

The National Agricultural Law Center

nationalaglawcenter.org | nataglaw@uark.edu | @nataglaw

Cottage Food Law Statutes:

Delaware



This material is based upon work supported by the National Agricultural Library, Agricultural Research Service, U.S. Department of Agriculture

A National Agricultural Law Center Research Publication Cottage Food Laws: Delaware

16 Del. Admin. Code 4458A §§ 1-9 3 Del. Admin. Code. 101 §§ 1.0-16.0

16 Del. Admin. Code 4458A §§ 1-9. Cottage Food Regulations

1.0 General Provisions

- 1.1 Preamble. These regulations shall be known as the State of Delaware Cottage Food Industry Regulations (Cottage Food Regs).
- 1.2 Purpose. Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 **Del.C.** §122. These regulations establish registration procedures and standards of practice for conducting food processing operations in home-style kitchens that safeguard public health and provide to consumers food that is safe, unadulterated and honestly presented.
- 1.3 Severability. In the event a particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect.

1.4 Exemptions

- 1.4.1 Establishments registered as food establishments in Delaware shall be exempt from the Cottage Food Regulations.
- 1.4.2 Establishments registered under these regulations shall be exempt from the Delaware Food Code.
- 1.4.3 Products offered at Bake Sales or private events as described in the definition of food establishment in the Delaware Food Code shall be exempt from these regulations.

1.5 Variance

- 1.5.1 Establishments may seek a variance from these regulations by making a request to the Delaware Division of Public Health (Division). The Division may grant a variance by modifying or waiving the requirements of these Regulations if in the opinion of the Division a health hazard or nuisance will not result from the variance.
- 1.5.2 The variance is rendered void if:
 - 1.5.2.1 Establishment undergoes renovation in the area addressed by the variance;
 - 1.5.2.2 Establishment ceases to operate for a period of greater than one year;
 - 1.5.2.3 There is a change of ownership of the establishment; or
 - 1.5.2.4 The producer relocates to a different establishment.

1.6 Inspections

1.6.1 The Division may conduct one or more preoperational inspections to verify that the cottage food establishment:

- 1.6.1.1 Is constructed and equipped in accordance with the registration application;
- 1.6.1.2 Has established standard operating procedures as specified; and 1.6.1.3 Is otherwise in substantial compliance with these Regulations.
- 1.6.2 Additional inspections may be conducted in response to complaints, reports of food-borne illness or other situations as deemed necessary by the Division.

2.0 Definitions

- "Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, \$402.
- "Approved" means acceptable to the Regulatory Authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.
- "Beverage" means a liquid for drinking, including water.
- "Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant and does not offer the food for resale.
- "Cottage Food Establishment" or "CFE" refers to facilities/locations where food items are made in a home-style kitchen for sale to and consumption by consumers.
- "Cottage Food Products" refers to a non-Time/Temperature controlled for safety food as specified in these Delaware Cottage Food Regulations that is offered for sale directly to consumers and only at a farmer's market or other approved venue.
- "Delaware Food Code" means the current State of Delaware Food Code.
- "Delaware State Registry of Cottage Food Establishments" means a list of establishments approved by the Division to sell approved products in cottage food establishments.
- "Direct Sales" means sales by the cottage food establishment that moves the products only within the State of Delaware directly to the consumer without the use of an independent retailer or other intermediary.
- "Division" means the Delaware Division of Public Health.
- "Drinking Water" means water that meets criteria as specified in 40 CFR 141
 National Primary Drinking Water Regulations. "Drinking water" is traditionally known as "potable water." "Drinking water" includes the term "water" except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.
- "Easily Cleanable" means a characteristic of a surface that: allows effective removal of soil by normal cleaning methods; is dependent on the material, design, construction, and installation of the surface; and varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

- "Employee" refers to an individual having supervisory or management duties; an individual on the payroll; a volunteer; an individual performing work under contractual agreement; or any other individual working in a cottage food establishment.
- "Equipment" means an article that is used in the operation of a food establishment such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or ware washing machine. "Equipment" does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.
- "Food-Contact Surface" means a surface of equipment or a utensil with which food normally comes into contact; or a surface of equipment or a utensil from which food may drain, drip or splash into a food or onto; or a surface normally in contact with food.
- "Food Establishment" refers to a State of Delaware food establishment where food or drink is prepared for sale or service on the premises or elsewhere; or an operation where food is served to or provided for the public with or without charge.
- "Home-style Kitchen" refers to a residential style kitchen. A residential style kitchen shall be in the permanent, primary residence of the producer.
- "Imminent Health Hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on: the number of potential injuries, and the nature, severity, and duration of the anticipated injury.
- "Major Food Allergen" means milk, egg, fish (such as bass, flounder, cod and including crustacean shellfish such as crab, lobster or shrimp), tree nuts (such as almonds, pecans or walnuts), wheat, peanuts and soybeans. This definition includes food ingredients that contain milk, eggs, fish, tree nuts, wheat, peanuts and soybeans.
- "Person" means an association, a corporation, individual, partnership, or other legal entity.
- "pH" refers to the symbol for the negative logarithm of the hydrogen ion concentration in gram equivalents per liter of solution where: pH values from 0 to 7 indicate acidity; pH values from 7 to 14 indicate alkalinity; and the pH value for pure distilled water, regarded as neutral, is 7.
- "Poisonous and Toxic Materials" means substances that are not intended for ingestion, including cleaners and sanitizers, pesticides, necessary maintenance substances, such as non-food grade lubricants, and personal care items, such as medicines, first aid supplies, cosmetics and toiletries.
- "Private Event" refers to an event restricted to organization members or another event that restricts the general public from attending.

