

INSPECTIONS AND APPEALS DEPARTMENT[481]

Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 34
“Home Food Processing Establishments”

Iowa Code section(s) or chapter(s) authorizing rulemaking: 137D.2(8)

State or federal law(s) implemented by the rulemaking: Iowa Code chapter 137D and 2023 Iowa Acts, House File 661

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 8, 2023
9:20 a.m.

Department of Inspections, Appeals,
and Licensing
6200 Park Avenue
Des Moines, Iowa

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis. Written or oral comments in response to this Regulatory Analysis must be received by the Department of Inspections, Appeals, and Licensing no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking repromulgates Chapter 34, “Home Food Processing Establishments,” and implements Iowa Code chapter 137D and 2023 Iowa Acts, House File 661, in accordance with the goals and directives of Executive Order 10 (January 10, 2023). The rulemaking administers Iowa Code section 137D.2 by establishing an application process and standards for payments, refunds, and reporting of gross sales. It also establishes basic standards to protect food from contamination and the health of consumers, including standards related to:

- The physical structure of the home food processing establishment, pest control, equipment, water supply, waste disposal, and handling of toxic material;
- Food handlers, including food safety hazard control, training, hygiene, and communicable disease prevention;
- Food received by the establishment, storage of food in the establishment, and distribution of foods from the establishment;
- Food protection, including temperature control, pH control, and water activity control.
- Food labeling;
- Sanitation of food contact surfaces and food processing areas; and
- Record requirements intended to trace, identify, and remove from the market foods that pose an immediate public health risk.

The rules also set forth the administrative process for enforcing Iowa Code chapter 137D and 481—Chapter 34, including the process for inspections and the denial, suspension, or revocation of a license.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

Home food processing establishment license holders will bear the costs of the proposed rulemaking.

- Classes of persons that will benefit from the proposed rulemaking:

Consumers that purchase and consume homemade food items prepared under the proposed rules will benefit from the proposed rulemaking. These rules also benefit home food processing establishment license holders by providing clear, simple, and effective food safety guidelines.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

Since the proposed rules focus more on control of food safety hazards by the permit holder and less on specific physical facility and equipment requirements, the quantitative costs are minimal and will vary depending on the scope and preferences of each establishment. There is a food safety training course that is required. The one-time cost of the course can range from \$10 for a basic course to \$200 for a comprehensive course.

The rules are written in such a manner that a typical residential kitchen would meet the regulatory requirements; however, each establishment may choose to purchase additional or specialized equipment to meet the needs of each establishment. Additional food thermometers may be required beyond what a typical residential kitchen possesses, and these food thermometers can be purchased for less than \$20. While most establishments will not require a recipe evaluation, those that do will incur a cost of \$10 to \$45 per recipe. If an establishment prepares food that uses pH as a safety control, a pH meter is necessary, and these can range in cost from \$50 to several hundred dollars.

There will be some costs associated with labeling and packaging, but the rules are written in such a manner that allows flexibility and incurs minimal cost. There will also be a cost of cleaning and sanitizing supplies, but the cost of these supplies is not more than general residential cleaning and sanitizing supplies.

- Qualitative description of impact:

The Department considered food safety science and pertinent national research in the drafting of these proposed rules. The science includes established food safety parameters, such as time and temperature control, pH, water activity, and frequency of cleaning, that are known to destroy, reduce, or control spread and growth of pathogens. Studies completed by the Food and Drug Administration have shown that food operations that have developed and implemented their own food safety management systems are less likely to cause a foodborne illness.

In the development of the rules, the Department chose a more proactive food safety approach, where the rules are more focused on ensuring the operators identify and control food safety hazards in their own establishment, and to focus less on more costly physical facilities and equipment requirements that may be different, depending on the scope of each establishment. The rules have a solid food safety, science-based foundation and contain the needed operational flexibility that a small home-based establishment requires to meet business needs.

From a public health standpoint, the rules provide necessary food safety measures that can be easily implemented in a residential food establishment without requiring a large financial investment on the part of the operator. It also allows each establishment to invest when necessary if the establishment's scope and scale warrant additional investment.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

Licenses issued under this chapter account for 1.6542 percent of the Department's licensed establishment inventory and consume an equivalent percentage of the budget. This equals an annual cost of \$93,000 to implement and enforce this chapter. The Department assumes similar costs based on the specific inventories of home food processing establishments for local health departments that regulate and enforce this rule under a 28E agreement with the Department.

- Anticipated effect on state revenues:

License fees generated for establishments regulated under this chapter are expected to be \$25,000 annually. License fees are legislatively established within Iowa Code chapter 137D and are not set by rule.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The Centers for Disease Control and Prevention (CDC) estimates that each year 48 million Americans get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die. Currently, Iowa has approximately 1 percent of the U.S. population. This translates to an estimated 480,000 Iowans who get sick from a foodborne illness, including 1,280 hospitalizations and 30 deaths. An article titled "State Estimates for the Annual Cost of Foodborne Illness" published in the Journal of Food Protection in June 2015 states the estimated health cost of a foodborne illness in Iowa was \$176 per resident and \$1,154 per case in 2013. The article also used an enhanced model that included the cost of pain and suffering

that nearly doubles these figures to \$301 per resident and \$1,972 per case. Based on CDC estimates and Iowa's population, the cost of foodborne illness to the State of Iowa is staggering, even using the 2013 figures included in the article.

