

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 15 FOOD

Chapter 04 Food and Drink Processing and Transportation

Authority: Health-General Article, §§18-102, 21-101, 21-102, 21-211, 21-234, 21-301, 21-304, 21-308, 21-309.1, and 21-336; Agriculture Article, §4-311; Annotated Code of Maryland

.01 Scope.

This chapter:

- A. Provides the minimum food safety and sanitation requirements for food processing plants, including warehouses and transfer stations, and the transportation of food;
- B. Establishes, along with COMAR 10.15.03, the standards of the Department of Health and Mental Hygiene's part of a program jointly administered with the Department of Agriculture under COMAR 15.04.01 and 15.11.11 to control Salmonella Enteritidis in shell eggs and egg-producing chickens; and
- C. Is not intended to govern a meat processing plant that solely processes meat products under the regulation and inspection of the United States Department of Agriculture in accordance with the Code of Federal Regulations.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) Adulterated Food.

(a) "Adulterated food" has the meaning stated in Health-General Article, §21-207, Annotated Code of Maryland.

(b) "Adulterated food" includes food that is:

(i) Spoiled;

(ii) Contaminated; or

(iii) Misbranded so that the food is unsafe for human consumption.

(2) "Approving authority" means the agency designated in the laws of another state or country to license or permit a food processing plant.

(3) "Approved source" means a source of food or food ingredients accepted by the Department because the food or food ingredients from the source:

(a) Are not adulterated or misbranded as defined in §B(1) and (19) of this regulation; and

(b) Where required, are regulated by the approving authority.

(4) "Commercially sterile" means the condition achieved by the:

(a) Application of heat, pressure, or other energy or matter that renders the food free of:

(i) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(ii) Viable microorganisms, including spores, that cause disease; or

(b) Control of water activity and the application of heat, pressure, or other energy or matter that renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(5) "Contamination" means:

(a) Microbiological, chemical, radiological, or physical substances that are capable of causing a food to be adulterated; or

(b) The result of adding the substances described in §B(5)(a) of this regulation to a food or food contact surface.

(6) "Critical control point" means a point in the processing of food where there is a reasonable likelihood that improper control may cause, allow, or contribute to a hazard to public health.

(7) "Critical factor" means a property, characteristic, condition, aspect, or other parameter, which, if varied, may affect a scheduled process.

(8) Critical Item.

(a) "Critical item" means a food safety requirement that if violated requires:

(i) Immediate correction;

(ii) The cessation of some or all processing operations; or

(iii) Plant closure.

(b) "Critical item" includes the following requirements:

(i) Food is obtained from an approved source;

(ii) Food is protected from contamination and adulteration;

(iii) Food processes provide safe food with proper control at critical control points;

(iv) Food worker sanitation provides food safety with effective hand washing and the absence of illness transmissible through food;

(v) Food equipment allows proper processing and sanitation;

(vi) Food is packaged and labeled for safety;

(vii) A sufficient volume of potable hot and cold water supply under pressure is available; and

(viii) Sewage is discharged in compliance with applicable laws and regulations.

(9) "Department" means the Department of Health and Mental Hygiene or the Department's designee.

(10) "Dry packaged food" means a nonperishable food that is:

(a) Not refrigerated; and

(b) Either:

(i) Dry food in a package; or

(ii) Liquid food in a watertight package.

(11) Farm.

(a) "Farm" means a place where agricultural commodities are grown, raised, or harvested for commercial purposes.

(b) "Farm" includes a place where, for commercial purposes:

(i) Crops are grown and harvested;

(ii) Fruit, nuts, or other agricultural commodities are harvested from trees; or

(iii) Animals are raised, fed, and managed for meat or other agricultural commodities.

(12) "Food" means:

(a) A substance that is used as food or drink for human beings or as a component of food or drink for human beings;
or

(b) Chewing gum or any substance that is a component of chewing gum.

(13) Food Processing Plant.

(a) "Food processing plant" means a place used for or in connection with commercial food:

(i) Manufacturing;

(ii) Preparing;

(iii) Processing;

(iv) Packaging;

(v) Canning;

(vi) Freezing;

(vii) Storing;

(viii) Distributing;

(ix) Labeling; or

(x) Holding.

(b) "Food processing plant" includes a:

(i) Bakery plant;

(ii) Cannery;

(iii) Confectionery plant;

(iv) Crab meat picking plant;

(v) Food manufacturing plant;

(vi) Food warehouse;

(vii) Food distribution center;

(viii) Frozen food processing plant;

(ix) Ice manufacturing plant;

(x) Shellfish plant or dealer;

(xi) Soft drink manufacturing plant;

(xii) Bottled water plant;

(xiii) Food transfer station;

(xiv) Meat processing plant or poultry processing plant that is not subject to regulation by the United States Department of Agriculture or by a meat inspection program or poultry inspection program administered by the Maryland Department of Agriculture;

(xv) Cider plant; and

(xvi) Producer mobile farmer's market unit.

(c) "Food processing plant" does not include a warehouse or distribution center that:

(i) Does not process food; and

(ii) Stores only sealed containers of whole bean, ground or instant coffee, leaf or instant teas, nondairy dehydrated whiteners, sugar, or sugar-free sweeteners.

(14) "Food transfer station" means a food processing plant where:

(a) Food is transferred between transportation vehicles; and

(b) The food transfer is not direct but rather involves food sorting or storage.

(15) "Generally recognized as safe (GRAS)" means that a substance is:

(a) Not harmful to humans consuming the substance under the intended conditions of use; and

(b) In accordance with 21 CFR §170.30.

(16) "HACCP plan" means a Hazard Analysis Critical Control Point (HACCP) as specified by:

(a) COMAR 10.15.10;

(b) 21 CFR Part 123; or

(c) The National Advisory Committee on the Microbiological Criteria for Food.

(17) "Label" means a display of written or graphic matter on the container, other than the package liner, of a food.

(18) "Labeling" means any label or other written or graphic material that:

(a) Is on a:

(i) Food;

(ii) Food container; or

(iii) Food wrapping; or

(b) Accompanies a food.

(19) "Misbranded" has the meaning stated in Health-General Article, §21-210, Annotated Code of Maryland.

(20) "Morgue area" means an area within a food processing plant in which food that is adulterated is temporarily stored awaiting disposition.

(21) "Person-in-charge" means:

(a) The licensee; or

(b) Another person responsible for the operation of the food processing plant.

(22) Potentially Hazardous Food.

(a) "Potentially hazardous food" means a natural or synthetic food that requires temperature control because the food is in a form capable of supporting:

(i) The rapid and progressive growth of infectious or toxigenic microorganisms;

(ii) The growth and toxin production of *Clostridium botulinum*; or

(iii) In raw shell eggs, the growth of *Salmonella Enteritidis*.

(b) "Potentially hazardous food" does not include a food with a:

(i) Water activity (a_w) value of 0.85 or less;

(ii) pH level of 4.6 or below when measured at 75°F; or

(iii) Commercially sterile food in a hermetically sealed container.

(23) "Poultry" means a domesticated bird whether dead or alive.

(24) "Principal display panel" means the part of a label that is the most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

(25) "Process" means:

(a) An operation involved in commercial food manufacturing and distribution, including the operations set forth in §B(13)(a) of this regulation; or

(b) A specific set of operations or procedures used to manufacture a food.

(26) "Process authority" means an individual having knowledge acquired through training and experience with a food process.

(27) Producer Mobile Farmer's Market Unit.

(a) "Producer mobile farmer's market unit" means a unit designed to ensure that food is:

(i) Protected from contamination during transportation from farm to farmer's market; and

(ii) Kept at temperatures that support the safety and wholesomeness of the food.

(b) "Producer mobile farmer's market unit" does not include a unit used to deliver:

(i) Prepackaged foods to fill an order of a customer;

(ii) Raw agricultural products; or

(iii) Non-potentially hazardous on-farm home processed foods.

(28) "Reduced oxygen package" means a food package in which the amount of oxygen in the package is below that found in the surrounding atmosphere due to the:

- (a) Mechanical evacuation of oxygen;
- (b) Displacement of oxygen with one or more other gases; or
- (c) Reduction of the oxygen content by other means.

(29) "Scheduled process" means a method or set of procedures determined by a process authority for processing a food, which takes into account the critical factors that may impact the food's safety or stability.

(30) "Shelf life study" means a food evaluation using microbiological, physical, chemical, organoleptic, or other tests to determine the length of time a food may be stored before the food becomes unfit for sale or human consumption.