- "Processing area" refers to the area of the Cottage Food Establishment where food prep and other food service activities occur.
- "Producer" refers to the person that manufactures cottage food products in a home-style kitchen.
- "Ready-to-eat Food" refers to food in a form that is edible without washing, cooking, or additional preparation by the food service facility or the consumer.
- "Registration Holder" means the entity that is legally responsible for the operation of the cottage food establishment such as the owner, the owner's agent, or other person; and possesses a valid registration to operate a cottage food establishment.
- "Regulatory Authority" means the Secretary, Delaware Department of Health and Social Services (DHSS), or authorized designee such as the Division of Public Health (Division).
- "Sanitization" refers to a heat or chemical treatment on cleaned food contact surfaces that is sufficient to yield a 99.999 percent reduction of the number of representative disease microorganisms of public health significance.
- "Single-service Articles" refers to an article designed, fabricated, and intended for one-time consumer use.
- "Single-use Articles" refers to an article intended by the manufacturer for onetime use by the preparer of the food.
- "Temperature Measuring Device" or "TMD" means a thermometer, thermocouple, thermistor or other device that indicates the temperature of food, air or water.
- "Time/Temperature Control for Safety Food" or "TCS" means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.
- 23 DE Reg. 52 (07/01/19)

3.0 Registration

- 3.1 Fees, Registration and Limitations
 - 3.1.1 Annual registration fees will be in the amount of \$30.00 per CFE.
 - 3.1.2 Registrations shall remain effective only during a year beginning April 1 and ending March 31 or any remaining portion of the year beginning on the date the registration is issued and ending March 31.
 - 3.1.3 Limitations
 - 3.1.3.1 CFE operating under these regulations are limited to gross annual sales of \$25,000 or less.
 - 3.1.3.2 CFE are only permitted to engage in direct sales with consumers in the State of Delaware.
 - 3.1.3.3 Online sales are not permitted. Online advertising and marketing are permitted.
 - 3.1.3.4 Wholesale or other sales to resellers or food establishments are not permitted by a CFE.
 - 3.1.3.5 A CFE shall only produce those specific food products listed on their registration. This registration shall be displayed at

farmers markets, craft fairs, charitable organization or other approved venues/functions where cottage foods are sold.

3.2 Allowable Products

- 3.2.1 Products produced in a CFE are limited to those listed on the approved list maintained by Division.
- 3.2.2 Production of food in a CFE is limited to foods that are non-TCS.
- 3.2.3 The manufacturing of baked goods shall be allowed in a CFE. Traditional bakery items include, but are not limited to: cakes, breads, cookies, rolls, muffins, brownies, fruit pies and pastries. Bakery items which as a finished product contain components (such as cream filling, meat, etc.) which meet the definition of TCS are not allowed.
- 3.2.4 The manufacturing of jams, jellies, and other fruit preserves shall be allowed in a CFE provided each product is produced in compliance with the requirements.
- 3.2.5 Candy products such as fudge, lollipops, chocolates, tortes, hard candy, and rock candy are allowed to be manufactured in a CFE provided the final products are non-TCS.
- 3.2.6 All labeling requirements set forth in subsection 8.2 must be met before the product is sold.

3.3 Application

- 3.3.1 Producers seeking registration as a CFE must submit to the Division an application demonstrating that they meet the requirements set forth in these regulations.
 - 3.3.1.1 The application shall include:
 - 3.3.1.1.1 The name, mailing address, e-mail address, telephone, and signature of the person applying for the registration and the name, mailing address, and physical address of the cottage food establishment;
 - 3.3.1.1.2 Information specifying whether the CFE is owned by an association, corporation, individual, partnership, or other legal entity;
 - 3.3.1.1.3 Information about products and processes including but not limited to products to be made, ingredients, example labels, processes and products.
 - 3.3.1.1.4 Floor plan of the processing area identifying appliances to be used, food contact surfaces (types of materials used for contact surfaces must be described,) areas for refrigeration and dry good storage, and restroom facilities.
 - 3.3.1.1.5 Proof of completion of training that satisfies Section 5.0.
 - 3.3.1.1.6 Types of venues where products will be sold.
 - 3.3.1.1.7 A statement signed by the applicant that:
 - 3.3.1.1.7.1 Attests to the accuracy of the information provided in the application,
 - 3.3.1.1.7.2 Affirms that the applicant will: comply with these Regulations, and
 - 3.3.1.1.7.3 Allows the Division access to the establishment as specified under subsection 4.1 and to the records specified under subsection 8.5.



- 3.3.2 Producers may first apply to the Division for registration as a CFE on or after October 1, 2016.
- 3.3.3 Following the submission of an application demonstrating that all requirements of these regulations have been met, up to and including the on-site inspection, the Division shall add the producer to the Delaware State Registry of Cottage Food Establishments and the producer may begin sales to consumers in accordance with these regulations.
- 3.3.4 Upon registration by the Division, a CFE and associated activities shall comply with the standards established by these regulations.
- 3.3.5 It shall be a violation of these regulations to operate in Delaware as a CFE, as defined by these regulations, if not registered with the Division.
- 3.3.6 Registration with the Division does not exempt producers or a CFE from other state, county or local codes unless specifically listed in subsection 1.4.
- 3.3.7 If the proposed CFE uses a private well as a source of potable water the well must be in compliance with State of Delaware Regulations Governing Public Drinking Water Systems.
 - 3.3.7.1 Private wells shall comply with chemical and bacteriological standards; a satisfactory analysis is required before a registration may be issued. Completion of any required sampling is the responsibility of the producers.
 - 3.3.7.2 Tests conducted within 60 days of the date of the initial or renewal application will be accepted to demonstrate compliance.
- 3.3.8 Establishments served by a public water supply and sewage systems do not require further evaluation.

