

Department of State Health Services
Council Agenda Memo for State Health Services Council
August 17 - 18, 2016

Agenda Item Title: Repeal of rules and new rules concerning current good manufacturing practice and good warehousing practice in manufacturing, packing, or holding human food and new sanitary transportation of human foods.

Agenda Number 4.i.

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background:

The Foods Group within the Regulatory Services Division Environmental and Consumer Safety Section inspects food manufacturers, food wholesalers, and salvage establishment statewide. The program includes licensing, inspections, complaint investigations, enforcement, technical guidance, and emergency response for manufactured, wholesaled, and salvaged foods.

Approximately 14,785 food manufacturers, 2700 food wholesalers, and 125 food salvagers are inspected using the Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food.

The Group is funded from dedicated fees charged for licenses issued to food manufacturers, food wholesalers, and salvage establishments.

Summary:

The purpose of the repeal and new rules is to incorporate changes to the federal rules regarding manufacturing, packing, or holding of human food and sanitary transportation of human foods adopted by the U.S. Food and Drug Administration in September 2015 and March 2016. The rule requirements phase in over three years.

Additionally, the proposed rule revision responds to the intent of Senate Bill 81, 82nd Legislature, Regular Session, 2011, requiring DSHS to provide more transparency on which specific federal rules, adopted as a state rule under Texas Health and Safety Code §431.241 and §431.244, apply to regulated industry and are enforced by DSHS. The new manufacturing rule includes requirements to train food safety staff, perform hazard analyses on products produced, adopt a food safety plan, and institute preventive controls to mitigate identified hazards. The rule also includes the requirements for risk-based environmental monitoring, product testing, and a supply chain program appropriate to the food. In addition, this rule contains specific requirements for companies manufacturing products under modified atmosphere packaging. The new sanitary transport rules include requirements for vehicles and transportation equipment, transportation operations, training, and record keeping.

Key Health Measures:

The proposed rules take a proactive approach to food safety with ultimate outcome of safer food supply. The rule focuses on elements that have been shown on a national level to cause recalls and foodborne illness outbreaks. The effectiveness of the proposed rule revisions will be indicated over time by a reduction of food recalls and foodborne illness outbreaks.

The program will collect and analyze data on violations issued related to food manufacturers, food wholesalers, and salvage establishments from the various databases, as well as monitor recall and food-borne illness outbreaks.

The program will use the quality assurance and enforcement action process to confirm the satisfactory resolution of food manufacturers, food wholesalers, salvage establishments, and food transport vehicles that have been found to be out of compliance. There may be a temporary increase in violations to the rules due to the transition from the current food rules.

The program will collect and analyze data on violations issued related to food manufacturers, food wholesalers, salvage establishments, and food transport vehicles from the various databases, as well as monitor recalls and food-borne illness outbreaks.

Summary of Input from Stakeholder Groups:

There was extensive stakeholder input at the federal level. The program sent a draft version of the manufacturing rules by email to several stakeholder groups in February 2016. The program posted a notice on the program website and send an email regarding the draft version of the manufacturing and transportation rules in June 2016. A stakeholder meeting was held June 21, 2016

Proposed Motion:

Motion to recommend HHSC approval for publication of rules contained in agenda item # 4.i.

Approved by Assistant Commissioner/Director: Kathryn C. Perkins, R.N., M.B.A. **Date:** 5/18/2016

Presenter: Julie Loera **Program:** Environmental and Consumer Safety Section **Phone No.:** 512-834-6770
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Approved by CPEA: Carolyn Bivens **Date:** 7/19/2016

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 229. Food and Drug

Subchapter E. Juice Hazard Analysis Critical Control Point (HACCP) Systems

Repeal §§229.61 - 229.73

Subchapter H. Seafood HACCP

Repeal §§229.121 - 229.129

Subchapter N. Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food.

Repeal §§229.210 - 229.222

New §§229.210 - 229.225

Subchapter GG. Sanitary Transportation of Human Foods

New §§229.801 - 229.806

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §§229.61 - 229.73, concerning Juice Hazard Analysis Critical Control Point (HACCP) Systems, §§229.121 – 229.129, concerning Seafood HACCP, and the repeal of §§229.210 – 229.222, new §§229.210 – 229.225, concerning Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food, and new §§229.801 – 229.806 concerning Sanitary Transportation of Human Food.