(30) "Shell eggs" means raw eggs produced by chickens for human consumption.

(31) "Vending machine" means a machine that dispenses or provides food to a consumer.

.03 Incorporation by Reference.

A. In this chapter, the following documents are incorporated by reference.

B. Documents Incorporated.

- (1) 9 CFR, as amended;
- (2) 21 CFR, as amended;
- (3) 21 U.S.C. §343, as amended
- (4) 21 U.S.C. §§451—471, as amended; and
- (5) 21 U.S.C. §§601—695, as amended.

.04 Compliance with Other Chapters.

The person-in-charge shall process, store, and transport food and design, operate, and maintain a food processing plant and the facilities and equipment associated with a food processing plant in compliance with this chapter and with COMAR 10.15.01, 10.15.02, 10.15.07, and 10.15.10, as applicable.

.05 Wholesomeness of Food.

The person-in-charge shall ensure that:

A. All food and food ingredients processed in a food processing plant:

- (1) Are safe for human consumption;
- (2) Are clean;
- (3) Are free of spoilage;

- (4) Are from an approved source;
- (5) Are GRAS; and
- (6) If applicable, conform to a standard of identity;

B. Shell eggs:

- (1) Are produced by flocks that meet the standards established under COMAR 15.11.11.05A;
- (2) That are received, used, or provided to the consumer are supplied by a packer and distributor that has registered in accordance with the requirements of the Agriculture Article, Title 4, Subtitle 3, Annotated Code of Maryland, and COMAR 15.04.01.09; and
- (3) From flocks in which Salmonella Enteritidis is isolated, are pasteurized or otherwise treated to kill Salmonella Enteritidis before being accepted or used at a food processing plant;

C. Adulterated food:

- (1) Is not offered as food to human beings;
- (2) Not for rework to ensure safety, wholesomeness, and proper labeling is:
 - (a) Destroyed or diverted to non-food uses; and
 - (b) When within a food processing plant, stored only in a morgue area that is:
 - (i) Separated from all other food and food process operations; and
 - (ii) Conspicuously marked as a morgue area;

D. Salvaged food:

- (1) Is offered for consumption only after being determined through examination to be wholesome; and
- (2) Does not include:
 - (a) Canned food with critical seam or can body defects that compromise the container's hermetic seal; and
 - (b) Food that has exceeded a regulated shelf life; and

E. A processed food imported into the State is processed in a food processing plant that is licensed or permitted by an approving authority.

.06 Food Protection.

The person-in-charge shall ensure that:

A. Food is protected at all times from contamination and sources of contamination including:

- (1) Pathogenic microorganisms;

- (2) Toxic or deleterious chemicals;
- (3) Foreign matter;
- (4) Dust;
- (5) Vermin;
- (6) Insects;
- (7) Unnecessary hand contact or other handling;
- (8) Overhead leakage; and
- (9) Animals;

B. During storage, transportation, processing, and transfer, including the time at a food transfer station, food is kept at temperatures that ensure the safety and wholesomeness of the food;

C. Except as provided in Regulation .14E of this chapter and §D of this regulation, the internal temperature of a potentially hazardous food is kept at 41°F or less or 135°F or greater;

D. The internal temperature of a food with a non-proteolytic *Clostridium botulinum* potential hazard is kept at 38°F or less during refrigerated storage;

E. Except as provided in Regulation .14E of this chapter, when a food is kept at temperatures other than those set forth in §§C and D of this regulation, a scheduled process that specifies a food temperature and time at temperature is:

- (1) Used; and
- (2) Available at the point of use for inspection by the Department;

F. Food is prevented from coming into contact with a surface or substance other than a surface or substance intended for food contact or incorporation into food;

G. Food is protected from an activity that has the potential to contaminate the food by:

- (1) Physical partitions;
- (2) Time separation; or
- (3) Distance separation; and

H. When specialized training is required by COMAR 10.15.01, 10.15.02, 10.15.07, or 10.15.10, or this chapter, the specialized training is obtained.

.07 Processing Practices.

A. The person-in-charge shall ensure that:

- (1) Food is processed using procedures, sanitary practices, and process controls that produce only safe and wholesome food;
- (2) When required by the Department in accordance with §B of this regulation:
 - (a) A scheduled process is used to manufacture a food; and
 - (b) Except as set forth in §A(3) of this regulation, a scheduled process or shelf life approved by the Department is not changed;
- (3) Before manufacturing a food or using a new food manufacturing process or shelf life, plans are:
 - (a) Submitted to the Department; and
 - (b) Approved by the Department based on a review that shows compliance with 21 CFR Part 110 and this chapter;
- (4) Foods are manufactured as set forth in written processing standard operating procedures that:
 - (a) Are available to employees in a form they understand; and
 - (b) Ensure the proper and safe manufacture of food;
- (5) Production aids and adjuvant substances comply with 21 CFR Part 178;
- (6) Steam that contacts food is free from deleterious or harmful matter that might adulterate food;
- (7) Heating and cooling media that are in close contact with food such as those in plate heat exchangers are:
 - (a) Food, food grade, or GRAS; or
 - (b) Through equipment design, provided a minimal chance of contacting food;
- (8) Processing, labeling, storing, and transporting food and design of, operating, and maintaining the food processing plant and the facilities and equipment associated with the food processing plant are in compliance with this chapter and with the requirements set forth in the documents incorporated by reference in Regulation .03 of this chapter;
- (9) Pressurized air in contact with food, such as in pneumatic transfer systems, is filtered to exclude contaminants from the food; and
- (10) The reclamation or rehabilitation of adulterated and misbranded food that has been detained by the Department is completed in accordance with a written plan approved by the Department based on a review that indicates the food will conform to this chapter after the food is reclaimed or rehabilitated.

B. The Department may require that a scheduled process, laboratory analysis, or shelf life study be completed by a process authority for a food based on:

- (1) Inherent hazards or risks associated with a food;
- (2) Requirements for a scheduled process required in COMAR 10.15.01, 10.15.02, 10.15.07, and 10.15.10, and this chapter;

- (3) Previous scientific research; or
- (4) A need to:
 - (a) Determine whether a food is potentially hazardous;
 - (b) Identify critical factors;
 - (c) Verify a food's shelf life; or
 - (d) Standardize a food process.

.08 Process Control, Monitoring, and Record Keeping.

A. The Department may require a processor to conduct a process hazard analysis, establish and monitor critical control points, and provide verification based on:

- (1) The requirements in COMAR 10.15.01, 10.15.02, 10.15.07, and 10.15.10, and this chapter; and
- (2) Potential hazards associated with a food.

B. While complying with §A of this regulation, the person-in-charge shall ensure that:

- (1) Each processing operation, such as receiving, holding, thermal processing, chilling, freezing, packaging, storing, transportation, and labeling is evaluated to determine whether the operation is a critical control point;
- (2) A processing operation that is a critical control point is:
 - (a) Controlled to prevent a hazard; and
 - (b) Monitored to verify control; and
- (3) A record is made that:
 - (a) Documents compliance with the requirements of this regulation;
 - (b) Identifies the immediate previous source of the food and food ingredients stored and processed in the plant and provides the following:
 - (i) The name, address, and telephone number of the immediate previous source;
 - (ii) The type of food or food ingredient received, including brand name and specific variety;
 - (iii) A lot code number or other identifier, if available;
 - (iv) The date the food or food ingredient was received; and
 - (v) The name, address, and phone number of the transporter of the food or food ingredient from the immediate previous source to the food processing plant;
- (c) For shell eggs, provides the information required in COMAR 15.04.01.03A(2)(a)—(e);

(d) Identifies the initial distribution of the food to facilitate, when necessary, the segregation of food that may have become adulterated or otherwise unfit for human consumption and provides the following:

(i) The name, address, and telephone number of the immediate subsequent recipient of the food released;

(ii) The type of food released, including brand name and specific variety;

(iii) A lot code number or other identifier, if available;

(iv) The date the food was released; and

(v) The name, address, and phone number of the transporter of the food to the immediate subsequent recipient of the food;

(e) After the control, observation, or monitoring is done, is maintained at the plant for:

(i) At least 2 years for a shelf stable or preserved food; or

(ii) At least 1 year for a fresh food; and

(f) Is available for inspection by the Department.

.09 Plant and Facilities — Design and Construction.

A. The person-in-charge shall ensure that the equipment and facilities needed to process food in accordance with the requirements of this chapter are provided and maintained in a sanitary and working condition.