3.4 Renewal

- 3.4.1 Registration must be renewed annually.
 - 3.4.1.1 A new application and registration fee is required prior to the new registration being issued.
- 3.5 Change of Ownership
 - 3.5.1 If the CFE where processing occurs undergoes a change of ownership, a new application shall be submitted and approved prior to selling any CFE products.
- 23 DE Reg. 52 (07/01/19)

4.0 Cottage Food Establishment Registrant Requirements

- 4.1 Conditions of the Cottage Food Registration
 - 4.1.1 Upon acceptance of the registration to operate a CFE issued by the Division the registration holder shall:
 - 4.1.1.1 Display the registration certificate at the farmers markets, craft fairs, charitable organization functions and any other approved venue where cottage foods are sold;
 - 4.1.1.2 Allow representatives of the Division access to the CFE during hours of operation and other reasonable times. After the Division representative presents official credentials and provides notice of the purpose of, and an intent to conduct, an

- inspection, the producer shall allow the Division representative to determine if the CFE is in compliance with these regulations by allowing access to the establishment, allowing inspection, and providing information and records to which the Division is entitled according to law;
- 4.1.1.3 Comply with the Division directives including time frames for corrective actions specified in inspection reports and other directives issued by the Division in regard to the registration holder's CFE. Comply with the conditions of a granted variance, and conditions of approved facility plans and specifications;
- 4.1.1.4 Accept notices issued and served by the Division according to the law. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with the regulations or the Division directives, including time frames for corrective actions specified in inspection reports and other directives;
- 4.1.1.5 Immediately discontinue operations and notify the Division if an imminent health hazard may exist because of an emergency such as fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger health;
- 4.1.1.6 Immediately contact the Division to report an illness of an employee who is diagnosed with Norovirus, Salmonella typhi (Typhoid fever), Shigella spp., Shiga toxin-producing E. Coli including 0157:H7, Hepatitis A virus or nontyphoidal salmonella;
- 4.1.1.7 Replace existing facilities and equipment with facilities and equipment that comply with the Code if:
 - 4.1.1.7.1 The Division directs the replacement because the surfaces and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the surfaces and equipment were accepted,
 - 4.1.1.7.2 The Division directs the replacement of the facilities and equipment because of a change of ownership, or
 - 4.1.1.7.3 The surfaces and equipment are replaced in the normal course of operation.
- 4.1.1.8 Prepare and maintain a current written contingency plan for use in initiating and affecting a recall.

5.0 Training Requirements

At least one employee during hours of operation shall be on location and have shown proficiency in food safety through passing a test that is part of a program approved by the Office of Food Protection.

6.0 Producer Requirements

- 6.1 The producer shall ensure that:
 - 6.1.1 Only approved cottage food items shall be made in the registered CFE;
 - 6.1.2 Only persons necessary to the CFE shall be allowed in the food preparation, food storage or ware washing areas during operation;
 - 6.1.3 Producers and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, or ware washing areas shall comply with these regulations;
 - 6.1.4 Producers and employees are effectively cleaning their hands, by routinely hand washing per specifications provided by the Division;
 - 6.1.5 Producers or employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by periodically evaluating foods upon their receipt:
 - 6.1.6 Producers or employees are verifying that foods delivered to the CFE during non-operating hours are from approved sources and are placed into appropriate storage locations such that they are maintained at the required temperatures, protected from contamination, unadulterated and accurately presented;
 - 6.1.7 Producers or employees are properly cooking TCS ingredients, being particularly careful in cooking those foods known to cause severe foodborne illness and death, and routinely monitor cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated;
 - 6.1.8 Producers or employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing per specifications provided by the Division;
 - 6.1.9 Producers and employees shall prevent cross-contamination of ready to eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single use gloves, or dispensing equipment;
 - 6.1.10 Producers and employees are properly trained in food safety, including food allergy awareness, as deemed by the Office of Food Protection; and
 - 6.1.11 Producers and employees are informed in a verifiable manner of their responsibility to report to the producer, information about their health and activities as they relate to diseases that are transmissible through food.

7.0 Facility Requirements

7.1 Outdoor Areas

7.1.1 Only durable, cleanable, vermin-proof refuse containers that are leak-proof and non-absorbent may be used and a means of cleaning these containers are provided. Cover or closed lids on all outdoor refuse containers are required, including dumpsters; if containers are fitted with a drainage port, a drain plug shall be used.

- 7.1.2 Outer Openings, Doors and Windows. All holes and gaps along floors, walls and roof lines shall be filled or closed.
- 7.1.3 Windows shall be tight-fitting. If windows will be opened for ventilation, inserts with 16 mesh to the inch screening shall be used.
- 7.1.4 If doors are kept open for ventilation, self-closing screened doors with 16 mesh screening will be used.

7.2 Indoor Areas

- 7.2.1 Materials that are smooth, durable and easily-cleanable shall be installed in the following areas:
 - 7.2.1.1 Food preparation; and
 - 7.2.1.2 Dry food storage.
- 7.2.2 Carpeting of any kind, shall not be used in the following areas:
 - 7.2.2.1 Food preparation; and
 - 7.2.2.2 Dry food storage.
- 7.2.3 Utility lines shall be installed inside walls, above ceiling or below floors, where possible.
- 7.2.4 Insect control devices shall not be installed over food preparation surfaces.

7.3 Artificial Interior Lighting

- 7.3.1 Provide minimum illumination intensities.
 - 7.3.1.1 At least 50 foot candles at a surface where a producer or employee is working with food or working with utensils or equipment such as knives, slicers, grinders or where the producer or employee safety is a factor.

7.4 Animals

- 7.4.1 No animals/pets shall be permitted in the CFE during the preparation, packaging, or handling of any cottage food products.
- 7.5 Poisonous and Toxic Materials
 - 7.5.1 Toxic substances shall be stored so they cannot contaminate food preparation or cooking equipment in home-style kitchen areas.
 - 7.5.2 Rodent bait shall be contained in covered, tamper-resistant bait stations. Toxic tracking powders shall not be used as a pesticide and nontoxic tracking powders shall not contaminate food, equipment or utensils.
 - 7.5.3 All medicines and first aid supplies shall be labeled and stored in a kit or container out of food preparation areas.
- 7.6 Plumbing in a Cottage Food Establishment.
 - 7.6.1 The plumbing shall meet the requirements of all municipal, county or state codes. Where there are no local codes the provision of the Division Regulations Governing a Detailed Plumbing Code.
 - 7.6.2 CFE shall have convenient access to permanent restroom facilities equipped with running potable water, paper towels and soap.

