



| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|--|---|-------------------------------------|--|
| §229.212. Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food. | (a) Applicability. | §229.213 Personnel | See §229.213 (3) and (4) below. |
| | (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. | | (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. |
| | (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. | | (4) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this section shall be clearly assigned to competent supervisory personnel. |
| | (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 of this title (relating to Definitions)-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. | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|-------------------------------------|--|
| | (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 | (k) Exemptions to Subchapter N. | §229.214 Exclusions | The following operations are not subject to this section: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities which are ordinarily cleaned and packed before being marketed to the consuming public. |
| | (1) Except as provided by paragraph (2) of this subsection, Subchapter N of this chapter 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 title that fall within the definition of "farm;" or | | |
| §229.213(k)(1)(E) Exemptions | (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). | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|-------------------------------------|--|
| | (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. | | | |
| | | | |
| §229.215.Applicability of Subchapter N to the Off-farm Packing and Holding of Raw Agricultural Commodities. | Subchapter N (GMPs) of this chapter 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 of this chapter or with the applicable requirements for packing and holding in Part 112. | | |
| | | | |
| §229.216.Records. | | | |
| | | | |
| §229.217.Personnel. | The management of the establishment must take all reasonable measures and precautions to ensure the following. | §229.213.Personnel. | The plant management shall take all reasonable measures and precautions to ensure the following: |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|-------------------------------------|---|
| §229.217.Personnel. | (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 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 be instructed to report such health conditions to their supervisors. | §229.213.Personnel. | (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, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors. |
| | (2) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must 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: | | (2) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to: |
| | (A) wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials; | | (A) wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials; |
| | (B) maintaining adequate personal cleanliness; | | (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 of this title (relating to Sanitary Facilities and Controls), before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated; | | (C) washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in a hand-washing facility that meets the provisions of §229.217(e) of this title (relating to Sanitary Facilities and Control), before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated; |
| §229.217(2).Personnel. | (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; | §229.213(2).Personnel. | (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; |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|-------------------------------------|--|
| | (E) maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition; | | (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; | | (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; | | (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 | | (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 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, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin. | | (I) taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin. |
| | <i>See 229.212 above for Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food.</i> | | (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. |
| | <i>See 229.212 above for Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food.</i> | | (4) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this section shall be clearly assigned to competent supervisory personnel. |
| | | | |
| §229.216.Records. | | | |
| | | | |
| | <i>See 229.213(k) Exemptions to Subchapter N above.</i> | §229.214 Exclusions | The following operations are not subject to this section: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities which are ordinarily cleaned and packed before being marketed to the consuming public. |
| | | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|--|--|
| §229.218.Plant and Grounds. | (a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include: | §229.215. Plant and Grounds. | (a) Grounds. The grounds around a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to: |
| | (1) properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests; | | (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; | | (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; | | (3) draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests; |
| | (4) operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed; and | | (4) operating systems for waste treatment and disposal in a manner so that they do not constitute a source of contamination in areas where food is exposed; and |
| | (5) if the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (1) through (4) of this subsection, care must 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. | | (5) if the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (1) through (4) of this subsection, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination. |
