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Cottage Food Law Statutes:

*Hawaii*



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# A National Agricultural Law Center Research Publication

## Cottage Food Laws: Hawaii

HI Admin Rules § 11-50-2  
HI Admin Rules § 11-50-3(c)  
HI Admin Rules § 11-50-31(a)  
HI Admin Rules § 11-50-35(c)

*Current through November 2024.*

### **HI Admin Rules § 11-50-2. Definitions.**

As used in this chapter:

"Adulterated" has the meaning stated in section 402 of the Federal Food, Drug, and Cosmetic Act.

"Approved" means acceptable to the department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

"Asymptomatic" means without obvious symptoms; not showing or producing indications of a disease or other medical condition, such as an individual infected with a pathogen but not exhibiting or producing any signs or symptoms of vomiting, diarrhea, or jaundice. Asymptomatic includes not showing symptoms because symptoms have resolved or subsided, or because symptoms never manifested.

"Aw" means water activity which is 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 Aw.

"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.

"Beverage" means a liquid for drinking, including water.

"Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

"Casing" means a tubular container for sausage products made of either natural or artificial (synthetic) material.



"Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

"CFR" means the 2013 Code of Federal Regulations. Citations in this chapter to the CFR refer sequentially to the Title, Part, and Section numbers, such as, 40 CFR 180.194 refers to Title 40, Part 180, Section 194.

"CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. The term does not include the cleaning of equipment such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

"Color additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, section 201(t) and 21 CFR 70.3(f).

"Commingle" means:

- (1) To combine shellstock harvested on different days or from different growing areas as identified on the tag or label; or
- (2) To combine shucked shellfish from containers with different container codes or different shucking dates.

"Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing. Comminuted includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and a mixture of two or more types of meat that have been reduced in size and combined, such as sausages made from two or more meats.

"Conditional employee" means a potential food employee to whom a job offer is made, conditional on responses to subsequent medical questions or examinations designed to identify potential food employees who may be suffering from a disease that can be transmitted through food and done in compliance with Title 1 of the Americans with Disabilities Act of 1990.

"Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness.

"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.

"Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged



influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

"Counter-mounted equipment" means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf.

"Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

"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 minimize the risk that the identified food safety hazard may occur.

"Cut leafy greens" means fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term "leafy greens" includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula, and chard. The term "leafy greens" does not include herbs such as cilantro or parsley.

"Dealer" means a person who is authorized by a shellfish control authority for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor of molluscan shellfish according to the provisions of the National Shellfish Sanitation Program.

"Department" means the department of health. State of Hawaii.

"Director" means the director of health of the department of health. State of Hawaii, or an authorized representative.

"Disclosure" means a written statement that clearly identifies the animal-derived foods which are, or can be ordered, raw, undercooked, or without otherwise being processed to eliminate pathogens, or items that contain an ingredient that is raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Drinking water" means water that meets criteria as specified in 40 CFR 141, entitled "National primary drinking water regulations", and is traditionally known as "potable water". Drinking water includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water", "mop water", "rainwater", "wastewater", and "nondrinking" water.

"Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous (time/temperature control for safety food) and dry goods such as single-service items.

"Easily cleanable" means a characteristic of a surface that:

- (1) Allows effective removal of soil by normal cleaning methods;



- (2) Is dependent on the material, design, construction, and installation of the surface; and
- (3) Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.
- (4) Easily cleanable includes a tiered application of the criteria that qualify the surface as easily cleanable as specified in paragraph (1) to different situations in which varying degrees of cleanability are required such as:
  - (A) The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or
  - (B) The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

"Egg" means the shell egg of avian species such as chicken, duck, goose, guinea, quail, ratites, or turkey. Egg does not include:

- (1) A balut;
- (2) The egg of reptile species such as alligator? or
- (3) An egg product.

"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. The term does not include food which contains eggs only in a relatively small proportion such as cake mixes.

"Employee" means the owner or operator, 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 establishment.

"EPA" means the U.S. Environmental Protection Agency.

"Equipment" means an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine. This does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.



"Exclude" means to prevent a person from working as an employee in a food establishment or entering a food establishment as an employee,

"FDA" means the U.S. Food and Drug Administration.