Preventing just 1 percent of the estimated 480,000 foodborne illnesses in Iowa could result in health cost savings for Iowans to the tune of \$5.53 million annually (\$1,154 per case x 4,800 cases = \$5.53 million). The cost savings only rise when the cost of an outbreak for the establishment is figured. An article published in Science News, dated April 16, 2018, cited a study from researchers at the Johns Hopkins Bloomberg School of Public Health. The research findings estimated that the cost of a single outbreak for a restaurant could be \$4,000 for a small outbreak when five people get sick to \$1.9 million for an outbreak when 250 people get sick.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

When the Department established the initial rules for this license in 2022, a significant effort was made to choose the least costly and least intrusive method to achieve the purpose and benefit of the rules. The rules are based on known food safety science, incorporate national studies, and are focused on ensuring individual establishments identify and control food safety hazards in individual establishments.

The least costly method to achieve public health was to establish rules that control food safety hazards without requiring an investment in commercial facilities and equipment. For instance, a residential kitchen equipped with typical residential appliances and utensils will meet the established rules. The individual establishment may choose to purchase additional or specialized equipment to meet individual business needs, but these are business decisions that are in the hands of the operator and not specifically required by the rule. Since the focus of the rules is on proactively identifying and controlling food safety hazards, much of the inspection is completed while reviewing policies, procedures, recipes and records that are developed by the operator and submitted to the agency electronically. This minimizes the time and resources required by both the operator and the agency. While there is still a public health need to conduct an inspection of the physical facilities and equipment to ensure basic standards are adequate to support safe food operations, a virtual inspection can accomplish this. Further, once a facility is able to demonstrate control over the food safety hazards in the facility's operation, less frequent inspections are necessary to ensure public health is protected.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

The Department researched and considered alternatives when establishing these rules in 2022, including home processed food sales and regulations in other states. It was determined that this chapter and the residential food operations covered in this chapter are unique to Iowa.

The Department's research showed that there are only two states, and none surrounding Iowa, that have laws allowing time/temperature control for safety foods prepared in a residential kitchen to be sold on a wholesale basis: Oregon and Wyoming. Of these two states, Oregon's law is most comparable to Iowa's Iowa Code chapter 137D in that Oregon's home kitchens are required to be licensed and inspected. Oregon's approach is that licensed "domestic kitchens" must meet Title 21 CFR Part 117, the federal regulations with which commercial food processing plants are required to comply (nationwide).

The Department considered using the Oregon approach whereby Iowa would adopt the same regulations that apply to commercial food establishments in Iowa, Title 21 CFR Part 117 or the 2017 FDA Model Food Code.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

The Department determined that some of the provisions for commercial food operations would be more difficult to apply in a residential kitchen and costlier to the licensee. Additionally, the expected scope of operations of a home food processing establishment was anticipated to be smaller in scale and focused on fewer products and processes. Accordingly, the Department chose to develop a more simplified set of rules that would protect public health, would require minimal financial investment for a license holder and could be uniformly applied in a typical residential kitchen. In addition, the rules developed by the Department are written in a straightforward and simple manner that is easy for the public to understand.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.

- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking’s compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

Home food processing establishments, as a whole, are more likely than other types of food processing establishments to be small businesses. As set forth above, the proposed rules are a less restrictive method to ensure food safety for these establishments. If a home food processing establishment identified a rule that was overly burdensome and the goals of which could be achieved in a manner that would reduce the impact on the small business, it could utilize the Department’s established waiver process.

Text of Proposed Rulemaking

ITEM 1. 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 (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 21 U.S.C. Section 342.

“*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.

“*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 same as defined in Iowa Code section 137D.1.

“*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 section 137D.1.

“*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” or “establishment” means the same as “home food processing establishment” as defined in Iowa Code section 137D.1.

“Homemade food item” means the same as defined in Iowa Code section 137D.1. 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 (a_w) greater than 0.85.

“Major food allergen” means milk, egg, fish, 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 the same as defined in Iowa Code section 137D.1.

“Raw agricultural commodity” means the same as defined in 21 U.S.C. 321.

“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.

“*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.

“*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 or 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 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.

“*Time/temperature control for safety*” or “*TCS*” means a food that requires time and temperature control for safety to limit pathogenic microorganism growth or toxin formation. TCS food does not include foods that have an equilibrium pH less than 4.60 or (a_w) content below 0.85. Examples of TCS 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 or a contractor. 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 for a license shall be completed using the department’s online application system at least 30 days prior to the anticipated opening of the home food processing establishment. If extenuating circumstances exist that prevent the applicant from completing the online application, paper applications are available from the department or a contractor.

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 or a contractor.

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 or a contractor prior to the effective date of the license. License fees are not refundable for a new home food processing establishment if a record review has occurred.

34.2(5) Expiration and renewal. A home food processing establishment license, unless sooner suspended or revoked, expires one year after the application for license is approved by the department or a contractor. A renewal should be submitted through the department’s online registration system with the required fee prior to expiration.