BACKGROUND AND PURPOSE

The purpose of the repeals and new §§229.210 – 229.225 is to update the rules based on the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 Code of Federal Regulations Part 117, (PC rule), adopted by U.S. Food and Drug Administration in September 2015. The PC Rule was promulgated under the authority granted by the Food Safety Modernization Act. These new rules incorporate the changes made due to the adoption of the PC Rule. The incorporation of the federal PC Rule into the new rules were accomplished in two ways. Subparts A and B of the federal PC rule were incorporated in the language of the state rules in newly proposed §§229.211 - 229.225. Subparts C, D, F, and G of the PC rule were adopted by reference in the newly proposed §229.210(d)(19). The PC rule requirements phase in over a three-year period as follows: small businesses as defined by §229.211(65) – September 18, 2017; very small businesses as defined by §229.211(74) – September 17, 2018; and all other businesses upon the effective date of new §§229.210-229.225. Second, these proposed rules will comply with Senate Bill 81, 82nd Legislature, Regular Session, 2011, requiring the department to provide more transparency on which specific federal rules, adopted as state rules under Texas Health and Safety Code, §431.241 and §431.244, apply to regulated industry and are enforced by the department. The rule, in proposed §229.210, lists each part of the Code of Federal Regulations that is a state rule.

New §§229.210 – 229.225 includes requirements to train food safety staff, perform hazard analyses on products produced, adopt a food safety plan, and institute preventive controls to mitigate identified hazards. The rules include the requirements for risk-based environmental monitoring, product testing, and a supply chain program appropriate to the food. In addition, the rules contain specific requirements for companies manufacturing products under a modified atmosphere packaging.

The purpose of the new §§229.801 – 229.806 is to comply with the new Sanitary Transportation of Human and Animal Food, 21 CFR Part 1 Subpart O, (Sanitary Transportation Rule), adopted by U.S. Food and Drug Administration in April 2016. This was promulgated under the authority granted by the

Food Safety Modernization Act. The new sanitary transportation rules include requirements for vehicles and transportation equipment, operations, training, and recordkeeping.

The rules are also in compliance with Government Code, §2001.039, that requires that each state agency review and consider for re adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 229.210 - 229.222 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subjects are required by statute and provides guidance for the department; however, revisions to the rules are necessary as outlined in this preamble.

SECTION-BY-SECTION SUMMARY

Sections §§229.61 - 229.73, §§229.121 - 229.129 are being repealed as state regulation rules and are adopted by reference in new §229.210 to be consistent with federal rules.

New §229.210 provides details on what types of regulated industry are subject to the rule and what other rules may apply in addition to this rule. This section identifies these rules apply in determining whether a food is adulterated as defined by the Texas Health and Safety Code, Chapter 431. This section identifies that other sections of the 25 Texas Administration Code Chapter 229 and the 21 Code of Federal Regulations Parts 1-199 may also apply to facilities required to comply with Subchapter N. This section identifies which parts of the Code of Federal Regulations and the United States Code apply to facilities who must also comply with Subchapter N. The listing of the Code of Federal Regulations includes subparts of 21 Code of Federal Regulations Part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, adopted in September 2015.

New §229.211 provides detailed definitions for terms needed to understand the requirements of Subchapter N.

New §229.212 details the training required for individuals working at establishments that manufacture, process, pack or hold human food, and the responsibility of the establishment to ensure the individuals are properly trained. This section also details the requirements to maintain records.

New §229.213 provides details on exemptions to Subchapter N and exemptions to 21 Code of Federal Regulations Part 117, adopted by reference in §229.210.

New §229.214 provides details on the applicability of specific sections of 21 Code of Federal Regulations Part 117 to facilities storing only unexposed packaged food.

New §229.215 provides details on the applicability of Subchapter N to farms packing and holding raw agricultural commodities at facilities located off-site from the farm.

New §229.216 provides details on what records the regulated industry is required to maintain under this Subchapter N and specific sections of 21 Code of Federal Regulations Part 117 proposed to be adopted by reference in §229.210.

New §229.217 specifies that establishments must ensure disease control and employee health, personal cleanliness, the washing of hands, removal of jewelry, the wearing of hair restraints, storing of personal belongings, restricting areas where food can be consumed, and the taking of any other precautions necessary to protect against the contamination of food, food contact surfaces, and food packaging materials.

New §229.218 provides details regarding the requirements a plant must adhere to in order to ensure the grounds about a food plant are kept in a condition that will protect against the contamination of food. This includes requirements for properly storing equipment, removing litter and waste, maintaining roads and parking lots, and providing adequate drainage. This section also includes details regarding the requirements a plant must adhere to in order to ensure plant construction and design facilitates maintenance and sanitation for food production purposes.

New §229.219 provides details on how the plant must be maintained in a clean and sanitary condition and in good repair. This section outlines the requirements for how cleaning and sanitizing of utensils must be conducted to prevent the contamination of food, food contact services, and food packaging material. This includes requirements for the storage of toxic materials, pest control, sanitation of food contact surfaces, sanitation of non-food contact surface, and storage and handling of portable equipment and utensils.

New §229.220 details the requirement of a plant to be equipped with sanitary facilities. This section outlines the requirements for water supply, plumbing, toilet facilities, hand-washing facilities, and rubbish and offal.