"Fish" means fresh or saltwater finfish, crustaceans and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, if such animal life is intended for human consumption. Fish includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner.

"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.

"Food additive" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, section 201 (s) and 21 CFR 170.3(e) (1).

"Food-contact surface" means:

- (1) A surface of equipment or a utensil with which food normally comes into contact; or
- (2) A surface of equipment or a utensil from which food may drain, drip, or splash:
  - (A) Into a food; or
  - (B) Onto a surface normally in contact with food.

"Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

"Food establishment" means:

- (1) Any place or portion thereof, maintained, used, or operated for the purpose of storing, preparing, serving, manufacturing, packaging, transporting, or otherwise handling food for distribution at retail or wholesale to the public; and
- (2) Any place or portion thereof, used in support of and in conjunction with any other food establishment.

"Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption, and provides food for sale or distribution to other business entities such as food processing plants or food establishments.

"Game animal" means an animal, the products of which are food, that is not classified as livestock, sheep, swine, goat, horse, mule, or other equine in 9 CFR 301.2, entitled "Definitions", or as poultry, or fish.



(1) Game animals includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat, and nonaquatic reptiles such as land snakes.

(2) Game animals does not include ratites.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175, entitled "Pesticides classified for restricted use".

"Grade A standards" means the requirements of the United States Public Health Service/FDA "Grade A Pasteurized Milk Ordinance" with which certain fluid and dry milk and milk products comply.

"HACCP" means Hazard Analysis and Critical Control Point,

"HACCP plan" means a written document that delineates the formal procedures for following the hazard analysis and critical control point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

"Hand-pounded poi" means a product made from the process of manually pulverizing cooked taro with a stone implement on a wooden board designed for the purpose of pounding poi.

"Handwashing sink" means a lavatory, a basin or vessel for washing, a wash basin, or a plumbing fixture especially placed for use in personal hygiene and designed for the washing of the hands. A handwashing sink includes an automatic handwashing facility.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

"Health practitioner" means a physician licensed to practice medicine, or if allowed by law, a nurse practitioner, physician assistant, or similar medical professional.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means persons who are more likely than other people in the general population to experience foodborne disease because they are:

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

(2) 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.

"Home kitchen" means a kitchen designed and intended for use by the residents of a home.

"Homemade food products" means not potentially hazardous food produced or packaged in a home kitchen but does not include fermented foods, acidified foods, canned or bottled foods, dried meats or seafood, low acid canned foods and garlic in oil.

"HRS" means the Hawaii Revised Statutes.

"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:

- (1) The number of potential injuries; and
- (2) The nature, severity, and duration of the anticipated injury.

"Injected" means manipulating meat to which a solution has been introduced into its interior by processes that are referred to as "injecting", "pump marinating", or "stitch pumping".

"Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The term does not include, for purposes of HACCP, liquids, purees, or concentrates that are not used as beverages or ingredients of beverages.

"Kitchenware" means food preparation and storage utensils.

"Law" means applicable local, state, and federal statutes, regulations, rules, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

"Major food allergen":

- (1) Means:
  - (A) Milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or
  - (B) A food ingredient that contains protein derived from a food as specified in subparagraph (A);

- (2) Major food allergen does not include:



(A) Any highly refined oil derived from a food specified in paragraph (1)(A) and any ingredient derived from such highly refined oil; or

(B) Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labeling and Consumer Protection Act of 2004 ( Public Law 108-282).

"Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified in section 11-50-31(g) (1) (C).

"Mechanically tenderized" means manipulating meat with deep penetration by processes which may be referred to as "blade tenderizing", "jaccarding", "pinning", "needling", or using blades, pins, needles or any mechanical device. The term does not include processes by which solutions are injected into meat.

"Menu change" means a modification of a food establishment's menu that would require a change in the food establishment's food preparation methods, equipment, or storage capacity previously approved by the director. These changes may include but are not limited to, the addition of potentially hazardous foods to a menu, installation of new food preparation or storage equipment, or increasing storage capacity.

"mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle,

"Natural disaster" means any disaster such as a tsunami, hurricane, volcanic eruption, typhoon, earthquake, or flood.