| | (b) Plant construction and design. The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e. manufacturing, processing, packing, and holding). The plant must: | | (b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall: |
| §229.218(b).Plant and Grounds. | (1) provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food; | §229.215(b). Plant and Grounds. | (1) provide sufficient space for the placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food; |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|--|---|
| | (2) permit the taking of adequate 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: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means; | | (2) permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices which may include the design, separation of operations, location, time, partition, air flow, enclosed systems, or other effective means; |
| | (3) permit the taking of adequate precautions to protect food in installed outdoor bulk fermentation vessels by any effective means, including: | | (3) permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including: |
| | (A) using protective coverings; | | (A) using protective coverings; |
| | (B) controlling areas over and around the vessels to eliminate harborages for pests; | | (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 | | (C) checking on a regular basis for pests and pest infestation; and |
| | (D) skimming the fermentation vessels, as necessary; | | (D) skimming the fermentation vessels, as necessary; |
| §229.218(b).Plant and Grounds. | (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; | §229.215(b). Plant and Grounds. | (4) be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact; |
| | (5) provide adequate lighting in: | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|--------------------------------------|--|
| | (A) hand-washing areas, dressing and locker rooms, and toilet rooms of at least 10 foot candles (greater than or equal to 108 lux); | | (5) provide sufficient lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage; |
| | (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 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) 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 | | (6) provide ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces; and |
| | (8) provide, where necessary, adequate screening or other protection against pests. | | (7) provide, where necessary, screening or other protection against pests. |
| | | | |
| §229.219.Sanitary Operations. | (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials. | §229.216.Sanitary Operations. | (a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair so that food does not become adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. |
| | (b) Substances used in cleaning and sanitizing; storage of toxic materials. | | (b) Substances used in cleaning and sanitizing; storage of toxic materials. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|---|
| | (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must 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: | | Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed: |
| | (A) those required to maintain clean and sanitary conditions; | | (1) those required to maintain clean and sanitary conditions; |
| | (B) those necessary for use in laboratory testing procedures; | | (2) those necessary for use in laboratory testing procedures; |
| | (C) those necessary for plant and equipment maintenance and operation; and; | | (3) those necessary for plant and equipment maintenance and operation; and |
| | (D) those necessary for use in the plant's operations. | | (4) those necessary for use in the plant's operations. |
| §229.219(b).Sanitary Operations. | (2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. | §229.216(c).Sanitary Operations. | (c) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other federal, state, and local government agencies for the application, use, or holding of these products should be followed. |
| | (c) Pest control. | | (d) Pest control. |
| | (1) All areas of the food plant must be kept free of rodents, insects, birds, and other pests which may contaminate food. Guard, 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 be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. This exclusion of pests includes: | | (1) No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. This exclusion of pests includes: |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|---|
| | (A) no evidence of pest activity in non-food areas; | | (A) no evidence of pest activity in non-food areas; |
| | (B) no evidence of pest activity in food storage or food preparation areas; and; | | (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. | | (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 be used according to label directions. Rodenticides must be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides. | | (2) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food processing facility may be used. Pesticides shall be used only according to label directions. Rodenticides shall be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides. |
| | (3) The use of pesticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. | | (3) The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. |
| §229.219(d).Sanitary Operations. | (d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as necessary to protect against allergen cross contact and against contamination of food. | §229.216(e).Sanitary Operations. | (e) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food. |
| | (1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use. | | (1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use. |
| | (2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must 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 be cleaned and sanitized as necessary. | | (2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|--|