B. The person-in-charge shall ensure that the water supplied to a fixture:

(1) Is potable;

(2) Meets the requirements of the Environment Article, Annotated Code of Maryland, and COMAR 26.04.01; and

(3) Is protected against backflow.

C. The person-in-charge shall ensure that the sewage disposal system for the plant:

(1) Meets all applicable State and local codes and properly disposes of wastewater; and

(2) Except where a National Pollutant Discharge Elimination System permit has been issued by the Maryland Department of the Environment, is used to dispose of all generated wastewater.

D. The person-in-charge shall ensure that, except as provided for in Regulation .18C(1) of this chapter and §§L and N of this regulation, a room or area in which food is processed or stored or in which utensils or equipment are cleaned, sanitized, or kept:

(1) Is separated from other rooms or areas in the plant by:

(a) Tight walls, ceilings, and self-closing doors; or

(b) A distance that precludes the contamination of food;

(2) If not refrigerated, is mechanically ventilated using exhaust and supply fans so that:

(a) Excessive grease vapors, steam, condensation, heat, and odors are removed;

(b) Filtered air is supplied to provide a positive air pressure in the room; and

(c) Condensation and grease do not accumulate on room surfaces and equipment;

(3) Has a floor, walls, and a ceiling that are smooth, washable, easily cleanable, and impervious to water;

(4) Has only the exposed overhead pipes, ducts, conduits, evaporators, and other structures that are needed for proper processing;

(5) Has floor-wall junctures that are:

(a) Coved; and

(b) Impervious to water;

(6) Other than a room or area solely used to store food, has hand sinks in the room or area:

(a) That are accessible to the workers;

(b) At the rate of one hand sink for each 15 employees or fraction of 15 employees that work in the area; and

(c) That are provided warm water of sufficient volume under pressure for effective hand washing;

(7) Has artificial lighting that provides a minimum of:

(a) 40 foot-candles of light on all work surfaces used for processing and utensil washing; and

(b) 20 foot-candles of light on surfaces used solely for food storage; and

(8) Has light shields that:

(a) Protect exposed light bulbs or light fixtures that are not shatter resistant from breakage by potential direct impact; and

(b) Prevents glass fragments from a bulb or light fixture that breaks or explodes from contacting food or food contact surfaces.

E. The person-in-charge shall ensure that, when a floor receives water as a result of processing or cleaning, the floor is sloped to one or more floor drains at a pitch of 1/8 to 1/4 inch per foot.

F. The person-in-charge shall ensure that floor drains are provided:

(1) To effectively remove all water from the floor; and

(2) At the rate of a minimum of one floor drain for each 400 square feet of floor area.

G. The person-in-charge shall ensure that a floor drain receives only wastewater that must be directed to the floor, such as water from:

- (1) Cleaning the floor or other room surfaces;
- (2) Cleaning equipment;
- (3) Ice used in processing; and
- (4) Incidental splash from equipment.

H. The person-in-charge shall ensure that the equipment and facilities needed for effective plant cleaning and for cleaning and sanitizing food contact and non-food contact surfaces as set forth in Regulation .12 of this chapter are provided and maintained in a sanitary condition.

I. The person-in-charge shall ensure that toilet rooms:

- (1) Are separate for men and women or allow separate use by the sexes;
- (2) Do not open directly into an area in which food is processed or in which containers, utensils, or equipment is washed or held;
- (3) Are provided with:
 - (a) A toilet at the rate of one toilet for each 15 employees or fraction of 15 employees;
 - (b) A lavatory at the rate of one lavatory for each 15 employees or fraction of 15 employees;
 - (c) Ventilation having:
 - (i) Mechanical air exhaust and entrance of an equal amount of makeup air at the rate of 2 cubic feet per minute of air for each square foot of floor area; or
 - (ii) A screened window that allows the entrance of outside air;
 - (d) Easily cleanable and durable walls and ceiling;
 - (e) A smooth, impervious, and easily cleanable floor;
 - (f) Artificial lighting that provides 20 footcandles of light as measured 30 inches above the floor; and
 - (g) A lavatory supplied with:
 - (i) Soap;
 - (ii) Warm water of sufficient volume under pressure for effective hand washing;
 - (iii) Paper towels or warm air hand drying devices; and
 - (iv) A trash receptacle.

J. The person-in-charge shall ensure that the design, construction, maintenance, and operation of the plant and the flow of food through the plant minimize the:

- (1) Potential for food contamination by cross-contamination;
- (2) Access of vermin and insects to:
 - (a) Food; and
 - (b) The plant; and
- (3) Harborage of vermin and insects.

K. The person-in-charge shall ensure that, except as provided in Regulation .18 of this chapter, food processing plants are completely separated from areas used as living quarters by solid, impervious floors, walls, and ceilings with no connecting openings.

L. The person-in-charge shall ensure that a room or area in which dry packaged food that is not subject to breakage or leakage is stored or broken down into smaller lots of packaged food has:

- (1) Smooth, impervious, and cleanable floors;
- (2) Walls and a roof and ceiling that:
 - (a) Are vermin and insect proof; and
 - (b) Afford protection against the weather;
- (3) Artificial lighting that provides 20 footcandles of light as measured 30 inches above the floor; and
- (4) Ventilation that complies with §D(2) of this regulation.

M. The person-in-charge shall ensure that waste containers are:

- (1) Adequate in number to maintain sanitary conditions;
- (2) Accessible to workers at locations where waste is generated;
- (3) Easily cleanable;
- (4) If the containers are located inside the plant:
 - (a) Leak proof; and
 - (b) Emptied and cleaned:
 - (i) In a manner that maintains a sanitary condition; and
 - (ii) At least daily; and
- (5) If the containers are outside waste containers:

(a) Leak proof or provided a drain that conveys wastewater from the container directly into a sewerage system that:

(i) Meets all applicable State and local codes; and

(ii) Properly disposes of wastewater;

(b) Placed on a hard and impermeable surface;

(c) Large enough to hold waste until the waste is taken off-site; and

(d) Unless removed daily or more often, vermin and insect proof.

N. The Department may accept plant and facilities designs and constructions other than those provided for in this regulation based on a review that shows that the alternative plant and facilities designs and constructions:

(1) Provide for food safety, food protection, and sanitation; and

(2) Are equivalent to regulatory and industry standards that predate this chapter.

.10 Equipment and Utensils — Design and Construction.

A. The person-in-charge shall ensure that:

(1) Equipment for processing food is:

(a) Designed to provide for food safety, food protection, and sanitation;

(b) When associated with a critical control point, provided with instrumentation to allow:

(i) The control of critical factors;

(ii) The monitoring of critical factor control and implementation; and

(iii) Verification of process control;

(c) Maintained in a sanitary and working condition;

(d) Monitored to verify that process requirements are met; and

(e) Tested and calibrated to ensure accuracy;

(2) Except as specified in §C of this regulation, materials used as food contact surfaces of equipment and utensils are:

(a) Nontoxic and do not impart toxic or deleterious matter to the food;

(b) Inert to food and do not migrate to or adulterate food;

(c) Nonporous and nonabsorbent;

- (d) Corrosion-resistant;
 - (e) Durable; and
 - (f) If stainless steel, made of stainless steel of American Iron and Steel Institute Type 304, or equivalent;
- (3) Food contact surfaces of equipment and utensils are designed, constructed, and maintained to be:
- (a) Smooth;
 - (b) Easily cleanable;
 - (c) Free of difficult to clean internal surfaces;
 - (d) Self-emptying or self-draining if an interior surface;
 - (e) Visible for inspection or readily disassembled for inspection;
 - (f) If manually cleaned:
 - (i) Readily accessible for cleaning without tools; or
 - (ii) If not readily accessible, readily disassembled for cleaning with the use of simple tools kept available at the equipment; and
 - (g) If cleaned and sanitized by pressurized cleaning-in-place, readily accessible to the cleaning and sanitizing solutions without disassembly;
- (4) Non-food equipment that receives splash or waste is smooth and easily cleanable;
- (5) If a vending machine with potentially hazardous foods is unable to maintain the temperatures set forth in Regulation .06C and D of this chapter, the machine:
- (a) Automatically prevents the dispensing or serving of food; and
 - (b) Remains in a condition to prevent food from being dispensed or offered until serviced; and
- (6) Cleaned and sanitized equipment and utensils are kept so that the equipment is protected from contamination.
- B. The Secretary recommends that the person-in-charge use equipment that is certified by a testing laboratory as complying with recognized food equipment standards, such as those published by the:
- (1) NSF;
 - (2) Bakery Industry Sanitation Standards Committee;
 - (3) National Automatic Merchandising Association;
 - (4) International Association of Milk and Food Sanitarians;
 - (5) American Society of Mechanical Engineers; or

(6) U. S. Department of Agriculture.

