

**RULES  
OF  
GEORGIA DEPARTMENT OF AGRICULTURE**

**CHAPTER 40-7-18  
MANUFACTURED FOOD REGULATIONS**

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**40-7-18-.01 Scope of Regulations.** The following regulations shall apply to all plants where food is processed, which are not covered elsewhere in these regulations.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled “Scope of Regulations” adopted. F. Apr. 14, 2010; eff. May 4, 2010.

**40-7-18-.02 Definitions.** The following definitions shall apply in the interpretation and enforcement of this Chapter.

- (1) **“Acid Foods”** or **“Acidified Foods”** means foods that have an equilibrium pH of 4.6 or below.
- (2) **“Act”** means The Georgia Food Act.
- (3) **“Adequate”** means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- (4) **“Adulterated”** as defined in Georgia Food Act Section 26-2-26.
- (5) **“Balut”** means an embryo inside a fertile egg that has been incubated for a period sufficient for the embryo to reach a specific stage of development after which it is removed from incubation before hatching.
- (6) **“Code of Federal Regulations”** means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government.
- (7) **“Commissioner”** means Commissioner of Agriculture of the State of Georgia.
- (8) **“Consumer”** means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.
- (9) **“Critical Control Point”** means 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.

(10) **“Critical limit”** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(11) **“Department”** means the Georgia Department of Agriculture.

(12) **“Department Representative”** means any officer, inspector, agent or employee of the Georgia Department of Agriculture who is authorized by the Commissioner with the duty of enforcing these regulations.

(13) **“Egg”** means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites or turkey. egg does not include:

- (a) Balut,
- (b) the egg of reptile species such as alligator; or
- (c) an egg product.

(14) **“Egg Product”** means all, or a portion of, the contents found inside eggs separated from the shell and pasteurized in a food processing plant, with or without added ingredients, intended for human consumption, such as dried, frozen or liquid eggs. Egg product does not include food which contains eggs only in a relatively small proportion such as cake mixes.

(15) **“Employee”** means the License Holder, person in charge, food employee, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food processing plant.

(16) **“Exemption”** means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

(17) **“Finished Product”** means:

- (a) The output of manufacturing or processing operations which is suitable for human consumption, and
- (b) An ingredient or other constituent of a food that will not be further treated or otherwise processed to control the most resistant microorganism of public health significance.

(18) **“Fish”** means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(19) **“Food”** means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(20) **“Food employee”** means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

(21) **“Food Processing Plant”** means an establishment that sells food products to other business entities as its primary function. The term "food processing plant" includes those facilities that manufacture, process, pack, and/or hold food. There can be a retail component on the premise providing food directly to consumers from that establishment. A food processing plant's primary function is to sell food directly to other business entities if the annual monetary value of sales of food products directly to other business entities exceeds the annual monetary value of sales of food products to consumers.

(22) **“HACCP Plan”** means a written document that delineates the formal procedures for following the Hazard Analysis and critical control point (HACCP) principals developed by the National Advisory Committee on Microbiological Criteria for foods.

(23) **“Hazard”** means a biological, chemical, or physical property that is likely to cause an unacceptable consumer health risk.

(24) **“Hermetically Sealed Container”** means a container which is designed and intended to secure against entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

(25) **“High Risk Facility”** means a facility which produces a high risk product or a lower-risk product distributed to highly susceptible populations or in such volume that a violative product poses a significant threat to public health.

(26) **“High Risk Product”** means a product, which has been classified by the classification committee appointed by the Commissioner, to carry a high potential for contamination or foodborne illness.

(27) **“Highly Susceptible Population”** means persons who are more likely than other people in the general population to experience foodborne disease because they are:

(a) Immunocompromised; preschool age children, or older adults; and

(b) Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care center, kidney dialysis center, hospital or nursing home, or nutritional or socialization services such as a senior center.

(28) **“Imminent Health Hazard”** means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on:

(a) The number of potential injuries, and

(b) The nature, severity, and duration of the anticipated injury.

