

*Effective Date*

This rule making will become effective on November 9, 2022.

The following rule-making action is adopted:

Rescind 481—Chapter 34 and adopt the following **new** chapter in lieu thereof:

CHAPTER 34

HOME FOOD PROCESSING ESTABLISHMENTS

**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 (aw) 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 “(aw)” 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:

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 (aw) 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.

“*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 (aw) 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.

“*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.

**481—34.2(137D) Licensing.**

**34.2(1)** *Application for license.* A person shall not operate a home food processing establishment until a license has been obtained from the department. Application for a license shall be made on a form furnished by the department containing the name of the business, name of the owner, physical address of the business, and list of all homemade food items the home food processing establishment intends to prepare. Applications shall be completed using the department's online application system unless extenuating circumstances exist that prevent the applicant from completing the online application. Paper applications are available from the Department of Inspections and Appeals, Food and Consumer Safety Bureau, Lucas State Office Building, Des Moines, Iowa 50319-0083, or from the department's contractors. An application for a license shall be submitted 30 days prior to the anticipated opening of the home food processing establishment.

**34.2(2)** *Homemade food item disclosure.* Homemade food items not listed on the application shall not be sold or distributed. New homemade food items may be added to an application at any time using the online application system or by submission of a paper form to the department.

**34.2(3)** *Transferability.* A license is not transferable to a new owner or location. Any change in business ownership or business location requires a new license.

**34.2(4)** *Refunds.* License fees are refundable only if the license is surrendered to the department prior to the effective date of the license. License fees are not refundable for a new home food processing establishment if an inspection has occurred.

**34.2(5)** *Expiration and renewal.* A home food processing establishment license, unless

sooner suspended or revoked, shall expire one year after the application for license is approved by the department. A home food processing establishment license shall be renewed annually through the department's online registration system, accompanied by the required fee, prior to expiration.

**34.2(6) *Renewal 60 days or more after expiration.*** A delinquent license shall only be renewed if application for renewal is made within 60 days of expiration of the license. If a delinquent license is not renewed within 60 days, an establishment shall apply for a new license and meet all of the requirements for an initial license. An establishment that has not renewed the license within 60 days of the expiration of the license shall be closed by the department or a contractor. An establishment shall not be reopened until a new license has been submitted and approved.

**34.2(7) *Documentation of gross sales.*** The license holder shall maintain documentation of annual gross sales of homemade food items. The documentation shall be provided to the regulatory authority upon request. The documentation submitted by the license holder will be kept confidential. Documentation shall include at least one of the following:

- a. A copy of the establishment's business tax return;
- b. Four quarters of gross sales of homemade food items;
- c. A letter from an independent tax preparer; or
- d. Other records documenting annual gross sales of homemade food items.

**34.2(8) *Returned payments.*** The department will attempt to redeem a payment submitted for an establishment that is not honored by the bank on which it is drafted. The department will notify the applicant of the need to provide sufficient payment. An additional fee of \$25 shall be assessed for each dishonored payment. If the department does

not receive payment, the establishment will be operating without a valid license.

**481—34.3(137D) Physical facilities and equipment.**

**34.3(1)** The floors, walls, ceilings, utensils, equipment, and supplies in the food processing and storage areas, and all vehicles used in the transportation of homemade food items, shall be maintained clean and in good repair.

**34.3(2)** Outer openings shall be protected by tight fitting doors, windows, or screens.

**34.3(3)** Dogs, cats, or other pets and animals shall be excluded from entering rooms where food is being processed or packaged.

**34.3(4)** Persons unnecessary to the production of homemade food items may not be allowed in food processing areas while homemade food items are exposed or being produced.