| | (3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored in appropriate containers and must 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. | | (4)* Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces. |
| | (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. | | (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. |
| | <i>See 229.219(b)(1) above.</i> | | (5)* Sanitizing agents shall be adequate for sanitization and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment. |
| | (f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination. | | (f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination. |
| | | | |
| §229.220.Sanitary Facilities and Controls. | Each plant must be equipped with adequate sanitary facilities and accommodations including, but not limited to: | §229.217.Sanitary Facilities and Controls. | Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to: |
| | (1) Water supply. The water supply must be adequate for the operations intended and must be derived from an approved source. | | (1) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an approved source. |
| | (A) Requirements for approved source. Sources in Texas must comply with the following requirements. | | (A) Requirements for approved source. Sources in Texas shall comply with the following requirements. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|--|--|--|---|
| | (i) Public water systems. Sources in Texas which are public water systems must comply with the Texas Health and Safety Code, Chapter 341, Subchapter C, drinking water standards and rules adopted by the Texas Commission on Environmental Quality, 30 Texas Administrative Code (TAC) Chapter 290. | | (i) Public water systems. Sources in Texas which are public water systems shall comply with the Texas Health and Safety Code, Chapter 341, Subchapter C, concerning drinking water standards and rules adopted by the Texas Commission on Environmental Quality, 30 Texas Administrative Code (TAC), §§290.101 - 290.122 (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Supply Systems), and §§290.38 - 290.47 (relating to Rules and Regulations for Public Water Systems). |
| | (ii) Other sources. Any other sources in Texas must comply with 30 TAC Chapter 290, Subchapter F, concerning drinking water standards. | | (ii) Other sources. Any other sources in Texas shall comply with 30 TAC, §§290.101 - 290.122 concerning drinking water standards and 30 TAC, §§290.38 - 290.43 and §290.46 concerning rules and regulations for public water systems. |
| | <i>No equivalent. It was removed from our rules.</i> | | (iii) Compliance with these sections is required as if the source were a public water system. |
| | (B) Sampling requirements. | | (B) Sampling requirements. |
| | (i) Approved community public water systems as defined by 30 TAC Chapter 290 Subchapter D (relating to Definitions). No additional source water sampling is required. | | (i) Approved community public water systems as defined by 30 TAC, §290.38(8) and (41) (relating to Definitions). No additional source water sampling is required. |
| | (ii) Source water obtained from other than a community public water system must be sampled and analyzed in accordance with the requirements found in 30 TAC, Chapter 290 Subchapter F pertaining to transient noncommunity water systems. | | (ii) Source water obtained from other than a community public water system shall be sampled in accordance with 30 TAC, §§290.101 - 290.122 for transient noncommunity water systems. |
| §229.220(1).Sanitary Facilities and Controls. | (C) Any water that is used for hand washing or contacts food, food-contact surfaces, or food packaging materials must 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 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 be adequate to meet peak hot water demands throughout the facility. | §229.217(1).Sanitary Facilities and Controls. | (C) Any water that is used for hand washing or contacts food or food-contact surfaces shall be safe and of sanitary quality for its intended use. Hot and cold running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities. Hot water generation and distribution systems shall be sufficient to meet peak hot water demands throughout the facility. |
| | (2) Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to: | | (2) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to: |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|--|--|--|---|
| | (A) carry adequate quantities of water to required locations throughout the plant; | | (A) carry sufficient quantities of water to required locations throughout the plant; |
| | (B) properly convey sewage and liquid disposable waste from 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; | | (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 | | (D) provide floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and |
| | (E) provide that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing. | | (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 be made into an approved sewerage system in accordance with applicable state regulations and local ordinances. | | (3) Sewage disposal. Sewage disposal shall be made into an approved sewerage system in accordance with applicable state regulations and local ordinances. |
| | | | (4) Toilet facilities. Each plant shall provide its employees with readily accessible toilet facilities adequate in number and location. Compliance with this requirement may be accomplished by: |
| | (4) Toilet facilities. Each plant must 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. | | (A) maintaining the toilet facilities in a sanitary condition; |
| §229.220(4).Sanitary Facilities and Controls. | | §229.217(4).Sanitary Facilities and Controls. | (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 | | (5) Hand-washing facilities. 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 |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|--|