"Non-continuous cooking" means the cooking of food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service. The term does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous cooking process.

"Owner" means a person who has vested rights in equity or at law in the real property or proprietary interests of the food establishment or any part of it.

"Operator" means the person responsible for the overall management of the food establishment.

"Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a food establishment or a food processing plant. The term does not include food wrapped or placed in a carry-out container to protect it during service or delivery to the consumer by a food employee.



"Permit" means the document issued by the director that authorizes a person to operate a food establishment.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance. Personal care items include medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

"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. Values between zero and seven indicate acidity and values between seven and fourteen indicate alkalinity. The value for pure distilled water is seven, which is considered neutral.

"PHF" means potentially hazardous food.

"Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that:

- (1) Is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or
- (2) Discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

"Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

- (1) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- (2) Pesticides, except sanitizers, which include substances such as insecticides and rodenticides;



(3) Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(4) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

"Potentially hazardous food (time/temperature control for safety food)" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(1) Potentially hazardous food includes:

(A) 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

(B) Except as specified in paragraph (2)(D), a food that because of the interaction of its Aw and pH values is designated as Product Assessment Required (PA) in Table 2-1 or Table 2-2:

Table 2-1 Interaction of pH and Aw for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged

| Aw values     | pH values            |                      |                      |
|---------------|----------------------|----------------------|----------------------|
|               | 4.6 or less          | >4.6 to 5.6          | >5.6                 |
| ≤0.92         | Non-PHF/non-TCS food | Non-PHF/non-TCS food | Non-PHF/non-TCS food |
| >0.92 to 0.95 | Non-PHF/non-TCS food | Non-PHF/non-TCS food | PA                   |
| >0.95         | Non-PHF/non-TCS food | PA                   | PA                   |



Table 2-2 Interaction of pH and Aw for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged

| Aw values     | pH values            |                      |                      |                      |
|---------------|----------------------|----------------------|----------------------|----------------------|
|               | <4.2                 | 4.2 to 4.6           | >4.6 to 5.0          | >5.0                 |
| <0.88         | Non-PHF/non-TCS food | Non-PHF/non-TCS food | Non-PHF/non-TCS food | Non-PHF/non-TCS food |
| 0.88 to 0.90  | Non-PHF/non-TCS food | Non-PHF/non-TCS food | Non-PHF/non-TCS food | PA                   |
| >0.90 to 0.92 | Non-PHF/non-TCS food | Non-PHF/non-TCS food | PA                   | PA                   |
| >0.92         | Non-PHF/non-TCS food | PA                   | PA                   | PA                   |

(2) Potentially hazardous food does not include:

(A) 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;

(B) 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;

(C) A food that because of its pH or Aw value, or interaction of Aw and pH values, is designated as a non-PHF/non-TCS food in Table 2-1 or Table 2-2 of this definition;

(D) A food that is designated as Product Assessment Required (PA) in Table 2-1 or Table 2-2 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

(E) A food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the paragraph (2)(A), (2)(B), (2)(C), or (2)(D) 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.

"Poultry" means:

- (1) Any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs), whether live or dead, as defined in 9 CFR 381.1; and
- (2) Any migratory waterfowl or game bird, pheasant, partridge, quail, grouse, or pigeon, whether live or dead, as defined in 9 CFR 362.1.

"Premises" means:

- (1) The physical facility, its contents, and the contiguous land or property under the control of the owner or operator; or
- (2) The physical facility, its contents, and the land or property not described in paragraph (1) if its facilities and contents are under the control of the owner or operator and may impact food establishment personnel, facilities, or operations, and a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank, or veal breast.

"Public water system" has the meaning stated in 40 CFR 141, entitled "National primary drinking water regulations".

"Ratite" means a flightless bird such as an emu, ostrich, or rhea.