(29) **“License”** means the document issued by the Department, which authorizes a person to operate a food processing plant.

(30) **“Low Risk Facility”** means a firm which produces or stores a low-risk product and whose target population or distribution does not increase the potential public health threat of a violative product.

(31) **“Low Risk Product”** means a product that has been classified by the classification committee appointed by the Commissioner, which carries a low potential for contamination or foodborne illness.

(32) **“Manufacturing/Processing”**

(a) Means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.

(b) 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.

(33) **“Moderate Risk Facility”** means a firm which produces a moderate risk product or which produces a lower-risk product distributed to highly susceptible populations or in such volume that a violative product poses a moderate threat to public health.

(34) **“Moderate Risk Product”** means a product that has been classified by the classification committee appointed by the Commissioner, which carries a moderate potential for contamination or foodborne illness.

(35) **“Molluscan Shellfish”** means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(36) **“Packing”** means 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 as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

(37) **“Person”** means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

(38) **“Person In Charge”** means the individual present at a food processing plant who is responsible for the operation at the time of inspection.

(39) **“pH”** means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

(40) **“Poisonous or Deleterious Substances”** means substances that are not intended for ingestion.

(41) **“Processing”** or **“Process”** means any or all of the physical and/or chemical alterations applied to a food; as it is taken from its original state; or any food which has been partially or fully processed previously; and either prepared further by cooking or made into another form before being marketed.

(42) **“Ratite”** means a flightless bird such as an emu, ostrich, or rhea.

(43) **“Raw Agricultural Product”** or **“Raw Agricultural Commodity”** means any agricultural commodity in its raw or natural state that has undergone little or no processing. This product would require further processing before consumption.

(44) **“Ready-to-Eat Food”** means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or consumer and that is reasonably expected to be consumed in that form.

(45) **“Regulatory Authority”** means an agency that is charged with the duty of enforcing specific regulations. The regulatory authority in this Chapter refers to the Georgia Department of Agriculture and the duly authorized agents.

(46) **“Retail Food Establishment”** means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes those facilities that manufacture, process, pack, and/or hold food. There can be a wholesale/distribution component on the premise providing food to other business entities from that establishment. 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.

(47) **“Risk”** means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

(48) "**Risk Classification**" means the designation or category assigned to a food processing plant, and is based on the following criteria:

- (a) the inherent risk of the food produced based on that commodity's history of foodborne illness outbreaks, pathogens of concern, and predicted mortality;
- (b) the food processing plant's history of compliance with Department rules and regulations;
- (c) distribution, whether intrastate, interstate, or export;
- (d) population served;
- (e) volume of products produced, including co-packing for another business or entity; and
- (f) inspectional effort required of the Department, based on size and complexity of the food processing plant's operations.

(49) "**Time/Temperature Control for Safety Food**"

- (a) Means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
- (b) "Time/temperature control for safety food" includes:
  1. An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures 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; and
  2. Except as specified in Subparagraph (c)4 of this definition, a food that because of the interaction of its  $a_w$  and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

**Table A. Interaction of pH and  $a_w$  for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged.**

| $a_w$ values  | pH: 4.6 or less | pH: > 4.6 - 5.6 | pH: > 5.6    |
|---------------|-----------------|-----------------|--------------|
| <0.92         | non-TCS food*   | non-TCS food    | non-TCS food |
| > 0.92 - 0.95 | non-TCS food    | non-TCS food    | PA**         |
| > 0.95        | non-TCS food    | PA              | PA           |

\* TCS food means time/temperature control for safety food

\*\* PA means Product Assessment required

**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.**

| $a_w$ values  | pH: < 4.2     | pH: 4.2 - 4.6 | pH: > 4.6 - 5.0 | pH: > 5.0    |
|---------------|---------------|---------------|-----------------|--------------|
| < 0.88        | non-TCS food* | non-TCS food  | non-TCS food    | non-TCS food |
| 0.88 – 0.90   | non-TCS food  | non-TCS food  | non-TCS food    | PA**         |
| > 0.90 – 0.92 | non-TCS food  | non-TCS food  | PA              | PA           |
| > 0.92        | non-TCS food  | PA            | PA              | PA           |

