

Chapter 5 – Food Safety Rules
Subchapter 1

GOOD MANUFACTURING PRACTICES FOR FOOD RULE

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. Chapter 85.

2.0 Purpose

This rule provides the requirements for the safe and sanitary manufacturing, packing or holding of human food products.

3.0 Scope

This rule applies to food establishments that process food for human consumption, and provide processed food for sale and distribution to other business entities such as other food establishments. Requirements do not pertain to food establishments that process food solely under the regulatory oversight of the Vermont Agency of Agriculture, Food, & Markets.

4.0 Definitions

Whenever used in these Regulations, the following terms shall be construed as follows:

- 4.1 “Acid foods or acidified food”** means foods that have an equilibrium pH of 4.6 or below.
- 4.2 “Adequate”** means that which is needed to accomplish the intended purpose in keeping with good public health practices.
- 4.3 “Batter”** means a semi-fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- 4.4 “Blanching, except for tree nuts and peanuts”** means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- 4.5 “Critical control point”** means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- 4.6 “Department”** means the Vermont Department of Health.
- 4.7 “Commissioner”** means the Commissioner for the Vermont Department of Health or a subordinate to whom the commissioner has assigned his or her

functions.

- 4.8 **“FDA”** means the U.S. Food and Drug Administration.
- 4.9 **“Food”** means any article used or intended to be used by human beings for food, drink, confection, or condiment, whether simple, mixed, or compound and all substances and ingredients used in the preparation thereof.
- 4.10 **“Food-contact surfaces”** are those surfaces that contact human food and those surfaces from which drainage onto surfaces that contact the food ordinarily occurs during the normal course of operations. Food-contact surfaces include utensils and food-contact surfaces of equipment.
- 4.11 **“Lot”** means the food produced during a period of time indicated by a specific code.
- 4.12 **“Low-acid food”** means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.
- 4.13 **“Microorganisms”** means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of these Regulations.
- 4.14 **“Pasteurize”** means to expose food to an elevated temperature for a period of time sufficient to destroy certain microorganisms that can produce disease or cause spoilage or undesirable fermentation of food.
- 4.15 **“Pest”** means any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
- 4.16 **“Plan review”** means the submission of blueprints, drawings, or plans for proposed new construction, renovation, or remodeling of a food processing facility.
- 4.17 **“Plant”** means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- 4.18 **“Process Authority Review”** means a product review conducted by a person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions.
- 4.19 **“Processed food”** means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, grinding, churning, separating, extracting, packaging, or milling, but does not mean the sorting, trimming, cleaning, or water-rinsing of food.

- 4.20 “Quality control operation”** means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of these Regulations.
- 4.21 “Rework”** means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
- 4.22 “Safe and suitable”** means that the ingredient performs an appropriate function in the food in which it is used and is used at a level no higher than necessary to achieve its intended purpose in that food.
- 4.23 “Safe-moisture level”** is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.
- 4.24 “Sanitize”** means 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.
- 4.25 “Significant renovation”** means a physical change to a facility or portion of a facility, including the following:
- 4.25.1** Replacing or upgrading any major system, such as the electrical, plumbing, heating, ventilation, or air-conditioning systems;
 - 4.25.2** Demolition of the interior or exterior of a building or portion of the building; and
 - 4.25.3** Replacement, demolition, or installation of interior walls and partitions, whether fixed or movable.
- 4.26 “Water activity (a_w)”** means a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

5.0 License Requirements

- 5.1** A person shall not maintain or operate a food processing or manufacturing facility or food warehouse unless such establishment is licensed pursuant to the provisions of 18 V.S.A. §4351.
- 5.1.1** Each individual establishment shall require a separate license, regardless of ownership. A food license expires annually, unless sooner revoked by the Department.