"Reduced oxygen packaging":

(1) Means:

- (A) The reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately twenty-one per cent at sea level); and
- (B) A process as specified in subparagraph (A) that involves a food for which the hazards *Clostridium botulinum* or *Listeria monocytogenes* require control in the final packaged form;

(2) Reduced oxygen packaging includes:



(A) Vacuum packaging, in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package;

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

(C) Controlled atmosphere packaging, in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material;

(D) Cook chill packaging, in which cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens; or

(E) Sous vide packaging, in which raw or partially cooked food is placed in a hermetically sealed, impermeable bag, cooked in the bag, rapidly chilled, and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens.

"Refuse" means solid waste not carried by water through the sewage system.

"Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

"Reminder" means a written statement concerning the health risk of consuming animal foods raw, undercooked, or without otherwise being processed to eliminate pathogens.

"Re-service" means the transfer of food that is unused and returned by a consumer after being served or sold and in the possession of the consumer, to another person.

"Restrict" means to limit the activities of a food employee so that there is no risk of transmitting a disease that is transmissible through food and the food employee does not work with exposed food, clean equipment, utensils, linens, or unwrapped single-service or single-use articles.

"Restricted egg" means any check, dirty egg, incubator reject, inedible, leaker, or loss as defined in 9 CFR 590.



"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175, entitled "Pesticides classified for restricted use" and that is limited to use by or under the direct supervision of a certified applicator.

"Risk" means the likelihood that an adverse health effect will occur within a population as a result of a hazard in a food.

"Safe material" means:

- (1) An article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food;
- (2) An additive that is used as specified in section 409 of the Federal Food, Drug, and Cosmetic Act; or
- (3) Other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five logs, which is equal to a 99.999 per cent reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that allow the entry or passage of moisture.

"Service animal" means an animal that meets the criteria as specified in 28 CFR 36, entitled "Nondiscrimination on the basis of disability in public places and commercial facilities".

"Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and boarding food.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

"Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce.

"Shellstock" means raw, in-shell molluscan shellfish.

"Shiga toxin-producing Escherichia Coli" (STEC) means any E. Coli capable of producing Shiga toxins (also called verocytotoxins). STEC infections can be asymptomatic or may result in a spectrum of illness ranging from mild non-bloody diarrhea, to hemorrhagic colitis (i.e.,



blood diarrhea), to hemolytic uremic syndrome (HUS - a type of kidney failure). Examples of serotypes of STEC include: E.coli O157:H7; E.coli O157:NM; E.coli O26:H11; E.coli O145:NM; E.coli O103:H2; and E.coli O111:NM. STEC are sometimes referred to as VTEC (verocytotoxigenic E.coli) or as EHEC (Enterohemorrhagic E.coli). EHEC are a subset of STEC of which can cause hemorrhagic colitis or HUS.

"Shucked shellfish" means molluscan shellfish that have one or both shells removed.

"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

"Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded. Single-use articles include items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications in sections 11-50-45(a) and 11-50-46(a) and (c) for multiuse utensils.

"Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of minus ten degrees Fahrenheit to twenty-five degrees Fahrenheit in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as shrimp.

"Smooth" means:

- (1) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel;
- (2) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and
- (3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that renders it difficult to clean.

"Special event" means a planned activity where food is distributed to the public with or without charge at a single specified location held indoors or outdoors, on public or privately owned property, and may include a sporting event, carnival, fairs, farmer's markets, public exhibition, festival, religious organization function, parade or other similar gathering.

"State" means the State of Hawaii.

"Support kitchen" means a food establishment that provides facilities or services in support of another food establishment for



cleaning, storage, food preparation, cooking, cooling, reheating, servicing water supply, or wastewater disposal. A private home kitchen shall not be used as an approved support kitchen.

"Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, and tumblers; and plates.

"TCS food" means time/temperature control for safety food.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; temperature sensing probes of food temperature measuring devices; and probe-type price or identification tags used in contact with food.

"Variance" means a written document issued by the director that authorizes a modification or waiver of one or more requirements of this chapter if, in the opinion of the director, a health hazard or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage areas and areas on the premises that are used to service and maintain the vending machines.

"Water activity" means the 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  $A_w$ .

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

"Warewashing" means the cleaning and sanitizing of utensils and food-contact surfaces of equipment.