7.7 Sewage Disposal

- 7.7.1 Individual sewage disposal systems require the approval of the Department of Natural Resources and Environmental Control prior to operating the establishment.
- 7.8 Temperature Measuring Devices (TMD)



- 7.8.1 In mechanically refrigerated food storage units, TMD shall be located to measure the air temperature in the warmest part of the unit.
- 7.8.2 TMD shall be readily accessible for use in ensuring attainment and maintenance of required food temperatures.
- 7.8.3 TMD shall be accurate to $\pm 1^{\circ}$ Celsius or $\pm 2^{\circ}$ Fahrenheit to measure food temperatures.
- 7.8.4 TMD shall not have sensors constructed of glass, except if encased in shatterproof coating.
- 7.9 Refrigeration and Cold Holding Equipment
 - 7.9.1 Freezer units shall be capable of maintaining stored food solidly frozen.
 - 7.9.2 Refrigeration and cold holding units shall be capable of maintaining stored foods at 41° Fahrenheit or below.

8.0 Product Requirements

- 8.1 Testing
 - 8.1.1 When required by the Division, laboratory testing of food products shall be the responsibility of the producer.
- 8.2 Labeling
 - 8.2.1 Products shall be properly labeled with the following: Name of CFE, name of product, name, address, phone number and email of CFE, net weight or unit count, date of production / lot number.
 - 8.2.2 Labels shall include a list of ingredients in decreasing order by weight. If the product label is too small to allow for printing of ingredients, the list shall be available at the request of the consumer.
 - 8.2.3 Labels shall include the name of the food source for each major food allergen contained in the food unless the food source is already part of the common or usual name of the respective ingredient.
 - 8.2.4 Labels shall include the following statement: "This food is made in a Cottage Food Establishment and is NOT subject to routine Government Food Safety Inspections".
 - 8.2.5 Labels shall be printed in at least 10-point type in a color that provides a clear contrast to the background label.
 - 8.2.6 Additional information as required by the Division must be made available for review upon request from the consumer.
- 8.3 Packaging
 - 8.3.1 The immediate food contact surface of any product packaging material shall be food grade in quality, and therefore meet the food safety requirements of 16 **Del.C.** Ch. 33.
- 8.4 Recall Plan
 - 8.4.1 The CFE shall:
 - 8.4.1.1 Prepare and maintain a current written contingency plan for use in initiating and affecting a recall of products;



- 8.4.1.2 Use sufficient coding of regulated products to make possible positive identification and to facilitate effective recall of all violative lots; and
- 8.4.1.3 Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records shall be maintained for 3 years.
- 8.5 Reporting and Records
 - 8.5.1 A CFE must maintain records for each batch of product indicating type of finished product, date of production, lot number, and date and location of sales. These records shall be maintained for 3 years.

9.0 Compliance and Enforcement Procedures

- 9.1 A person may not operate a CFE without a valid registration to operate issued by the Division.
- 9.2 General
 - 9.2.1 If the Division determines that a CFE is operating without a valid registration: that one or more conditions exist which represent an imminent health hazard; or that serious violations, repeat violations, or general unsanitary conditions are found to exist, administrative action may occur. Administrative action will be conducted in accordance with the following:
 - 9.2.1.1 Operation without a registration
 - 9.2.1.1.1 Immediate Closure Order. If a CFE is found operating without a registration as required by subsection 9.1 of this regulation, the Division shall order the establishment immediately closed.
 - 9.2.1.1.2 Notice of Closure. The closure shall be effective upon receipt of a written notice by the producer or employee of the CFE. A closure notice statement recorded on the inspection report by a representative of the Division constitutes written notice.
 - 9.2.1.1.3 Duration of Closure. The food establishment shall remain closed until a registration application; applicable fees and any required plans have been received and approved by the Division.
 - 9.2.1.2 Imminent Health Hazard(s)
 - 9.2.1.2.1 Registration suspension without Hearing. If some condition is determined to exist in a CFE which presents an imminent health hazard to the public, the Division may suspend the registration of the CFE without a prior hearing. The suspension shall be effective upon receipt of written notice by the producer or employee of the CFE. A Suspension statement recorded on an inspection report by the Division constitutes written notice.
 - 9.2.1.2.2 A registration suspended pursuant to subsection 9.2.1.2.1 shall not be suspended for a period longer than ten (10) government business days without a hearing. Failure to hold a hearing within the ten (10) government business day period shall automatically terminate the suspension.

- 9.2.1.3 Serious Violations, Repeat Violations and General Unsanitary Conditions. When conditions exist in a CFE that represent serious violations, repeat violations or general unsanitary conditions, the Division may initiate a corrective action plan.
- 9.3 In response to the order to close, the facility may:
 - 9.3.1 Take no action, in which case the order to close shall remain in effect.
 - 9.3.2 Take action to correct the unsafe and unsanitary practices identified during the survey.
 - 9.3.2.1 The facility may submit evidence through a written plan of correction showing that the deficient practices, identified during the investigation, have been addressed and corrected.
 - 9.3.2.1.1 A change of location for the facility does not nullify an order to close and an acceptable plan of correction must still be submitted.
 - 9.3.2.2 The Department shall determine if the plan of correction is acceptable.
 - 9.3.2.3 Once accepted, the Department shall schedule a revisit as soon as possible.
 - 9.3.3 Request, in writing, an administrative hearing with the Secretary of the Department to contest the order to close.
 - 9.3.3.1 Such request must be received within 20 calendar days from the date on which the order to close was issued.
 - 9.3.3.1.1 As soon as possible, but in no event later than 60 calendar days after the issuance of the closure order, the Department shall convene a hearing on the reasons for closure.
 - 9.3.3.1.2 The Department shall make a determination based upon the evidence presented.
 - 9.3.3.1.2.1 A written copy of the determination and the reasons upon which it is based shall be sent to the facility within 30 calendar days.
 - 9.3.3.1.3 A facility may request an expedited hearing.
 - 9.3.3.1.3.1 The Department shall schedule the hearing on an expedited basis provided that the Department receives the facility's written request for an expedited hearing within five (5) calendar days from the date on which the facility received notification of the Department's decision to close the facility.
 - 9.3.3.1.3.2 The Department shall convene an expedited hearing within 15 calendar days of the receipt by the Department of such a request.
 - 9.3.3.1.3.3 The Department shall make a determination based upon the evidence presented.
 - 9.3.3.1.3.4 A written copy of the determination and the reasons upon which it is based shall be sent to the facility within 30 calendar days.
 - 9.3.3.2 During an administrative hearing:
 - 9.3.3.2.1 The facility has the right to be represented by counsel.
 - 9.3.3.2.2 All statements made shall be under oath.