- 5.2** A completed Application for License to Operate a Food And Lodging Establishment, a check or money order for the applicable fees determined in 18 V.S.A. §4353, and copies of all other required documentation and permits must be submitted to the Department for review no less than 30 days before the expected start of operation.
- 5.3** Additional documentation, when applicable and requested by the Department, including but not limited to:
 - 5.3.1** Wastewater system documentation and permits from the Vermont Agency of Natural Resources;
 - 5.3.2** Water system documentation for water systems requiring a permit;
 - 5.3.3** Local permit or zoning approval for proposed operation;
 - 5.3.4** Documentation of Process Authority Review for low-acid canned foods, acidified foods, and products where the Department has requested documentation that there are no biological concerns with the food production process.
- 5.4** Establishments shall submit a plan review prior to any new construction or significant renovation of an existing facility.
- 5.5** Transference of Licenses
 - 5.5.1** A license shall not be transferred from one person or corporation to another.
 - 5.5.2** When a licensed establishment is sold, the corporation changes, or the establishment relocates or enlarges its operation, the license held by the former entity or person shall be returned to the Department.
 - 5.5.3** The new proprietor or management must apply for and receive a license before operating the business.
- 5.6** A variance may be granted by the Commissioner to modify or waive one or more requirements of this rule if the Commissioner determines that a health hazard, safety hazard, or nuisance will not result from the variance.
 - 5.6.1** Each person requesting a variance shall submit the following to the department:
 - 5.6.1.1** A written statement of the proposed variance of the regulatory requirement;
 - 5.6.1.2** Documentation of how the proposed variance addresses public health hazards at the same level of protection as that of the original requirement; and
 - 5.6.1.3** Any other relevant information if required by the Commissioner.
 - 5.6.2** For each variance granted, the licensee shall meet the following requirements:
 - 5.6.2.1** Follow the plans and procedures approved by the Commissioner;

5.6.2.2 Maintain a permanent record of the variance at the establishment;
and

5.6.2.3 Maintain and provide to the Commissioner, upon request, records
that demonstrate that the variance is being followed.

6.0 **Current Good Manufacturing Practice**

6.1 Applicability and Scope - The criteria and definitions in these Regulations shall
apply in determining whether food is adulterated as defined in 18 V.S.A. § 4059.

6.2 Personnel – The plant management shall take all reasonable measures and
precautions to ensure the following:

6.2.1 Disease Control

6.2.1.1 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.

6.2.1.2 Personnel shall be instructed to report such health conditions to
their supervisors.

6.2.2 Cleanliness

6.2.2.1 All persons working in direct contact with food, food-contact
surfaces, and food-packaging materials shall conform to accepted
industry standard hygienic practices while on duty to the extent
necessary to protect against contamination of food.

6.2.2.2 The methods for maintaining cleanliness include, but are not
limited to:

6.2.2.2.1 Wearing clean garments suitable to the operation in a
manner that protects against the contamination of
food, food-contact surfaces, or food-packaging
materials.

6.2.2.2.2 Maintaining adequate personal cleanliness.

6.2.2.2.3 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.

- 6.2.2.2.4** 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.
- 6.2.2.2.5** Using utensils or wearing gloves for food handling if product is ready-to-eat and maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable, non-latex material.
- 6.2.2.2.6** Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.
- 6.2.2.2.7** Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
- 6.2.2.2.8** 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. Additional restrictions concerning use of tobacco are contained in 18 V.S.A. Chapter 37.
- 6.2.2.2.9** 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.

6.2.3 Education and Training

- 6.2.3.1** Personnel responsible for identifying sanitation failures or food contamination shall 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, when available.

6.2.3.2 Food handlers and supervisors shall receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

6.2.4 Supervision: Responsibility for assuring compliance by all personnel with all requirements of these Regulations shall be clearly assigned to supervisory personnel.

7.0 Plants and Grounds

7.1 Grounds – The grounds around a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

7.1.1 Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests;

7.1.2 Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed;

7.1.3 Adequate draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests;

7.1.4 Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed;

7.1.5 If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in the above sections (7.1.1-7.1.3) of this Rule, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

7.2 Plant Construction and Design – Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

7.2.1 Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food;

7.2.2 Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

- 7.2.3 Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:
 - 7.2.3.1 Using protective coverings;
 - 7.2.3.2 Controlling areas over and around the vessels to eliminate harborage for pests;
 - 7.2.3.3 Checking on a regular basis for pests and pest infestation;
 - 7.2.3.4 Skimming the fermentation vessels, as necessary.
- 7.2.4 Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
- 7.2.5 Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
- 7.2.6 Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
- 7.2.7 Provide tight fitting doors and outer openings and, where necessary, adequate screening or other protection against pests.

