

DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

Statutory Authority: 3 Delaware Code,
Sections 101 and 302 (3 Del.C. §§101 & 302)

101 On-Farm Home Food Processing Operations

PUBLIC NOTICE

The State of Delaware, Department of Agriculture, proposes these regulations pursuant to 3 Del.C. §§101 and 302. The proposed regulations contain the following general sections: Authority, Purpose, Scope, Construction, Definitions, Registration, License/permits, Operator qualifications, Labeling, Supervision, Washing of hands, Physical plant characteristics, Program administration, Violations and hearing procedures, Appeals, Civil penalties. These regulations are intended to allow on-farm home processing of non-potentially hazardous foods and clearly define the role of DDA in on-farm home processing of non-potentially hazardous foods.

The On-Farm Home Food Processing Program will exempt certain small food processors, who process and produce specified non-potentially hazardous food products, from the statutory requirements of Title 16 Delaware Code, Chapter 1, §122 and §134, and from the regulatory requirements of State of Delaware Food Code as it relates to the specified non-potentially hazardous food products; and the program will ensure protection of the public health through processor compliance with regulatory requirements of the **On-Farm Home Food Processing Program**.

The proposed regulations will be considered at a public hearing scheduled for August 1, 2005 at the Delaware Department of Agriculture building conference room #1 located at 2320 S. Dupont Hwy, Dover, DE. The hearing is being held for the purpose of receiving information, factual evidence, and public reaction as it relates to proposed on-farm home processing regulations under 3 Del.C. §§101 and 302. The hearing will be conducted in accordance with Title 29, Chapter 101, and the Administrative Procedures Act.

Copies of the proposed regulations may be obtained from the Department of Agriculture by calling the 1-800-282-8685; by writing the Delaware Department of Agriculture, 2320 S. Dupont Hwy., Dover, DE 19901; or, by visiting the Register of Regulations site at: <http://www.delregs.state.de.us/index.html>. Public comments may be submitted in writing to Mark Davis, Executive Assistant to the Secretary of the Department of Agriculture on or before 1:00 p.m. on August 1, 2005 and/ or in person at the public hearing.

PROPOSED REGULATION

101 On-Farm Home Food Processing Operations

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 Delaware Code, Chapter 1, §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 wrapper;

“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 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; 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-treated; a food of plant origin that is heat-treated 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 a_w 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 probe-type 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 (A_w)” 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;
- 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;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.
- 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.

8.4While 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 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 and 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 \$40,000 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.

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.

11.1.1.3 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. 12 (7/1/05)(Prop.)