**34.3(5)** Adequate lighting and ventilation shall be available in all areas where food is processed or stored.

**34.3(6)** An establishment shall have an adequate supply of hot and cold potable water under pressure from an approved and safe source. In addition:

- a.* There shall be no direct or indirect connection of safe and unsafe water;
- b.* If the residence is not served by a public water system, the water shall be tested at least annually for nitrates and coliforms;
- c.* In the event a water test shows coliforms are present or nitrates are at an unsafe level, the home food processing establishment shall cease operations and notify the regulatory authority. The home food processing establishment may not resume operations until approved by the regulatory authority; and
- d.* In the event a home food processing establishment's water source is under a water

advisory indicating the water may be unsafe to consume, the home food processing establishment shall not produce homemade food items until the advisory is lifted.

**34.3(7)** There shall be a conveniently located sink in each food processing area that is maintained clean and accessible for handwashing during production and packaging. The sink shall be supplied with hot and cold running water, hand soap, and sanitary towels.

**34.3(8)** An establishment shall have adequate equipment, such as a sink or dishwasher, to wash, rinse, and sanitize utensils.

**34.3(9)** An establishment shall have proper and conveniently located toilet facilities, equipped with a hand-washing sink, complete with hot and cold potable water under pressure and hand soap. A supply of sanitary towels or a hand-drying device providing heated air shall be conveniently located near the hand-washing sink.

**34.3(10)** All waste and waste water produced by the home food processing establishment shall be disposed of in a sanitary manner in compliance with applicable laws. In the event the home food processing establishment has a waste backup, the home food processing establishment shall cease operation and notify the regulatory authority. The home food processing establishment may not resume preparation of homemade food items until approved by the regulatory authority.

**34.3(11)** All garbage and refuse shall be kept in containers and removed from the premises regularly to eliminate insects and rodents, offensive odors, or other health hazards. Garbage and refuse containers shall be durable, easy to clean, insect- and rodent-resistant, and of material that neither leaks nor absorbs liquid.

**34.3(12)** Food processing and storage areas shall be free of pests. Pesticides, if used, shall be approved for use in commercial food establishments, clearly labeled, and used as

directed by the manufacturer.

**34.3(13)** Hazardous chemicals or other toxic materials shall be stored, applied and used as directed by the manufacturer in a manner that protects food, equipment, and food contact surfaces from contamination.

**34.3(14)** Refrigeration design and capacity shall be adequate to maintain safe temperature control including safe cooling temperatures, prevent cross contamination, prevent allergen cross contact, and protect food from other sources of contamination. Dedicated refrigeration may be required for homemade food items if shared refrigeration equipment is inadequate to maintain the food safety required by this rule.

**34.3(15)** All refrigeration units shall be equipped with an accurate thermometer.

**34.3(16)** Appropriate thermometers shall be used to accurately measure the internal temperature of food during processing and storage.

**34.3(17)** All food contact surfaces shall be intended for use with food, made of safe materials, easy to clean, smooth, nonabsorbent, and noncorrosive.

#### **481—34.4(137D) Management and personnel.**

**34.4(1)** *Person in charge.* There shall be a person in charge of operations during all hours of food processing who has a thorough understanding of food safety principles and is able to demonstrate control over food safety hazards including:

- a.* Time/temperature controls for cooking, hot holding, cooling, cold holding, and reheating foods;
- b.* Cross contamination during storage and preparation;
- c.* Major food allergens and allergen cross contact;
- d.* Sanitation of food contact surfaces;

- e. Food handling, hygienic practices, and communicable diseases;
- f. Receiving and distribution; and
- g. If applicable, pH and (aw).

**34.4(2) *Food safety training.*** The person in charge shall attend a food safety training course approved by the department and provide proof of attendance prior to the issuance of a home food processing establishment license.

**34.4(3) *Exclusions from handling food.*** Food handlers shall be excluded from handling food, utensils, or packaging materials in the following instances:

- a. If they are diagnosed with a communicable or contagious disease that can be transmitted through food;
- b. If they have experienced diarrhea or vomiting in the past 24 hours;
- c. If they are jaundiced;
- d. If they have a sore throat with a fever; or
- e. If they have exposed sores or infected wounds on their hands or arms.