New §229.221 details the requirement for all plant equipment used in the manufacturing, processing, packing, or holding of food to be designed in such a manner that it can be adequately cleaned and that such equipment must be adequately maintained. In addition, this section outlines the requirements for temperature measuring devices, instruments measuring pH, water activity, and other conditions that control the growth of microorganisms in food, and the use of compressed air or other gases.

New §229.222 details the requirements that plants operations must be conducted according to adequate sanitation procedures, employ appropriate quality control operations, ensure production procedures do not contribute to allergen cross contact or the contamination of food, utilize testing procedures to identify sanitation or allergen cross contact failures. This section outlines the requirements for raw materials and other ingredients and manufacturing operations. There are specific requirements for food that support the growth of microorganisms, work in progress, protection of finished product from raw ingredients, heat blanching, batters and breadings, filling operations, dry foods, acidified foods, modified atmosphere packaging, pecans, and ice.

New §229.223 details the requirements for natural or unavoidable defects in food that present no health hazard.

New §229.224 details the requirements for good warehousing practices. This section outlines the requirements for plants and grounds, sanitary facilities including toilet and handwashing facilities, and sanitary operations.

New §229.225 details the enforcement authorities granted to the department under the Texas Health and Safety Code, Chapter 431.

New §229.801 provides details on what types of regulated industry are subject to the rule. This section identifies these rules apply in determining whether a food is adulterated as defined by the Texas Health and Safety Code, Chapter 431.

New §229.802 provides detailed definitions for terms needed to understand the requirements of Subchapter N.

New §229.803 details the requirements for vehicles and transportation equipment. This section outlines the requirements for equipment design as to allow for adequate cleaning and temperature control, the maintenance of equipment in a sanitary conditions, and proper storage.

New §229.804 details the requirements for transportation operations. This section outlines the requirements for ensuring operations are conducted conditions to prevent food becoming adulterated, maintaining separation between processed food, raw food, and nonfood items during transport, and ensuring food is transported under appropriate temperatures. In addition, this section outlines the responsibilities of different roles in the transportation chain (supplier, loader, carrier), including requirements for written procedures.

New §229.805 details the requirements for training. This section outlines the requirements for training including records that must be maintained.

New §229.806 details the requirements for record keeping and maintenance.

FISCAL NOTE

Jon Huss, Section Director, Environmental and Consumer Safety Section, has determined that for each year of the first five years that the new sections are in effect, there will no fiscal implications to the state and local governments as a result of enforcing and administering the sections as proposed. It is anticipated that the average inspection time for state inspections will increase in the first three years by two hours due to increased record review and a learning curve for both the state inspectors and the industry. This could reduce the number of inspections per inspector by up to four inspections per month. However, as the staff and the regulated industry become more familiar with the requirements of the rule, and the three-year phase-in of the rule is complete, we anticipate the average inspection time will fall back to the current average by the end of the first five years.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Huss has also determined there may an adverse impact on small or micro-businesses required to comply with the sections as proposed.

For new §§229.210 - 229.225, the costs to small and micro-businesses may include, training of food workers, development of a hazard analysis, development of a food safety plan, validation of the plan to ensure the plan adequately address identified hazards, and maintenance of records. The State rule mirrors the federal requirements. The new rule sections primarily incorporate the changes made by the federal government with the adoption of the federal PC rule in September 2015. All Texas food operations will have to comply with federal PC rule unless they meet a specific exemption, this is regardless of intra or interstate commerce. A very small business is defined, in part, by the federal PC rule as a business averaging less than \$1,000,000 during a three year period. Very small businesses can apply to the U.S. Food and Drug Administration for an exemption to portions of the federal PC rule. Micro-businesses as defined by the Texas Government Code, Chapter 2006, therefore, would also qualify to apply for the exemption as they fit in the federal definition of very small business. Some small businesses as defined by the Texas Government Code, Chapter 2006 (any of those with greater than \$1,000,000 in annual gross receipts) would still be required to comply with the new PC rule requirements. As this rule set incorporates those federal definitions and exemptions, business with less than \$1,000,000 in food sales would qualify to apply for an exemption to the new requirements. Businesses would still have to comply with the §§229.210 - 229.225, excluding the requirements of 21 Code of Federal Regulations, Part 117, proposed to be adopted by reference. Costs for companies meeting this very small business requirement would still include new training requirements for food workers.

One proposed section of §229.222(c)(16), added by the department, and not currently in the federal PC Rule addresses modified atmosphere packaging. This new section may have an adverse impact on small or micro-businesses as it requires firms that package specific products utilizing modified atmosphere packings to comply with parts of the federal PC, regardless of exemptions. This requirement would be more likely to affect micro and very small businesses as they would otherwise be exempt from these requirements. The costs would be associated with the development of a food safety plan and validation of the plan. As the department does not track specifically which firms perform these activities, the department does not have an estimate of how many facilities would be affected. The department anticipates it would be a small percentage of 5400 facilities listed in the following paragraph that are exempt from the federal PC rule, proposed to be adopted by reference.