### **HI Admin Rules § 11-50-3. Permits, Special Events, Homemade Food Products and Hand-Pounded Poi, and Exemptions**



(a) Permits. No person may operate a food establishment without a valid permit issued by the director, which shall remain valid for one year from the date of issuance unless suspended by the director, after which it shall become void unless renewed in accordance with section 11-50-4, except as otherwise provided in this section.

(b) Special events. Any person who intends to operate a food establishment in conjunction with a special event may apply for a special event permit;

(1) A special event permit shall not be issued until the applicant has submitted documents and information in accordance with, and otherwise conforms to, the requirements of section 11-50-4.

(2) The director may issue a special event permit to operate a food establishment in conjunction with a special event only if the documents and other information provided pursuant to section 11-50-4, or otherwise requested by the director, are consistent with the protection of public health and the environment.

(3) The director may attach special conditions to any special event permit that, in its discretion, is reasonably necessary to mitigate any potential impact on public health or the environment associated with the special event. Any violation of a special condition shall be enforceable as a violation of this chapter.

(4) A special event permit shall be valid only for the particular dates of operation, or period(s) of operation, indicated on the special event permit, and in no event shall the particular dates or period(s) of operation indicated on any one permit cumulatively exceed thirty-one days in a three hundred sixty-five day period,

(5) Any person who operates a food establishment in conjunction with a special event shall comply with all the requirements of this chapter except sections 11-50-70, 11-50-71, 11-50-72(d)-(k), 11-50-73 and 11-50-74.

(c) Homemade food products and hand-pounded poi. Any person who operates a food establishment that produces or packages only homemade food products in a home kitchen or only produces hand-pounded poi shall be exempt from the provisions of this chapter, except that they shall remain subject to the inspection in accordance with section 11-50-8 and, the provisions of sections 11-50-10, 11-50-11, 11-50-14, and shall adhere to the following special conditions, violations of which shall constitute violations of this chapter:

(1) Obtain food safety certification in accordance with section 11-50-20(c);

(2) Ensure that a handwashing sink with appropriate cleaning compound is available at all times during food preparation



activities and is used to maintain cleanliness pursuant to sections 11-50-22(b) and (c);

(3) Label all food in accordance with the requirements of section 11-50-35(c); and

(4) Distribute food products only directly to the consumer.

(d) Exemptions. The following food establishments shall be exempt from the provisions of this chapter except that they shall remain subject to inspection in accordance with section 11-50-8 and the provisions of sections 11-50-10, 11-50-11, and 11-50-14, and shall adhere to the following special conditions, violations of which shall constitute violations of this chapter:

(1) A food establishment that is inspected by another federal, state or county regulatory agency, provided that the agency has entered into a memorandum of understanding or a memorandum of agreement with the director and the agency maintains regulatory responsibility for the establishment;

(2) A food establishment that sells or otherwise distributes only prepackaged foods that are not potentially hazardous food (time/temperature control for safety food) manufactured and packaged in a food establishment permitted by the director or otherwise approved by an equivalent agency in another jurisdiction;

(3) A food establishment that sells or otherwise distributes only pre-packaged frozen confections produced in a food establishment permitted by the department or otherwise approved by an equivalent agency in another jurisdiction;

(4) A food establishment that sells or otherwise distributes only not potentially hazardous hot beverages served directly into sanitary single-service articles; and

(5) A home kitchen operated by a child-care provider where food is served to no more than twelve children, or a home kitchen operated by an adult-care provider or bed-and-breakfast where food is served to no more than six guests, so long as the person in charge obtains food protection certification pursuant to section 11-50-20(c), food operations are limited to those risk categories enumerated in section 11-50-7(e) (1)-(4), and signage, with lettering no smaller than one inch in height, remains posted at the entrance to the kitchen within the home notifying any consumer that the food served is "Made in a home kitchen not routinely inspected by the Department of Health".

### **HI Admin Rules § 11-50-31. Source, Specifications for Receiving, Original Containers and Records.**

(a) Compliance with food law.