**34.4(4) *Hygienic practices.***

- a. All food handlers must keep themselves and their clothing clean, hair must be effectively restrained, and hands must be washed as often as necessary to protect food and food contact surfaces from contamination;
- b. Ready-to-eat foods must not be handled with bare hands; and
- c. Eating, drinking, and use of tobacco is prohibited in food processing areas while homemade food items are exposed or being produced.

**481—34.5(137D) Receiving, storage, and distribution.**

**34.5(1) *Receiving.*** All foods and ingredients shall be obtained from an approved source,

and those foods shall have been produced in compliance with applicable law. Honey from an unlicensed establishment and eggs from the home food processing establishment's own flock may be used in the preparation of homemade food items. All food shall be received in sound condition; at safe temperatures; free from spoilage, filth, or other contamination; unadulterated; and safe for human consumption.

**34.5(2) Storage.** Food storage areas shall be clean and located in an area which protects the food from contamination at all times. All food products shall be stored off of the floor. If removed from the original container, foods shall be stored in labeled and closed containers. Containers shall be of a material that will not cause the food to become adulterated.

**34.5(3) Distribution.**

*a.* Foods containing raw or undercooked foods of animal origin may not be sold or distributed in a ready-to-eat form.

*b.* Foods produced in a home food processing establishment shall not be distributed for further processing by a food processing plant or another home food processing establishment.

*c.* Time/temperature control for safety homemade food items shall not be distributed or otherwise provided to a business or end consumer at any temperature above 41°F.

*d.* A home food processing establishment shall not distribute made-to-order foods.

*e.* Time/temperature control for safety homemade food items shall be maintained at or below 41°F during shipping and transportation.

*f.* No one may produce, distribute, offer for sale, or provide adulterated food to the public. Adulterated food shall be disposed of in a reasonable manner as determined by the

department.

**481—34.6(137D) Food preparation and protection.**

**34.6(1) *Food protection.*** Foods shall be processed, stored, and distributed in a manner that protects food from contamination, including cross contamination and contamination from the environment. Foods containing one or more major food allergens shall be processed, stored, and distributed in a manner that prevents allergen cross contact.

**34.6(2) *Cooking.*** All animal foods or foods containing animal products, if cooked, shall be cooked to an internal temperature sufficient to destroy organisms which are injurious to health. Homemade food items shall not contain raw or undercooked animal foods except for packaged raw meat or poultry items labeled with safe handling instructions informing the consumer how to safely store, prepare, and handle raw meat and poultry products in the home.

**34.6(3)  *Holding.*** All time/temperature control for safety foods shall be held at an internal temperature of 41°F or less or 135°F or higher to control bacterial growth or toxin formation.

**34.6(4) *Cooling.***

*a.* Time/temperature control for safety foods that have been heat-treated shall be cooled from 135°F to 70°F within two hours and from 70°F to 41°F within an additional four hours. Total cooling time shall not exceed six hours.

*b.* Time/temperature control for safety foods prepared with ingredients above 41°F shall be cooled to 41°F or below within four hours from the beginning of preparation.

**34.6(5) *Reheating.***

*a.* Homemade food items that are time/temperature control for safety and have been

previously heated and cooled shall be reheated to an internal temperature of 165°F within two hours or less.

*b.* Commercially processed time/temperature control for safety foods shall be reheated to 135°F within two hours or less.

**34.6(6) Preparation methods.**

*a.* High-acid foods that are produced and sold under the home food processing establishment license and that are controlled by pH such as barbeque sauce, condiments, and dressings may be produced as homemade food items if:

- (1) The products have been produced following a standardized recipe;
- (2) The product does not contain more than 10 percent low-acid food ingredients by weight;
- (3) The product recipe including the name and weight of each ingredient is submitted and approved by the regulatory authority;
- (4) The equilibrium pH of each batch is tested with a calibrated pH tester designed for use with food. The pH shall be below 4.60, and the pH value shall be recorded on a production or batch record; and
- (5) The product is adequately heated to destroy spoilage organisms.