There are approximately 8000 facilities that would be considered micro-businesses and very small businesses. Approximately 5400 of those facilities would only be subject to the §§229.210-229.225 and not to the federal PC rule, proposed to be adopted by reference.

For new §§229.801 - 229.806, the cost to small and micro-businesses may include the development and implementation of written procedures, the cost of training for carriers, and record keeping and maintenance. All Texas transport companies will have to comply with federal Sanitary Transportation Rule unless they fall under the definition of a non-covered business or they qualify for a specific exemption, this is regardless of intra or interstate commerce. A non-covered business is a shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000 in average revenues. The Sanitary Transportation Rule defines a small business as a business employing fewer than 500 full-time equivalent employees, except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business having less than \$27,500,000 in annual receipts. Micro-businesses as defined by the Texas Government Code, therefore, may qualify to apply as a non-covered business. Small business, depending on their annual receipts. Small businesses as defined by the Texas Government Code, would qualify for a one year delay in the implementation of the rules.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There is an anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment. Jon Huss, Section Director, Environmental and Consumer Safety Section, has also determined there may be an adverse impact on small or micro-businesses required to comply with the sections as proposed.

The costs to small and micro-business for the §§229.210 - 229.225 may include, training of food workers, development of a hazard analysis, development of a food safety plan, validation of the plan to ensure the plan adequately address identified hazards, and maintenance of records. The State rule mirrors the federal requirements. The new rule sections primarily incorporate the changes made by the federal government with the adoption of the federal PC rule in September 2015.

For new §§229.801 - 229.806, the cost to small and micro-businesses may include the development and implementation of written procedures, the cost of training for carriers, and record keeping and maintenance. The new rule sections incorporate the new rule made by the federal government with the adoption of the Sanitary Transportation Rule in April 2016.

All Texas food operations will have to comply with the federal PC rule and the Sanitary Transportation Rule unless they meet a specific exemption, this is regardless of intrastate or interstate commerce.

PUBLIC BENEFIT

In addition, Mr. Huss has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. This rule, by adopting the new provisions of the PC Rule and the Sanitary Transportation Rule, requires facilities to take a proactive approach to food safety to include performing a hazard analysis, to adopt a food safety plan, to institute preventive controls to mitigate identified hazards. The public benefit anticipated as a result of enforcing these sections is a safer food supply.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Julie Loera, P.O Box 149347, Mail Code 2833 Austin, Texas 78714-9347, or by email to Julie.loera@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

PUBLIC HEARING

A public hearing to receive comments on the proposal will be scheduled after publication in the *Texas Register* and will be held at the Department of State Health Services, 8407 Wall Street, Austin, Texas 78754. The meeting date will be posted on the Foods Program website <http://www.dshs.state.tx.us/foods/draft-rules.aspx>. Please contact Julie Loera at Julie.loera@dshs.state.tx.us if you have questions.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The new sections and repeals are authorized by Texas Health and Safety Code, §431.241 and §431.244, which provides the department with the authority to adopt rules for the efficient enforcement of this chapter and adopts specific rules under the Federal Act as a rule under this chapter; and Government Code, §531.0055, and Texas Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the rules implements Government Code, §2001.039.

The new section and repeals affect Texas Health and Safety Code, Chapters 431 and 1001; and Government Code, Chapter 531.

Sections for repeal.

§§229.61 – 229.73. Juice Hazard Analysis Critical Control Point (HACCP) Systems

§§229.121 – 229.129. Seafood HACCP

§§229.210 – 229.222. Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food

Subchapter N. Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food.

New §§229.210 - 229.225

Subchapter GG. Sanitary Transportation of Human Foods

New §§229.801 - 229.806

Legend: (Proposed New Rules)

Regular Print = Proposed new language

Subchapter N. Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding of Human Food.

§229.210. Purpose and Scope.

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

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

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

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

(1) United States Code Title 21 Chapter 9, Subchapter IV, §343(w) et seq. as amended;

(2) 21 Code of Federal Regulations §§1.20-1.22 and §1.24, General Enforcement Regulations, as amended;

(3) 21 Code of Federal Regulations §70.20 and §70.25, Color Additives, as amended;

(4) 21 Code of Federal Regulations Part 73 Subpart A, Listing of Color Additives Exempt from Certification, as amended;

(5) 21 Code of Federal Regulations Part 74 Subpart A, Listing of Color Additives Subject to Certification, as amended;