C. The person-in-charge may use equipment that does not meet a requirement set forth in §A(2)(c)—(f) of this regulation when written approval is given from the Department based on a review by the Department that indicates the equipment and its use are:

- (1) Not harmful to public health; and
- (2) Consistent with industry standards and practice.

.11 Worker Sanitation.

The person-in-charge shall ensure that:

A. An individual in the plant:

- (1) Practices good personal hygiene so that the individual does not contaminate the food;
- (2) Is excluded from working with food and food contact surfaces:
 - (a) As provided in COMAR 10.06.01.06E; and
 - (b) When the individual has an:
 - (i) Illness transmissible through food; or
 - (ii) Exposed and open sore or cut;
- (3) While working with food or handling food contact surfaces, washes the individual's hands frequently and after an activity that is likely to soil the hands;
- (4) Wears clean outerwear, a hair and beard covering, and no jewelry;
- (5) If handling food, maintains trim and clean fingernails and does not wear false fingernails;
- (6) Stores personal items in a designated non-food area; and
- (7) Does not smoke or engage in an activity that might contaminate food;

B. The facilities that help ensure good personal hygiene are provided in the plant and, except as provided in Regulation .18 of this chapter, include:

- (1) Lockers or similar storage facilities for the secure storage of personal items in an area that is not used for food or food utensils;
- (2) Adequate hand washing facilities;
- (3) Signage in toilet rooms that instructs individuals to wash their hands before returning to work;
- (4) A water fountain or other water dispenser that provides potable water without the use of reusable cups;

(5) An area for employees to eat and drink beverages that is not used in conjunction with food processing; and

(6) Where needed for food safety, sanitizer foot baths and hand dips;

C. Education and training in food handling, personal hygiene, and plant sanitation is provided to employees;

D. Workers using gloves while working with food or food contact surfaces:

(1) Wash hands thoroughly before putting on the gloves;

(2) After an activity that is likely to soil the gloves:

(a) Replace the gloves; or

(b) Clean and sanitize the gloves while on the hands in accordance with §E of this regulation; and

(3) Use gloves that are intended for food contact; and

E. While on the hands, gloves are cleaned and sanitized using methods or equipment scientifically proven to clean and sanitize in accordance with Regulation .12D, H, and I of this chapter.

.12 Plant and Equipment Sanitation.

The person-in-charge shall ensure that:

A. The grounds around a food processing plant are:

(1) Maintained free of unused equipment, debris, litter, waste, high weeds, or grass that provide an attractant, breeding place, or harborage for vermin and insects; and

(2) Adequately drained to:

(a) Promote sanitation; and

(b) Prevent breeding places for pests and insects;

B. Food contact surfaces are cleaned and sanitized:

(1) Using a process that removes soils and kills pathogens;

(2) As often as needed to prevent food contamination; and

(3) Except as provided in §D of this regulation, at a minimum:

(a) Following processing;

(b) When there is an interruption in processing of greater than 2 hours; and

(c) During the processing of a potentially hazardous food, after a continuous use of not more than 6 hours;

C. When a time greater than 8 hours separates the start of processing from previous cleaning and sanitizing, food contact surfaces are sanitized again before work resumes;

D. When a cleaning and sanitization schedule other than that set forth in §§B(3) and C of this regulation is used, that the cleaning and sanitizing schedule has been shown through scientific study to comply with §B(1) and (2) of this regulation;

E. When a piped clean-in-place system is used:

(1) A cleaning agent and a sanitizing agent are:

(a) Fully circulated through a fixed system to contact all food contact surfaces;

(b) Effective in cleaning and sanitizing food contact surfaces;

(c) Used in accordance with the chemical manufacturer's instructions; and

(d) Removed from equipment and food contact surfaces before the equipment's or food contact surface's coming into contact with food by:

(i) Rinsing with potable water; or

(ii) Other means that evacuate the cleaning and sanitizing agents;

(2) The design, construction, maintenance, and operation of the piped clean-in-place system prevents the contamination of food by cleaning and sanitizing agents; and

(3) The operation of the piped clean-in-place system using chemicals that are potentially hazardous to public health is a critical control point that is controlled, monitored, and documented as set forth in Regulation .08 of this chapter;

F. Non-food-contact plant and equipment surfaces that receive splash or waste are cleaned and sanitized:

(1) As often as necessary to maintain a sanitary condition; and

(2) At a minimum following each day's use;

G. Non-food contact plant and equipment surfaces that do not receive splash or waste are cleaned as often as necessary to maintain a sanitary condition;

H. Cleaning procedures:

(1) If wet, include the use of detergents or other cleaning agents; and

(2) Remove soils;

I. The sanitization of surfaces is effective in killing pathogens on the treated surfaces;

J. Before cleaning, all food and food packaging is removed from the area being cleaned;

K. Cleaning and sanitizing occur in a manner that protects food from contamination;

L. Cleaned equipment and utensils are stored to prevent contamination of the equipment and utensils;

M. Unused equipment and nonessential items are not stored in the plant;

N. The facility is:

(1) Maintained free of vermin and insects; and

(2) Protected against the entrance and harborage of vermin and insects;

O. Vermin and insects are eliminated so that there is no potential for food contamination;

P. When used to exterminate vermin and insects, pesticides:

(1) Comply with Agriculture Article, Title 5, Subtitle 1, Annotated Code of Maryland; and

(2) Are used:

(a) As set forth in:

(i) Agriculture Article, Title 5, Subtitle 2, Annotated Code of Maryland; and

(ii) §V(1) of this regulation; and

(b) Unless specifically approved for use in food areas, only in non-food areas;

Q. Waste is:

(1) Held in a sanitary manner; and

(2) Disposed of to:

(a) Maintain the plant and the plant grounds in a sanitary condition; and

(b) Comply with the requirements in Environment Article, Title 9, Annotated Code of Maryland;

R. Food contact surfaces, utensils, equipment, and general plant surfaces are cleaned or cleaned and sanitized as set forth in written sanitation standard operating procedures that:

(1) Are available to employees in a form they understand; and

(2) Ensure proper sanitation;

S. When equipment and utensils are washed, rinsed, and sanitized using a three- compartment sink:

(1) Each sink compartment is large enough to allow the immersion of the equipment or utensils; and

(2) The washed, rinsed, and sanitized items are dry before stacking or nesting;

T. Dry cleaning methods such as vacuuming and sweeping are used:

- (1) Only when effective in removing filth and soils; and
- (2) In a manner that prevents contamination of food and food contact surfaces;

U. Dock and overhead doors are open only when food or other items are being moved between transportation facilities and plant receiving areas; and

V. Toxic chemicals are:

- (1) Used:
 - (a) So that food contamination is prevented; and
 - (b) In accordance with the manufacturer's directions; and
- (2) Stored so that:
 - (a) Food and food contact surfaces are not exposed to the chemicals; and
 - (b) The chemical manufacturer's labeling is on the chemical container.

.13 Unit Processing Operations — Storage and Transportation.

A. The person-in-charge shall ensure that:

- (1) Except as provided in §C of this regulation, a stored item and a stationary bulk storage rack are:
 - (a) Away from walls;
 - (b) At least 6 inches off the floor; and
 - (c) Maintained to allow:
 - (i) Inspection;
 - (ii) Cleaning;
 - (iii) Repair to walls; and
 - (iv) Vermin and insect control;
- (2) Incoming food is inspected for:
 - (a) Spoilage;
 - (b) Wholesomeness;
 - (c) Damage; and
 - (d) The presence of vermin and insects;