*b.* Dried foods that are produced and sold under the home food processing establishment license that are controlled by active water (aw) such as dehydrated or freeze-dried food may be produced as a homemade food item if:

- (1) The products have been produced following a standardized recipe;
- (2) The homemade food items do not contain raw or undercooked foods of animal origin;

(3) Each batch is tested for active water (aw) or the standardized written procedure for each homemade food item has been validated to ensure the final product is at or below 0.85 (aw).

*c.* Jams, jellies, preserves, and fruit butters that are produced and sold under the home food processing establishment license shall meet the standard of identity specified in 21 CFR Part 150 and be produced following a standardized recipe. The home food processing establishment shall provide documentation, such as an analysis from an accredited food laboratory, that a product meets the standard of identity when requested by the regulatory authority.

*d.* Nonstandardized fruit jellies shall be produced following a standardized recipe and made with 45 parts of fruit to 55 parts of sugar and concentrated to 65 percent soluble solids. The home food processing establishment shall provide documentation, such as an analysis from an accredited food laboratory, that a product meets this requirement when requested by the regulatory authority.

*e.* Nonstandardized nonfruit jellies shall be produced following a standardized recipe and shall have a soluble solids content of 65 percent. The home food processing establishment shall provide documentation, such as an analysis from an accredited food laboratory, that a product meets this requirement when requested by the regulatory authority.

*f.* Standardized sweeteners and table syrups shall meet the standard of identity specified in 21 CFR Part 168. The home food processing establishment shall provide documentation that a product meets this requirement when requested by the regulatory authority.

g. A home food processing establishment that wishes to prepare foods using fermentation shall submit a HACCP plan to the department that has been validated by a recognized process authority. A list of recognized process authorities is maintained on the department's website. A home food processing establishment shall not ferment food until the department has approved the HACCP plan.

h. A home food processing establishment shall not engage in the following processes to produce homemade food items:

- (1) Low-acid canning (e.g., canned vegetables);
- (2) Acidification to produce shelf-stable acidified foods (e.g., salsa, pickled vegetables, hot sauce);
- (3) Curing (e.g., bacon, jerky, meat sticks); or
- (4) Smoking food for preservation rather than flavor enhancement.

#### **481—34.7(137D) Packaging and labeling requirements.**

**34.7(1)** *Legible labels.* All required labeling information shall be legibly written or printed on the label in a location that is easily identifiable by the consumer.

**34.7(2)** *Labels and packaging on homemade food items, exception.* A homemade food item shall be packaged in the home food processing establishment, and all required labeling shall be affixed to the homemade food item before it is delivered to the consumer, with the exception of a homemade food item picked up by the consumer in person at the home food processing establishment. In the case of the exception, the homemade food item shall still be protected from contamination and all required labeling information shall be provided to the consumer.

**34.7(3)** *Raw meat and poultry products.* Packaged homemade food items that contain

raw meat or poultry shall be labeled with safe handling instructions informing the consumer how to safely store, prepare, and handle raw meat and poultry products in the home.

**34.7(4) *Expiration date.*** Refrigerated time/temperature control for safety homemade food items that are ready-to-eat foods shall be labeled with an expiration date not to exceed seven days from the date of preparation, and the date of preparation is counted as day one. Time/temperature control for safety homemade food items may be labeled with an expiration date that exceeds seven days if the expiration date has been determined to be safe by an accredited food science institution and documentation is provided to the regulatory authority upon request.

**34.7(5) *Contents.***

*a.* A home food processing establishment shall label homemade food items with all of the following information:

(1) The name or license number of the home food processing establishment. If the name used on the label is different from the name stated on the issued home food processing establishment license, the license number shall be included in the labeling.

(2) The common or usual name of the food.

(3) The ingredients (including sub-ingredients) of the homemade food item in descending order of predominance by weight.

(4) The net quantity of contents (weight, volume, or numeric count).