| | 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. | | (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. Rubbish and Offal must 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. | | (6) Waste. 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 Chapters 330, 332, and 335 or 4 TAC Chapter 55. | | (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 Title 30, Texas Administrative Code (TAC), Chapters 330, 332, and 335, or Title 4, TAC, Chapter 55. |
| | | | |
| §229.221.Equipment and Utensils. | (a) Design and Construction. | §229.218.Equipment and Utensils. | (a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives. |
| §229.221.Equipment and Utensils. | (1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be cleanable, and must be maintained to protect against allergen cross-contact and contamination. | §229.218.Equipment and Utensils. | |
| | (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. | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|--|---|
| | (b) Seams on food-contact surfaces must 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. | | (b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms. |
| | (c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be constructed so that it can be kept in a clean and sanitary condition. | | (c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be constructed so that it can be kept in a clean condition. |
| | (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed and constructed so as to be maintained in an appropriate clean and sanitary condition. | | (d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be designed and constructed so as to be maintained in an appropriate sanitary condition. |
| §229.221(e).Equipment and Utensils. | (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to accurately show the temperature accurately within the compartment. | §229.218(e).Equipment and Utensils. | (e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to accurately show the temperature within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation. |
| | (f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses. | | (f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and 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 be treated in such a way that food is not contaminated with unlawful indirect food additives. | | (g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful food additives. |
| | | | |
| §229.222.Production and Process Controls. | (a) General. | §229.219.Production and Process Controls. | |
| | (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspections, transporting, and segregating) must be conducted in accordance with adequate sanitation principles. | | All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|--|---|
| | (2) Quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. | | <p>accordance with good public health and sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.</p> <p>Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Testing procedures shall be used where necessary to identify sanitation failures or possible food contamination by chemicals, microbes, or extraneous materials. All food that has become contaminated to the extent that it is adulterated within the meaning of the Act shall be rejected, or if permissible, treated or processed to eliminate the contamination.</p> |
| | (3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function. | | |
| | (4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source. | | |
| §229.222(a).Production and Process Controls. | (5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination. | §229.219.Production and Process Controls. | |
| | (6) All food that has become contaminated to the extent that it is adulterated must be rejected, treated or processed to eliminate the contamination. | | |
| | (b) Raw materials and other ingredients. | | |
| | (1) Food, including raw ingredients and finished product, must be obtained from an approved source. | | (1) Raw materials and other ingredients. |
| | (2) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. 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. | | (A) Food including raw ingredients and finished product shall be obtained from an approved source. |
| | | | (B) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of sanitary quality for its intended use. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of food. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|---|
| | (3) Raw materials and other ingredients must either: not contain levels of microorganisms that may render the food injurious to the health of humans; or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated. | | (C) Raw materials and other ingredients shall either: not contain levels of microorganisms that may produce food poisoning or other disease in humans; or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the Act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification. |
| §229.222(b).Production and Process Controls. | (4) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with current Food and Drug Administration regulations for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. | §229.219(1).Production and Process Controls. | (D) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins. |
| | (5) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable Food and Drug Administration regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. | | (E) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination. |
| | (6) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at a temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such. | | (F) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at a temperature and relative humidity and in a manner to prevent the food from becoming adulterated within the meaning of the Act. Material scheduled for rework shall be identified as such. |
