

Texas Administrative Code
Title 25 Health Services Part 1 Department of State Health Services
Chapter 229 Food and Drug Subchapter N

Good Manufacturing Practice and Good Warehousing Practice in Manufacturing, Packing, or Holding Human Food

§ 229.210 **Purpose and Scope** ~~General Provision~~

(a) This subchapter applies to every person engaged in food manufacturing and/or wholesale food distribution regardless of the license or permit held under §§229.181 - 229.184, 229.370 - 229.374, and 229.541 - 229.554 of this title, or if the person is exempt from licensure. Retail food establishments, such as grocery stores and restaurants that are located outside the jurisdiction of a local health authority, must also comply with the requirements of ~~Chapter 228 §§229.161 – 229.171 and 229.173 – 229.175~~ of this title (relating to Texas Food Establishment Rules) except for the manufacture or wholesale of food as defined by the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, §§431.221(2) and ~~431.224~~(3). Retail establishments that are located within the jurisdiction of a local health authority that permits and inspects retail food establishments and that are required to license as a food manufacturer under §§229.181 - 229.184 of this title, must also comply with the applicable rules enforced by the local health authority.

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~~(b) The criteria and definitions in this part shall subchapter apply in determining whether a food is adulterated within the meaning of Texas Health and Safety Code, §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 Texas Health and Safety Code §431.081(a)(4) 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.~~

~~(c) Food subject to the requirements of these sections may also be subject to specific regulations found in Title 21, Code of Federal Regulations Parts 1-199, or in other sections of this title (25 Texas Administrative Code Chapter 229).~~

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(d) The department adopts by reference the following laws and regulations

- (1) United States Code Title 21 Chapter 9, Subchapter IV, §343(w) et seq. as amended;
- (2) 21 Code of Federal Regulations §§1.20-1.22 and §1.24, General Enforcement Regulations, as amended;
- (3) 21 Code of Federal Regulations §70.20 and §70.25, Color Additives, as amended;
- (4) 21 Code of Federal Regulations Part 73 Subpart A, Listing of Color Additives Exempt from Certification, as amended;
- (5) 21 Code of Federal Regulations Part 74 Subpart A, Listing of Color Additives Subject to Certification, as amended;
- (6) 21 Code of Federal Regulations Part 81, General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics, as amended;

(7) 21 Code of Federal Regulations Part 82, Listing of Certified Provisionally Listed colors and Specifications, as amended;

(8) 21 Code of Federal Regulations §100.155, General, as amended;

(9) 21 Code of Federal Regulations Part 101, Food Labeling, as amended;

(10) 21 Code of Federal Regulations Part 102, Common or Usual Name for Non Standardized Foods, as amended;

(11) 21 Code of Federal Regulations Part 104, Nutritional Quality Guidelines for Foods, as amended.

(12) 21 Code of Federal Regulations Part 105, Foods for Special Dietary Use, as amended;

(13) 21 Code of Federal Regulations Part 106, Infant Formula Quality Control Procedures, as amended;

(14) 21 Code of Federal Regulations Part 107, Infant Formula, as amended;

(15) 21 Code of Federal Regulations Part 108, Emergency Permit Control, as amended;

(16) 21 Code of Federal Regulations Part 109, Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, as amended;

(17) 21 Code of Federal Regulations Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, as amended;

(18) 21 Code of Federal Regulations Part 114, Acidified Foods, as amended;

(19) 21 Code of Federal Regulations Part 117 Subpart C, D, F, and G, Current Good Manufacturing Practice, Hazard Analysis, and risk Based Preventive Controls for Human Food, as amended.

(20) 21 Code of Federal Regulations Part 120, Hazard Analysis and Critical Control Point (HACCP) Systems, as amended;

(21) 21 Code of Federal Regulations Part 123, Fish and Fishery Products, as amended;

(22) 21 Code of Federal Regulations Part 129, Processing and Bottling of Bottled Drinking Water, as amended;

(23) 21 Code of Federal Regulations Part 130, Food Standards: General, as amended;

(24) 21 Code of Federal Regulations Part 131, Milk and Cream, as amended;

(25) 21 Code of Federal Regulations Part 133, Cheese and Related Cheese Products, as amended;

(26) 21 Code of Federal Regulations Part 135, Frozen Desserts, as amended;

- (27) 21 Code of Federal Regulations Part 136, Bakery Products, as amended;
- (28) 21 Code of Federal Regulations Part 137, Cereal Flours and Related Products, as amended;
- (29) 21 Code of Federal Regulations Part 139, Macaroni and Noodle Products, as amended;
- (30) 21 Code of Federal Regulations Part 145, Canned Fruits, as amended;
- (31) 21 Code of Federal Regulations Part 146, Canned Fruit Juices, as amended;
- (32) 21 Code of Federal Regulations Part 150, Fruit Butters, Jellies, Preserves, and Related Products, as amended;
- (33) 21 Code of Federal Regulations Part 152, Fruit Pies, as amended;
- (34) 21 Code of Federal Regulations Part 155, Canned Vegetables, as amended;
- (35) 21 Code of Federal Regulations Part 156, Vegetable Juices, as amended;
- (36) 21 Code of Federal Regulations Part 158, Frozen Vegetables, as amended;
- (37) 21 Code of Federal Regulations Part 160, Eggs and Egg Products, as amended;
- (38) 21 Code of Federal Regulations Part 161, Fish and Shellfish, as amended;
- (39) 21 Code of Federal Regulations Part 163, Cacao Products, as amended;
- (40) 21 Code of Federal Regulations Part 164, Tree Nut and Peanut Products, as amended;
- (41) 21 Code of Federal Regulations Part 165, Beverages, as amended;
- (42) 21 Code of Federal Regulations Part 166, Margarine, as amended;
- (43) 21 Code of Federal Regulations Part 168, Sweeteners and Table Syrups, as amended;
- (44) 21 Code of Federal Regulations Part 169, Food Dressings and Flavorings, as amended;
- (45) 21 Code of Federal Regulations Part 170, Food Additives, as amended;
- (46) 21 Code of Federal Regulations Part 172, Food Additives Permitted For Direct Addition To Food For Human Consumption, as amended;
- (47) 21 Code of Federal Regulations Part 173, Secondary Direct Food Additives Permitted in food For Human Consumption, as amended;
- (48) 21 Code of Federal Regulations Part 174, Indirect Food Additives General, as amended;

(49) 21 Code of Federal Regulations Part 175, Indirect Food Additives Adhesives and Components of Coatings, as amended;

(50) 21 Code of Federal Regulations Part 176, Indirect Food Additives Paper and Paperboard Components, as amended;

(51) 21 Code of Federal Regulations Part 177, Indirect Food Additives Polymers, as amended;

(52) 21 Code of Federal Regulations Part 178, Indirect Food Additives Adjuvants, Production Aids, and Sanitizers, as amended;

(53) 21 Code of Federal Regulations Part 180, Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study, as amended;

(54) 21 Code of Federal Regulations Part 181, Prior-Sanctions Food Ingredients, as amended;

(55) 21 Code of Federal Regulations Part 182, Substances Generally Recognized as Safe, as amended;

(56) 21 Code of Federal Regulations Part 184, Direct Food Substances Affirmed as Generally Recognized as Safe, as amended;

(57) 21 Code of Federal Regulations Part 186, Indirect Food Substances Affirmed as Generally Recognized as Safe, as amended; and

(58) 21 Code of Federal Regulations Part 189, Substances Prohibited From Use in Human Food, as amended.