8.0 Sanitary Operations

- 8.1 General Maintenance – Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of these Regulations. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- 8.2 Substances Used in Cleaning and Sanitizing – Storage of Toxic Materials
 - 8.2.1 Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of

these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

8.2.1.1 Those required to maintain clean and sanitary conditions;

8.2.1.2 Those necessary for use in laboratory testing procedures;

8.2.1.3 Those necessary for plant and equipment maintenance and operation;

8.2.1.4 Those necessary for use in the plant's operations.

8.2.2 Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products shall also be followed.

8.3 Pest Control – No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

8.4 Sanitation of Food-Contact Surfaces – All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

8.4.1 Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

8.4.2 In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

8.4.3 Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

- 8.4.4** Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
- 8.4.5** Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
- 8.5** Storage and Handling of Cleaned Portable Equipment and Utensils – Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

9.0 Sanitary Facilities and Controls

- 9.1** Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:
 - 9.1.1** Water Supply – The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. The facility shall comply with requirements regarding water quality and the site and location of the source of the water supply will meet criteria as specified in rule by the Vermont Department of Environmental Conservation.
 - 9.1.1.1** Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality.
 - 9.1.1.2** Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.
 - 9.1.2** Plumbing – A plumbing system shall be designed, constructed, and installed according to all applicable federal, state, and local requirements. Plumbing shall be of adequate size and design and adequately installed and maintained to:
 - 9.1.2.1** Carry sufficient quantities of water to required locations throughout the plant;
 - 9.1.2.2** Properly convey sewage and liquid disposable waste from the plant;
 - 9.1.2.3** Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition;

room(s) and in all other areas where employees may handle such food, materials, or surfaces.

9.1.5.6 Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

9.1.6 Rubbish and Offal Disposal – Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

10.0 Equipment and Utensils

10.1 All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.

10.1.1 The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

10.1.2 All equipment shall be installed and maintained as to facilitate the cleaning of the equipment and of all surrounding spaces.

10.1.3 Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

10.2 Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

10.3 Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

10.4 Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

10.5 Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and shall be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

- 10.6** Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained and adequate in number for their designated uses.
- 10.7** Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

11.0 Production and Process Controls

- 11.1** All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.
 - 11.1.1** Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.
 - 11.1.2** Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function.
 - 11.1.3** All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination.
 - 11.1.4** All food that has become contaminated to the extent that it is adulterated as defined in 18 V.S.A. § 4059, shall be rejected or if permissible, treated or processed to eliminate the contamination.
- 11.2** Raw Materials and Other Ingredients
 - 11.2.1** Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration.
 - 11.2.1.1** Raw materials shall be washed or cleaned as necessary to remove soil or other contamination.
 - 11.2.1.2** Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality.
 - 11.2.1.3** Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.
 - 11.2.1.4** Containers and carriers of raw materials shall be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.
 - 11.2.2** Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in

humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of these Regulations. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

11.2.3 Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with 18 V.S.A § 4062, this Rule, and applicable action levels/regulations for poisonous or deleterious substances promulgated by the FDA before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

11.2.4 Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with the provisions of section 13.0 of this Rule regarding defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification or examination of these materials for contamination.

11.2.5 Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of these Regulations. Material scheduled for rework shall be identified as such.

11.2.6 Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of these Regulations.

11.2.7 Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

11.3 Manufacturing Operations

11.3.1 Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

11.3.2 All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food. One way to comply with this requirement is careful

monitoring of physical factors such as time, temperature, humidity, a_w , pH, pressure, and flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

- 11.3.3** Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated as defined in 18 V.S.A. § 4059. Compliance with this requirement shall be accomplished by any effective means, including:
- 11.3.3.1** Maintaining refrigerated foods at 41°F (5°C) or below as appropriate for the particular food involved;
 - 11.3.3.2** Maintaining frozen foods in a frozen state;
 - 11.3.3.3** Maintaining hot foods at 135°F (57°C) or above;
 - 11.3.3.4** Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures;
 - 11.3.3.5** Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.
- 11.3.4** Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of these Regulations.
- 11.3.5** Work-in-process shall be handled in a manner that protects against contamination.
- 11.3.6** Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.
- 11.3.6.1** When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food.
 - 11.3.6.2** Food transported by conveyor shall be protected against contamination as necessary.
- 11.3.7** Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