- (1) Food shall be obtained from sources that comply with law;
- (2) Food prepared in a private home may not be used or offered for human consumption in a food establishment;
- (3) Fish, other than those specified in section 11-50-33(e)(2), that are intended for consumption in raw or undercooked form and allowed as specified in section 11-50-33(a) (4), may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified in section 11-50-33(e); or if they are frozen on the premises as specified in section 11-50-33(e) and records are retained as specified in section 11-50-33(f);
- (4) Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in section 11-50-33(a)(3) shall be:
  - (A) Obtained from a food processing plant that, upon request by the purchaser, packages the steaks and labels them, to indicate that the steaks meet the definition of whole-muscle, intact beef; or
  - (B) Deemed acceptable by the director based on other evidence, such as written buyer specifications or invoices, that indicates that the steaks meet the definition of whole-muscle, intact beef; and
  - (C) If individually cut in a food establishment:
    - (i) Cut from whole-muscle intact beef that is labeled by a food processing plant as specified in subparagraph (A) or identified as specified in subparagraph (B);
    - (ii) Prepared so they remain intact; and
    - (iii) If packaged for undercooking in a food establishment, labeled as specified in subparagraph (A) or identified as specified in subparagraph (B).
- (5) Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(1) and 9 CFR 381.125(b);
- (6) Eggs that have not been specifically treated to destroy all viable Salmonellae shall be labeled to include safe handling instructions as specified in law, including 21 CFR 101.17(h).

(b) Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.



(c) Fluid milk and milk products shall be obtained from sources that comply with Grade A Standards as specified in law.

(d) Fish.

(1) Fish that are received for sale or service shall be:

(A) Commercially and legally caught or harvested; or

(B) Approved for sale or service;

(2) Molluscan shellfish that are recreationally caught may not be received for sale or service.

(e) Molluscan shellfish.

(1) Molluscan shellfish shall be obtained from sources according to law or the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish;

(2) Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

(f) Wild mushrooms.

(1) Except as specified in paragraph (2), mushroom species picked in the wild shall not be offered for sale or service by a food establishment unless the food establishment has been approved to do so by the department;

(2) This section does not apply to:

(A) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or

(B) Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

(g) Game animals. If game animals are received for sale or service they shall be:

(1) Commercially raised for food and:

(A) Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction; or

(B) Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction; and



(C) Raised, slaughtered, and processed according to:

(i) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program; and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;

(2) Under a voluntary inspection program administered by the USDA for game animals such as exotic animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR 352, entitled "Exotic animals and horses; voluntary inspection" or rabbits that are "inspected and certified" in accordance with 9 CFR 354, entitled "Voluntary inspection of rabbits and edible products thereof";

(3) As allowed by law, for wild game animals that are live caught:

(A) Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction; and

(B) Slaughtered and processed according to:

(i) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program; and

(ii) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee; or

(4) As allowed by law, for field-dressed wild game animals under a routine inspection program that ensures the animals:

(A) Receive a postmortem examination by an approved veterinarian or veterinarian's designee; or

(B) Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program; and

(C) Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.



(h) Temperature when received.

- (1) Except as specified in paragraph (2), refrigerated, potentially hazardous food (time/temperature control for safety food) shall be at a temperature of forty-one degrees Fahrenheit or below when received;
- (2) If a temperature other than forty-one degrees Fahrenheit for a potentially hazardous food (time/temperature control for safety food) is specified in law governing its distribution, such as laws governing milk and molluscan shellfish, the food may be received at the specified temperature;
- (3) Raw eggs shall be received in refrigerated equipment that maintains an ambient air temperature of forty-five degrees Fahrenheit or less;
- (4) Potentially hazardous food (time/temperature control for safety food) that is cooked to a temperature and for a time specified in section 11-50-33(a) to (c) and received hot shall be at a temperature of one hundred thirty-five degrees Fahrenheit or above;
- (5) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen;
- (6) Upon receipt, potentially hazardous food (time/temperature control for safety food) shall be free of evidence of previous temperature abuse.

(i) Food may not contain unapproved food additives or additives that:

- (1) Exceed amounts specified in 21 CFR 170-180 relating to food additives;
- (2) Generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181-186;
- (3) Substances that exceed amounts specified in 9 CFR Subpart C Section 424,21(b), entitled "Food ingredients and sources of radiation"; or
- (4) Pesticide residues that exceed provisions specified in 40 CFR 180, entitled "Tolerances and exceptions for pesticide chemical residues in food".

