahrenheit or lower as appropriate for the food.

(i) After October 5, 2003, the internal temperature of potentially hazardous foods shall be maintained at 41 degrees Fahrenheit or lower as appropriate for the food.

(ii) Frozen foods shall be kept frozen at all times.

(iii) Shell eggs, after initial packing, must be transported and stored at a temperature of 45 degrees Fahrenheit or less. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine by law that a lower temperature must be maintained, the lower temperature shall prevail.

(iv) The temperature of molluscan shellstock from the harvester through the original shellfish dealer shall be maintained in accordance with §§241.58-241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellstock shall be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale.

(v) Hot foods shall be maintained at 140 degrees Fahrenheit (60 degrees Celsius) or above.

(vi) Acid or acidified foods shall be heat treated to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(D) 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, must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the Act.

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

(F) 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.

(G) 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.

(H) 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.

(I) 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 confirmed to be safe within the meaning of the Act before being incorporated into other food.

(J) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, soaking, tempering, 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 cleaning and sanitizing all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(K) 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 sufficient operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of sanitary quality for its intended use.

(L) Batters, breading, 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 proper 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 a sufficient temperature during manufacturing; or
- (vi) disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(M) 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 control points are identified and controlled during manufacturing;
- (ii) proper 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 for their intended use;
- (iv) providing physical protection from contamination, particularly airborne contamination; and
- (v) using sanitary handling procedures.

(N) 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 aw of food;
- (ii) controlling the soluble solids-water ratio in finished food; and
- (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.

(O) Acid food, acidified food, and similar 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 both of the following practices:

(i) monitoring the pH of raw materials, food in process, and finished food; and

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

(P) Unshelled pecans shall be thoroughly cleaned to remove foreign matter before cracking. After cleaning, unshelled pecans shall be sanitized.

(Q) 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.

(R) 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.

**229.220. 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 United States 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) Compliance with defect action levels does not excuse violation of the requirement in the Health and Safety Code, Chapter 431, §431.081(a)(3) that food not be prepared, packed, or held under unsanitary conditions or the requirements in this section 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.

(c) 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.

(d) 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 Texas Department of Health, Manufactured Foods Division, 1100 West 49th Street, Austin, Texas, 78756.

## **229.221. Good Warehousing Practice**

### (a) Plant and grounds.

(1) Storage and transportation of 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.

(2) Food storage facilities shall be properly constructed and maintained. All walls, ceilings, and floors shall be intact to preclude entry of vermin and environmental contaminants.

(3) Doors and loading docks shall be tight-fitting and kept closed at all times when not in use, or adequately screened during normal operating hours to prevent entry of rodents, birds, or other pests.

(4) Outer premises, including trash receptacles, shall be kept clean and free of odors, debris, high weeds, or standing water which could harbor or attract vermin.

(5) Adequate lighting shall be provided to facilitate cleaning and inspection of stored goods.

### (b) Sanitary facilities.

(1) Hand-washing and toilet facilities shall be provided and maintained, including hot and cold running water, hand soap, and single-service towels as deemed appropriate by the regulatory authority for the types of foods handled by the licensee.

(2) Wastewater shall be disposed of in a manner approved by the regulatory authority.

### (c) Sanitary operations.

(1) All foods, including refrigerated and frozen foods, shall be stored off the floor and away from walls to help prevent contamination by vermin (rodents and insects for example) and moisture, and to facilitate cleaning and inspection.

(2) Food storage facilities and transportation vehicles shall be kept free of rodents, insects, birds, and other pests which may contaminate food.

(3) Damaged, distressed, and infested foods shall be stored in a "morgue area," adequately separated from undamaged foods and shall be disposed of in a timely manner to preclude further contamination.

(4) The internal temperature of potentially hazardous foods during transport and storage shall be maintained at 45 degrees Fahrenheit or lower as appropriate for the food.

(A) After October 5, 2003, the internal temperature of potentially hazardous foods shall be maintained at 41 degrees Fahrenheit or lower as appropriate for the food.

(B) Frozen foods shall be kept frozen at all times.

(C) Shell eggs after initial packing, must be transported and stored at a temperature of 45 degrees Fahrenheit or less. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine by law that a lower temperature must be maintained, the lower temperature shall prevail.

(D) The temperature of molluscan shellstock from the harvester through the original shellfish dealer shall be maintained in accordance with §§241.58-241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellstock shall be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale.

(5) During warehousing and transporting, all chemicals shall be properly stored and physically separated from foods to preclude contamination.

(6) Foods being warehoused shall be rotated on a "first in, first out" basis or by oldest date of pack.

(7) Food storage facilities and transportation vehicles operated under the control of the licensee shall be kept clean and free of excessive dust, dirt, spillage, and other debris, including excess moisture.

(8) Food transport vehicles shall be operated in compliance with federal regulations pertaining to back-hauling.

(9) Each incoming lot shall be examined at the time of receipt and contaminated or adulterated foods shall not be accepted.

(10) Swollen, leaking, and/or severely dented containers of food shall be segregated and promptly placed in the "morgue area" and further contamination, attraction of vermin, or sale prior to reconditioning shall be prevented.

(11) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food warehouse and/or food processing facility may be used. Pesticides shall be used only according to label directions. Rodenticides shall be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides.

(d) Other provisions.

(1) Distressed foods salvaged by the licensee shall be salvaged in accordance with §§229.191-229.202 of this title (relating to Regulation of Food, Drug, Device, and Cosmetic Salvage Establishments and Brokers).

(2) Food wholesalers engaged in the receipt and distribution of over-the-counter or prescription drugs shall comply with §229.253 of this title (relating to Minimum Standards for Licensure).

(3) The licensee shall keep accurate distribution records so that any foods found to be unfit for human consumption may be recalled expeditiously.

#### **229.222. Penalties**

(a) Criminal penalties as provided in Health and Safety Code §431.059 may be assessed for violations of these sections.

(b) Civil penalties as provided in Health and Safety Code §431.0585 may be assessed for violations of these sections.

(c) Administrative penalties as provided in Health and Safety Code §431.054 and in §229.261 of this title (relating to Assessment of Administrative or Civil Penalties), may be assessed for violation of these sections.