| | (7) Frozen raw materials and other frozen ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated. | | (G) Frozen raw materials and other frozen ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the Act. |
| | (8) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects allergen cross-contact and against contamination. | | (H) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|---|
| | (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. | | <i>No equivalent in old GMPs.</i> |
| | (c) Manufacturing operations. | | (2) Manufacturing operations. |
| §229.222(c).Production and Process Controls. | (1) Equipment and utensils and finished food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. In so far as necessary, equipment must be taken apart for thorough cleaning. | §229.219(2).Production and Process Controls. | (A) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing. As necessary, equipment shall be taken apart for thorough cleaning. |
| | (2) All food manufacturing, processing, packaging, packing and holding must 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. | | (B) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. Compliance with this requirement may be accomplished by careful monitoring of physical factors such as time, temperature, humidity, a _w , pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food. |
| | (3) 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. | | (C) 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 be kept frozen at all times. | | (i) Frozen foods shall be kept frozen at all times. |
| | (C) Shell eggs, after initial packing, must be transported and stored at the lower of 45 degrees Fahrenheit or as required by The United States Department of Agriculture. | | (ii) Shell eggs, after initial packing, must be transported and stored at a temperature of 45 degrees Fahrenheit or less. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine by law that a lower temperature must be maintained, the lower temperature shall prevail. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|--|
| | (D) The temperature of molluscan shellfish from the harvester through the original shellfish dealer must be maintained in accordance with 25 TAC §§241.57- 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish must be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale. | | (iii) The temperature of molluscan shellfish from the harvester through the original shellfish dealer shall be maintained in accordance with §§241.58 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish shall be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale. |
| | (E) Hot foods must be maintained at an internal temperature of 135 degrees Fahrenheit (60 degrees Celsius) or above. | | (iv) Hot foods shall be maintained at 135 degrees Fahrenheit (60 degrees Celsius) or above. |
| §229.222(c).Production and Process Controls. | (F) Seafood intended for wholesale distribution must comply with temperature requirements specified in 21 Code of Federal Regulations Part 123. | §229.219(2).Production and Process Controls. | 229.219(C) above. |
| | 229.222 (c) (2) or (4) | | (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. |
| | (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 must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated. | | (D) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling a _w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the Act. |
| | (5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and the growth of undesirable microorganisms. | | (E) Work-in-process shall be handled in a manner that protects against contamination. |
| | (6) Effective measures must 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 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 be protected against contamination. | | (F) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|--|
| | (7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination. | | (G) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination. |
| | (8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food. | | (H) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means. |
| §229.222(c).Production and Process Controls. | (9) Food, raw materials, and other ingredients that are adulterated: | §229.219(2).Production and Process Controls. | (I) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and confirmed to be safe within the meaning of the Act before being incorporated into other food. |
| | (A) Must 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 be: | | |
| | (i) reconditioned using a method that has been proven to be effective; or | | |
| | (ii) reconditioned and reexamined and subsequently found not to be adulterated before being incorporated into other food. | | |
| | (10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must 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. | | (J) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, soaking, tempering, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by cleaning and sanitizing all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|---|
| | (11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must 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 microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing. | | (K) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of sufficient operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of sanitary quality for its intended use. |
| | (12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must 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. | | (L) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following: |
| §229.222(c).Production and Process Controls. | | §229.219(2).Production and Process Controls. | (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. |
| | (13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination, and the growth of undesirable microorganisms. | | (M) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including: |