§ 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 Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431, 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**--Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431.

(3) **Adequate**--That which is needed to accomplish the intended purpose in keeping with good public health practice.

(4) **Adulterated**--Has the meaning as defined in the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431.

(5) Affiliate--Any facility that controls, is controlled by, or is under common control with another facility.

(6) Allergen cross-contact--The unintentional incorporation of a food allergen into a food.

(7) 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.

(8) Audit--the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess a supplier's food safety processes and procedures.

(9) 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.

(10) Blanching (except for tree nuts and peanuts)--A prepackaging heat treatment of foodstuffs for an ~~adequate~~ 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.~~

(11) Calendar day--Every day shown on the calendar.

(12) Cleaning--Physical removal of dirt (soil) from surfaces which includes the use of clean water and detergent.

(13) Conventional handwashing -- The washing of hands that relies on hot running water of at least 100 degrees Fahrenheit and a hand cleaning agent to cleanse the hands.

(14) Conventional handwashing sink--A lavatory, trough basin, or vessel for washing, a wash basin, or plumbing fixture especially placed for use in personal hygiene and designed only for washing hands that relies on hot running water of at least 100 degrees Fahrenheit and a hand cleaning agent to cleanse the hands.

(15) Correction--An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

(16) Corrosion Resistant Material--A material that maintains acceptable surface cleanability characteristics under prolonged influence of a food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

(17) Critical control point--A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

(18) Defect action level--A level of a non-hazardous, naturally occurring, unavoidable defect at which a food product may be regarded as "adulterated" and subject to enforcement action under Texas Health and Safety Code, §431.081(a)(3).

(19) Environmental pathogen--A pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this subchapter include Listeria monocytogenes and Salmonella spp. but do not include the spores of pathogenic sporeforming bacteria.

(20) Facility.

(A) A person who manufactures, wholesales, or otherwise holds food and is subject to the requirements of Texas Health and Safety Code, Chapter 431.

(B) A domestic facility or a foreign facility that is required to register under the Federal Food, Drug, and Cosmetic Act, §415 in accordance with the requirements of 21 Code of Federal Regulations Part 1, Subpart H.

(21) Farm--means:

(A) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (A)(iii)(II)(-a-) of this definition; and

(iii) Manufacture/process food, provided that:

(I) All food used in such activities is consumed on that farm or another farm under the same management; or

(II) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(-a-) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of

additional manufacturing/processing is slicing);

(-b-) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(-c-) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(B) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (A)(ii) and (iii) of this definition.

(22) FDA--The Food and Drug Administration.

(238) Food—A raw, cooked, or processed edible substance, ice, beverage, chewing gum or ingredient used or intended for use or for sale in whole or in part for human consumption, including raw materials. Articles used for food or drink for human consumption; chewing gum; and articles used for components of any such article.

(24) Food allergen--a major food allergen is:

(A) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(B) A food ingredient that contains protein derived from a food specified in paragraph (A) of this paragraph, except the following:

(i) Any highly refined oil derived from a food specified in paragraph (A), and any ingredient derived from such highly refined oil.

(ii) A food ingredient that is exempt under United States Code Title 21 Chapter 9, Subchapter IV, §343(w)(6) and (7).

(259) 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.

(26) Full-time equivalent employee--Is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and

subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

(27) Harvesting--applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

(28) Hazard--Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

(29) Hazard requiring a preventive control--A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

(30) Holding--Storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallet loads), but does not include activities that transform a raw agricultural commodity into a processed food. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

(31) Known or reasonably foreseeable hazard--A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

(3240) Lot--Food produced during a period of time and identified ~~indicated~~ by an establishment's specific code.

(33) Manufacturing/processing--Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified

atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

~~(344) **Microorganisms**--Yeasts, molds, bacteria, and--viruses, protozoa, and microscopic parasites and includes species that are pathogens. 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.~~

Commented [L(4): Undesirable micro-organisms was added as a separate definition. See (70)

(35) Mixed-type facility--An establishment that engages in both activities that are exempt from registration under of the Federal Food, Drug, and Cosmetic Act §415 and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

(36) Modified atmosphere packaging--A method of packaging food in which the atmosphere of a package of food is modified so that its composition is different from air, which contains 21% oxygen, but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes: reduction in the proportion of oxygen, total replacement of oxygen, removal of air, or an increase in the proportion of other gases such as carbon dioxide or nitrogen.

(37) Monitor--To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

(38) Non-Time/Temperature Control for Safety (TCS) food (NTCS)--(formerly non-Potentially Hazardous Food (non-PHF)) An air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable *salmonella*. 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. A food that because of its pH or A_w value, or interaction of A_w and pH values, is designated as a NTCS food in Table A and Table B in §229.211(69). A food that is not designated as an NTCS food in Figure A and Figure B in §229.211(69) and for which there is scientific and technical evidence that a control measure or combination of control measures, when properly implemented, effectively controls the identified hazards in such a manner that growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food, is precluded due to either:

(A) intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;

(B) extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use;

(C) a combination of intrinsic and extrinsic factors; or

(D) a food that does not support the growth of or toxin formation of pathogenic microorganisms in accordance with one or more of the conditions above in this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

(39) Nonprofit food establishment--A charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

(40) Packaging--(when used as a verb) Placing food into a container that directly contacts the food and that the consumer receives.

(41) Packing--Placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food.

(42) Pathogen--A microorganism of public health significance.

(4312) Pests--Any objectionable animal or insect including, but not limited to, birds, rodents, flies, and larvae.

(4413) Plant--The building or structure~~facility~~, or parts thereof, used for or in connection with the manufacturing, processing, 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

Commented [L5]: See new term Time/Temperature Control for Safety Food (69)

~~cause illness, but that does not support the growth of microorganisms as specified in the definition of a potentially hazardous food.~~

~~(4515) pH--(Potential of Hydrogen) A measure of the degree of the acidity or the alkalinity of a solution.~~

~~(46) Preventive controls--Those risk-based, procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.~~

~~(47) Preventive controls individual--An individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.~~

~~(48) Processed food--Any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as but not limited to, canning, cooking, freezing, dehydration, or milling.~~

~~(4916) Processing--Including, but not limited, to the preparing, blending, filtering, preserving, treating, changing into different market forms, manufacturing, packing, repacking, or labeling of food ingredients and or products.~~

~~(50) Qualified auditor--A person who is an individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 21 Code of Federal Regulations §117.180(c)(2). Examples of potential qualified auditors include:~~

~~(A) a government employee, including a foreign government employee; and~~

~~(B) an audit agent of a certification body that is accredited in accordance with regulations in 21 CFR Part 1, Subpart M of this chapter.~~

~~(51) Qualified end-user--with respect to a food, the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in this section) that:~~

~~(A) is located;~~

~~(i) in the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or~~

~~(ii) not more than 275 miles from such facility; and~~

~~(B) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.~~

(52) Qualified facility--(when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(A) during the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this section) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(B) the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(53) Qualified facility exemption--An exemption applicable to a qualified facility under 21 Code of Federal Regulations §117.5(a).