\* TCS food means time/temperature control for safety food

\*\* PA means Product Assessment required

(c) "Time/temperature control for safety food" does not include:

1. 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 salmonellae;
2. 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;
3. A food that because of its pH or  $a_w$  value, or interaction of  $a_w$  and pH values, is designated as a non-TCS food in Table A or B of this definition;
4. A food that is designated as Product Assessment Required (PA) in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:
  - (i) Intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients,
  - (ii) 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, or
  - (iii) A combination of intrinsic and extrinsic factors; or
5. A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the Subparagraphs (c)1 – 4 of 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.

(50) "U.S. Federal Food, Drug, and Cosmetic Act" (abbreviated as FFDCA, FDCA, or FD&C) gives authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics.

(51) "Water Activity" means a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol " $a_w$ ".

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Definitions" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

#### **40-7-18-.03 Right of Entry.**

(1) The Commissioner or his duly authorized agent shall have free access during all hours of operation and at all other reasonable hours to any factory, warehouse, or establishment in which food is manufactured, processed, packed, or held for introduction into commerce and any vehicle being used to transport or hold such foods to commerce for the following purposes:

(a) Of inspecting such factory, warehouse, establishment, or vehicle, any records of pathogen destruction, and any records of testing of samples or specimens of foods, ingredients, or environmental for the presence of poisonous or deleterious substances or other contaminants and the results thereof as may be required to determine if any of the provisions of this article are being violated; and

(b) Of securing samples or specimens of any food or environmental samples, after paying or offering to pay for such samples.

(2) It shall be the duty of the Commissioner to make or cause to be made examinations of samples secured under 40-7-18-.07 to determine whether or not this article is being violated.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Right of Entry" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

**40-7-18-.04 Preventing Food and Ingredient Contamination.** Food shall be protected from cross contamination by:

(a) Separating raw agricultural products requiring pathogen destruction during storage, preparation, and holding from ready-to-eat foods not requiring further processing, except when combined as ingredients.

(b) As specified under 40-7-1-.12.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Preventing Food and Ingredient Contamination" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

**40-7-18-.05 Laboratory Requirements.** Any food processing plant subject to any testing requirements pursuant to this chapter shall cause such required tests to be performed consistent and in accordance with testing standards and procedures outlined in the federal Food and Drug Administration's Bacterial Analytical Manual and standards developed by the Association of Analytical Communities (AOAC) International, International Organization for Standardization, or another internationally recognized certification body.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Laboratory Requirements" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

#### **40-7-18-.06 Testing.**

(1) The Commissioner shall require testing of finished products leaving the food processing facility, including ingredients going to other facilities for use in other products, for the presence of poisonous or deleterious substances or other contaminants rendering such foods or ingredients injurious to health; testing shall be conducted according to the risk category of the food processing plant.

(a) The food processing facility risk category shall be determined according to the highest risk product the facility produces. The three designated risk categories and minimum testing requirements are:

1. Low risk facilities – quarterly testing.
2. Moderate risk facilities – monthly testing.
3. High risk facilities – semimonthly testing.

(b) Reasonable representative samples according to the scale of the operation/processing shall be tested at regular intervals.

(c) Each firm shall determine, according to the product they are producing, which test shall be sufficient to detect the presence of poisonous or deleterious substances or other contaminants that would cause a food or ingredient to be injurious to health.

(d) Testing shall be conducted by a laboratory as prescribed in 40-7-18-.05.

(e) All positive results shall be reported to the Department in accordance with 40-7-18- .07(1).

(f) Finished product and finished product ingredient testing is Georgia law, and may not be equivalent to any testing regimen required by the Food and Drug Administration. Food processing plants are encouraged to consult with the Department to ensure their testing program is compliant with Georgia laws and regulations.