| | | | (i) use of a quality control operation in which the control points are identified and controlled during manufacturing; |
| | | | (ii) proper cleaning and sanitizing of all food-contact surfaces and food containers; |
| | | | (iii) using materials for food containers and food-packaging materials that are safe and suitable for their intended use; |
| | | | (iv) providing physical protection from contamination, particularly airborne contamination; and |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|--|---|
| | | | (v) using sanitary handling procedures. |
| | (14) Food such as, 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 be processed to and maintained at a safe moisture level. | | (N) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices: |
| | | | (i) monitoring the a_w of food; |
| | | | (ii) controlling the soluble solids-water ratio in finished food; and |
| §229.222(c).Production and Process Controls. | | | §229.219(2).Production and Process Controls. |
| | (15) Food such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms, 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. | | (O) Acid food, acidified food, and similar food that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or both of the following practices: |
| | | | (i) monitoring the pH of raw materials, food in process, and finished food; and |
| | | | (ii) controlling the amount of acid or acidified food added to low-acid food. |
| §229.222(c)(16).Production and Process Controls. | (16) Modified Atmosphere Packaging. Manufacturers using Modified Atmosphere Packaging: | §229.219(2)(P).Production and Process Controls. | (P) 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 <i>Clostridium botulinum</i> and the growth of <i>Listeria monocytogenes</i> . | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|--|
| | (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) shall maintain Standard Operating Procedures (SOPs) that: |
| | (i) identifies the food to be packaged; | | (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; |
| §229.222(c)(16)(B). Production and Process Controls. | (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: | §229.219(2)(P)(i).Production and Process Controls. | (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: |
| | (I) has an a_w of 0.91 or less; | | (-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 |
| | (II) has a pH of 4.6 or less; | | (-b-) keep the food refrigerated at 41 degrees Fahrenheit or below; |
| | (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; | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|--|--|---|---|
| | (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). | | (III) require employees that contact foods with bare hands to wash hands properly or utilize proper utensils; |
| §229.222(c)(16)(C). <i>Production and Process Controls.</i> | | §229.219(2)(P)(i)(IV). <i>Production and Process Controls.</i> | (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: |
| | | 21 CFR 117.190 Implementation Records required for Subpart C- <i>Hazard analysis and Risk-Based Preventive Controls</i> | |
| | | | (II) the date the food was packaged; and |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|--|
| | | | (III) the name of the operator performing the food packaging; |
| | 229.222(c)(16)(B)(ii) | | (iv) shall limit the types of foods that are packaged to a food that does not support the growth of <i>Clostridium botulinum</i> because it complies with one of the following: |
| §229.222(c)(16)(C). Production and Process | 229.222(c)(16)(B)(ii)(I) | §229.219(2)(P)(iv). Production and Process | (I) has a water activity (a_w) of 0.91 or less; |
| | 229.222(c)(16)(B)(ii)(II) | | (II) has a hydrogen ion concentration (pH) of 4.6 or less; |
| | 229.222(c)(16)(B)(ii)(III) | | (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 |
| | 229.222(c)(16)(B)(ii)(IV) | | (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 <i>Clostridium botulinum</i> ; |
| | | | (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 <i>Clostridium botulinum</i> , <i>Listeria</i> and <i>Salmonella</i> ; and |
| | (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; | | (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). |
| | (E) Cheese . A facility that packages cheese using a Modified Atmosphere Packaging method must: | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|--|--|---|---|
| §229.222(c)(16)(E). <i>Production and Process Controls.</i> | (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 §133.169 Pasteurized process cheese or 21 Code of Federal Regulations §133.187 Semisoft cheeses; | §229.219(2)(P)(vii). <i>Production and Process Controls.</i> | |
| | (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)-(IV) 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. | | |
| | (17) Unshelled pecans intended to be consumed raw must be thoroughly cleaned to remove foreign matter before cracking. After cleaning, unshelled pecans must be sanitized. | | (Q) Unshelled pecans shall be thoroughly cleaned to remove foreign matter before cracking. After cleaning, unshelled pecans shall be sanitized. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|---|
| §229.222(c)(18).Production and Process Controls. | (18) When ice is used in contact with food, it must 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 be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this subchapter. | §229.219(2)(R). Production and Process Controls. | (R) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part. |
| | <i>No equivalent in new GMPs- It was removed.</i> | | (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. |
| | | | |