(54) Qualified individual--A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

(5517) 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.

(5618) 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.

(57) Ready-to-eat food (RTE food)--Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

(58) Receiving facility--A facility that is subject to 21 Code of Federal Regulations Part 117 Subparts C and G and that manufactures/processes a raw material or other ingredient that it receives from a supplier.

~~(19) Reduced oxygen packaging--The reduction of the amount of oxygen in a package by mechanically evacuating the oxygen; displacing the oxygen with another gas or combination of gases; or otherwise controlling the oxygen content in a package to a level below that normally found in the surrounding atmosphere, which is 21% oxygen. The term includes methods that may be referred to as altered atmosphere, modified atmosphere, controlled atmosphere, low oxygen, and/or vacuum packing including sous vide.~~

Commented [L(6)]: Definition moved to Modified Atmosphere Packaging (36)

(59) Restaurant--A facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers. Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants.

(60) Retail food establishment-- An establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(A) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(B) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(C) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

~~(6120)~~ **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.

~~(621)~~ **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, processing, packing, and holding, storage, and distribution. The maximum safe moisture level for a food is related to 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.

~~(63)~~ **Sanitize**--Following cleaning, a process to treat a clean surface that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

~~(22)~~ **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.

~~(23)~~ **Shall** Term to state mandatory requirements.

~~(24)~~ **Should** Term to state recommended or advisory procedures or identify recommended equipment.

~~(64)~~ **Significantly minimize**--To reduce to an acceptable level, including to eliminate.

~~(65)~~ **Small business**--For purposes of this subchapter, a business employing fewer than 500 full-time equivalent employees.

~~(66)~~ **Subsidiary**--Any company which is owned or controlled directly or indirectly by another company.

~~(67)~~ **Supplier**--The establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

~~(68)~~ **Supply-chain-applied control**--A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

~~(69)~~ **Time/Temperature Control for Safety (TCS) food (TCS)**--(formerly Potentially Hazardous Food (PHF)) A food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. An animal based food that is raw or heat-treated. A plant based food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixture of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation. Except as specified in Tables A and B of this definition, a food that because of the interaction of A_w and pH values is designated as requiring scientific and technical evidence that a control measure or combination of control measures, when properly implemented, effectively controls the identified hazards:

Figure: 25 TAC §228.2(69)

(70) Undesirable microorganisms--Includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

(71) Unexposed packaged food--Packaged food that is not exposed to the environment.

(72) Validation--Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

(73) Verification--The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

(74) Very small business--For purposes of this subchapter, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

(7525) 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.

(76) Written procedures for receiving raw materials and other ingredients--Written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

(77) You--For purposes of this subchapter, the owner, operator, or agent in charge of a facility.

Figure: 25 TAC §228.2(69)

Table A. Interaction of PH and AW for control of spores in FOOD heat-treated to destroy vegetative cells and subsequently PACKAGED

<u>AW values</u>	<u>pH: 4.6 or less</u>	<u>pH: > 4.6 - 5.6</u>	<u>pH: > 5.6</u>
<u><0.92</u>	<u>NTCS FOOD*</u>	<u>NTCS FOOD</u>	<u>NTCS FOOD</u>
<u>> 0.92 - 0.95</u>	<u>NTCS FOOD</u>	<u>NTCS FOOD</u>	<u>NOTE**</u>
<u>> 0.95</u>	<u>NTCS FOOD</u>	<u>NOTE</u>	<u>NOTE</u>

* NTCS FOOD means NON-TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOOD

** Note - Considered a TCS Food unless facility provides scientific and technical evidence that a control measure or combination of control measures, when properly implemented, effectively controls the identified hazards.

Table B. Interaction of PH and A_w for control of vegetative cells and spores in FOOD not heat-treated or heat-treated but not PACKAGED

<u>A_w values</u>	<u>pH: < 4.2</u>	<u>pH: 4.2 - 4.6</u>	<u>pH: > 4.6 - 5.0</u>	<u>pH: > 5.0</u>
<u>< 0.88</u>	<u>NTCS food*</u>	<u>NTCS food</u>	<u>NTCS food</u>	<u>NTCS food</u>
<u>0.88 – 0.90</u>	<u>NTCS food</u>	<u>NTCS food</u>	<u>NTCS food</u>	<u>NOTE**</u>
<u>> 0.90 – 0.92</u>	<u>NTCS food</u>	<u>NTCS food</u>	<u>NOTE</u>	<u>NOTE</u>
<u>> 0.92</u>	<u>NTCS food</u>	<u>NOTE</u>	<u>NOTE</u>	<u>NOTE</u>

* NTCS FOOD means NON-TIME/TEMPERATURE CONTROL FOR SAFETY (TCS) FOOD

** Note - Considered a TCS Food unless facility provides scientific and technical evidence that a control measure or combination of control measures, when properly implemented, effectively controls the identified hazards.

§ 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 regulations found in Title 21, Code of Federal Regulations (CFR), or in other sections of this title (25 Texas Administrative Code).

Commented [L(7): Moved to 229.210 (b) and (c)

§229.212. Qualification of Individuals Who Manufacture, Process, Pack, or Hold Food.

(a) Applicability.

(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to 21 Code of Federal Regulations Part 117 Subparts B and F are qualified to perform their assigned duties.

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to 21 Code of Federal Regulations Part 117 Subparts C, D, E, F, or G are qualified to perform their assigned duties.

(b) Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in §229.211--i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and

(2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

(c) Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this subchapter must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

(d) Records. Records that document training required by subsection (b)(2) of this section must be established and maintained.

§229.213. Exemptions.

(a) Except as provided by 21 Code of Federal Regulations Part 117 Subparts E, C and G does not apply to a qualified facility. Qualified facilities are subject to the modified requirements in 21 Code of Federal Regulations, §117.201.

(b) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply with respect to activities that are subject to 21 Code of Federal Regulations Part 123, Fish and Fishery Products, at a facility if you are required to comply with, and are in compliance with, Part 123 with respect to such activities.