(2) In addition to any regular tests required, the Commissioner may order any food processing plant to have samples or specimens of its foods and ingredients tested for the presence of any poisonous or deleterious substances or other contaminants whenever in his or her determination there are reasonable grounds to suspect that such food or ingredients may be injurious to health.

(3) The food processing plant shall be responsible for the cost of any testing required pursuant to these regulations and may conduct such testing either internally or via a third party as prescribed in 40-7-18-.05.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Testing" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

#### **40-7-18-.07 Reporting.**

(1) Whenever any person or firm operating a food processing plant in this state obtains information from testing of samples or specimens of finished foods or finished food ingredients which, based on a confirmed positive test result, indicates the presence of a substance that would cause a manufactured food bearing or containing the same to be adulterated with the presence of poisonous or deleterious substances or other contaminants, such person or firm shall report such test result(s) to the Department within 24 hours after obtaining such result.

(a) The person or firm that operates a food processing plant shall be required to report the presence of poisonous or deleterious substances or other contaminants even if the product was not distributed and the problem was corrected.

(b) A presumptive positive test result or test result requiring further typing or numeration shall be carried out through additional testing, utilizing the same sample that yielded the presumptive, to obtain a final result.

(2) Firms reporting positive products shall be placed on an accelerated sampling program as determined by the Department.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Reporting" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

**40-7-18-.08 Records.** Records of the results of any tests required pursuant to this Code section shall be kept by a food processing plant and made available to the Department for inspection for a period of not less than two years from the date the results were reported by the laboratory.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Records" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

#### **40-7-18-.09 Written Food Safety Plan.**

(1) Each written Food Safety Plan shall be submitted to the Department for review. If an operator of a food processing plant, in its discretion, submits to the department a written food safety plan for such plant and such plan conforms to rules and regulations then such food processing plant shall comply with the requirements of such written food safety plan including, but not limited to, any test regimen provided by such plan, in lieu of complying with a test regimen as specified under 40-7-18-.06.



(2) Minimum standards and requirements for a written food safety plan, such as a hazard analysis critical control point plan, that may be submitted by an operator of a food processing plant to document and describe the procedures used at such plant to prevent the presence of hazards such as poisonous or deleterious substances or other contaminants that would render finished foods or finished ingredients as manufactured at such plant injurious to health, shall include:

- (a) A hazard categorization of the types of products that are to be produced.
- (b) A flow diagram by specific food or category type identifying critical control points and providing information on the following:
  - 1. Ingredients, materials, and equipment used in the preparation of that food, and
  - 2. Formulations or recipes that delineate methods and procedural control measures that address the food safety measures;
- (c) Required sampling and testing of finished products leaving the food processing facility including ingredients going to other facilities for use in other products, for the presence of poisonous or deleterious substances or other contaminants rendering such foods or ingredients injurious to health.
  - 1. Type of testing prescribed for each product.
  - 2. Frequency of testing.
- (d) Food employee and supervisory training that addresses food safety measures;
- (e) A statement of standard operating procedures for the plan under consideration including clearly identifying:
  - 1. Each critical control point;
  - 2. The critical limits for each critical control point;
  - 3. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge;
  - 4. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;
  - 5. Action to be taken by the person in charge if the critical limits for each critical control point are not met;
  - 6. Records to be maintained by the person in charge to demonstrate that the plan is properly followed and effective;
  - 7. Verify proper cleaning and sanitation.
  - 8. Validation of each critical control point.
- (f) Additional scientific data or other information, as required by the Department, supporting the determination that food safety is not compromised by the proposal.

(3) Food safety plans prepared per the requirements of the Code of Federal Regulations Title 21 – Part 117 are considered equivalent to the written food safety plan described in this section, and shall be accepted by the Department prior to implementing an alternative testing regimen.