(5) For refrigerated time/temperature control for safety foods, an expiration date based on food safety.

(6) The following statement: “This product was produced at a home food processing establishment.”

(7) If the homemade food item contains one or more major food allergens, an additional allergen statement identifying each major allergen contained in the food by the common name of the allergen.

(8) Labeling statements. Labels or other marketing materials associated with homemade food items must be truthful and not misleading.

*b.* Claims on labels or other marketing materials associated with homemade food items that are related to the following must conform to the United States Food and Drug Administration's (FDA's) Food Labeling Guide. A link to the labeling guide may be found on the department's website or on the FDA's website.

(1) Health claims;

(2) Qualified health claims;

(3) Nutrient content claims (i.e., low sodium, high fiber, low fat, sugar free); or

(4) Structure/function claims.

*c.* Homemade food items labeled or marketed as a special dietary use food must conform to 21 CFR Part 105. The home food processing establishment shall provide documentation, such as a nutritional analysis by an accredited food laboratory, to the regulatory authority upon request.

*d.* Labels or other marketing materials shall not contain any claims that the homemade food item can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

#### **481—34.8(137D) Sanitation.**

**34.8(1)** There shall be sufficient means to clean, rinse, and sanitize all multi-use food contact surfaces. Cleaners and sanitizers used for these purposes shall be intended and approved for use in a commercial food establishment.

**34.8(2)** All food contact surfaces shall be clean to sight and touch when not in use.

**34.8(3)** All food contact surfaces shall be cleaned and sanitized:

- a.* Between each use;
- b.* At least every four hours if under continuous use to control microbial growth;
- c.* At a frequency necessary to prevent cross contamination; and
- d.* At a frequency necessary to prevent allergen cross contact.

**34.8(4)** If chemical sanitizers are used, they shall be used according to the manufacturer directions for use and a means shall be provided for testing the proper level of chemical concentration, such as test strips designed specifically for the chemical being used.

**34.8(5)** Food processing, handling, and storage areas shall be neat; clean; and free from excessive accumulation of product, dust, trash, and unnecessary articles.

**481—34.9(137D) Maintenance of records by licensee.**

**34.9(1)** A home food processing establishment shall maintain standardized recipes for each homemade food item.

**34.9(2)** For recall and traceback purposes, a home food processing establishment shall maintain production or batch records that include, at a minimum, product name, date of production, and date of packaging.

**34.9(3)** For recall and traceback purposes, a home food processing establishment shall maintain records of foods received as ingredients. Records shall include, at a minimum, the name and address of the supplier, name of the ingredient, and date received. A receipt of purchase is a sufficient record if it contains all of the required information.

**34.9(4)** For recall and traceback purposes, a home food processing establishment shall maintain distribution records of all homemade food items that are distributed for resale.

The distribution records shall contain the product name, the name and address of the business where the homemade food items were distributed, the date distributed, the quantity distributed, and the date the homemade food item was produced.

**34.9(5)** A license holder whose home food processing establishment is not served by a public water system shall maintain records of annual water tests.

**34.9(6)** If the home food processing establishment produces homemade food items that require food safety parameters to be monitored throughout production, such as temperature, pH, or (aw), the testing instruments shall be used as directed by the manufacturer and calibrated for accuracy according to the manufacturer's instructions. Monitoring results shall be documented as part of the batch record.

**34.9(7)** A license holder shall maintain all required records for a minimum of six months. All required records shall be made available for official review or copying upon request by the regulatory authority.

**481—34.10(137D) Violations and enforcement.**

**34.10(1)** All violations shall be corrected within a time frame not to exceed 90 days. The license holder shall make a written report to the regulatory authority, stating the action taken to correct the violation, within five days of correction.

**34.10(2)** Violation of these rules or any provision of Iowa Code chapter 137D shall be subject to a civil penalty in the amount of \$100 per violation. Each day that the violation continues constitutes a separate violation.