(c) 21 Code of Federal Regulations Part 117 Subparts C and G of this part do not apply with respect to activities that are subject to 21 Code of Federal Regulations Part 120, Hazard Analysis and Critical Control Point (HACCP) Systems, at a facility if you are required to comply with, and are in compliance with, Part 120 with respect to such activities.

(d) Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers.

(1) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply with respect to activities that are subject to 21 Code of Federal Regulations Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, at a facility if you are required to comply with, and are in compliance with 21 Code of Federal Regulations Part 113 with respect to such activities.

(2) The exemption in paragraph (1) of this subsection is applicable only with respect to the microbiological hazards that are regulated under 21 Code of Federal Regulations Part 113.

(e) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of 21 Code of Federal Regulations Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, and the Federal Food, Drug, and Cosmetic Act, §761, Serious Adverse Event Reporting for Dietary Supplements.

(f) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to activities of a facility that are subject to the Federal Food, Drug, and Cosmetic Act, §419, Standards for Produce Safety.

(g) Low Risk packing or holding activity/food combinations.

(1) The exemption in paragraph (3) of this subsection applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the “farm” definition in §229.211 of this title (relating to Definitions). Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of 21 Code of Federal Regulations Part 117 Subparts C and G and therefore do not need to be specified in the exemption.

(2) For the purposes of paragraphs (3) and subsection (h)(3) of this section, the following terms describe the foods associated with the activity/food combinations. Several foods that are fruits or vegetables are separately considered for the purposes of these activity/food combinations (i.e., coffee beans, cocoa beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods.

(A) Dried/dehydrated fruit and vegetable products includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(B) Other fruit and vegetable products includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in paragraph (2)(A) of this subsection. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).

(C) Peanut and tree nut products includes processed food products such as roasted

peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

(D) Processed seeds for direct consumption include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

(E) Dried/dehydrated herb and spice products includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(F) Other herb and spice products includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in paragraph(2)(E) of this subsection. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.

(G) Grains include barley, dent or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

(H) Milled grain products include processed food products such as flour, bran, and corn meal.

(I) Baked goods include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.

(J) Other grain products include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in paragraph (2)(H) of this subsection or baked goods as described in paragraph(2)(I) of this subsection.

(3) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to on-farm packing or holding of food by a small or very small business, and 21 Code of Federal Regulations §117.201 does not apply to on-farm packing or holding of food by a very small business, if the only packing and holding activities subject to the Federal Food, Drug, and Cosmetic Act, §418 that the business conducts are the following low-risk packing or holding activity/food combinations--i.e., packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(A) baked goods (e.g., bread and cookies);

(B) candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);

(C) cocoa beans (roasted);

(D) cproducts;

(E) coffee beans (roasted);

(F) game meat jerky;

(G) gums, latexes, and resins that are processed foods;

(H) honey (pasteurized);

(I) jams, jellies, and preserves;

(J) milled grain products (e.g., flour, bran, and corn meal);

(K) molasses and treacle;

(L) oils (e.g., olive oil and sunflower seed oil);

(M) other fruit and vegetable products (e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);

(N) other grain products (e.g., dried pasta, oat flakes, and popcorn);

(O) other herb and spice products (e.g., chopped or ground dried herbs, herbal extracts);

(P) peanut and tree nut products (e.g., roasted peanuts and tree nut flours);

(Q) processed seeds for direct consumption (e.g., roasted pumpkin seeds);

(R) soft drinks and carbonated water;

(S) sugar;

(T) syrups (e.g., maple syrup and agave syrup);

(U) trail mix and granola;

(V) vinegar; and

(W) any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

(h) Low risk manufacturing/processing activity/food combinations.

(1) The exemption in paragraph (3) of this subsection applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the "farm" definition. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried

herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the “farm” definition. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the “farm” definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the “farm” definition. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of 21 Code of Federal Regulations Part 117 Subparts C and G and therefore, do not need to be specified in the exemption.

(2) The terms in subsection (g)(2) of this section describe certain foods associated with the activity/food combinations in paragraph (3) of this subsection.

(3) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and 21 Code of Federal Regulations §117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to the Federal Food, Drug, and Cosmetic Act, §418 that the business conducts are the following low- risk manufacturing/processing activity/food combinations:

(A) boiling gums, latexes, and resins;

(B) chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts);

(C) coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens);

(D) drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea);

(E) extracting (including by pressing, by distilling, and by solvent extraction) from dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh mint, chopped dried mint);

(F) freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables);

(G) grinding/cracking/crushing/milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);

(H) labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products, (provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

(I) making baked goods from milled grain products (e.g., breads and cookies);

(J) making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream);

(K) making cocoa products from roasted cocoa beans;

(L) making dried pasta from grains;

(M) making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;

(N) making molasses and treacle from sugar beets and sugarcane;

(O) making oat flakes from grains;

(P) making popcorn from grains;

(Q) making snack chips from fruits and vegetables (e.g., making plantain and potato chips);

(R) making soft drinks and carbonated water from sugar, syrups, and water;

(S) making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;

(T) making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;

(U) making vinegar from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt);

(V) mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

(W) packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

(X) pasteurizing honey;

(Y) roasting and toasting baked goods (e.g., toasting bread for croutons);

(Z) dalting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and

(AA) sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour).

(i) Alcoholic beverages.

(1) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(A) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or Chapter 51 of Subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(B) Under the Federal Food, Drug, and Cosmetic Act, §415, the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (1) of this subsection, provided such food:

(A) is in prepackaged form that prevents any direct human contact with such food; and

(B) constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k) Exemptions to Subchapter N.

(1) Except as provided by paragraph (k)(2) of this subsection, Subchapter N does not apply to any of the following:

(A) “farms;”

(B) fishing vessels that are not subject to the registration requirements of 21 Code of Federal Regulations Part 1, Subpart H in accordance with 21 Code of Federal Regulations §1.226(f);

(C) establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(D) activities of “farm mixed-type facilities” as defined under mixed-type facility in §229.211 of this that fall within the definition of “farm;” or

(E) establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts except in the case where the nut is cracked and/or shelled and is intended to be consumed raw (without additional manufacturing/processing, such as roasting nuts).

(2) If a “farm” or “farm mixed-type facility” dries/dehydrates raw agricultural commodities

that are produce as defined in 21 Code of Federal Regulations Part 112, to create a distinct commodity, Subchapter N of this chapter applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with Subchapter N of this chapter or with the applicable requirements for packing and holding in 21 Code of Federal Regulations Part 112.

§229.214. Applicability of 21 Code of Federal Regulations Part 117 Subparts C, D, and G to a Facility Solely Engaged in the Storage of Unexposed Packaged Food.

(a) Applicability of 21 Code of Federal Regulations Part 117 Subparts C and G. 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to a facility solely engaged in the storage of unexposed packaged food.

(b) Applicability of 21 Code of Federal Regulations Part 117 Subpart D. A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged time/temperature controlled for safety (TCS) food is subject to the modified requirements in 21 Code of Federal Regulations §117.206 for any unexposed packaged TCS food.