(6) 21 Code of Federal Regulations Part 81. General Restrictions for Provisional Color Additives for Use in Foods, Drugs, and Cosmetics, as amended;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (23) 21 Code of Federal Regulations Part 130, Food Standards: General, as amended;
- (24) 21 Code of Federal Regulations Part 131, Milk and Cream, as amended;
- (25) 21 Code of Federal Regulations Part 133, Cheese and Related Cheese Products, as amended;
- (26) 21 Code of Federal Regulations Part 135, Frozen Desserts, as amended;
- (27) 21 Code of Federal Regulations Part 136; Bakery Products, as amended;
- (28) 21 Code of Federal Regulations Part 137, Cereal Flours and Related Products, as amended;
- (29) 21 Code of Federal Regulations Part 139, Macaroni and Noodle Products, as amended;
- (30) 21 Code of Federal Regulations Part 145, Canned Fruits, as amended;
- (31) 21 Code of Federal Regulations Part 146, Canned Fruit Juices, as amended;
- (32) 21 Code of Federal Regulations Part 150, Fruit Butters, Jellies, Preserves, and Related Products, as amended;
- (33) 21 Code of Federal Regulations Part 152, Fruit Pies, as amended;
- (34) 21 Code of Federal Regulations Part 155, Canned Vegetables, as amended;
- (35) 21 Code of Federal Regulations Part 156, Vegetable Juices, as amended;
- (36) 21 Code of Federal Regulations Part 158, Frozen Vegetables, as amended;
- (37) 21 Code of Federal Regulations Part 160, Eggs and Egg Products, as amended;
- (38) 21 Code of Federal Regulations Part 161, Fish and Shellfish, as amended;
- (39) 21 Code of Federal Regulations Part 163, Cacao Products, as amended;
- (40) 21 Code of Federal Regulations Part 164, Tree Nut and Peanut Products, as amended;
- (41) 21 Code of Federal Regulations Part 165, Beverages, as amended;
- (42) 21 Code of Federal Regulations Part 166, Margarine, as amended;
- (43) 21 Code of Federal Regulations Part 168, Sweeteners and Table Syrups, as amended;
- (44) 21 Code of Federal Regulations Part 169, Food Dressings and Flavorings, as amended;

(45) 21 Code of Federal Regulations Part 170, Food Additives, as amended;

(46) 21 Code of Federal Regulations Part 172, Food Additives Permitted For Direct Addition To Food For Human Consumption, as amended;

(47) 21 Code of Federal Regulations Part 173, Secondary Direct Food Additives Permitted in food For Human Consumption, as amended;

(48) 21 Code of Federal Regulations Part 174, Indirect Food Additives General, as amended;

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

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

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

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

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

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

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

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

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

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

§229.211. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise. Those definitions and interpretations of terms of the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431, are also applicable when used in this subchapter.

- (1) Acid foods or acidified foods--Foods that have an equilibrium pH of 4.6 or below.

(2) Act--Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431.

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

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

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

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

(7) Approved source--A supplier of food that complies with applicable state and federal laws and is licensed, if required, and inspected by the regulatory authority having jurisdiction over the processing and distribution of food.

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

(9) Batter--A semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(10) Blanching (except for tree nuts and peanuts)--A prepackaging heat treatment of foodstuffs for an adequate time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

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

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

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

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

(15) Correction--An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as

actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

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

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

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

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

(20) Facility.

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

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

(21) Farm--means:

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

(i) Pack or hold raw agricultural commodities;

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

(iii) Manufacture/process food, provided that:

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

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

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

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

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

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

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

(23) Food--A raw, cooked, or processed edible substance, ice, beverage, chewing gum or ingredient used or intended for use or for sale in whole or in part for human consumption, including raw materials.

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

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

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

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

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

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

(26) Full-time equivalent employee--Is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

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

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

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

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

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

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

(33) Manufacturing/processing--Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) is located:

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

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

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

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

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

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

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

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

(55) Quality control operation--A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

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

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

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

(59) Restaurant--A facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to

consumers. Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants.

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

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

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

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

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

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

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

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

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

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

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

(62) Safe-moisture level--A level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An (a_w) will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given (a_w) will not support the growth of undesirable microorganisms.

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

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

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

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

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

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

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

scientific and technical evidence that a control measure or combination of control measures, when properly implemented, effectively controls the identified hazards:

Figure: 25 TAC §228.2(69)

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

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

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

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

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

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

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

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

Figure: 25 TAC §228.2(69)

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

| | | | |
|-----------|-----------------|-----------------|-----------|
| AW values | pH: 4.6 or less | pH: > 4.6 - 5.6 | pH: > 5.6 |
|-----------|-----------------|-----------------|-----------|

| | | | |
|---------------|------------|-----------|-----------|
| <0.92 | NTCS FOOD* | NTCS FOOD | NTCS FOOD |
| > 0.92 - 0.95 | NTCS FOOD | NTCS FOOD | NOTE** |
| > 0.95 | NTCS FOOD | NOTE | NOTE |

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

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

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

| AW values | pH: < 4.2 | pH: 4.2 - 4.6 | pH: > 4.6 - 5.0 | pH: > 5.0 |
|---------------|------------|---------------|-----------------|-----------|
| < 0.88 | NTCS food* | NTCS food | NTCS food | NTCS food |
| 0.88 – 0.90 | NTCS food | NTCS food | NTCS food | NOTE** |
| > 0.90 – 0.92 | NTCS food | NTCS food | NOTE | NOTE |
| > 0.92 | NTCS food | NOTE | NOTE | NOTE |

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

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

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

(a) Applicability.