- (3) Spoiled, unwholesome, vermin-infested and insect-infested food, and other adulterated food is:
- (a) Not allowed entry into the food processing plant;
 - (b) Placed in a morgue area awaiting disposition; or
 - (c) Properly discarded;
- (4) Breakage and spills in food storage areas are cleaned up immediately;
- (5) Food storage areas are kept clean and sanitary;
- (6) Toxic and obnoxious odors and fumes are prevented from accumulating in food storage areas;
- (7) A refrigerated room and a refrigerated area of a vehicle used to store or transport food is:
- (a) Maintained at temperatures that ensure safe and wholesome food;
 - (b) For potentially hazardous food, maintained at an air temperature of:
 - (i) 41°F or less for foods without a non-proteolytic *Clostridium botulinum* potential hazard; and
 - (ii) 38°F or less for foods with a non-proteolytic *Clostridium botulinum* potential hazard;
 - (c) Designed and filled to allow free circulation of air around food;
 - (d) Cleaned and sanitized as needed to maintain a sanitary condition;
 - (e) Loaded so that evaporators do not expose food to drippage;
 - (f) Provided with an indicating thermometer that is:
 - (i) Accurate to within plus or minus 2°F; and
 - (ii) Conspicuous; and
 - (g) Except as provided in §B of this regulation, when monitoring and verifying temperature at a critical control point, provided one or more recording thermometers that:
 - (i) Document the air temperature within the refrigerated room or vehicle area at a time interval not to exceed 1 hour;
 - (ii) Produce a record that is available to the Department as set forth in Regulation .08B(3)(e) of this chapter;
 - (iii) Are accurate to within plus or minus 2°F; and
 - (iv) Are calibrated in accordance with Regulation .15P of this chapter;
- (8) When a freezer used to store or transport frozen food:
- (a) Provided a recording thermometer, datalogger, or similar device in accordance with §A(7)(g) of this regulation; and

- (b) Maintained at an air temperature of 0°F or below except during cycles for defrosting;
 - (9) The food storage area of a transportation vehicle is maintained:
 - (a) In a clean and sanitary manner;
 - (b) In good repair; and
 - (c) To protect food from contamination;
 - (10) For food being transported, a record such as an invoice or bill of lading is available to the Department on request;
 - (11) After its manufacturing, processing, or packaging, a food is not refrozen after having been permitted to thaw from a prior freezing;
 - (12) A frozen food when removed from refrigeration in order to be segregated, organized, or moved shall remain frozen; and
 - (13) A vending machine maintains potentially hazardous foods at the temperatures set forth in Regulation .06C and D of this chapter.
- B. The person-in-charge may use a method of monitoring and verification other than that specified in §A(7)(g) of this regulation if:
- (1) The Department has issued written approval of the alternative method based on a review that determines equivalency; and
 - (2) The Department's written approval is available for inspection.
- C. The person-in-charge may store palletized food on the floor for a period not to exceed 1 month pending:
- (1) Shipment;
 - (2) Movement to allow cleaning under a pallet; or
 - (3) Relocation to permanent storage racks or other facilities.

.14 Unit Processing Operations — Processing Food for Safety and Shelf Life.

The person-in-charge shall ensure that:

- A. Food pathogens are excluded or eliminated from food before offering the food for human consumption;
- B. The thermal processing of food:
 - (1) Eliminates or reduces the number of pathogens in the food so that the food is safe for human consumption;
 - (2) Achieves the necessary reduction in spoilage organisms for a stated or desired shelf life under normal conditions of storage and distribution; and

(3) For a commercially sterile product, produces the condition set forth in Regulation .02B(4) of this chapter;

C. The cooling of potentially hazardous foods:

(1) Uses methods that prevent food contamination; and

(2) Steadily cools hot foods:

(a) From 135°F to 70°F within 2 hours and from 70°F to 41°F within an additional 4 hours; or

(b) By using other cooling time and temperature relationships in a scheduled process;

D. Except as provided in §§E and F of this regulation, a potentially hazardous food is maintained at temperatures set forth in Regulation .06C of this chapter during processing;

E. Except for a food with a non-proteolytic *Clostridium botulinum* potential hazard and as provided in §F of this regulation, when it is necessary for a period of time during preparation or processing to keep a potentially hazardous food at ambient temperatures that may result in the food's internal temperatures not complying with the requirements set forth in Regulation .06C of this chapter:

(1) The cumulative time that the food is kept at ambient temperatures:

(a) Is minimized;

(b) If the food is a raw food that:

(i) Will not be fully thermally processed following the time the food is kept at ambient temperatures, does not exceed a verifiable period of 2 hours; or

(ii) Will be fully thermally processed following the exposure to ambient room temperatures, does not exceed a verifiable period of 4 hours; and

(c) If the food is a cooked food, does not exceed a verifiable period of 2 hours;

(2) The food is rapidly returned to and maintained at the temperatures set forth in Regulation .06C of this chapter;

(3) The food is discarded if the maximum allowed time of exposure to ambient room temperatures set forth in §E(1)(b) and (c) of this regulation is exceeded; and

(4) A hazard analysis of the food and food process is completed;

F. A scheduled process is used if:

(1) Time and food temperature relationships during food processing are other than the times and temperatures specified in this chapter; and

(2) A food with a non-proteolytic *Clostridium botulinum* potential hazard is kept at temperatures other than the temperatures specified in Regulation .06C and D of this chapter;

G. Canning is done in accordance with COMAR 10.15.01;

H. Crab meat is processed in accordance with COMAR 10.15.02;

I. Shellfish is processed is in accordance with COMAR 10.15.07;

J. Seafood is processed and handled in accordance with COMAR 10.15.10;

K. A shelf life study of food:

(1) Mimics the normal conditions of storage and use; and

(2) Is performed by a process authority;

L. When the Department requires a scheduled process pursuant to Regulation .07B of this chapter, the scheduled process is:

(1) Established by a process authority;

(2) Used to manufacture the target food;

(3) Documented by:

(a) Production records; and

(b) Process deviation records; and

(4) Verified by techniques such as:

(a) Production records review;

(b) Equipment calibration; and

(c) Laboratory testing;

M. A potentially hazardous food that is placed in a vending machine is removed from the vending machine and not offered for human consumption:

(1) Within 3 days of the food's manufacture when no shelf life study is performed for the food;

(2) Before the expiration of its determined shelf life when a shelf life study is performed for the food; and

(3) If the vending machine fails to maintain food temperatures as set forth in Regulation .06C and D of this chapter;

N. Records that document compliance with §§K and L of this regulation are:

(1) Maintained; and

(2) Available for inspection by the Department;

O. A potentially hazardous bakery product, such as a pumpkin pie containing unpasteurized shell eggs, that is not maintained at the temperatures set forth in Regulation .06C of this chapter while on display for retail sale is:

- (1) Manufactured in a licensed food processing plant;
- (2) Thermally processed to:
 - (a) Eliminate Salmonella Enteritidis; and
 - (b) Raise the internal temperature of the food to at least 180°F;
- (3) Packaged to:
 - (a) Protect the food; and
 - (b) Maintain aerobic conditions within the packaging;
- (4) Allowed a maximum shelf life:
 - (a) Determined by a shelf life study;
 - (b) Not to exceed 3 days after the day of manufacture; and
 - (c) That is clearly and prominently displayed on the container label; and
- (5) Labeled as set forth in Regulation .16A(2)(h); and

P. Thermometers used to monitor temperatures at critical control points are calibrated annually using:

- (1) A thermometer with an accuracy certified by the National Institute of Standards and Technology;
- (2) An ice bath for thermometers used to monitor cold temperatures; or
- (3) A boiling water bath for thermometers used to monitor hot temperatures.

.15 Unit Processing Operations — Packaging Food.

The person-in-charge shall ensure that:

A. Food packaging is:

- (1) Designed and installed to maintain food:
 - (a) Safety; and
 - (b) Integrity;
- (2) Made from materials that:
 - (a) Are safe;
 - (b) Are appropriate for the intended use;

(c) Do not migrate to or might be absorbed by food; and

(d) Comply with the requirements of the United States Food and Drug Administration in 21 CFR Parts 174—178 for indirect food additives;

(3) Evaluated before use for characteristics that may impact the food, such as:

(a) Permeability to:

(i) Water and water vapor;

(ii) Oxygen; and

(iii) Other gases;

(b) Tolerance to:

(i) Heat;

(ii) Cold; and

(iii) Chemicals used in processing;

(c) Strength; and

(d) Elasticity;

B. A hermetic seal of packaging:

(1) Excludes the entry of microorganisms;

(2) Is inspected after the sealing operation and before distribution; and

(3) Is protected to maintain seal integrity;

C. Before the use of hermetic seals and reduced oxygen packages, a hazard analysis is performed;

D. Food packaging allows the labeling of the food with the information set forth in Regulation [.17] .16 of this chapter; and

E. Food packaging and hermetic seals that fail to comply with the requirements of this regulation are replaced in a manner that ensures food safety.

.16 Unit Processing Operations — Food Labeling.