**34.10(3)** The department may employ various remedies if violations are discovered including, but not limited to:

- a.* Suspension or revocation of the license;

- b. Issuance of a civil penalty;
- c. Injunction; or
- d. Issuance of an embargo, a stop-sale, or recall orders.

**481—34.11(137D) Denial, suspension, or revocation of license.**

**34.11(1)** *Denial, suspension, or revocation of a license.* Unless otherwise stated, notice of denial, suspension, or revocation of a license will be provided by the department and shall be effective 30 days after mailing or personal service of the notice. The department may suspend or revoke a license issued pursuant to this chapter if any of the following occurs:

- a. The home food processing establishment does not conform to a provision of this chapter or a rule adopted pursuant to this chapter.
- b. The license holder conducts an activity constituting a criminal offense in the home food processing establishment and is convicted of a serious misdemeanor or a more serious offense as a result. A certified copy of the final order or judgment of conviction or plea of guilty shall be conclusive evidence of the conviction of the license holder.

- c. A deferred judgment shall be considered a conviction for purposes of this rule.

**34.11(2)** *Immediate suspension of license.* To the extent not inconsistent with Iowa Code chapters 17A and 137D and rules adopted pursuant to those chapters, the department or contractor may immediately suspend a license in cases of an imminent health hazard, as defined by chapter 8 of the 2017 FDA Food Code (the “food code”). The procedures of Iowa Code section 17A.18A and chapter 8 of the food code shall be followed in cases of an imminent health hazard.

**34.11(3)** *Contesting denial, suspension, or revocation of license.* The department’s

decision to deny, suspend, or revoke a license may be contested by the adversely affected party pursuant to the provisions of rule 481—34.14(137D).

**481—34.12(137D) Inspection and access to records.**

**34.12(1)** The department shall provide for periodic inspection of a home food processing establishment, either in person or virtually through use of video technology. The inspection frequency for a home food processing establishment shall be based upon a risk assessment.

**34.12(2)** The inspector may enter the home food processing establishment at any reasonable hour to make the inspection. The department shall inspect only those areas related to preparing or storing food for sale. The manager or person in charge of the home food processing establishment shall afford free access to records and every part of the premises where homemade food items and ingredients are stored or prepared and shall render all aid and assistance necessary to enable the inspector to make a thorough and complete inspection.

**481—34.13(137D) Public examination of records.**

**34.13(1)** *Public information.* Generally, information collected by the food and consumer safety bureau and contractors is considered public information. Records are stored in computer files and are not matched with any other data system. Inspection reports are available for public viewing at [iowa.safefoodinspection.com](http://iowa.safefoodinspection.com). Other information is available for public review and will be provided when requested from the department.

**34.13(2)** *Confidential information.*

*a.* The following are examples of confidential records:

(1) Trade secrets and proprietary information including items such as formulations,

standardized recipes, processes, policies and procedures, and customer lists;

(2) Health information related to foodborne illness complaints and outbreaks;

(3) The name or any identifying information of a person who files a complaint with the department; and

(4) Other state or federal agencies' records.

*b.* A party claiming that information submitted to the department contains trade secrets or proprietary information should clearly mark those portions of the submission as confidential/trade secret.

**34.13(3)** *Other agencies' records.* For records of other state or federal agencies, the department shall refer the requester of such information to the appropriate agency.

#### **481—34.14(137D) Appeals.**

**34.14(1)** All decisions of the food and consumer safety bureau may be contested by an adversely affected party. A request for a hearing shall be made in writing to the Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083, within 30 days of the mailing or service of a decision. Appeals and hearings are controlled by 481—Chapter 9.

**34.14(2)** For contractors, license holders shall have the opportunity for a hearing before the local board of health. If the hearing is conducted before the local board of health, the license holder may appeal to the department and shall follow the process for review in rule 481—9.3(10A,17A).

These rules are intended to implement Iowa Code chapter 137D as amended by 2022 Iowa Acts, House File 2431.