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

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

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

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

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

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

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

§229.213. Exemptions.

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

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

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

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

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

comply with, and are in compliance with 21 Code of Federal Regulations Part 113 with respect to such activities.

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

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

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

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

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

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

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

(B) Other fruit and vegetable products includes those processed food

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

(C) Peanut and tree nut products includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

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

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

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

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

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

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

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

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

- (A) baked goods (e.g., bread and cookies);**
- (B) candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);**
- (C) cocoa beans (roasted);**
- (D) cocoa products;**
- (E) coffee beans (roasted);**
- (F) game meat jerky;**
- (G) gums, latexes, and resins that are processed foods;**
- (H) honey (pasteurized);**
- (I) jams, jellies, and preserves;**
- (J) milled grain products (e.g., flour, bran, and corn meal);**
- (K) molasses and treacle;**
- (L) oils (e.g., olive oil and sunflower seed oil);**
- (M) other fruit and vegetable products (e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);**
- (N) other grain products (e.g., dried pasta, oat flakes, and popcorn);**
- (O) other herb and spice products (e.g., chopped or ground dried herbs,**

herbal extracts);

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

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

(R) soft drinks and carbonated water;

(S) sugar;

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

(U) trail mix and granola;

(V) vinegar; and

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

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

(1) The exemption in paragraph (3) of this subsection applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the “farm” definition. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the “farm” definition. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the “farm” definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the “farm” definition. Activities that are within the “farm” definition, when conducted on a farm mixed-type facility, are not subject to the requirements of 21 Code of Federal Regulations Part 117 Subparts C and G and therefore, do not need to be specified in the exemption.

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

(3) 21 Code of Federal Regulations Part 117 Subparts C and G do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and 21 Code of Federal Regulations §117.201 does not apply to on-

farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to the Federal Food, Drug, and Cosmetic Act, §418 that the business conducts are the following low- risk manufacturing/processing activity/food combinations:

(A) boiling gums, latexes, and resins;

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

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

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

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

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

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

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

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

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

(K) making cocoa products from roasted cocoa beans;

(L) making dried pasta from grains;

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

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

(O) making oat flakes from grains;

(P) making popcorn from grains;

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

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

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

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

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

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

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

(X) pasteurizing honey;

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

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

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

(i) Alcoholic beverages.

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

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

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

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

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

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

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

(k) Exemptions to Subchapter N.

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

(A) “farms;”

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

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

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

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

(2) If a “farm” or “farm mixed-type facility” dries/dehydrates raw agricultural commodities that are produce as defined in 21 Code of Federal Regulations Part 112, to create a distinct commodity, Subchapter N of this chapter applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with Subchapter N of this chapter or with the applicable requirements for packing and holding in 21 Code of Federal Regulations Part 112.

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

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

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

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

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

§229.216. Records.

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

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

§229.217. Personnel.

The management of the establishment must take all reasonable measures and precautions to ensure the following.

(1) Disease control and employee health. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness; open lesion, including boils, sores, or infected wounds; or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must 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.

(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:

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

(B) maintaining adequate personal cleanliness;

(C) washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility that meets the provisions of §229.220 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;

(D) removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials;

(E) maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition;

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

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

(H) confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco; and

(I) taking any other 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.

§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:

(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;

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

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

(4) operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed; and

(5) if the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (1) through (4) of this subsection, care must 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:

(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;

(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;

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

(A) using protective coverings;

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

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

(D) skimming the fermentation vessels, as necessary;

(4) be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact;

(5) provide adequate lighting in:

(A) hand-washing areas, dressing and locker rooms, and toilet rooms of at least 10 foot candles (greater than or equal to 108 lux);

(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

(8) provide, where necessary, adequate 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.

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

(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:

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

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) Pest control.

(1) All areas of the food plant must be kept free of rodents, insects, birds, and other pests which may contaminate food. 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:

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

(2) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food processing facility may be used. Pesticides must 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.

(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.

(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.

(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.

(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.

(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.

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

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

§229.220. Sanitary Facilities and Controls.

Each plant must 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.

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

(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.

(ii) Other sources. Any other sources in Texas must comply with 30 TAC Chapter 290, Subchapter F, concerning drinking water standards.

(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.

(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.

(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.

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

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

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

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

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

(E) provide that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

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

(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.

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

(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.

(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.

§229.221. Equipment and Utensils.

(a) Design and Construction.

(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.

(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.

(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.