(j) Eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in United States Standards, Grades, and Weight Classes for Shell Eggs, AMS 56.200 et seq., administered by the Agricultural Marketing Service of USDA.

(k) Eggs and milk products, pasteurized.

- (1) Egg products shall be obtained pasteurized;
- (2) Fluid and dry milk and milk products shall:
  - (A) Be obtained pasteurized; and



- (B) Comply with Grade A Standards as specified in law;
- (3) Frozen milk products, such as ice cream, shall be obtained pasteurized as specified in 21 CFR 135, entitled "Frozen desserts".
- (4) Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified in the CFR, such as 21 CFR 133, entitled "Cheeses and related cheese products", for curing certain cheese varieties.
- (l) Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.
- (m) Ice for use as a food or a cooling medium shall be made from drinking water.
- (n) Shucked shellfish, packaging and identification.
- (1) Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the:
- (A) Name, address, and certification number of the shucker, packer, or repacker of the molluscan shellfish; and
- (B) The "sell by" or "best if used by" date for packages with a capacity of less than one-half gallon or the date shucked for packages with a capacity of one-half gallon or more;
- (2) A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified in paragraph (1) shall be subject to a hold order, as allowed by law, or seizure and destruction.
- (o) Shellstock identification.
- (1) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester or dealer that depurates, ships, or reships the shellstock, as specified in state rules or the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and:
- (A) Except as specified in paragraph (3), the harvester's tag or label shall list the following information in the following order:
- (i) The harvester's identification number that is assigned by the shellfish control authority;
- (ii) The date of harvesting;
- (iii) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area



designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested;

(iv) The type and quantity of shellfish; and

(v) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days"; and

(B) Except as specified in paragraph (4), each dealer's tag or label shall list the following information in the following order:

(i) The dealer's name and address, and the certification number assigned by the shellfish control authority;

(ii) The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested;

(iii) The same information as specified for a harvester's tag in subparagraph (A)(ii) to (iv); and

(iv) The following statement in bold, capitalized type; "This tag is required to be attached until container is empty and thereafter kept on file for 90 days";

(2) A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified in paragraph (1) shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D, entitled "Specific administrative decisions regarding interstate shipments". Section 1240.60(d);

(3) If a space is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first;

(4) If the harvester's tag or label is designed to accommodate each dealer's identification as specified in paragraph (1)(B)(i) and (ii), individual dealer tags or labels need not be provided.

(p) When received by a food establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded,

(q) Juice treated. Pre-packaged juice shall:

(1) Be obtained from a processor with a HACCP system as specified in 21 CFR Part 120, entitled "Hazard analysis and critical control (HACCP) systems"; and



(2) Be obtained pasteurized or otherwise treated to attain a five-log reduction of the most resistant microorganism of public health significance as specified in 21 CFR Part 120.24, entitled "Process Controls".

(r) Molluscan shellfish, original container.

(1) Except as specified in paragraphs (2) to (4), molluscan shellfish may not be removed from the container in which they are received other than immediately before sale or preparation for service;

(2) For display purposes, shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

(A) The source of the shellstock on display is identified as specified in subsection (o) and recorded as specified in subsection (s); and

(B) The shellstock are protected from contamination;

(3) Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

(A) The labeling information for the shellfish on display as specified in subsection (n) is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

(B) The shellfish are protected from contamination;

(4) Shucked shellfish may be removed from the container in which they were received and repacked in consumer self service containers where allowed by law if:

(A) The labeling information for the shellfish is on each consumer self service container as specified in subsection (n) and section 11-50-35(b)(1) and (2)(A) to (D);

(B) The labeling information as specified in subsection (n) is retained and correlated with the date when, or dates during which, the shellfish are sold or served;

(C) The labeling information and dates specified in subparagraph (B) are maintained for ninety days; and

(D) The shellfish are protected from contamination.

(s) Shellstock, maintaining identification.