A. The person-in-charge shall ensure that:

(1) Except as provided in §B of this regulation, or as otherwise stipulated in COMAR 10.15.01, 10.15.02, 10.15.07, or 10.1510, food labeling is accomplished by:

(a) Placing the information required in §A(2) of this regulation on the food container by:

(i) Imprinting;

(ii) Embossing;

(iii) Lithography; or

(iv) Ink jetting; or

(b) Another method:

(i) Set forth in 21 CFR Parts 100 and 101; or

(ii) In conformance with §A(3) of this regulation;

(2) Except as provided in §B of this regulation, the following information is provided on a label of food in packaged form:

(a) Common or usual name of the food;

(b) Statement of ingredients that gives the common or usual name of the ingredients in descending order of prominence;

(c) Name and address of the manufacturer or distributor with:

(i) The full street address including the zip code if the manufacturer or distributor is not listed in a current city directory or telephone directory; or

(ii) A minimum of the town and zip code if the manufacturer or distributor is listed in a current city directory or telephone directory;

(d) Net quantity in terms of:

(i) Weight in English or avoirdupois units and equivalent metric units;

(ii) Measure;

(iii) Numerical count; or

(iv) Combination of numerical count and weight;

(e) If a food coloring has been added, the food coloring in the statement of ingredients;

(f) If a chemical preservative has been added, a label declaration stating:

(i) The common or usual name of the ingredient; and

(ii) A separate description of its function such as "preservative" or "mold inhibitor";

(g) For a food that requires refrigeration for safety, the words "keep refrigerated" or equivalent;

(h) For a food that requires refrigeration for safety after the food's packaging is opened, the words "refrigerate after opening" or equivalent;

(i) For a food that is frozen for safety or quality:

(i) The words "keep frozen" or equivalent; and

(ii) The date the food was frozen in either a code date or an actual date;

(j) When a health or nutrition claim is made, the nutritional labeling required in 21 CFR §101.9;

(k) A "sell by" date if the package contains a potentially hazardous food that is:

(i) In a vending machine; or

(ii) A bakery product manufactured, packaged, and labeled as set forth in Regulation .14O of this chapter;

(l) A "use by date" if the package contains a potentially hazardous food whose safety is assured only until the date specified on the label;

(m) For a food that is frozen during processing or after processing and then thawed before being offered for human consumption, the words "previously frozen, should not refreeze";

(n) A code date with the date of manufacture and the batch number if the food is:

(i) Pasteurized crab meat;

(ii) Canned food; or

(iii) Bottled water;

(o) The exact words "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." for a juice product that has not been processed in a manner that will produce, as proven through scientific study, a reduction in Salmonella and enterohemorrhagic Escherichia coli of at least 5-log values (that is, 100,000 fold);

(p) For shell eggs, the information set forth in COMAR 15.04.01.08; and

(q) For a poultry product produced under the exemption provided in 9 CFR §381.10(a)(5) or (6), the statement "Exempted—P.L. 90-492";

(3) A food label and the labeling information in §A(2) of this regulation are:

(a) Durable;

(b) Conspicuous;

(c) Legible; and

(d) Able to remain on a container in conformance with §A(3)(a)—(c) of this regulation for the shelf life of the food;

(4) The information required in §A(2)(a)—(f) of this regulation is located on the principal display panel;

(5) If the food is not manufactured by the business whose name appears on the label, the business name is qualified by a phrase that reveals the connection the business has with the food, such as "Manufactured for" or "Distributed by";

(6) If the address given on the label is not the place where the food was actually manufactured, packaged, or distributed, it is the address of the principal place of business of the manufacturer or distributor given on the label;

(7) A food's labeling or packaging is not false or misleading in any way; and

(8) A food that has been frozen or thermally processed is not labeled "fresh".

B. In accordance with Health-General Article, §21-212, Annotated Code of Maryland, a federal rule that exempts a food from label requirements is effective automatically in the State.

C. The person-in-charge may forego:

(a) Declaring on the label the common or usual name of each ingredient for incidental additives that:

(i) Are at insignificant levels;

(ii) Have no technical or functional effect in the food; and

(iii) Are not required by a federal rule to be declared; and

(b) Complying with the requirements in §A(2)(a)—(f) and (j) of this regulation for a shipment of food that, in accordance with the practice of trade, is processed, labeled, or repacked in substantial quantity at an establishment other than where originally processed or packed if:

(i) The person who introduced the shipment of food into interstate commerce is the operator of the establishment where the food is to be processed, labeled, or repacked; or

(ii) The shipment or delivery to the establishment is made under a written agreement as set forth in 21 CFR §101.100(d).

.17 Facility and Process Plan Review.

A. The person-in-charge shall ensure that properly prepared plans and specifications are submitted to the Department:

(1) Before:

(a) A food processing plant is:

(i) Constructed;

(ii) Remodeled; or

(iii) Materially altered;

- (b) An existing building or structure is converted or remodeled for use as a food processing plant; or
- (c) A food process is added or modified so that:
 - (i) A plant or plant facilities require modification; and
 - (ii) Process critical control points are added;
- (2) That include the following information:
 - (a) A scale drawing in horizontal view that shows the:
 - (i) Layout and arrangement of work areas;
 - (ii) Location of food equipment including exhaust ventilation hoods; and
 - (iii) Location of plumbing and plumbing fixtures such as water lines, sewer lines, hand sinks, toilets, utility sinks, utensil washing sinks, floor drains, floor sinks, and hose stations;
 - (b) Specifications for the:
 - (i) Construction materials for the building and interior finishes;
 - (ii) Disposal of sewage;
 - (iii) Provision of potable water;
 - (iv) Ventilation of the plant and individual areas within the plant;
 - (v) Methods and facilities for waste storage and disposal; and
 - (vi) Lighting;
 - (c) Manufacturer and model number of equipment and facilities;
 - (d) Written standard operating procedures for:
 - (i) Processing a food;
 - (ii) Worker and plant sanitation; and
 - (iii) A scheduled process when required;
 - (e) When required by COMAR 10.15.01, 10.15.02, 10.15.07, or 10.15.10, or this chapter, a HACCP plan; and
 - (f) Any other information that may be required by the Department for the proper review of the plans and specifications.

B. The person-in-charge may not construct a new food processing plant, remodel an existing food processing plant, or manufacture a food using a new or modified process before receiving written approval of the plans and specifications from the Department.

C. The Department shall:

- (1) Review the plans and specifications to ensure compliance with the applicable regulations;
- (2) Inform the submitter in writing:
 - (a) Of additional information that may be required; and
 - (b) Following the review, whether the plans and specifications are approved or denied; and
- (3) If the plans are denied, provide the submitter with information on how to appeal the decision, as set forth in the State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.

.18 On-Farm Home Processing.

A. The Department may issue a food processing plant license to an individual who owns a farm to process food in a home or domestic kitchen located on the individual's farm as set forth in this regulation.

B. In addition to the training required in Regulation .06H of this chapter, before an individual may be licensed as set forth in §A of this regulation, the individual shall complete a course given or approved by the Department that provides a minimum of 8 hours of training in:

- (1) Sanitation;
- (2) Cross-contamination controls; and
- (3) Food security.

C. While operating with a license issued in accordance with §A of this regulation, the person-in-charge:

- (1) Shall comply with this chapter except for:
 - (a) Regulation .09D(2)(b), (4), and (5) of this chapter;
 - (b) Regulation .09K of this chapter; and
 - (c) Regulation .11B(1), (3), and (4) of this chapter;
- (2) Except as provided in §D(1) and (2) of this regulation, shall manufacture and process only non-potentially hazardous foods such as:
 - (a) Baked cakes, muffins, or cookies with a water activity of .85 or less;
 - (b) Fruit pies with an equilibrated pH of 4.6 or less;
 - (c) Canned acid foods with an equilibrated pH of 4.6 or less;
 - (d) Herbs in vinegar with an equilibrated pH of 4.6 or less;
 - (e) Honey and herb mixtures; and

- (f) Dried fruit and vegetables;
- (3) May not process:
 - (a) Low-acid canned foods;
 - (b) Cured or fermented foods;
 - (c) Except as provided in §D(2) of this regulation, seafood;
 - (d) Apple cider or other juices;
 - (e) Grade A milk product or manufactured grade milk product as defined in Health-General Article, §21-401, Annotated Code of Maryland; and
 - (f) A frozen dessert as defined in Health-General Article, §21-801(b), Annotated Code of Maryland;
- (4) Shall process food in accordance with manufacturing procedures and standard processes as set forth in Regulation .07 of this chapter;
- (5) Shall limit processed food production to:
 - (a) An amount of food that can safely be produced in the domestic kitchen as evidenced by sanitation and process and cross-contamination control; and
 - (b) \$40,000 of sales;
- (6) Shall process commercially only during times when the kitchen is not being used for domestic purposes;
- (7) Immediately before and after processing commercially, shall clean and sanitize all food contact surfaces, equipment, and utensils;
- (8) While processing commercially, shall:
 - (a) Use only building areas, equipment, and utensils that the Department has reviewed or inspected and approved; and
 - (b) Exclude pets and other animals and individuals not involved in the manufacturing from the kitchen; and
- (9) Shall store ingredients for commercial manufacturing and finished manufactured food in a separate area from foods used domestically.