| §229.223.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. | §229.221.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, §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 observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated, 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 at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. | | (b) Compliance with defect action levels does not excuse violation of the requirement in the Health and Safety Code, Chapter 431, §431.081(a)(3) that food not be prepared, packed, or held under unsanitary conditions or the requirements in this section that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. |
| §229.223.Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard. | (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 regardless of the defect level of the final food. | §229.221.Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard. | (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. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|--|
| | (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, P.O. Box 149347, Mail Code 1987, Austin, Texas 78714-9347. | | (d) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Department of State Health Services, 1100 West 49th Street, Austin, Texas, 78756. |
| | | | |
| §229.224.Good Warehousing Practice. | (a) Plant and grounds. | §229.221.Good Warehousing Practice. | (a) Plant and grounds. |
| | | | |
| | (1) Storage and transportation of food must be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. | | (1) Storage and transportation of food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. |
| | (2) Food storage facilities must be properly constructed and maintained. All walls, ceilings, and floors must be intact to preclude entry of vermin and environmental contaminants. | | (2) Food storage facilities shall be properly constructed and maintained. All walls, ceilings, and floors shall be intact to preclude entry of vermin and environmental contaminants. |
| | (3) Doors and loading docks must 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. | | (3) Doors and loading docks shall be tight-fitting and kept closed at all times when not in use, or adequately screened during normal operating hours to prevent entry of rodents, birds, or other pests. |
| | (4) Outer premises, including trash receptacles, and non food storage areas must be kept clean and free of odors, debris, high weeds, or standing water which could harbor or attract vermin. | | (4) Outer premises, including trash receptacles, shall be kept clean and free of odors, debris, high weeds, or standing water which could harbor or attract vermin. |
| | (5) Adequate lighting of at least 108 lux (10 foot candles) must be provided to facilitate cleaning and inspection of food storage areas. | | (5) Adequate lighting shall be provided to facilitate cleaning and inspection of stored goods. |
| | (b) Sanitary facilities. | | (b) Sanitary facilities. |
| §229.224(b).Good Warehousing Practice. | (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. | §229.221(b).Good Warehousing Practice. | |
| | (2) Handwashing Facilities: | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--|---|---|
| | (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. | | (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. |
| | (B) For warehouse facilities with no direct hand contact with food, hand-washing facilities separate from toilet facilities are not required. | | |
| | (C) Wastewater must be disposed of in a manner approved by the regulatory authority. | | (2) Wastewater shall be disposed of in a manner approved by the regulatory authority. |
| | (c) Sanitary operations. | | (c) Sanitary operations. |
| | (1) Food including raw ingredients and finished food products must be obtained from an approved source. | | <i>See 229.221(e) below.</i> |
| | (2) All foods, including refrigerated and frozen foods, must be stored to prevent direct contact with 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. | | (1) All foods, including refrigerated and frozen foods, shall be stored off the floor and away from walls to help prevent contamination by vermin (rodents and insects for example) and moisture, and to facilitate cleaning and inspection. |
| | (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. | | |
| §229.224(c).Good Warehousing Practice. | (4) Food storage facilities and transportation vehicles must be kept free of rodents, insects, birds, and other pests which may contaminate food which includes: | §229.221(c).Good Warehousing Practice. | (2) Food storage facilities and transportation vehicles 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; | | (A) no evidence of pest activity in non-food areas; |
| | (B) no evidence of pest activity in food storage areas; and | | (B) no evidence of pest activity in food storage areas; and |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|---|
| | (C) no evidence of pest activity in or on food products, food packaging or food preparation utensils, equipment or devices. | | (C) no evidence of pest activity in or on food products, food packaging or food preparation utensils, equipment or devices. |
| | (5) Damaged, distressed, and infested foods and food packaging material must be stored in a designated "morgue area", adequately separated from undamaged foods and must be disposed of in a timely manner to preclude further contamination. | | (3) Damaged, distressed, and infested foods shall be stored in a "morgue area," adequately separated from undamaged foods and shall be disposed of in a timely manner to preclude further contamination. |
| | (6) 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. | | |
| | (A) Time/temperature controlled for safety foods must be maintained at an internal temperature of 41 degrees Fahrenheit or below. | | (4) 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. |
| | (B) Frozen foods must be kept frozen at all times. | | (A) Frozen foods shall be kept frozen at all times. |