- (1) Except as specified in paragraph (3)(B), shellstock tags or labels shall remain attached to the container in which the shellstock are received until the container is empty;
- (2) The date when the last shellstock from the container is sold or served shall be recorded on the tag or label;
- (3) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for ninety calendar days from the date that is recorded on the tag or label, as specified in paragraph (2), by:
  - (A) Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date that is recorded on the tag or label, as specified in paragraph (2); and
  - (B) If shellstock are removed from its tagged or labeled container:
    - (i) Preserving source identification by using a record keeping system as specified in subparagraph (A); and
    - (ii) Ensuring that shellstock from one tagged or labeled container are not commingled with shellstock from another container with different certification numbers; different harvest dates; or different growing areas as identified on the tag or label before being ordered by the consumer.

### **HI Admin Rules § 11-50-35. Food Identity, Presentation, and On-Premises Labeling.**

#### **(a) Honestly presented.**

- (1) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer;
- (2) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food.

#### **(b) Food labels.**

- (1) Food packaged in a food establishment, shall be labeled as specified in law, including 21 CFR 101, entitled "Food labeling", and 9 CFR 317 entitled "Labeling, marking devices, and containers".
- (2) The director may waive the packaged food labeling requirement for, but not limited to:

- (A) Foods manufactured in food establishments such as restaurants, bakeries, and markets, and sold only in those food establishments;
- (B) Foods of no nutritional significance such as coffee;



(C) Bulk food for further processing; and

(D) Raw fruits, vegetables, and fish;

(3) Label information shall include:

(A) The common name of the food, or absent a common name, an adequately descriptive identity statement;

(B) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food;

(C) An accurate declaration of the quantity of contents;

(D) The name and place of business of the manufacturer, packer, or distributor; and

(E) The name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient;

(4) Bulk food that is available for consumer self-dispensing shall be prominently labeled with the following information in plain view of the consumer:

(A) The manufacturer's or processor's label that was provided with the food; or

(B) A card, sign, or other method of notification that includes the information specified in paragraph (2) (A) and (B);

(5) Bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specification need not be labeled if:

(A) A health, nutrient content or other claim is not made;

(B) There are no state or local laws requiring labeling; and

(C) The food is manufactured or prepared on the premises of the food establishment or at another food establishment or a food processing plant that is owned by the same person and is regulated by the food regulatory agency that has jurisdiction.

(c) Other forms of information.

(1) If required by law, consumer warnings shall be provided;

(2) Food establishment or manufacturers' dating information on foods may not be concealed or altered.

(3) Homemade food products shall bear a label with the following information;



- (A) A statement that reads "Made in a home kitchen not routinely inspected by the Department of Health";
- (B) The common name of the food or, if no common name exists, an adequately descriptive identity statement;
- (C) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight;
- (D) Name and contact information of the homemade food product producer;

(4) Hand-pounded poi shall bear a label that contains the following information:

- (A) A statement that reads "This hand-pounded poi was prepared in a facility not inspected by the Department of Health";
- (B) Name and contact information of the producer.

(d) Consumption of animal foods that are raw, undercooked, or not otherwise processed to eliminate pathogens.

(1) Except as specified in sections 11-50-33(a)(3) and (4)(D) and 11-50-37(a)(3), if an animal food such as beef, eggs, fish, lamb, pork, poultry, or shellfish is served or sold raw, undercooked, or without otherwise being processed to eliminate pathogens, either in ready-to-eat form or as an ingredient in another ready-to-eat food, the owner or operator shall inform consumers of the significantly increased risk of consuming such foods by way of a disclosure and reminder, as specified in paragraphs (2) and (3) using brochures, deli case or menu advisories, label statements, table tents, placards, or other effective written means;

(2) Disclosure shall include:

(A) A description of the animal-derived foods, such as "oysters on the half shell (raw oysters)", "raw-egg Caesar salad", and "hamburgers (can be cooked to order)"; or

(B) Identification of the animal-derived foods by asterisking them to a footnote that states that the items are served raw or undercooked, or contain (or may contain) raw or undercooked ingredients;

(3) Reminder shall include asterisking the animal-derived foods requiring disclosure to a footnote that states:

(A) Regarding the safety of these items, written information is available upon request;



(B) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; or

(C) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase the risk of foodborne illness especially in consumers with certain medical conditions.