**40-7-18-.10 Exemption.**

(1) Section 40-7-18-.06 of this chapter shall not apply to the following products or processes:

- (a) Food products produced under a federal grant of inspection from the United States Department of Agriculture Food Safety and Inspection Service and which are not produced under regulatory jurisdiction of the U.S. Food and Drug Administration (FDA);
- (b) Grade A milk products that are governed under the Pasteurized Milk Ordinance (PMO);
- (c) Bottled water products regulated under Georgia Department of Agriculture Food Division Regulations Chapter 40-7-6 Additional Regulations Applicable to Commercially Bottled Water and Water Vending Machines;
- (d) Shellfish products governed by the National Shellfish Sanitation Program (NSSP) Model Ordinance;
- (e) Raw agricultural products requiring further processing as specified under 40-7-18-.02(43).
- (f) Classified as a small business producing low volume food products as defined by U.S. Food and Drug Administration. Businesses qualifying under this exemption must submit supporting documentation to the Department.

(2) Facilities that produce both covered and exempt food products, as described in subparagraph (1) above, must still perform the required testing on those covered products manufactured or otherwise processed in their food processing plants.

(3) The exemptions granted by the Commissioner based on criteria apply only to the testing requirements of this Chapter. However, if an exemption is granted it can be revoked.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Exemption" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

**40-7-18-.11 Trade Secrets – Confidentiality.** The Department shall treat as confidential information that qualifies as a trade secret that is contained on inspection report forms and in the plans or specifications submitted as required to comply with this chapter.

Authority O.C.G.A. Sec. 26-2-27.1. **History.** Original Rule entitled "Trade Secrets - Confidentiality" adopted. F. Apr. 14, 2010; eff. May 4, 2010.

**40-7-18-.12 Adoption of Reference.** Hereinafter, the following is adopted by reference and therefore all applicable provisions become part of this chapter:

(1) Federal Food, Drug and Cosmetic Act, as amended and regulations issued thereunder.

(2) The Code of Federal Regulations, Title 21 Parts 1 (ONLY § 1.20-1.24, and Subpart O § 1.900-1.934), 7 (ONLY § 7.1-7.13 and § 7.40-7.59), 70 (ONLY § 70.20-70.25), 73 (ONLY § 73.1- § 73.615), 74 (ONLY § 74.101-706), 81, 82 (ONLY § 82.3- § 82.706), 100 (ONLY § 100.155 and § 101.100), 101 (EXCEPT § 101.69 and § 101.108), 102 (EXCEPT § 102.19), 104, 105, 106 (EXCEPT § 106.120), 107 (EXCEPT § 107.200- § 107.280), 108 (ONLY § 108.25- § 108.35), 109, 110, 117, 113, 114, 115, 118, 120, 123, 129, 130 (EXCEPT § 130.5-6 and § 130.17), 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 165, 166, 168, 169, 170 (EXCEPT § 170.6, § 170.15, and § 170.17), 172, 173, 174, 175, 176, 177, 178, 180, 181, 182, 184, 186, and 189.

(3) Department Rules 40-7-1 Retail Food Sales, only for food processing plants that perform sales to the end consumer on their same premise. These retail components shall be subject to the requirements and standards set forth in 40-7-1. All other areas of the food processing plant, whose operations do not directly involve sales to the end consumer, shall remain under the provisions of these regulations; including the federal laws and regulations adopted by reference in paragraphs (1) and (2) of this section.

#### **40-7-18-.13 Civil Penalties.**

(1) A food processing plant that fails to comply with the testing regiment as specified under 40-7-18-.06 or Written Food Safety Plan as specified under paragraph (1) and (2) of this section;

(a) Shall be imposed a fine not to exceed \$5,000.00 for each violation.

(b) An imposition of a \$7,500.00 civil penalty for any food processing plant that knowingly fails to comply.

(c) In addition to such civil penalties, within 30 days of the determination by the Commissioner that such violation has occurred, such food processing plant shall submit to the Commissioner a Written Plan as specified under paragraph (2) of this section.

(2) Any person who knowingly fails to make the report required by section 40-7-18-.07 of this Chapter shall be guilty of a misdemeanor. The punishment shall be supplemental to any other applicable provisions of law.

(3) Any person who knowingly violates record keeping as required by section 40-7-18-.08 shall be guilty of a misdemeanor. The punishment shall be supplemental to any other applicable provisions of law.