§229.215. Applicability of Subchapter N to the Off-farm Packing and Holding of Raw Agricultural Commodities.

Subchapter N applies to the off-farm packaging, packing, and holding of raw agricultural commodities. Compliance with this requirement for raw agricultural commodities that are produce as defined in 21 Code of Federal Regulations Part 112 may be achieved by complying with Subchapter N or with the applicable requirements for packing and holding in Part 112.

§229.216. Records.

(a) Records that document training required by §229.212(b)(2) of this title (relating to Qualification of Individuals Who Manufacture, Process, Pack, or Hold Food) must be established and maintained.

(b) The records that must be established and maintained are subject to the requirements of 21 Code of Federal Regulations Part 117 Subpart F.

§ 229.217 Personnel

The ~~plant~~ management of the establishment must shall take all reasonable measures and precautions to ensure the following:

(1) **Disease control and employee health.** 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, must shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g. by an impermeable cover). Personnel must 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 ~~must shall~~ conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and 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 allergen cross-contact and 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 an adequate hand-washing facility that meets the provisions of §229.220.217(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 allergen cross-contact and 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

Commented [L(8)]: Training is now covered in the new §229.212

~~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 and packed before being marketed to the consuming public.~~

Commented [L(9)]: Exemptions now covered in §229.213

§ 229.218~~5~~ Plant and Grounds

(a) Grounds. The grounds ~~about~~ ~~around~~ a food plant under the control of the operator ~~must shall~~ be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds ~~must~~ 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; 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 ~~must 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. ~~The plant must~~ ~~Plant buildings and structures shall~~ be suitable in size, construction, and design to facilitate maintenance and sanitary operations for ~~food-production purposes (i.e. manufacturing, processing, packing, and holding).~~ ~~food-manufacturing purposes.~~ The plant ~~must:~~ ~~and facilities shall:~~

(1) provide ~~adequate sufficient~~ space for ~~such the~~ 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 ~~adequate proper~~ precautions to reduce the potential for ~~allergen cross-contact and for~~ contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for ~~allergen cross-contact and for~~ contamination may be reduced by adequate food safety controls and operating practices ~~or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one of the following means: which may include the design, separation of operations,~~ location, time, partition, air flow ~~systems,~~ ~~dust control systems,~~ enclosed systems, or other effective means;

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

(A) using protective coverings;

(B) controlling areas over and around the vessels to eliminate harborages 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 ~~adequate~~ sufficient lighting in:

(A) hand-washing areas, dressing and locker rooms, and toilet rooms of at least 10 foot candles (greater than or equal to 108 lux); and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and

(B) all areas where food is held and where equipment or utensils are cleaned of at least 20 foot candles (greater than or equal to 220 lux); and

(C) all areas where food is examined, manufactured, processed, or packed of at least 50 foot candles (greater than or equal to 540 lux).

(6) provide shatter-resistant 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;

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

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

§ 229.2196 Sanitary Operations

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant ~~must shall~~ be maintained in a clean and sanitary condition and ~~must shall~~ be kept in repair to prevent so that food from becoming does not become adulterated, ~~within the meaning of the act~~. Cleaning and sanitizing of utensils and equipment ~~must shall~~ be conducted in a manner that protects against allergen cross-contact and 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 must shall be free from undesirable microorganisms and must 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 in areas where food is processed or exposed:

- (A) ~~(+)~~ those required to maintain clean and sanitary conditions;
- (B) ~~(=)~~ those necessary for use in laboratory testing procedures;
- (C) ~~(=)~~ those necessary for plant and equipment maintenance and operation; and
- (D) ~~(+)~~ those necessary for use in the plant's operations.

(2) ~~(=)~~ Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must 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.

(1) All areas of the food plant must be kept free of rodents, insects, birds, and other pests which may contaminate food. ~~No pests shall be allowed in any area of a food plant. Guard Guard, or guide, or pest detecting~~ -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 must shall be taken to exclude pests from the processing-manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. This exclusion of pests includes:

- (A) no evidence of pest activity in non-food areas;
- (B) no evidence of pest activity in food storage or food preparation areas; and
- (C) no evidence of pest activity in or on food products, food packaging or food preparation utensils, equipment, or devices.

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

(3) The use of pesticides 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) ~~(e)~~ Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must shall be cleaned ~~as frequently~~ as necessary to protect against allergen cross-contact and against contamination of food.

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

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must 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 must 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.~~

Commented [L(10)]: Moved and updated to (e) below

(~~3~~4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must should be stored in appropriate containers and must shall be handled, dispensed, used, and disposed of in a manner that protects against allergen cross-contact and 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.~~

(e) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

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

§ 229.220~~17~~ Sanitary Facilities and Controls

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

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

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

(i) Public water systems. Sources in Texas which are public water systems must shall comply with the Texas Health and Safety Code, Chapter 341, Subchapter C, concerning drinking water standards and rules adopted by the Texas Commission on Environmental Quality, 30 Texas

Administrative Code (TAC), Chapter 290, §§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 must shall comply with 30 TAC, Chapter 290, Subchapter F, concerning drinking water standards, §§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, Chapter 290, Subchapter D, §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 must shall be sampled and analyzed in accordance with the requirements found in 30 TAC, Chapter 290 Subchapter F pertaining to §§290.101—290.122 for transient noncommunity water systems.

(C) Any water that is used for hand washing or contacts food, or food-contact surfaces, or food packaging materials must shall be safe and of adequate sanitary quality for its intended use. Hot and cold running water at a suitable temperature, and under pressure as needed, must 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. Hot water generation and distribution systems must shall be adequate sufficient to meet peak hot water demands throughout the facility.

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

(A) carry adequate 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 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; 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 must shall be made into an approved sewerage system in accordance with applicable state regulations and local ordinances.

(4) Toilet facilities. Each plant must shall provide its employees with adequate and readily accessible toilet facilities. Toilet facilities must be kept clean and must be constructed and maintained in a manner as to not be a potential source of contamination of food, food-contact surfaces, or food-

packaging materials. If the toilet facility opens directly into a manufacturing area the facility must have self-closing doors or an alternate means to protect against contamination, 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. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. Facilities that utilize conventional hand washing must provide a conventional handwashing sink, hot running water of at least 100 degrees Fahrenheit, hand cleaning agent, and individual disposable towels, continuous towel system that supplies a user with a clean towel, or an air drying device.

~~Hand-washing facilities shall be adequate in number and location and be furnished with:~~

~~(A) running water at a temperature of at least 110 degrees Fahrenheit;~~

~~(B) a supply of hand cleaning liquid, powder, or bar soap; and~~

~~(C) individual disposable towels, continuous towel system that supplies a user with a clean towel, or a heated air hand drying device.~~

(6) ~~Rubbish and Offal. Waste. Rubbish and offal must Waste 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, except as allowed in paragraph (7) of this section.

