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481—34.1(137D) Definitions. As used in this chapter, unless the context otherwise requires:

"Acidified foods" means low-acid foods to which an acid or high-acid food is added. Acidified foods have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.60 or below. These foods may be called or may purport to be "pickles" or "pickled."

"Active water" or "water activity" or " (a_w) " means the measured free moisture in a food. The quotient of the water vapor pressure of the food divided by the vapor pressure of pure water at the same temperature provides the measured free moisture in the food.

"Adulterated" means the same as stated in the Federal Food, Drug and Cosmetic Act, Section 402. "Allergen cross contact" means the unintentional incorporation of a food allergen into a food.

"Contractor" means a municipal corporation, county, or other political subdivision that contracts with the department to license and inspect under Iowa Code chapter 137D. A list of contractors is maintained on the department's website.

"Cross contamination" means the inadvertent transfer of bacteria or other contaminants from one surface, substance, etc., to another, especially because of unsanitary handling procedures.

"Demonstrate control" means the ability to provide clear and convincing evidence that a home food processing establishment has implemented written standard processes and practices that are intended to control food safety hazards including but not limited to standardized recipes, standard operating procedures, personal hygiene standards, temperature monitoring records, equipment calibration records, production or batch records, sanitation records, predefined corrective actions, training documents, distribution records, and receiving records.

"Department" means the department of inspections and appeals.

"Equilibrium pH" means the final pH measured in a food after all the components of the food have achieved the same acidity.

"Fermentation" means a metabolic process in which an organism converts a carbohydrate, such as starch or a sugar, into an alcohol or an acid. For example, yeast performs fermentation by converting sugar into alcohol. Bacteria perform fermentation by converting carbohydrates into lactic acid.

"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.

"Food" means the same as defined in Iowa Code chapter 137F.

"Food contact surface" means a surface of equipment or utensil with which food normally comes into contact; or a surface of equipment or utensil from which food may drip, drain, or splash into a food or onto a surface normally in contact with food.

"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 or as poultry or fish.

- 1. "Game animal" 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 animal" does not include ratites.

"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.

"High-acid food" means a food that has an equilibrium pH of 4.60 or lower without the addition of an acid

"Home food processing establishment" means a business on the premises of a residence in which homemade food items are produced for sale or resale, for consumption off the premises, if the business has gross annual sales of less than \$50,000. However, "home food processing establishment" does not include a residence in which food is prepared to be used or sold by churches, fraternal societies, charitable organizations, or civic organizations.

"Homemade food item" means a food that is produced and, if packaged, packaged in a home food processing establishment. "Homemade food item" includes food that is not time/temperature control for safety food but does not include such food if it is produced and sold under Iowa Code section 137F.20. Homemade food items do not include the following:

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- 1. Unpasteurized fruit or vegetable juice;
- 2. Raw sprout seeds;
- 3. Foods containing game animals;
- 4. Fish or shellfish;
- 5. Alcoholic beverages;
- 6. Bottled water;
- 7. Packaged ice;
- 8. Consumable hemp products;
- 9. Food that will be further processed by a food processing plant or another home food processing establishment;
 - 10. Time/temperature control for safety food packaged using a reduced oxygen packaging method;
 - 11. Milk or milk products regulated under Iowa Code chapters 192 and 194;
- 12. Meat or meat food products, and poultry or poultry products regulated under Iowa Code chapter 189A, except for any of the following products when sold directly to the end consumer:
- Poultry, poultry byproduct, or poultry food product if the producer raised the poultry pursuant to the exemption set forth in 9 CFR 381.10(c)(1) limiting the producer to slaughtering not more than one thousand poultry during the calendar year;
- Poultry, poultry byproduct, or poultry food product if the poultry is from an inspected source exempted pursuant to 9 CFR 381.10(d); or
- Meat, meat byproduct, or meat food product if the meat is from an inspected source exempted pursuant to 9 CFR 303.1(d); or
- 13. A raw agricultural commodity. Other than raw bean or seed sprouts, raw agricultural commodities do not require a license issued by the department to sell and may be sold by home food processing establishments, although they are not homemade food items.