| | (C) Shell eggs, after initial packing, must be transported and stored at the lower of 45 degrees Fahrenheit or as required by The United States Department of Agriculture. | | (B) Shell eggs after initial packing, must be transported and stored at a temperature of 45 degrees Fahrenheit or less. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine by law that a lower temperature must be maintained, the lower temperature shall prevail. |
| §229.224(c).Good Warehousing Practice. | (D) The temperature of molluscan shellfish from the harvester through the original shellfish dealer must be maintained in accordance with 25 TAC §§241.57 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish must be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale. | §229.221(c).Good Warehousing Practice. | (C) The temperature of molluscan shellfish from the harvester through the original shellfish dealer shall be maintained in accordance with §§241.58 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish 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. | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|---|
| | (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. | | |
| | (7) During warehousing and transporting, all chemicals must be properly stored and physically separated from foods to preclude contamination. | | (5) During warehousing and transporting, all chemicals shall be properly stored and physically separated from foods to preclude contamination. |
| | | | (6) Foods being warehoused shall be rotated on a "first in, first out" basis or by oldest date of pack. |
| | (8) Food storage facilities and transportation vehicles operated under the control of the facility must be kept clean and free of excessive dust, dirt, spillage, and other debris, including excess moisture. | | (7) Food storage facilities and transportation vehicles operated under the control of the licensee shall be kept clean and free of excessive dust, dirt, spillage, and other debris, including excess moisture. |
| | (9) Food transport vehicles must be operated in compliance with federal regulations pertaining to back-hauling. | | (8) Food transport vehicles shall be operated in compliance with federal regulations pertaining to back-hauling. |
| | (10) Each incoming lot must be examined at the time of receipt and contaminated or adulterated foods must not be accepted. | | (9) Each incoming lot shall be examined at the time of receipt and contaminated or adulterated foods shall not be accepted. |
| | (11) Swollen, leaking, and/or severely dented containers of food must be segregated and promptly placed in the "morgue area" and further contamination, attraction of vermin, or sale prior to reconditioning must be prevented. | | (10) Swollen, leaking, and/or severely dented containers of food shall be segregated and promptly placed in the "morgue area" and further contamination, attraction of vermin, or sale prior to reconditioning shall be prevented. |
| | (12) 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 be used only according to label directions. Rodenticides must be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides. | | (11) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food warehouse and/or food processing facility may be used. Pesticides shall be used only according to label directions. Rodenticides shall be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides. |
| | (d) Other provisions. | | (d) Other provisions. |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|---|---|---|
| | (1) Distressed foods salvaged by the facility must be salvaged in accordance with §§229.541 - 229.555, 229.571 - 229.584, 229.601 - 229.614, and 229.631 - 229.644 of this title (relating to Regulation of Food, Drug, Device, and Cosmetic Salvage Establishments and Brokers). | | (1) Distressed foods salvaged by the licensee 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 comply with §229.251 of this title (relating to Minimum Standards for Licensure). | | (2) Food wholesalers engaged in the receipt and distribution of over-the-counter or prescription drugs shall comply with §229.253 of this title (relating to Minimum Standards for Licensure). |
| | (3) The facility must keep accurate distribution records so that any foods found to be unfit for human consumption may be recalled expeditiously. | | (3) The licensee shall keep accurate distribution records so that any foods found to be unfit for human consumption may be recalled expeditiously. |
| | <i>See 229.224(c)(1) above.</i> | | (e) Food including raw ingredients and finished food products shall be obtained from an approved source. |
| | | | |
| §229.225.Enforcement. | (a) Criminal penalties as provided in Texas Health and Safety Code, §431.059 may be assessed for violations of these sections. | §229.222.Enforcement. | (a) Criminal penalties as provided in Health and Safety Code, §431.059 may be assessed for violations of these sections. |
| | (b) Civil penalties as provided in Texas Health and Safety Code, §431.0585 may be assessed for violations of these sections. | | (b) Civil penalties as provided in Health and Safety Code, §431.0585 may be assessed for violations of these sections. |
| §229.225.Enforcement. | (c) Administrative penalties as provided in Texas 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 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. | §229.222.Enforcement. | (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 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. | | (d) Emergency orders as provided in Health and Safety Code, §431.045 may be issued by the Commissioner or the Commissioner's designee. |
| | | | |

| Modernized GMPs Effective August 2, 2017 | | Old GMPs Prior to August 2, 2017 | |
|---|--------------------------------|--|--|
| 21 CFR Part 123 Seafood HACCP | Use this as of August 2, 2017. | <i>§229.121-129. Seafood HACCP</i> | <i>Repealed. Don't Use as of August 2, 2017.</i> |
| 21 CFR Part 120 Juice HACCP | Use this as of August 2, 2017. | <i>§229.61-73. Juice HACCP</i> | <i>Repealed. Don't Use as of August 2, 2017.</i> |