(7) Food waste. Bread, nonmeat pastry products, and produce that have been completely removed from all packaging may be disposed of by alternate means according to any applicable requirements of 30 TAC Title 30, Texas Administrative Code (TAC), Chapters 330, 332, and 335, or Title 4, TAC, Chapter 55.

§ 229.22148 Equipment and Utensils

(a) Design and Construction.

(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must shall be so designed and of such material and workmanship as to be cleanable, and must shall be properly maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid

the adulteration or contamination of food.

(3) Equipment must be installed so as to permit the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source.

~~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 must 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 and allergen cross-contact.

(c) Equipment that is in areas where food is the-manufactured, ing, processed, packed, or held or food-handling-area and that does not come into contact with food must shall be constructed so that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must shall be designed and constructed so as to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to accurately 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 must shall be accurate and precise and adequately maintained, and adequate in number for their designated uses, in sufficient quantity for their designated uses. ~~The instruments shall be operated, maintained, and calibrated according to the manufacturer's directions.~~

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

§ 229.~~222~~**219** Production and Process Controls

(a) General.

(1) All operations in the ~~manufacturing, processing, packing and holding of food (including operations directed to receiving, inspecting, transporting, segregating); preparing, manufacturing, packaging, and storing of food~~ ~~must shall~~ be conducted in accordance with ~~adequate good public health and~~ sanitation principles.

(2) ~~Appropriate~~ Quality control operations ~~must shall~~ be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant ~~must shall~~ be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) ~~Adequate~~ All reasonable precautions ~~must shall~~ be taken to ensure that production procedures do not contribute to ~~allergen cross-contact and to~~ contamination from any source.

(5) ~~Chemical, microbial, or extraneous-material~~ Testing procedures ~~must shall~~ be used where necessary to identify sanitation failures or possible ~~allergen cross-contact and~~ food contamination. ~~by chemicals, microbes, or extraneous materials.~~

(6) All food that has become contaminated to the extent that it is adulterated ~~within the meaning of the Act~~ ~~must shall~~ be rejected, ~~or if permissible,~~ treated or processed to eliminate the contamination.

~~(b)~~ Raw materials and other ingredients.

(1A) Food, including raw ingredients and finished product, ~~must shall~~ be obtained from an approved source.

(2B) Raw materials and other ingredients ~~must shall~~ be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and ~~must shall~~ be stored under conditions that will protect against ~~allergen cross-contact and against~~ contamination and minimize deterioration. Raw materials ~~must shall~~ be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food ~~must shall~~ be safe and of ~~adequate~~ sanitary quality. ~~for its intended use.~~ Water may be reused for washing, rinsing, or conveying food if it does not ~~cause allergen cross-contact or~~ 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.~~

(3C) Raw materials and other ingredients ~~must shall~~ either: not contain levels of microorganisms that may ~~render the food injurious to the health of humans; produce food poisoning or other disease in humans;~~ or they ~~must 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.~~

~~(4D) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must 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.~~

~~(5E) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must 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.~~

~~(6F) Raw materials, other ingredients, and rework must shall be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must shall be held at a temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated, within the meaning of the Act. Material scheduled for rework must shall be identified as such.~~

~~(7G) Frozen raw materials and other frozen ingredients must shall be kept frozen. If thawing is required prior to use, it must shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated, within the meaning of the Act.~~

~~(8H) Liquid or dry raw materials and other ingredients received and stored in bulk form must shall be held in a manner that protects against allergen cross-contact and against contamination.~~

~~(9) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.~~

~~(c2) Manufacturing operations.~~

~~(1A) Equipment and utensils and finished food containers must shall be maintained in an acceptable-adequate condition through appropriate cleaning and sanitizing, as necessary. In so far as necessary, equipment must shall be taken apart for thorough cleaning.~~

~~(2B) All food manufacturing, processing, packaging, packing, and holding must including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food, 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.~~

~~(3C) Food that can support the rapid growth of undesirable microorganisms must be held at~~

temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

~~The internal temperature of potentially hazardous foods during transport and storage shall be maintained at or below 41 degrees Fahrenheit as appropriate for the food using methods, that include refrigeration, pre-chilled insulated coolers, dry ice, or storage on ice made from potable water. The method used must maintain the required temperature for the entire length of time the food is in transport or storage.~~

(A) Time/temperature controlled for safety foods must be maintained at an internal temperature of 41 degrees Fahrenheit or below.

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

(C) Shell eggs, after initial packing, must be transported and stored at the lower of a temperature of 45 degrees Fahrenheit or less or as required by the United States Department of Agriculture. 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 shellfish from the harvester through the original shellfish dealer must shall be maintained in accordance with 25 TAC §§241.578 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish must shall be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale.

(E) Hot foods must shall be maintained at an internal temperature of 135 degrees Fahrenheit (60 degrees Celsius) or above.

~~(v) 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.~~

Commented [L(11)]: Moved to 229.222(c)(15)

(F) Seafood intended for wholesale distribution must comply with temperature requirements specified in 21 Code of Federal Regulations Part 123.

(G) Milk received directly from a facility under the jurisdiction of the Pasteurized Milk Ordinance must be received at an internal temperature of 45 degrees F or below. Further storage and transportation of the milk must be maintained at an internal 41 degrees or below.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, 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.

(5) Work-in-process and rework must shall be handled in a manner that protects against allergen cross-contact, contamination, and the growth of undesirable microorganisms.

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

(7G) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or other food ~~must shall~~ be constructed, handled, and maintained during manufacturing, processing, packing, and holding ~~or storage in~~ a manner that protects against allergen cross-contact and against contamination.

(8H) ~~Adequate Effective~~ measures ~~must 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.~~

(9I) Food, raw materials, and other ingredients that are adulterated: ~~within the meaning of the act~~

(A) ~~must shall~~ be disposed of in a manner that protects against the contamination of other food; or.

(B) If the adulterated food is capable of being reconditioned, it ~~must shall~~ be:

(i) reconditioned using a method that has been proven to be effective; or

(ii) ~~it shall be reconditioned and~~ reexamined and subsequently found not to be adulterated ~~confirmed to be safe within the meaning of the Act~~ before being incorporated into other food.

(10J) ~~Mechanical manufacturing S~~ steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, ~~soaking, tempering,~~ and forming ~~must shall~~ be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food. ~~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.~~

(11K) Heat blanching, when required in the preparation of food capable of supporting microbial growth, ~~must should~~ be ~~affected~~ 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. Growth and contamination by thermophilic micro organisms ~~Thermophilic growth and contamination in~~ blanchers ~~must should~~ be minimized by the use of adequate ~~sufficient~~ operating temperatures and by periodic cleaning and sanitizing. ~~Where the blanched food is washed prior to filling, water used shall be safe and of sanitary quality for its intended use.~~

(12L) Batters, breadings, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time ~~must shall~~ be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms. ~~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.~~

~~(13M) Filling, assembling, packaging, and other operations must shall be performed in such a way that the food is protected against allergen cross-contact, contamination, and the growth of undesirable microorganisms. 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.~~

~~(14N) 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 must 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; 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.~~

~~(15O) Food such as acid and acidified food Acid food, acidified food, and similar food that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall-must be monitored and maintained at a pH of 4.6 or below. Acid or acidified foods must be heat treated to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures. 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.