- 9.3.3.2.3 The facility has the right to examine and cross-examine witnesses.
- 9.3.3.2.4 A stenographic recording will be made by a qualified court reporter. At the request and expense of any party, such record shall be transcribed with a copy to the other party.
- 9.3.3.2.5 The decision of the Department shall be based upon sufficient legal evidence. If the charges are supported by such evidence, the Department may continue, modify or revoke the closure order.
- 9.3.3.3 Upon reaching its conclusion of law and determining an appropriate disciplinary action, the Department shall issue a written decision and order in accordance with §10128 of Title 29.
- 9.3.3.4 All decisions of the Department shall be final and conclusive. Where the facility is in disagreement with the action of the Department, the facility may appeal the Department's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the facility. The appeal shall be on the record to the Superior Court and shall be as provided in §§10142 10145 of Title 29.

9.3.4 Examination of Food

- 9.3.4.1 Food may be examined or sampled by the Division as often as necessary for enforcement of this regulation.
- 9.3.4.2 All food shall be wholesome and free from spoilage. Food that is spoiled or unfit for human consumption shall not be kept on the premises. The establishment administrative procedures for the implementation and enforcement of the provision of Chapter 33 of Title 16 of the Delaware Code, relating to the embargo of misbranded or adulterated food, and penalties shall be applicable to this section.

9.4 Penalties

- 9.4.1 Operation in Violation of Regulation
 - 9.4.1.1 Any person (or responsible office of that person) who violates a provision of this Regulation, and any person (or responsible officer of that person) who is the holder of a permit or who otherwise operates a food establishment that does not comply with the requirements of this Regulation shall be subject to the penalties found in Section 107 of Title 16 of the Delaware Code.
- 9.4.2 Refusal, Failure or Neglect to Comply with Order of the Division
 - 9.4.2.1 Whoever violates this chapter or refuses, neglects or fails to comply with this chapter shall, for the first offense, be fined not less than \$25 nor more than \$100, for the second offense not less than \$100 nor more than \$150.
 - 9.4.2.2 If any person engaged in the canning business within the provisions of this chapter is convicted a third time for any violation of this chapter, the Superior Court may close the factory in which such third offense is committed, and the person convicted may be prohibited from engaging in the canning business until further order of the Court.

9.5 Injunction. The Division may seek to enjoin violations of the Regulation.

20 DE Reg. 176 (09/01/16); 23 DE Reg. 52 (07/01/19)

3 Del. Admin. Code. 101 §§ 1.0-16.0. On-Farm Home Processing of Non-Potentially Hazardous Foods

1.0 Authority

This regulation is written under the authority of Title 3, Chapters 1 and 3, and Sections 101 and 302 of the Delaware Code.

2.0 Purpose

This regulatory foundation establishes standards of practice for on-farm home food processing operations that safeguard public health and provide consumers with food that is safe, unadulterated, and honestly presented.

3.0 Scope

This regulatory foundation sets forth definitions, describes operator qualifications, establishes operational food safety and physical facility requirements, and provides the regulatory authority with procedures to ensure compliance with this foundation.

4.0 Construction

- 4.1 This regulatory foundation shall be construed and interpreted to ensure the maximum protection of the public health and to reduce the risk of foodborne illness, while exempting certain small food processors, who process and produce specified non-potentially hazardous products on-farm utilizing domestic kitchens, from the statutory requirements of Title 16 Del.C. §122 and §134, and from the regulatory requirements of State of Delaware Food Code; and the program will ensure protection of the public health through processor compliance with regulatory requirements of the On-farm Home Food Processing Program.
- 4.2 Where a conflict with local custom or usage arises, the regulatory authority will enforce this foundation in a manner that applies sound scientific principles in a consistent and impartial manner.

5.0 Definitions

The following words and terms when used in these regulations mean:

- "Acid foods" or "acidified foods" means foods that have an equilibrium pH of 4.6 or below.
- "Approved" means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.
- "Certified" means any on-farm home-based processor who has met the requirements of the Delaware Cooperative Extension Service's eight



- (8) hours of training in sanitation, cross-contamination controls, and food security.
- "Consumer" means a person who is a member of the public, takes possession of food, is not functioning as an operator of a food establishment or food processing plant, and does not offer the food for resale.
- "DDA" means the Delaware Department of Agriculture
- "Drinking water" means water that meets 40 CFR 141 National Primary Drinking Water Regulations; and is traditionally known as "potable water."
- "Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single-service items.
- "Easily cleanable" means a characteristic of a surface that allows effective removal of soil by normal cleaning methods; and is dependent on the material, design, construction, and installation of the surface; and varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.
- "Easily movable" means portable; mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.
- "Equipment" means an article that is used in a food processing operation such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine.
- "Exclude" means to prevent a person from working as a food employee or entering a food establishment, except for those areas open to the general public.
- "Farm" means a place where agricultural commodities are grown, raised, or harvested for commercial purposes. "Farm" includes a place where, for commercial purposes crops are grown and harvested; fruit, nuts, or other agricultural commodities are harvested from trees; or animals are raised, fed, and managed for meat or other agricultural commodities.
- "Farmers' market" means a physical location listed with the Delaware Department of Agriculture for the direct-to-consumer marketing of limited Delaware/Delmarva grown and produced food products.
- "Food" means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption.
- "Food-contact surface" means a surface of equipment or a utensil with which food normally comes in contact; or a surface of equipment or a utensil from which food may drain, dip, or splash into a food, or onto a surface normally in contact with food.
- "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