- 11.3.8** Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.
- 11.3.9** Food, raw materials, and other ingredients that are adulterated within the meaning of these Regulations shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of these Regulations before being incorporated into other food.
- 11.3.10** Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces and by using time and temperature controls at and between each manufacturing step.
- 11.3.11** Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay.
- 11.3.11.1** Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.
- 11.3.11.2** Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.
- 11.3.12** Batters, breading, sauces, gravies, dressings, spices, and other similar preparations shall be treated or maintained in such a manner that they are safe and protected against contamination. Compliance with this requirement shall be accomplished by any effective means, including one or more of the following:
- 11.3.12.1** Using ingredients free of contamination and verified by testing;
- 11.3.12.2** Employing adequate heat processes where applicable;
- 11.3.12.3** Using adequate time and temperature controls minimizing time food is in temperature danger zone of 41°F (5°C) to 135°F (57°C);
- 11.3.12.4** Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them;

- 11.3.12.5** Cooling to an adequate temperature during manufacturing;
 - 11.3.12.6** Disposing of batters at appropriate intervals to protect against the growth of micro-organisms;
 - 11.3.12.7** Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.
- 11.3.13** Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement shall be accomplished by any effective means, including:
- 11.3.13.1** Use of a quality control operation in which the critical control points are identified and controlled during manufacturing;
 - 11.3.13.2** Adequate cleaning and sanitizing of all food-contact surfaces and food containers;
 - 11.3.13.3** Using materials for food containers and food-packaging materials that are safe and suitable, as defined in these Regulations;
 - 11.3.13.4** Providing physical protection from contamination, particularly airborne contamination;
 - 11.3.13.5** Using sanitary handling procedures;
 - 11.3.13.6** Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.
- 11.3.14** Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement shall be accomplished by any effective means, including employment of one or more of the following practices:
- 11.3.14.1** Monitoring the a_w of food;
 - 11.3.14.2** Controlling the soluble solids-water ratio in finished food;
 - 11.3.14.3** Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level;
 - 11.3.14.4** Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.
- 11.3.15** Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement shall be accomplished by any

effective means, including employment of one or more of the following practices:

- 11.3.15.1** Monitoring the pH of raw materials, food in process, and finished food;
 - 11.3.15.2** Controlling the amount of acid or acidified food added to low-acid food;
 - 11.3.15.3** Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.
- 11.3.16** When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in these Regulations.
- 11.3.17** Food-manufacturing areas and equipment used for manufacturing human food shall not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

12.0 Warehousing and Distribution

12.1 Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

13.0 Defect Action Levels – Natural or Unavoidable Defects In Food For Human Use That Present No Health Hazard

- 13.1** Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- 13.2** Defect action levels are established by the FDA for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information. The current Defect Action Levels handbook may be downloaded from the FDA website through: <http://www.fda.gov/>.
- 13.3** Food that has been adulterated as defined in 18 V.S.A. § 4059 shall still be in violation of this Rule even if the food manufacturer is in compliance with defect action levels.
- 13.4** The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of these Regulations, regardless of the defect level of the final food.

14.0 Adoption by Reference

- 14.1** Federal Food, Drug, and Cosmetic Act: §201(m) [21 USC §321 Definitions], §301(e), (f), (k), (v) [21 USC §331 Prohibited Acts], and §703 [21 USC §373 - Records of Interstate Shipment] are adopted by reference.
- 14.2** Code of Federal Regulations: 21 CFR Parts 70.20-70.25, 73.1-73.615, 74.101-706, 81, 82.3-82.706, 100.155, 101 (except 101.69 and 101.108), 102 (except 102.19), 104, 105, 106 (except 106.120), 107 (except 107.200-107.280), 108.25-108.35, 109, 113, 114, 118, 120, 123, 129-130 (except 130.5-130.6 and 130.17), 136-170 (except 168.140, 170.6, 170.15, and 170.17), 172-178, and 180-189 are adopted by reference.