(16P) Modified Atmosphere Packaging. Manufacturers using Modified Atmosphere Packaging: Reduced oxygen packaging. Manufacturers performing reduced oxygen packaging:

(A) Except for a facility that is subject to 21 Code of Federal Regulations Part 117, Subchapter C Hazard Analysis and Risk-Based Preventive Controls or the product being produced is subject to 21 Code of Federal Regulations Part 123, Fish and Fishery Products, a facility that packages a Time/Temperature Control for Safety (TCS) food using a modified atmosphere packaging method shall control the growth and toxin formation of *Clostridium botulinum* and the growth of *Listeria monocytogenes*.

(B) a facility that packages TCS food using a modified atmosphere packaging method must implement a food safety plan that contains the information specified under 21 Code of Federal Regulations §117.135 a(1)-c(3) and that:

(i) identifies the food to be packaged;

(ii) except as specified under subparagraphs (C) and (D) of this paragraph, requires that the packaged food shall be maintained at 5 degrees Celsius (41 degrees Fahrenheit) or less and meet at least one of the following criteria:

(I) has an a_w of 0.91 or less;

(II) has a pH of 4.6 or less;

(III) is a meat or poultry product cured at a food processing plant regulated by the USDA or the department using substances specified in 9 Code of Federal Regulations §424.21, use of food ingredients and sources of radiation, and is received in an intact package; or

(IV) is a food with a high level of competing organisms such as raw meat, raw poultry, or raw vegetables;

(iii) describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(I) maintain the food at 5 degrees Celsius (41 degrees Fahrenheit) or below; and

(II) discard the food if within 30 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;

(iv) limits the refrigerated shelf life to no more than 30 calendar days from packaging to consumption, except the time the product is maintained frozen, or the original manufacturer's "sell by" or "use by" date, whichever occurs first;

(C) a facility that packages TCS food using a modified atmosphere packaging method must ensure individuals performing modified atmosphere packaging have the appropriate training and documentation as required by §229.212 of this title (relating to Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food.

(D) Except for fish that is frozen before, during, and after packaging, a facility may not package fish using a modified atmosphere packaging method unless the product is subject to 21 Code of Federal Regulations Part 123, Fish and Fishery Products;

(E) Cheese. A facility that packages cheese using a Modified Atmosphere Packaging method must:

(i) limit the cheeses packaged to those that are commercially manufactured in a food processing plant with no ingredients added in a facility other than the original food processing plant and that meet the Standards of Identity as specified in 21 Code of Federal Regulations §133.150, Hard cheeses, 21 Code of Federal Regulations Part 133.169 Pasteurized process cheese or 21 Code of Federal Regulations §133.187 Semisoft cheeses;

(ii) have a food safety plan that contains the information specified under 21 Code of Federal Regulations §117.135 a(1)-c(3); and

(iii) label the package on the principal display panel with a “use by” date that does not exceed 30 days from its packaging or the original manufacturer’s sell by date, or “use by” date, whichever occurs first.

(F) A facility using a Modified Atmosphere Packaging method for TCS Foods, intended to be frozen after packaging other than those specified in subparagraph (B)(ii)(I)-(V), of this paragraph must:

(i) implement a food safety plan that contains the information specified under 21 Code of Federal Regulations §117.135 a(1)-c(3);

(ii) immediately freeze the product following packaging;

(iii) label the product Keep Frozen; and

(iv) provide instructions for safe handling after thawing.

(G) Foods other than those specified in subparagraphs (B)(ii), (D), (E) (F) of this paragraph may be packaged utilizing modified atmosphere packaging if the facility complies with 21 Code of Federal Regulations Part 117, Subchapter C, Hazard Analysis and Risk Based Preventive Controls.

(i) shall maintain Standard Operating Procedures (SOPs) that:

(i) limit the shelf life of foods to not more than 14 calendar days from the date the food is packaged to the date the food is consumed or the original manufacturer's "sell by" or "use by" date, whichever comes first, except as described in clause (vi) of this subparagraph;

~~(II) describe how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:~~

~~(a) "use by" and provide a date that is within 14 calendar days of packaging or provide a date as allowed by clause (v) of this subparagraph; and~~

~~(b) keep the food refrigerated at 41 degrees Fahrenheit or below;~~

~~(III) require employees that contact foods with bare hands to wash hands properly or utilize proper utensils;~~

~~(IV) designate raw food and ready to eat food areas and place physical barriers or effective methods that minimize the risk of cross-contamination between raw foods and ready to eat foods and restrict access to the food processing equipment to personnel who are trained to operate the equipment and understand the risks of cross-contamination;~~

~~(V) describe cleaning and sanitization procedures for food contact surfaces; and~~

~~(VI) describe the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:~~

~~(a) concepts required for safe operation;~~

~~(b) equipment and facility; and~~

~~(c) procedures specified in clauses (i)(II) —(V) and (iii) —(vii) of this subparagraph;~~

~~(ii) shall maintain records that document employee training. Records documenting training must be maintained for at least one year after the employee leaves the company or is moved to other duties that do not include vacuum packaging. The records must be available at the packaging facility or corporate offices for review by the regulatory authority;~~

~~(iii) shall maintain food processing records for at least one year from the time the food is packed. The records must be available at the facility or corporate offices for review by the regulatory authority. The records must contain the following information:~~

~~(I) the identity of the food that is packaged;~~

~~(II) the date the food was packaged; and~~

~~(III) the name of the operator performing the food packaging;~~

~~(iv) shall limit the types of foods that are packaged to a food that does not support the growth of Clostridium botulinum because it complies with one of the following:~~

~~(I) has a water activity (a_w) of 0.91 or less;~~

~~(II) has a hydrogen ion concentration (pH) of 4.6 or less;~~

~~(III) is a meat or poultry product cured at a food processing plant regulated by the U.S. Department of Agriculture or the department, and is received in an intact package; or~~

~~(IV) is a food with a high level of competing organisms such as raw meat or poultry;~~

~~(v) food products, other than those specified in clause (iv) of this subparagraph may be vacuum packaged if the firm provides written documentation of product testing such as shelf life studies of the product under the same storage and packaging conditions or scientific studies of the product which must be the same species, market form, packaging, and holding conditions that prove the reduced oxygen packaged product will not support the growth of Clostridium botulinum;~~