- "Home" means a primary residence occupied by the processor, that contains only two (2) ranges, ovens, or double-ovens, and no more than three (3) refrigerators used for cold storage. This equipment shall have been designed for home use and not for commercial use, and shall be operated in the kitchen within the residence
- "Home-based processor" means a farmer who, in the farmer's home, produces or processes whole fruit and vegetables, baked cakes, muffins, or cookies with a water activity of .85 or less, candy (non-chocolate), containerized fruit preparations consisting of jellies, jams, preserves, marmalades, and fruit butters, fruit pies with an equilibrated pH of 4.6 or less, herbs in vinegar with an equilibrated pH of 4.6 or less, honey and herb mixtures, dried fruit and vegetables, spices or herbs, maple syrup and sorghum, snack items such as popcorn, caramel corn, and peanut brittle, and roasted nuts.
- "Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury.
- "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of 3 Del.C. §§101 and 302 that any word, statement, or other information appearing on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of the article, or is easily legible through the outside container or rapper;
- "Law" means applicable local, state, and federal statutes, regulations, and ordinances.
- "On-farm home food processing operation" means a person who, on the person's farm, produces food items that are not potentially hazardous foods, which are limited to:
 - Baked breads, cakes, muffins, or cookies with a water activity of 0.85 of less
 - Candy (non-chocolate)
 - Containerized fruit preparations consisting of jellies, jams, preserves, marmalades, and fruit butters with an equilibrated pH of 4.6 or less or a water activity of 0.85 or less;
 - Herbs in vinegar with an equilibrated pH of 4.6 of less;
 - Honey and herb mixtures; and
 - Dried fruit and vegetables;
 - Spices or herbs
 - Maple syrup and sorghum
 - Snack items such as popcorn, caramel corn, and peanut brittle
 - Roasted nuts
- "On-farm market", also known as farm stands, means a site on the farm where the farmer sells agricultural and value added products



- from his farm directly to consumers at a stand or kiosk located on or near his farm or along a road near the farm.
- "Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a food establishment or a food processing plant.
- "Permit" means the document issued by the regulatory authority that authorizes a person to conduct an on-farm food processing operation.
- "Permit holder" means the entity that is legally responsible for the processing operation such as the owner or other person; and possesses a valid permit to conduct on-farm food processing operation.
- "Person" means an association, corporation, individual, partnership, or other legal entity.
- "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.
- "Plumbing fixture" means a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.
- "Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Potentially hazardous food (PHF)"

- PHF means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms; or the growth and toxin production of Clostridium botulinum; or in raw shell eggs, the growth of Salmonella enteritidis.
- "Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heat-threated; a food of plant origin that is heattreated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures
- Also included as potentially hazardous foods are low acid canned foods (vegetable, fish, meat, etc.) and acidified foods (pickled vegetables, fish, meat, eggs, etc.)
- "Potentially hazardous food" does not include an air-cooled hard-boiled egg with shell intact; a food with an aw value of 0.85 or less; a food with a pH level of 4.6 or below when measured at 24°C (75°F); a food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution; a food for which laboratory evidence demonstrates that the rapid and progressive growth of combination of barriers that inhibit the growth of microorganisms; or a food that does not support the growth of microorganisms as specified above in this definition

even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

"Premises" means the physical facility, its contents, and the contiguous land or property under the control of the permit holder; or the physical facility, its contents, and the land or property not described above in this definition, if its facilities and contents are under the control of the permit holder and may impact food operation, personnel, facilities, or operations, and a food operation is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Ready-to-eat food" means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form. "Ready-to-eat food" includes potentially hazardous food that is unpackaged and cooked to the temperature and time required; and raw, washed, cut fruits and vegetables; whole, raw fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet; and other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks, or shells are removed.

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

"Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance; and to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

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

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

"Value-added" means any activity or process that allows farmers to retain ownership and that alters the original agricultural product or commodity for the purpose of gaining a marketing advantage. Value- added may include bagging, packaging, bundling, pre-cutting, etc.

"Waste water system" means that portion of a plumbing system that normally conveys liquid waste and sewage away from the fixtures and equipment of the premises of the food operation.

"Water activity (AW)" means a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

6.0 Registration

- 6.1 In order to be able to inspect and license on-farm home food processing operation facilities that produce non-potentially hazardous foods for commercial sale, DDA will require the registration of all on-farm premises in Delaware where non-potentially hazardous foods are processed for commercial sale. This will allow facility inspection, safeguard public health, and provide consumers with food that is safe, unadulterated, and honestly presented.
- 6.2 The registration form, available from DDA, shall include at a minimum the following information:
 - 6.2.1 Name,
 - 6.2.2 Address,
 - 6.2.3 Telephone number of owner/processor,
 - 6.2.4 Type of Non-potentially hazardous foods being processed,
 - 6.2.5 The geo-reference coordinates (latitude/longitude state plane coordinates NAD 83) of the home kitchen; (if not available, DDA will provide)

7.0 License and Permits

- 7.1 The Delaware Department of Agriculture may issue an on-farm home food processing operation license to an individual who owns a farm to process non-potentially hazardous food in a home or domestic kitchen located on the individual's farm as set forth in this regulation.
- 7.2 All on-farm home food processing facilities that manufacture, process, pack or hold for introduction into commerce must obtain and maintain a current license (known as an On-Farm Home Food Processing License) from the Delaware Department of Agriculture Food Products Inspection Section in accordance with 3 Del.C. §§101 and 302.

8.0 Operator qualifications

The below framework provides for the operator to possess the knowledge and demonstrate the abilities needed to safely perform production under the on-farm home food processing program.

- 8.1 Education and training.
 - 8.1.1 Persons responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers should receive appropriate training in proper food handling techniques and food protection principles, and should be informed of the dangers of poor personal hygiene and unsanitary practices.
 - 8.1.2 An individual who wishes to process non-potentially hazardous foods in a domestic kitchen shall have adequate knowledge of safe food handling practices and shall have successfully

completed a course offered through the Cooperative Extension Program prior to applying for a permit. The course shall be approved by DDA and provide a minimum of 8 hours of training in:

8.1.2.1 Sanitation;

8.1.2.2 Cross-contamination controls; and

8.1.2.3 Food security/defense.

8.2 Disease control:

8.2.1 Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to the regulatory authority.