D. An individual licensed in accordance with this regulation may:

- (1) Weigh, label, and sell or distribute raw meat or poultry that is under the jurisdiction of the United States Department of Agriculture;
- (2) Weigh, package, label, and sell or distribute raw meat or poultry that is inspected by the Maryland Department of Agriculture in accordance with Regulation .20 of this chapter;
- (3) Process only animals that were:

- (a) Commercially raised, fed, or managed on the farm; and
- (b) Slaughtered and processed in accordance with Regulation .20 of this chapter;
- (4) While operating a fish farm, clean, weigh, package, label, and sell or distribute raw finfish from the farm that are not associated with histamine intoxication; and
- (5) Use shared equipment and utensils for both domestic and commercial uses provided that the equipment and utensils are:
 - (a) Designed and constructed as set forth in Regulation .10 of this chapter; and
 - (b) Cleaned and sanitized as set forth in Regulation .12 of this chapter and §C(7) of this regulation.
- E. An individual licensed in accordance with this regulation may weigh, label, and store cheese that:
 - (1) Is made on a licensed out-of-State dairy farm using only the raw milk produced by the herd on the dairy farm licensed by the Department; and
 - (2) Meets the definition and standards of a hard cheese, as set forth in 21 CFR Part 133.
- F. When a farm ceases to be a farm, a food processing license issued in accordance with this regulation becomes void.
- G. In the absence of a license issued in accordance with COMAR 10.15.03, a license issued in accordance with this regulation shall provide for the sale on the farm of food processed on the farm by the licensee.
- H. Except as provided in Regulation .20 of this chapter, a person may not process food for human consumption on a farm without the license required in Regulation .21A of this chapter.

.19 Producer Mobile Farmer's Market Unit.

- A. The Department may issue a food processing plant license to operate a producer mobile farmer's market unit to transport for sale at a farmer's market potentially hazardous food products:
 - (1) Produced or stored on the farm by the licensee under an on-farm home processing plant license;
 - (2) Produced or stored on the farm by the licensee, as authorized by the Department in regulation; or
 - (3) That have been inspected, licensed, or certified for food safety by the Maryland Department of Agriculture.
- B. The person-in-charge shall ensure that the producer mobile farmer's market unit:
 - (1) Complies with Regulation .13A(7)—(12) of this chapter; and
 - (2) Displays the license on the unit during operation.
- C. A county health department shall:
 - (1) Enforce §B of this regulation;

(2) Levy fines as established in local law, ordinance, or regulation; and

(3) Notify the Department of any violations occurring in the county.

.20 Animal Slaughtering, Meat Processing, and Poultry Processing.

A person that slaughters animals and processes meat shall ensure that:

A. Animal slaughtering, meat processing, poultry processing, meat sales, and poultry sales are regulated and inspected in conformance with the applicable federal, State, and local laws and regulations;

B. Cattle, sheep, swine, goats, horses, mules, and other equine are slaughtered and processed in accordance with:

(1) The Federal Meat Inspection Act, 21 U.S.C. §§601—695; and

(2) Applicable federal, State, and local regulations;

C. Poultry are slaughtered and processed in accordance with:

(1) The Poultry Products Inspection Act, 21 U.S.C. §§451—471; and

(2) Applicable federal, State, and local regulations; and

D. When slaughtered and processed for food for the public, domesticated animals including poultry and rabbits that are not required by federal law or regulation to be inspected by the United States Department of Agriculture are:

(1) Inspected by:

(a) The United States Department of Agriculture under a voluntary inspection program;

(b) The Maryland Department of Agriculture under a voluntary inspection program; or

(c) An approving authority; and

(2) Processed into human food while being regulated:

(a) By the United States Department of Agriculture under a voluntary inspection program;

(b) By a meat inspection program or poultry inspection program administered by the Maryland Department of Agriculture; or

(c) By an approving authority.

.21 Licensing.

A. In order to operate a food processing plant, a person shall obtain a food processing license pursuant to the provisions of:

(1) Health-General Article, §§21-211 and 21-305, Annotated Code of Maryland; and

(2) This chapter.

B. The Department shall specify on the food processing license what foods or food types the licensee is authorized to process.

C. The Department shall deny an application for a license if the applicant:

(1) Does not meet the requirements of:

(a) Health-General Article, §21-211 or Title 21, Subtitle 3, Annotated Code of Maryland; or

(b) A regulation promulgated under Health-General Article, §21-211 or Title 21, Subtitle 3, Annotated Code of Maryland; or

(2) Fraudulently or deceptively attempts to obtain a license.

D. The Department may suspend or revoke a license if the licensee:

(1) Violates or fails to meet the requirements of:

(a) Health-General Article, §21-211 or Title 21, Subtitle 3, Annotated Code of Maryland; or

(b) A regulation promulgated under Health-General Article, §21-211 or Title 21, Subtitle 3, Annotated Code of Maryland; or

(2) Fraudulently or deceptively obtains a license.

E. The Department may deny an application for a food processing plant license and may suspend or revoke a license pursuant to the provisions of:

(1) Health-General Article, §§21-211, 21-311, and 21-314—21-317, Annotated Code of Maryland; and

(2) State Government Article, §10-226, Annotated Code of Maryland.

F. The person-in-charge shall ensure that:

(1) Food is not processed without the license required by Health-General Article, §21-305, Annotated Code of Maryland;

(2) The required food processing license is conspicuously posted in the plant; and

(3) The processing operations in the plant are limited to the food type or types specified on the license pursuant to §B of this regulation.

G. Except as provided in §H of this regulation, a license may not be transferred from one person to another person or from one food processing plant to another.

H. On the death of a licensee, the approving authority may transfer a food processing plant license if:

(1) An application is filed in accordance with Health-General Article, §21-306, Annotated Code of Maryland; and

(2) Written evidence establishes that the applicant's relationship with the deceased was as a:

(a) Spouse of the deceased licensee;

(b) Blood relative to the first degree of consanguinity; or

(c) Current officer or surviving partner in the business operating the food processing plant.

.22 Plan Review.

A. The person-in-charge shall ensure that plans and specifications are submitted to and approved by the approving authority before a food processing plant is:

(1) Constructed;

(2) Remodeled; or

(3) Materially altered.

B. The person-in-charge shall ensure that the information submitted to the approving authority includes:

(1) A drawing of the proposed facility that identifies the layout and arrangement of work areas and the location of all equipment;

(2) A description of:

(a) Materials to be used for interior finishes;

(b) The layout and types of lighting to be used;

(c) The proposed ventilation system; and

(d) Methods and facilities for trash storage and disposal;

(3) A plumbing diagram, including specifications of the method of sewage disposal and the source of potable water;

(4) A complete list of specifications for the proposed food equipment;

(5) A written description of the foods to be processed or stored;

(6) General food handling information and procedures for:

(a) Receiving food;

(b) Storing food; and

(c) Processing food; and

(7) Any other information that is required by the approving authority to ascertain compliance of the plans and specifications with all applicable State and local laws, regulations, and ordinances.

C. The person-in-charge shall ensure that before a new or remodeled food processing plant is operated:

- (1) An inspection by the Department is scheduled and completed;
- (2) The Department has issued written approval for the use of the new or remodeled plant; and
- (3) For a new plant, a food processing license is obtained.

D. The approving authority shall:

- (1) Conduct a priority assessment of the facility based on the information obtained pursuant to §B of this regulation; and
- (2) Classify a food processing plant as a:
 - (a) High priority facility if the food processing plant manufactures:
 - (i) Potentially hazardous food;
 - (ii) Low-acid canned food; or
 - (iii) Acidified food;
 - (b) Moderate priority facility if the food processing plant:
 - (i) Manufactures food that is not potentially hazardous; or
 - (ii) Is a food warehouse that stores and distributes potentially hazardous food; or
 - (c) Low priority facility if the food processing plant is a food warehouse that stores and distributes only non-potentially hazardous food.

.23 Inspections.