(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.

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

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device installed to show the temperature accurately within the compartment.

(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.

(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.

§229.222. Production and Process Controls.

(a) General.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(c) Manufacturing operations.

(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.

(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.

(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.

(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.

(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.

(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.

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

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

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

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(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.

(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.

(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.

(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.

(9) Food, raw materials, and other ingredients that are adulterated:

(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.

(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.

(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.

(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.

(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.

(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.

(16) Modified Atmosphere Packaging. Manufacturers using Modified Atmosphere Packaging:

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

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

(i) identifies the food to be packaged;

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

(I) has an a_w of 0.91 or less;

(II) has a pH of 4.6 or less;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) immediately freeze the product following packaging;

(iii) label the product Keep Frozen; and

(iv) provide instructions for safe handling after thawing.

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

(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.

(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.

§229.223. 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.

(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.

(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.

(d) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from foods.regulatory@dshs.state.tx.us or Texas Department of State Health Services Foods Group, PO Box 149347, Mail Code-1987 Austin, Texas 78714-9347.

§229.224. 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.

(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.

(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.

(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.

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

(b) Sanitary facilities.

(1) Toilet Facilities. Each warehouse facility must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and in good repair. Toilet facilities must be equipped with a hand washing sink with running water of at least 100 degrees Fahrenheit, hand cleaning agent, and single service towels or an air drying device.

(2) Handwashing Facilities:

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

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

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

(c) Sanitary operations.

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

(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.

(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.

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

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

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

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

(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.

(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.

(B) Frozen foods must 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.

(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.

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

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

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

(8) Food storage facilities and transportation vehicles operated under the control of the licensee must 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.

(10) Each incoming lot must be examined at the time of receipt and contaminated or adulterated foods must 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.

(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.

(d) Other provisions.

(1) Distressed foods salvaged by the licensee must be salvaged in accordance with §§229.541 - 229.554, 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).

(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).

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

§229.225. Enforcement.

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

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

(c) Administrative penalties as provided in 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.

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

Legend: (Proposed New Rules)

Regular Print = Proposed new language

Subchapter GG. Sanitary Transportation of Human Foods

§229.801. Purpose and Scope.

(a) Except for non-covered businesses as defined in §229.802 of this title and as provided for in paragraph (b) of this section, the requirements of this subchapter apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. The requirements of this subchapter apply in addition to any other requirements of this chapter that are applicable to the transportation of food, e.g., in §§229.210 - 229.225 and §§229.541 - 229.555 of this title.

(b) The requirements of this subchapter do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations:

(1) Of food that is transshipped through the United States to another country; or

(2) Of food that is imported for future export, in accordance with the Federal Food, Drug, and Cosmetic Act, §801(d)(3) and that is neither consumed nor distributed in the United States; or

(3) Of food when it is located in food facilities as defined in 21 Code of Federal Regulations, §1.227, that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)

(c) The criteria and definitions of this subchapter apply in determining whether food is adulterated within the meaning of Texas Health and Safety Code, §431.081(a) in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this subchapter.

(d) The failure by a shipper, carrier by motor vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this subchapter is a prohibited act under Texas Health and Safety Code, §431.021.

§229.802. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise. Those definitions and interpretations of terms of the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431, are also applicable when used in this subchapter.

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

(2) Animal food--Food for animals other than man, and includes pet food, animal feed, and raw materials and ingredients.

(3) Bulk vehicle--A tank truck, hopper truck, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

(4) Carrier--A person who physically moves food by motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

(5) Cross-contact--The unintentional incorporation of a food allergen into food.

(6) Farm--Means:

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

(i) pack or hold raw agricultural commodities;

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

(iii) manufacture/process food, provided that:

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

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

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

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

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

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

(7) Food allergen--A major food allergen is:

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

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

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

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

(8) Food contact substance--Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

(9) Food not completely enclosed by a container--Any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subchapter.

(10) Full-time equivalent employee--A term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

(11) Loader--A person that loads food onto a motor or during transportation operations.

(12) Non-covered business--A shipper, loader, receiver, or carrier engaged in transportation operations that has less than \$500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

(13) Operating temperature--A temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, e.g., seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, and type of food product, the operation will meet the requirements of §229.804(a)(3) of this title (relating to Transportation Operations).

(14) Pest--Any objectionable animals or insects including birds, rodents, flies, and larvae.

(15) Receiver--Any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

(16) Shipper--A person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

(17) Small business--A business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to §229.801(a) having less than \$27,500,000 in annual receipts.

(18) Transportation--Any movement of food in by motor vehicle or in commerce within the United States.

(19) Transportation equipment--Equipment used in food transportation operations, e.g., bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a trailer not attached to a tractor.

(20) Transportation operations--All activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

(21) Vehicle--A land conveyance that is motorized, e.g., a motor vehicle, which is used in transportation operations.