8.3 Cleanliness:

- 8.3.1 All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
 - Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials;
 - Maintaining adequate personal cleanliness;
 - Washing hands thoroughly (and sanitizing if necessary to protect
 against contamination with undesirable microorganisms) in an adequate
 hand washing facility before starting work, after each absence from the
 work station, and at any other time when the hands may have become
 soiled or contaminated.
 - Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials;
 - Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material:
 - Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints;
 - Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed;



- Confining the following to areas other than where food may be exposed
 or where equipment or utensils are washed: eating food, chewing gum,
 drinking beverages, or using tobacco.
- Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
- No animals or fowls shall be kept in or permitted to enter the premises of any on-farm food operations.
- 8.4 While operating with a license issued in accordance with this regulation, the person-in-charge shall manufacture and process only non-potentially hazardous foods such as:
 - Baked breads, cakes, muffins, or cookies with a water activity of .85 or less
 - Candy (non-chocolate)
 - Containerized fruit preparations consisting of jellies, jams, preserves, marmalades, and fruit butters with an equilibrated pH of 4.6 or less or a water activity of 0.85 or less;
 - Fruit pies with an equilibrated pH of 4.6 or less or a water activity of 0.85 or less;
 - Herbs in vinegar with an equilibrated pH of 4.6 or less;
 - · Honey and herb mixtures; and
 - Dried fruit and vegetables;
 - Spices or herbs
 - Maple syrup or sorghum
 - Snack items such as popcorn, caramel corn, and peanut brittle
 - Roasted nuts
- 8.5 While operating with a license issued in accordance with this regulation, the person-in-charge shall **not** process potentially hazardous foods for commercial sale such as:
 - Low-acid canned foods, such as home-canned or jarred fruits, vegetables, pickled products, sauces, relishes.
 - Cream, custard, pumpkin, meat, or other single-crust pies or cream or cheese-filled baked goods
 - Cured or fermented foods;
 - Seafood;
 - Apple cider or other juices;
- 8.6 While operating with a license issued in accordance with this regulation, the person-in-charge shall limit processed food production to:
 - 8.6.1 An amount of food that can safely be produced in the domestic kitchen as evidenced by sanitation and process and cross-contamination control;
 - 8.6.2 \$50,000 of sales of on-farm home processed foods.
- 8.7 While operating with a license issued in accordance with this regulation, the person-in-charge shall process commercially only during times when the kitchen is not being used for domestic purposes;



- 8.8 While operating with a license issued in accordance with this regulation immediately before and after processing commercially, the person-in-charge shall clean and sanitize all food contact surfaces, equipment, and utensils;
- 8.9 While operating with a license issued in accordance with this regulation while processing commercially, the person-in-charge shall:
 - 8.9.1 Use only building areas, equipment, and utensils that DDA has reviewed or inspected and approved;
 - 8.9.2 Shall store ingredients for commercial manufacturing and finished manufactured food in a separate area from foods used domestically.

17 DE Reg. 316 (09/01/13)

9.0 Labeling

- 9.1 Products must be properly labeled as follows:
 - 9.1.1 Name of product
 - 9.1.2 Name and address of manufacturer
 - 9.1.3 Ingredients listed in decreasing order by weight
 - 9.1.4 Net weight or unit count
 - 9.1.5 The following statement in ten (10) point type: "This product is home-produced and processed"
 - 9.1.6 The date the product was processed.
- 9.2 Food products identified as non-potentially hazardous in these regulations and not labeled in accordance with subsection (9.1) of these regulations are deemed misbranded.
- 9.3 Food products identified in subsection (8.4) of Section 8 of these regulations and produced, processed, and labeled in accordance with these regulations are acceptable food products that may only be offered for sale by farmers' markets, roadside produce stands, or the processor's farm.

10.0 Supervision

10.1 Responsibility for assuring compliance with all requirements of this part shall be clearly assigned to the permit holder of the processing operation.

11.0 Washing of hands:

- 11.1 Employees engaged in food preparation, service, and warewashing operations shall thoroughly wash their hands and the exposed portions of their arms with soap or detergent and warm water before starting work, after smoking, eating, or using the toilet, and as often as is necessary during work to keep them clean. All persons shall keep their fingernails trimmed and clean.
 - 11.1.1 Handwashing facilities
 - 11.1.1.1 A supply of hand-cleansing soap or detergent shall be available from a dispensing unit at each handwashing facility. A supply of sanitary towels or a hand-drying device providing heated air shall be conveniently located near each handwashing facility. Common towels are prohibited. If disposable towels are used, easily

- cleanable waste receptacles shall be conveniently located near the handwashing facilities.
- 11.1.1.2 Handwashing facilities, soap or detergent dispensers, hand-drying devices, and all related facilities shall be kept clean and in good repair.
- 11.1.3 Adequate hand washing facilities separate from the utensil cleaning facilities, which includes hot and cold water, single service paper towels and hand soap are required. Properly supplied hand washing facilities provided in toilet facilities located within the structure containing the domestic kitchen may suffice for this provision.

12.0 Physical plant characteristics

The following requirements are the minimum acceptable standards for food processing areas:

- 12.1 **Food contact surfaces** shall be smooth and easily cleanable. The use of wood or glass for food preparation is not approved;
- 12.2 **Non-food contact surfaces** in the facility, including floor, walls and ceilings, shall be smooth and cleanable. The use of carpeting in the processing area is not approved;
- 12.3 **Refrigeration**: All facilities shall have a sufficient number of mechanical refrigeration units capable of holding raw materials requiring refrigeration at a minimum of 41°F. Each such mechanical refrigerator shall be equipped with a thermometer located in the warmest portion of the refrigerator;
- 12.4 **Water supply**: All facilities shall have hot and cold running water under pressure, supplied to all sinks in the processing room. If a non-public water supply is used, the laboratory results of a satisfactory water quality test (bacteriological and chemical) shall be submitted to the regulatory authority at least once each year;
- 12.5 **Waste water system**: All wastewater and other liquid waste generated during processing operations shall be disposed of through an approved wastewater system designed and installed according to law. A non-public wastewater system shall be approved and permitted by the Delaware Department of Natural Resources and Environmental Control (DNREC);
- 12.6 **Warewashing:** For manual cleaning and sanitizing of cooking equipment, and utensils, a sink of three (3) compartments shall be provided and used. A two-compartment sink, with an additional portable tub is acceptable.
 - 12.6.1 Mechanical cleaning and sanitizing shall be conducted as follows: A domestic or home-style dishwasher may be used if the following performance criteria are met:
 - 12.6.1.1 The dishwasher shall effectively remove physical solids from all surfaces of dishes.
 - 12.6.1.2 The dishwasher shall sanitize dishes by the application of sufficient accumulative heat.
 - 12.6.1.3 The operator shall provide and use daily a maximum registering thermometer or a heat thermal label to determine that the dishwasher's internal temperature is at least 150 degrees Fahrenheit after the final rinse and drying cycle;



