

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 122(3)u.1. (16 **Del.C.** §122(3)u.1.
16 **DE Admin. Code** 4458A

PROPOSED

PUBLIC NOTICE

4458A Cottage Food Regulations

Pursuant to 16 **Del.C.** §122(3)u.1., the Health Systems Protection section within the Division of Public Health, Department of Health and Social Services, is proposing revisions to the Cottage Food Regulations. The revisions include:

- Addition of "sesame" to the list of major food allergens;
- Removal of the gross annual sales cap for cottage food establishments;
- Removal of the owner's name and full home address of cottage food establishments on product labels, and in its place requiring the product label list the cottage food establishment's town/city in Delaware; and
- Technical corrections.

Copies of the proposed regulations are available for review in the July 1, 2023 edition of the *Delaware Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Division of Public Health at (302) 744-4700.

Any person who wishes to make written suggestions, testimony, briefs, or other written materials concerning the proposed regulations must submit them by Tuesday, August 1, 2023, at:

Division of Public Health
417 Federal Street
Dover, DE 19901
Email: DHSS_DPH_regulations@delaware.gov
Phone: (302) 744-4700

4458A 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~~ 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~~ "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 Health. The Division may grant a variance by modifying or waiving the requirements of these ~~Regulations~~ 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~~ regulations.
- 1.6.2 Additional inspections may be conducted in response to complaints, reports of food-borne ~~illness~~ illness, or other situations as deemed necessary by the Division.

23 DE Reg. 52 (07/01/19)

2.0 Definitions

“Adulterated” ~~has the meaning~~ means as stated in the Federal Food, Drug, and Cosmetic Act, §402.

“Approved” means acceptable to the ~~Regulatory Authority~~ 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~~ plant, and does not offer the food for resale.

“Cottage Food Establishment 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 food products” refers to a ~~non-Time/Temperature~~ non-time/temperature controlled for safety food as specified in these ~~Delaware Cottage Food Regulations~~ 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 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 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 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~~ means 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~~ 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~~ drip, or splash into a food or onto; or a surface normally in contact with food.

“Food Establishment establishment” ~~refers to~~ means 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 kitchen" ~~refers to~~ means a residential style kitchen. A residential style kitchen shall be in the permanent, primary residence of the producer.

"Imminent Health Hazard 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 food allergen" means milk, egg, fish (such as bass, flounder, cod and including crustacean shellfish such as crab, ~~lobster lobster,~~ or shrimp), tree nuts (such as almonds, ~~pecans pecans,~~ or walnuts), wheat, ~~peanuts and soybeans~~ peanuts, soybeans, and sesame. This definition includes food ingredients that contain milk, eggs, fish, tree nuts, wheat, ~~peanuts and soybeans~~ peanuts, soybeans, and sesame.

"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 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~~ cosmetics, and toiletries.

"Private Event event" ~~refers to~~ means an event restricted to organization members or another event that restricts the general public from attending.

"Processing area" ~~refers to~~ means the area of the ~~Cottage Food Establishment~~ cottage food establishment where food ~~prep~~ preparation and other food service activities occur.

"Producer" ~~refers to~~ means the person that manufactures cottage food products in a home-style kitchen.

"Ready-to-eat Food food" ~~refers to~~ means food in a form that is edible without washing, cooking, or additional preparation by the food service facility or the consumer.

"Registration Holder 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 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~~ means 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 articles" ~~refers to~~ means an article designed, fabricated, and intended for one-time consumer use.

"Single-use Articles articles" ~~refers to~~ means an article intended by the manufacturer for one-time use by the preparer of the food.

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

"Time/Temperature Control for Safety Food 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 3.1.3.1 CFE are only permitted to engage in direct sales with consumers in the State of Delaware.

3.1.3.3 3.1.3.2 Online sales are not permitted. Online advertising and marketing are permitted.

3.1.3.4 3.1.3.3 Wholesale or other sales to resellers or food establishments are not permitted by a CFE.

~~3.1.3.5~~ 3.1.3.4A CFE shall only produce those specific food products listed on their registration. This registration shall be displayed at farmers markets, craft fairs, charitable ~~organization~~ 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~~ 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 to the Division 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~~ email 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~~ processes, and ~~products~~ 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~~ facilities;
 - 3.3.1.1.5 Proof of completion of training that satisfies Section ~~5.0-5.0~~ 5.0;
 - 3.3.1.1.6 Types of venues where products will be ~~sold~~ sold; and
 - 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~~ application;
 - 3.3.1.1.7.2 Affirms that the applicant ~~will~~ will comply with these ~~Regulations~~ 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. [Reserved.]~~
- 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~~ water, the well must be ~~in compliance~~ compliant 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 ~~3.4~~ 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 3.5~~ 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 functions,~~ or 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~~ regarding the registration holder's CFE. ~~Comply with CFE,~~ 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 and be~~ 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~~ 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,~~ accepted;

4.1.1.7.2 The Division directs the replacement of the facilities and equipment because of a change of ~~ownership,~~ 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.

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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~~ 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,~~ 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~~ 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~~ monitoring 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.

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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~~ Covered 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~~ 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~~ shall be used.

7.2 Indoor Areas

- 7.2.1 Materials that are smooth, ~~durable and easily cleanable~~ 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,~~ 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~~ 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~~ 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~~ grinders, or where the producer or employee safety is a factor.

7.4 Animals

~~7.4.1~~ ~~7.4~~ No ~~animals/pets~~ animals or 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~~ 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~~ 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~~ county, or state codes. Where there are no local codes the ~~provision of the Division~~ State of Delaware Regulations Governing a Detailed Plumbing Code applies.

7.6.2 The CFE shall have convenient access to permanent restroom facilities equipped with running potable water, paper ~~towels~~ towels, and soap.

~~7.7 Sewage Disposal~~

~~7.7.1~~ 7.7 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.

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8.0 ~~Product Requirements~~

8.1 Testing

~~8.1.1~~ 8.1 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~~ "town/city, Delaware", phone number ~~and~~ or email of CFE, net weight or unit count, date of ~~production/lot~~ production or 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~~ 8.3 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~~

~~8.5.4~~ 8.5A 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.

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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;~~ 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;~~ application, applicable ~~fees~~ fees, and any required plans have been received and approved by the Division.

9.2.1.2 Imminent Health ~~Hazard(s)~~ Hazards

- 9.2.1.2.1 Registration suspension without ~~Hearing~~ 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~~ 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~~ 10 business days without a hearing. Failure to hold a hearing within the ~~ten (10) government~~ 10 business day period shall automatically terminate the suspension.

9.2.1.3 Serious Violations, Repeat ~~Violations~~ Violations, and General Unsanitary Conditions. When conditions exist in a CFE that represent serious violations, repeat ~~violations~~ violations, or general unsanitary conditions, the Division may initiate a corrective action plan.

9.3 In response to the order to close, the ~~facility~~ CFE 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)~~ 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~~ 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 ~~9.4.1~~ Any person (or responsible officer of that person) who violates a provision of this ~~Regulation~~ 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~~ 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~~ 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~~ regulation.

20 DE Reg. 176 (09/01/16)

23 DE Reg. 52 (07/01/19)

27 DE Reg. 30 (07/01/23) (Prop.)