§229.803. Vehicles and Transportation Equipment.

(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming adulterated within the meaning of Texas Health and Safety Code, §431.081(a)(1), (2), and (4) during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming adulterated during transportation operations.

(c) Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming adulterated during transportation operations.

(d) Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming adulterated during transportation operations.

§229.804. Transportation Operations.

(a) General requirements.

(1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, loaders, and receivers engaged in transportation operations. A person may be subject to these requirements in multiple capacities, e.g., the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subchapter. An entity subject to this subchapter (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this subchapter to

another party subject to this subchapter. The written agreement is subject to the records requirements of §229.806(d) of this title (relating to Records).

(2) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this subchapter must be assigned to competent supervisory personnel.

(3) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming adulterated during transportation operations including:

(i) Taking effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load.

(ii) Taking effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

(iii) Taking effective measures to ensure that food that requires temperature control for safety is transported under food specific adequate temperature control.

(4) The type of food, and its production stage, e.g., raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation.

(5) Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section. The written procedures are subject to the records requirements of §229.806(e) of this title.

(6) If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food adulterated during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food adulterated.

(b) Requirements applicable to shippers engaged in transportation operations.

(1) Unless the shipper takes other measures in accordance with paragraph (3) of this subsection to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., that will prevent the food from becoming adulterated, the shipper must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. One-time notification shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in §229.806(a) of this title.

(2) Unless the shipper takes other measures in accordance with paragraph (5) of this subsection to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, a shipper of such food must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase. One-time notification shall be sufficient unless a factor, e.g., the conditions of shipment, changes, necessitating a change in the operating temperature, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in §229.806(a) of this title.

(3) A shipper must develop and implement written procedures, subject to the records requirements of §229.806(a) of this title, adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subchapter under a written agreement subject to the records requirements of §229.806(a) of this title.

(4) A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of §229.806(a) of this title, adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subchapter under a written agreement subject to the records requirements of §229.806(a) of this title.

(5) The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures, subject to the records requirements of §229.806(a) of this title, to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subchapter under a written agreement subject to the records requirements of §229.806(a) of this title and must include measures equivalent to those specified for carriers under subsection (e)(1) - (3) of this section.

(c) Requirements applicable to loaders engaged in transportation operations.

(1) Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment the loader must determine, considering, as appropriate, specifications provided by the shipper in accordance with subsection (b)(1) of this subsection, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, e.g., it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.

(2) Before loading food that requires temperature control for safety, the loader must verify, considering, as appropriate, specifications provided by the shipper in accordance with subsection (b)(2) of this section, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation.

(d) Requirements applicable to receivers engaged in transportation operations. Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors.

(e) Requirements applicable to carriers engaged in transportation operations. When the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation, the carrier is responsible for the following functions as applicable per the agreement:

(1) A carrier must ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.

(2) A carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper in accordance with subsection (b)(2) of this section and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper in accordance with subsection (b)(2) of this section. Such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.

(3) Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper in accordance with subsection (b)(2) of this section.

(4) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle.

(5) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle.

(6) A carrier must develop and implement written procedures subject to the records requirements of §229.806(b) of this title that:

(i) Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required by §229.803(b) of this title (relating to Vehicles and Transportation Equipment);

(ii) Describe how it will comply with the provisions for temperature control in paragraph (2) of this subsection; and

(iii) Describe how it will comply with the provisions for the use of bulk vehicles in paragraphs (4) and (5) of this subsection.

§229.805. Training.

(a) When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation

practices to address those potential problems, and the responsibilities of the carrier under this subchapter. The training must be provided upon hiring and as needed thereafter.

(b) Carriers must establish and maintain records documenting the training described in paragraph (a) of this section. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of §229.806(c) of this title (relating to Records).

§229.806. Records.

(a) Shippers must retain records.

(1) That demonstrate that they provide specifications and operating temperatures to carriers as required by §229.804(b)(1) and (2) of this title (relating to Transportation Operations) as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.

(2) Of written agreements and the written procedures required by §229.804(b)(3) - (5) of this title for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(b) Carriers must retain records of the written procedures required by §229.804(e)(6) of this title for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(c) Carriers must retain training records required by §229.805(b) of this title (relating to Training) for a period of 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.

(d) Any person subject to this subchapter must retain any other written agreements assigning tasks in compliance with this subchapter for a period of 12 months beyond the termination of the agreements.

(e) Shippers, receivers, loaders, and carriers, which operate under the ownership or control of a single legal entity in accordance with the provisions of §229.804(a)(5) of this title, must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.

(f) Shippers, receivers, loaders, and carriers must make all records required by this subchapter available to a duly authorized individual promptly upon oral or written request.

(g) All records required by this subchapter must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(h) Except for the written procedures required by §229.804(e)(6)(i) of this title, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by §229.804(e)(6)(i) of this title must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.