- 12.6.1.4 The dishwasher shall be installed and operated according to manufacturer's instruction for the highest level possible when sanitizing the kitchen facilities' utensils and tableware. A copy of the manufacturer's instructions shall be available on the premises.
- 12.7 **Handwashing:** Adequate hand washing facilities separate from the utensil cleaning facilities, which includes hot and cold water, single service paper towels and hand soap are required. Properly supplied hand washing facilities provided in toilet facilities located within the structure containing the domestic kitchen may suffice for this provision.
- 12.8 **Plumbing system** in the processing area shall be designed and installed according to law under a valid plumbing permit with a satisfactory plumbing inspection;
- 12.9 **Refuse:** recyclables and returnable waste generated during processing operations shall be stored in heavy duty, cleanable waste containers equipped with tight fitting lids;
- 12.10 **Artificial lighting** (electrical lamps) in the processing area shall be protected from shattering by either shielding or an approved shatter-resistant coating;
- 12.11 **Toilet facility**: A completely enclosed toilet room equipped with a toilet and a hand washing sink shall be located on premises. The toilet room shall have a tight fitting door, and shall have either mechanical ventilation or an open-able window. The hand washing sink shall be supplied with hot and cold running water, under pressure and be supplied with liquid soap, paper towels and a wastebasket.
- 12.12 **Exterior openings:** All exterior doors and windows in the process area shall be tight fitting to prevent the entry of vermin. If these doors or windows are to be kept open for ventilation they shall be covered with screening, not less than 16 mesh to the inch. Exterior doors shall be self-closing;
- 12.13 **Service sink** shall be provided separately for the disposal of mop water and other liquid waste;
- 12.14 **Equipment and utensils** intended for use in food processing shall be separate from those used to cook domestic meals;
- 12.15 **Storage areas** for both raw ingredients and finished product shall protect these items from contamination;
- 12.16 **Ventilation** that is adequate to prevent an accumulation of excess steam, heat, and condensation on floors, walls and ceilings of the processing area shall be provided; and
- 12.17 **Poisonous and toxic materials** shall be stored so they cannot contaminate raw ingredients, utensils, equipment, packaging materials and finished products. This requirement also applies to medicines and medical items intended for use by humans or on livestock.

13.0 Program administration

13.1 Permit required. A person may not conduct an on-farm food processing operation without a valid permit issued by the DDA. DDA may establish and collect a fee for this permit.



- 13.2 Application procedure. An applicant shall submit a written application for permit using forms provided by DDA authority at least 30 days before the date planned to begin an on-farm food processing operation.
- 13.3 Application review. DDA will review the application and may set forth specific conditions or stipulations under which a permit will be issued to the applicant. DDA may establish and collect a fee for this review.
- 13.4 Inspection and approval. No food processing by the applicant or on the premises may begin without an initial approval for permit issue of DDA; such approval may be contingent upon an inspection of the premises to assess compliance with this regulatory foundation. The operator shall allow the DDA access to the premises, equipment and records of the processing operation at reasonable times to inspect and assess compliance, as required.
- 13.5 Variance. The applicant may request in writing a modification or waiver of any provision of this regulatory foundation, according to procedures established by DDA.
- 13.6 Permit retention. The permit is not transferable. The permit holder shall renew the permit when required. The permit holder shall surrender the permit and cease operations, if so ordered by DDA. By acceptance of the permit, the permit holder shall be subject to regulatory, administrative, civil, injunctive and criminal remedies authorized by law for failure to comply with this and other directives issued by competent authority.

14.0 Violations and hearing procedures.

- 14.1 Failure to comply with these regulations may result in the assessment of a civil penalty.
- 14.2 No civil penalty shall be imposed until an administrative hearing is held before the Secretary of Agriculture or his or her designee. Administrative hearings for the provisions of this chapter shall be conducted within 30 days of the violation of this chapter. The Department shall issue a decision in writing to the person(s) charged with a violation of this chapter within 30 days of the conclusion of the administrative hearing.
- 14.3 The person(s) charged with a violation of this chapter will be notified in writing of the date and time of the aforementioned administrative hearing. The aforementioned person(s) shall have the right to appear in person, to be represented by counsel and to provide witnesses in his or her own behalf.
- 14.4 The Secretary, for the purposes of investigation of a possible violation of this chapter and for its hearings, may issue subpoenas, compel the attendance of witnesses, administer oaths, take testimony and compel the production of documents. In case any person summoned to testify or to produce any relevant or material evidence refuses to do so without reasonable cause, the Department of Agriculture may compel compliance with the subpoena by filing a motion to compel in Superior Court which shall have jurisdiction over this matter.
- 14.5 The Department shall preserve a full record of the proceedings and a transcript may be purchased by any interested person.

15.0 Appeal.

15.1 Any party, including an individual or corporation that feels aggrieved by decision of the Secretary or his or her designee after an administrative hearing may take appeal to the Superior Court within thirty days of the date the decision is mailed to that party by the DDA. After a full hearing, the Court shall make such decree as seems just and proper. Written notice of such appeal, together with the grounds therefore, shall be served upon the Secretary of the DDA.

16.0 Civil penalties.

- 16.1 It shall be unlawful for any person to interfere with the DDA in its effort to enforce these regulations and will subject the violator to a civil penalty of no less than \$100 nor more than \$1,000 per proven violation.
- 16.2 It shall be unlawful for any person to violate a cease and desist order issued by the DDA and will subject the violator to a civil penalty of no less than \$500 nor more than \$1,000 per proven violation.
- 16.3 The payment of penalties assessed under these regulations may be made on a payment schedule approved by the Secretary of the DDA.

9 DE Reg. 1057 (01/01/06) 17 DE Reg. 316 (09/01/13)