~~(vi) the shelf life of a vacuum packaged product may be extended past the 14 day shelf life limit as specified in clause (i)(I) of this subparagraph if the firm provides written documentation of product testing such as shelf life studies of the product under the same storage and packaging conditions or scientific studies of the product which must be the same species, market form, packaging, and holding conditions that prove the extended shelf life of the reduced oxygen packaged product will not support the growth of Clostridium botulinum, Listeria and Salmonella; and~~

~~(vii) fish shall not be packaged in reduced oxygen packaging unless the fish is frozen before, during, and after packaging unless the firm is subject to §§229.121– 229.129 of this title (relating to Seafood HACCP).~~

~~(17Q) Unshelled pecans **intended to be consumed raw must shall** be thoroughly cleaned to remove foreign matter before cracking. After cleaning, unshelled pecans **must shall** be sanitized.~~

~~(18R) When ice is used in contact with food, it **must shall** be made from water that is safe and of adequate sanitary quality **in accordance with §229.220 of this title (relating to Sanitary Facilities and Controls)**, and **must shall** be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this ~~part~~**subchapter**.~~

~~(S) 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.~~

§ 229.2230 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 [Texas 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 must 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 must 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 foods.regulatory@dshs.state.tx.us or [Texas Department of State Health Services Foods Group, PO Box 149347, Mail Code-1987 Austin, Texas 78714-9347](#), ~~the Department of State Health Services, 1100 West 49th Street, Austin, Texas, 78756~~.

§ ~~229.2241~~ **Good Warehousing Practice**

(a) Plant and grounds.

(1) Storage and transportation of food must 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 must shall be properly constructed and maintained. All walls, ceilings, and floors must shall be intact to preclude entry of vermin and environmental contaminants.

(3) Doors and loading docks must 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, and non food storage areas must shall be kept clean and free of odors, debris, high weeds, or standing water which could harbor or attract vermin.

(5) Adequate lighting of at least 108 lux (10 foot candles) must shall be provided to facilitate cleaning and inspection of food storage areas ~~stored goods~~.

(b) Sanitary facilities.

(1) Toilet Facilities. Each warehouse facility must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and in good repair. Toilet facilities must

be equipped with a hand washing sink with running water of at least 100 degrees Fahrenheit, hand cleaning agent, and single service towels or an air drying device.

(2) Handwashing Facilities:

(A) For warehouse facilities that have direct hand contact with food, the facility must provide hand-washing facilities separate from the toilet facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature. Facilities that utilize conventional handwashing must provide a conventional handwashing sink, hot running water of at least 100 degrees Fahrenheit, hand cleaning agent, and individual disposable towels, continuous towel system that supplies a user with a clean towel, or an air drying device.

(B) For warehouse facilities with no direct hand contact with food, hand-washing facilities separate from toilet facilities are not required.

~~(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.~~

~~(32)~~ Wastewater must shall be disposed of in a manner approved by the regulatory authority.

(c) Sanitary operations.

(1) Foods including raw ingredients and finished food products must shall be obtained from an approved source.

~~(24)~~ All foods, including refrigerated and frozen foods, must shall be stored to prevent direct contact with the floor 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.

~~(3)~~ All food packaging material that are intended to come in direct contact with food must be stored to prevent direct contact with the floor

~~(42)~~ Food storage facilities and transportation vehicles must shall be kept free of rodents, insects, birds, and other pests which may contaminate food which includes:

(A) no evidence of pest activity in non-food areas;

(B) no evidence of pest activity in food storage areas; and

(C) no evidence of pest activity in or on food products, food packaging or food preparation utensils, equipment or devices.

~~(53)~~ Damaged, distressed, and infested foods and food packaging material must shall be stored in a designated "morgue area," adequately separated from undamaged foods and must shall be disposed of in a timely manner to preclude further contamination.

Commented [L12]: Not new language moved from 229.221(e)

~~(64)~~ Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

~~The internal temperature of potentially hazardous foods during transport and storage shall be maintained at or below 41 degrees Fahrenheit as appropriate for the food using methods that include refrigeration, pre-chilled insulated coolers, dry ice, or storage on ice made from potable water. The method used must maintain the required temperature for the entire length of time the food is in transport or storage.~~

~~(A) Time/temperature controlled for safety foods must be maintained at an internal temperature of 41 degrees Fahrenheit or below.~~

~~(BA)~~ Frozen foods ~~must shall~~ be kept frozen at all times.

~~(CB)~~ Shell eggs after initial packing, must be transported and stored at the lower of a temperature of 45 degrees Fahrenheit or less or as required by The United States Department of Agriculture.

~~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.~~

~~(DC)~~ The temperature of molluscan shellfish from the harvester through the original shellfish dealer ~~must shall~~ be maintained in accordance with 25 TAC §§241.578 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish ~~must shall~~ be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale.

~~(E) Seafood intended for wholesale distribution must comply with temperature requirements specified 21 Code of Federal Regulations Part 123, Seafood Safety.~~

~~(F) Milk received directly from a facility under the jurisdiction of the PMO must be received at an internal temperature of 45 degrees F or below. Further storage and transportation of the milk must be maintained at an internal 41 degrees or below~~

~~(75)~~ During warehousing and transporting, all chemicals ~~must 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.~~

~~(87)~~ Food storage facilities and transportation vehicles operated under the control of the licensee ~~must shall~~ be kept clean and free of excessive dust, dirt, spillage, and other debris, including excess moisture.

~~(98)~~ Food transport vehicles ~~must shall~~ be operated in compliance with federal regulations pertaining to back-hauling.

~~(109)~~ Each incoming lot ~~must shall~~ be examined at the time of receipt and contaminated or adulterated foods ~~must shall~~ not be accepted.

(1140) Swollen, leaking, and/or severely dented containers of food ~~must shall~~ be segregated and promptly placed in the "morgue area" and further contamination, attraction of vermin, or sale prior to reconditioning ~~must shall~~ be prevented.

(1211) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food warehouse and/or food processing facility may be used. Pesticides ~~must shall~~ be used only according to label directions. Rodenticides ~~must 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 ~~must shall~~ be salvaged in accordance with §§229.541 - 229.554, 229.571 - 229.584, 229.601 - 229.614, and 229.631 - 229.647 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 ~~must shall~~ comply with §229.253 of this title (relating to Minimum Standards for Licensure).

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

~~(e) Food including raw ingredients and finished food products shall be obtained from an approved source.~~

Commented [L13]: Not deleted. Moved to 229.224(c)(1)

§ 229.2252 Enforcement

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

(b) Civil penalties as provided in Texas 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, §431.055, §431.056, §431.057, §431.058, and in §229.261 of this title (relating to Assessment of Administrative Penalties), may be assessed for violation of these sections. If the person charged with the violation does not request a hearing, the Commissioner of the Texas Department of State Health Services (Commissioner) or the Commissioner's designee may assess a penalty after determining that a violation has occurred and the amount of the penalty.

(d) Emergency orders as provided in Texas Health and Safety Code, §431.045 may be issued by the Commissioner or the Commissioner's designee.