A. The person-in-charge shall permit a representative of the approving authority to:

- (1) Enter a food processing plant at a reasonable time for the purpose of making inspections to determine compliance with this chapter; and
- (2) Examine the records of the facility that pertain to information regarding food and supplies purchased, received, or used.

B. The person-in-charge shall inform the approving authority of a food ingredient or a recipe that the person-in-charge considers a trade secret, except as provided in §C of this regulation.

C. The person-in-charge shall furnish information to the approving authority regarding a food ingredient or recipe that the person-in-charge considers a trade secret if:

- (1) An immediate and substantial danger to public health exists involving the food ingredient or recipe; or

(2) The approving authority determines that the information about the food ingredient or recipe is necessary to conduct a foodborne disease investigation.

D. The person-in-charge shall ensure that:

(1) Compliance with this chapter is continuous and not intermittent;

(2) Violations are corrected within the time for correction given by the Department;

(3) When a violation of a critical item exists:

(a) The violation is corrected immediately;

(b) Food processing affected by the critical item violation ceases; or

(c) The food processing plant is closed; and

(4) For a food processing plant that operates seasonally or intermittently, inspection and regulation by the Department is facilitated by notifying the Department of:

(a) The dates and times of operation; or

(b) Information necessary to ensure that the Department has the opportunity to inspect the food processing plant during plant operation.

E. The approving authority shall maintain the confidentiality of trade secret information in accordance with State Government Article, §10-617, and Health-General Article, §21-259, Annotated Code of Maryland.

F. When an inspection of a food processing plant is made, the approving authority shall:

(1) Document:

(a) The inspection results on an inspection report form provided by the Department; and

(b) On the report:

(i) Conditions found that violate the provisions of this chapter; and

(ii) Critical item violations, noted separately from all other violations;

(2) Furnish one copy of the inspection report to the person-in-charge of the plant; and

(3) Make the completed inspection report form available for public disclosure in accordance with State Government Article, §§10-611—10-628, Annotated Code of Maryland.

G. The approving authority shall ensure that a food processing plant is inspected:

(1) As needed for the enforcement of this chapter;

(2) When a high and moderate priority plant, at a minimum of twice a year; and

(3) When a low priority plant, at a minimum of once a year.

.24 Enforcement Procedures.

A. The approving authority shall ensure that when a food processing plant is found in violation of any provision of this chapter, the licensee is notified:

- (1) Of the specific findings;
- (2) Of a specific date by which the licensee shall correct the violations or deficiencies; and
- (3) That, if the licensee fails to correct the violation by the date specified, the approving authority may suspend or revoke the license.

B. When a person is violating any provision of this chapter, the approving authority may serve the person with a written order pursuant to Health-General Article, §21-318 or 21-261, Annotated Code of Maryland, directing the person to abate the violation within a specified time period.

C. The approving authority shall ensure that an opportunity for a hearing is provided to a person served with an order, pursuant to State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.

D. In order to preserve a right to a hearing under any provision of this regulation, a person shall:

- (1) Make a request for a hearing in writing; and
- (2) Submit the request to the approving authority that issued the order or inspection report:
 - (a) Within 10 days of receipt of the order;
 - (b) Sooner if specified in the order; or
 - (c) Within 24 hours if the violation requires immediate correction or correction within 24 hours.

E. The approving authority shall suspend or revoke the license of a food processing plant if the licensee fails or neglects to:

- (1) Correct a violation within the specified time period;
- (2) Comply with an approved written schedule of compliance; or
- (3) Correct a critical item immediately.

F. The approving authority shall ensure that:

- (1) An action to suspend or revoke a license, complies with the provisions of:
 - (a) State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland; and
 - (b) Health-General Article, §21-315, Annotated Code of Maryland; and

(2) The person against whom the action is contemplated is given an opportunity for a hearing in accordance with Health-General Article, §21-316, Annotated Code of Maryland.

G. When an immediate and substantial danger is found to exist to public health, safety, or welfare that imperatively requires emergency action, pursuant to State Government Article, §10-226(c)(2), Annotated Code of Maryland, the:

(1) Approving authority shall:

(a) Summarily suspend the license at a food service facility;

(b) Order the food service facility to cease operation immediately; and

(c) Promptly provide the licensee with:

(i) A written notice of suspension of the license;

(ii) The reasons for the suspension; and

(iii) An opportunity to be heard; and

(2) Person-in-charge shall immediately cease the operation of the food processing plant.

H. The person-in-charge shall ensure that a food processing plant that has been required under the provisions of this regulation to cease operations does not resume operations until a reinspection by the approving authority shows that the condition or conditions responsible for the requirement to cease operations no longer exist.

I. The approving authority shall ensure that appropriate steps are taken to ensure that the licensee ceases operation of the food processing plant on suspension or revocation of the license, including:

(1) Taking and keeping physical possession of the license until the license is reinstated;

(2) Posting a sign on the facility door stating that the license has been suspended or revoked by the approving authority; or

(3) Taking another measure within the law that will ensure that the facility does not operate.

J. A person whose food processing plant license has been suspended or revoked may apply for reinspection and reinstatement of the license by submitting to the approving authority a written request that details the actions taken by the person to correct each violation of a food statute or regulation that caused the suspension or revocation.

.25 Foodborne Disease Investigation and Control.

The approving authority shall ensure that:

A. When there is reasonable cause to suspect foodborne disease transmission from a food processing plant employee:

(1) A morbidity history of the suspected employee is taken;

(2) An investigation is conducted; and

(3) The appropriate follow-up action is taken that may include:

(a) Immediate exclusion of the employee from all food handling positions within the plant; and

(b) Immediate closing of the food processing plant until medical and epidemiological evidence shows that the likelihood of further foodborne disease transmission is low; and

B. An investigation, a report, and the control of a foodborne disease outbreak is conducted in accordance with the provisions of COMAR 10.06.01.

.26 Sampling, Detention, and Condemnation of Food.

The approving authority shall:

A. Sample and examine food as often as necessary for enforcement of this chapter;

B. Sample food in accordance with Health-General Article, §§21-249 and 21-251, Annotated Code of Maryland; and

C. Take action on a food in accordance with Health-General Article, §§21-211, 21-253, and 21-254, Annotated Code of Maryland, by:

(1) Issuing a detention order;

(2) Destroying the food; or

(3) Making the food unusable for consumption.

.27 Penalties.

A person who violates any of the provisions of this chapter or refuses, neglects, or fails to comply with the provisions and requirements of this chapter is subject to penalties, fines, and imprisonment as set forth in Health-General Article, 21-309.1(f)(1)—(3), 21-1214, and 21-1215, Annotated Code of Maryland.

.28 Federal Compliance.

In addition to the other requirements set forth in this chapter, the person in charge shall ensure that the food processing plant meets all of the requirements applicable to food sources, storage, and preparation that are set forth at:

A. 9 CFR, as amended;

B. 21 CFR, as amended;

C. 21 U.S.C. §343, as amended

D. 21 U.S.C. §§451—471, as amended; and

E. 21 U.S.C. §§601—695, as amended.

Administrative History

Effective date: November 18, 1960

Amended effective January 1, 1964; June 8, 1965; July 1, 1966; April 1, 1967; December 1, 1970

Regulation .29 adopted effective September 21, 1979 (6:19 Md. R. 1519)

Regulation .29 amended effective December 14, 1979 (6:25 Md. R. 1980)

Chapter revised as an emergency provision effective August 2, 1989 (16:17 Md. R. 1882); adopted permanently effective December 25, 1989 (16:25 Md. R. 2711)

Regulation .01B amended effective September 28, 1992 (19:19 Md. R. 1708)

Regulation .02B amended effective September 28, 1992 (19:19 Md. R. 1708); April 3, 2000 (27:6 Md. R. 641)

Regulation .31 amended effective September 28, 1992 (19:19 Md. R. 1708)

Regulation .33A amended effective March 4, 1991 (18:4 Md. R. 447); September 28, 1992 (19:19 Md. R. 1708); October 6, 1997 (24:20 Md. R. 1404)

Regulations .01—.37 repealed and new Regulations .01—.20 adopted effective November 22, 2004 (31:23 Md. R. 1652)

Regulation .02B amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .03B amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .08A amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .09B amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .10D amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .17A amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .19C, D amended effective May 4, 2009 (36:9 Md. R. 651)

Regulation .19G adopted effective May 4, 2009 (36:9 Md. R. 651)

Regulation .21 adopted effective May 4, 2009 (36:9 Md. R. 651)

Chapter revised as an emergency provision effective October 1, 2010 (37:23 Md. R. 1607)