34.2(6) *Renewal 60 days or more after expiration.* A delinquent license will only be renewed if application for renewal is made within 60 days of expiration. 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 expiration will be closed by the department or a contractor.

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

- 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 or a contractor will attempt to redeem a payment submitted for an establishment that is not honored by the bank on which it is drafted and will notify the applicant of the need to provide sufficient payment. An additional fee of \$25 will be assessed for each dishonored payment. If the department or a contractor 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 food preparation areas when food is being processed or packaged.

34.3(4) Persons unnecessary to the production of homemade food items are not 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 establishment shall cease operations and notify the regulatory authority. The establishment will not resume operations until approved by the regulatory authority; and
- d. If the establishment's water source is under a water advisory indicating the water may be unsafe to consume, it 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 and 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) There shall be conveniently located toilet facilities, equipped with a handwashing sink supplied with hot and cold running water, hand soap and sanitary towels or a hand-drying device.

34.3(10) All waste and waste water produced by the establishment shall be disposed of in a sanitary manner in compliance with applicable laws. If the home food processing establishment has a waste backup, it shall cease operation and notify the regulatory authority. It will 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 and hot holding equipment design and capacity shall be adequate to maintain safe temperature control, including safe cooling temperatures, to prevent cross contamination and allergen cross contact and protect food from other sources of contamination. Dedicated refrigeration or hot holding equipment may be required if shared equipment is inadequate to maintain food safety.

34.3(15) All refrigeration and hot holding 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, holding, and storage.

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

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.* A food handler shall be excluded from handling food, utensils, or packaging materials if the food handler:

- a. Is diagnosed with a communicable or contagious disease that can be transmitted through food;
- b. Has experienced diarrhea or vomiting in the past 24 hours;
- c. Is jaundiced;
- d. Has a sore throat with a fever; or
- e. Has exposed sores or infected wounds on the food handler's hands or arms.

34.4(4) Hygienic practices.

- a. A food handler must keep the food handler's person and clothing clean and hair effectively restrained and wash the food handler's hands 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.
- c. Eating, drinking, and use of tobacco is not permitted 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 have been produced in compliance with applicable law. Honey from an unlicensed establishment and eggs from the 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 that 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 that are 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 will 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 be maintained at safe temperatures during shipping and transportation to an end consumer, a mobile food unit, a farmers market food establishment, or a temporary food establishment operated by the same owner as the home food processing establishment.

d. Time/temperature control for safety homemade food items sold or distributed to other businesses for resale shall be maintained at or below 41°F during shipping and transportation.

e. 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 approved 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 from the environment, and 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 that 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 by the establishment and that are controlled by pH, such as barbeque sauce, condiments, and dressings, may be produced as homemade food items if:

- (1) The product has 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 product's 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 (a_w), 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; and
- (3) Each batch is tested for (a_w) or the standardized written procedure for each homemade food item has been validated to ensure the final product is at or below 0.85 (a_w).

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, such as those provided 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 legible and 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. Homemade food items will be identified as required by Iowa Code section 137D.2(7).
b. Labels or other marketing materials associated with homemade food items must be truthful and not misleading.
c. 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 (e.g., low sodium, high fiber, low fat, sugar free); or
- (4) Structure/function claims.

d. Homemade food items labeled or marketed as a special dietary use food will 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.

e. 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) An establishment shall maintain standardized recipes for each homemade food item.

34.9(2) An establishment shall maintain production or batch records, including, at a minimum, product name, date of production, and date of packaging, with the exception of made-to-order food.

34.9(3) An establishment shall maintain records of foods received as ingredients, including, 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) An establishment shall maintain distribution records of all homemade food items that are distributed for resale, including 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) An establishment not served by a public water system shall maintain records of annual water tests.

34.9(6) An establishment, if it produces homemade food items that require food safety parameters to be monitored throughout production, such as temperature, pH, or (a_w), shall use testing instruments 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) An establishment 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) An establishment that violates this chapter or Iowa Code chapter 137D is subject to a civil penalty as set forth in Iowa Code chapter 137D.

34.10(3) The department may employ various remedies in response to violations, including but not limited to civil penalty; suspending or revoking the license; injunction; or embargo, 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.* Denial, suspension, or revocation of a license is effective 30 days after mailing or personal service of the notice. The department may suspend or revoke a license as set forth in Iowa Code section 137D.8. A certified copy of a final order or judgment of conviction or plea of guilty is conclusive evidence of a conviction.

A deferred judgment, until discharged, is 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 a 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.

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

34.12(1) Home food processing establishments will be periodically inspected based on a risk assessment basis, either in person or virtually using video technology.

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

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

34.13(1) *Public information.* Information collected by the department and contractors is public information unless otherwise provided for by law. 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.

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.* Requests for records of other state or federal agencies will be referred to the appropriate agency.

481—34.14(137D) Appeals. An establishment may contest adverse action taken pursuant to this chapter by submitting a request for hearing to the department within 30 days of the mailing or service of the department's action. Appeals and hearings are governed by 481—Chapter 9. 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.