(4) Any person who knowingly introduces into commerce finished foods or finished food ingredients as manufactured at a food processing plant knowing that it contains a substance that would cause a manufactured food bearing or containing the same to be adulterated with the presence of poisonous or deleterious substances or other contaminates shall be guilty of a felony, and, upon conviction, shall be punished by imprisonment for not less than one nor more than 20 years, a fine not to exceed \$20,000.00, or both. The punishment shall be supplemental to any other applicable provisions of law.

(5) Each day a violation continues after the violation has been documented by the Department shall be considered a separate violation.

(6) Such penalties shall be subject to review in the manner prescribed by the Department's Administrative Rules of Practice and Procedure Rules 40-1-2.

#### **40-7-18-.14 License to Operate.**

(1) Prerequisite for Operation. A person may not operate a food processing plant without a valid license to operate issued by the Department.

(2) Form of Submission. A person desiring to operate a food processing plant shall submit to the Department a written application for a license on a form provided by the Department.

(3) License Fees.

(a) The license fee structure is as follows:

1. Tier 1 fee is \$100;

2. Tier 2 fee is \$150;

3. Tier 3 fee is \$200;

4. Tier 4 fee is \$250; and

5. Tier 5 fee is \$300.

(b) Food processing plants will be assigned a license tier based on the following factors:

1. The hazards and inherent risk hazard of the products and processes of the food processing plant, including:

- (i) Pathogens of concern for a given product/commodity,
- (ii) Severity of the illness or mortality associated with processing deviations,
- (iii) Previous history of foodborne illness outbreaks associated with a given product/commodity, and
- (iv) Population served;

2. The procedural effort required by the Department to conduct an inspection, including review of records and supporting documentation; and

3. The volume and distribution of the products manufactured by the food processing plant.

(c) A list of current Firm Type categories and their associated license tier levels shall be posted and maintained on the Department's public facing website.

(4) Qualifications and Responsibilities of Applicants. To qualify for licensing, an applicant shall:

(a) Be an owner of the establishment or an officer of the legal ownership;

(b) Comply with the requirements of these regulations;

(c) Agree to, that after the Department Representative presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the Department Representative to determine if the food processing plant is in compliance with these Regulations by allowing access to the establishment, allowing inspection, and providing information and records specified in these Regulations and to which the Department is entitled according to law, during the food processing plant's hours of operation and other reasonable times.

(d) Agree to comply with directives of the Department including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the Department in regard to the license holder's food processing plant. Further, a license holder shall at the time of inspection, correct a critical violation of these regulations and/or implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.

(e) Agree to be subject to the administrative, civil, injunctive, and criminal remedies authorized under law for failure to comply with these regulations or a directive of the Department, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

(5) License Not Transferable. A license may not be transferred from one person to another person, from one processing plant to another, or from one type of operation to another.

(6) Refusal to Sign Acknowledgment. The regulatory authority shall:

(a) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings that:

1. An acknowledgment of receipt is not necessarily an agreement with findings,

2. Refusal to sign an acknowledgment of receipt will not affect the license holder's obligation to correct the violations noted in the inspection report within the time frames specified, and

3. A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the Department historical record for the food processing plant; and

(b) Make a final request that the person in charge sign an acknowledgment of receipt of inspectional findings.

(7) Ceasing Operations and Reporting - Imminent Health Hazard.

(a) Except as specified in paragraph (b) of this section, a license holder shall immediately discontinue operations and notify the Department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health;

(b) A license holder need not discontinue operations in an area of a food processing plant that is unaffected by the imminent health hazard.

(8) Resumption of Operations.

(a) If operations are discontinued as specified under 40-7-18-.14(7) or otherwise according to law, the permit holder shall obtain approval from the Department before resuming operations

(b) Embargoed Food. The removal or disposal of embargoed or detained food is prohibited without official release from the Department.

**History:** Original Rule entitled "License to Operate" adopted. F. Aug. 14, 2012; eff. Sep. 3, 2012.