"Low-acid canned food" means a thermally processed low-acid food packaged in a hermetically sealed container.

"Low-acid food" means any food, other than alcoholic beverages, with a pH greater than 4.60 and (a_w) greater than 0.85.

"Made-to-order food" means foods that are customarily provided by restaurants, snack bars, cafeterias or catering operations that are regularly prepared immediately upon an order; promptly served, delivered, or otherwise provided to a consumer; and intended for immediate consumption. Made-to-order food does not include meal kits, foods that have been prepared and then cooled, or other packaged foods that are provided to the consumer in a refrigerated or frozen state.

"Major food allergen" means milk, egg, fish (such as bass, flounder, or cod), crustacean shellfish (such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, soybeans, and sesame; or a food ingredient that contains protein derived from these foods.

"Packaged" means bottled, canned, cartoned, bagged, or wrapped. "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

"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 0 and 7 indicate acidity, and values between 7 and 14 indicate alkalinity. The value for pure distilled water is 7, which is considered neutral

"Produce" means to prepare a food item by cooking, baking, drying, mixing, cutting, fermenting, preserving, freezing, dehydrating, growing, raising, or other process. "Produce" does not include the following preparation methods:

- 1. Low-acid canning;
- 2. Acidification;
- 3. Curing food; or
- 4. Smoking for preservation rather than flavor enhancement.

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"Raw agricultural commodity" means any food in its raw or natural state, including all fruits or vegetables that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

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

"Recall" means an action taken when a food producer takes a product off the market because there is reason to believe the product may cause consumers to become ill. In some situations, government agencies may request a food recall. Food recalls may happen for many reasons, including but not limited to:

- 1. Discovery of organisms, including bacteria such as Salmonella or parasites such as Cyclospora;
- 2. Discovery of foreign objects such as broken glass or metal; or
- 3. Discovery of a major allergen that does not appear on the product label.

"Reduced oxygen packaging" means reducing 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 21 percent at sea level). Reduced oxygen packaging includes vacuum packaging, modified atmosphere packaging, controlled atmosphere packaging, cook chill packaging, and sous vide packaging.

"Revoke" means to void or annul by recalling or withdrawing a license issued under Iowa Code chapter 137D. The entire application process, including the payment of applicable license fees, shall be repeated to regain a valid license following a revocation.

"Shellfish"

- 1. "Crustacean shellfish" means crab, lobster and shrimp.
- 2. "Molluscan shellfish" means any edible species of oysters, clams, mussels, or scallops.

"Special dietary use food" includes a food that contains an artificial sweetener, except when specifically and solely used for achieving a physical characteristic in the food that cannot be achieved with sugar or other nutritive sweetener. In addition, "special dietary use food" means a food that is used for the following:

- 1. Supplying particular dietary needs that exist by reason of a physical, physiological, pathological, or other condition including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
- 2. Supplying particular dietary needs that exist by reason of age including but not limited to the ages of infancy and childhood; or
- 3. Supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

"Sprouts" means seeds or beans used to grow sprouts that are harvested with their seed or root intact.

"Standardized recipe" means a recipe that has been tried, adapted, and retried several times for use by a given food service operation and has been found to produce the same good results and yield every time when the exact procedures are followed with the same type of equipment and same quantity and quality of ingredients. At a minimum, a standardized recipe includes the recipe name, listing of each ingredient, a measurement of each ingredient, equipment and utensils used, preparation instructions, and procedures to ensure the safety of the food.

"Suspend" means to render a license issued under Iowa Code chapter 137D invalid for a period of time, with the intent of resuming the validity of a license at the end of that period.

"Time/temperature control for safety" or "TTCS" means a food that requires time and temperature control for safety to limit pathogenic microorganism growth or toxin formation. TTCS food does not include foods that have an equilibrium pH less than 4.60 or an active water (a_w) content below 0.85. Examples of TTCS foods include:

- 1. Animal food that is raw or heat-treated.
- 2. Plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes, or garlic-in-oil mixtures.

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"Traceback" means to determine and document the distribution and production chain, and the source(s) of a product that has been implicated in a foodborne illness investigation.

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