RULES AND REGULATIONS PERTAINING TO CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING OR HOLDING HUMAN FOOD

[R21.27; 21-31; 23-1- GMP]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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INTRODUCTION

These *Rules and Regulations Pertaining to Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food* [*R21-27; 21-31; 23-1-GMP*] are promulgated pursuant to the authority set forth in Chapters 21-27, 21-31 and 23-1 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimum safety standards for manufacturing, packing or holding human food that are comparable to those established by the U.S. Food and Drug Administration (FDA) pursuant to 21 CFR 110.

Pursuant to the provisions of §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at these regulations:

(1) Alternative approaches to the regulations;

(2) Duplication or overlap with other state regulations; and

(3) Significant economic impact on small business.

Based on the available information, no known overlap, duplication or alternative approach was identified.

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Section 1.0 ***Definitions***

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

1.1 ***Acid foods or acidified foods*** means foods that have an equilibrium pH of 4.6 or below.

1.2 ***Adequate*** means that which is needed to accomplish the intended purpose in keeping with good public health practice.

1.3 ***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.

1.4 ***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.

1.5 ***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.

1.6 ***Department*** means the Rhode Island Department of Health.

1.7 ***Director*** means the Director of the Rhode Island Department of Health or a subordinate to whom the Director has assigned his or her functions.

1.8 ***FDA*** means the U.S. Food and Drug Administration.

1.9 ***Food*** means:

(1) Articles used for food or drink for man or other animals;

(2) Chewing gum;

(3) Articles used for components of any such article; and

(4) Includes raw materials and ingredients.

1.10 ***Food-contact surfaces*** are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. Food-contact surfaces includes utensils and food-contact surfaces of equipment.

1.11 ***Lot*** means the food produced during a period of time indicated by a specific code.

1.12 ***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[1] 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.

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[1] These Regulations may also use the adjective "microbial" instead of using an adjectival phrase containing the word "microorganism".

1.13 ***Pest*** refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

1.14 ***Plant*** means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

1.15 ***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 washing, canning, cooking, freezing, dehydration, or milling.

1.16 ***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.

1.17 ***Rework*** means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

1.18 ***RIGL*** means the General Laws of Rhode Island, as amended.

1.19 ***Safe and suitable*** means that the ingredient:

(1) Performs an appropriate function in the food in which it is used.

(2) Is used at a level no higher than necessary to achieve its intended purpose in that food.

1.20 ***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.

1.21 ***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.

1.22 ***These Regulations*** mean all parts of Rhode Island *Rules and Regulations Pertaining to Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food* [*R21.27; 21-31; 23-1-GMP*]

1.23 ***Water activity (a_w)*** is 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.

Section 2.0 ***Current Good Manufacturing Practice***

2.1 **Applicability and Scope.** The criteria and definitions in these Regulations shall apply in determining whether a food is adulterated:

(a) Within the meaning of RIGL §21-31-10(1)(iii) in that the food has been manufactured under such conditions that it is unfit for food; or

(b) Within the meaning of RIGL §21-31-10(1)(iv) in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

2.2 The criteria and definitions in these Regulations also apply in determining whether a food is in violation of §361 of the Public Health Service Act (42 U.S.C. 264).

2.3 Food covered by specific current good manufacturing practice regulations is also subject to the requirements of those regulations.

2.4 For the purpose of these Regulations, a food shall be deemed to be adulterated:

(a) **Poisonous, Insanitary, or Deleterious Ingredients.**

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) (i) If it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive or a color additive) that is unsafe within the meaning of §406 of the Federal Food, Drug, and Cosmetic Act; or

(ii) If it bears or contains a pesticide chemical residue that is unsafe within the meaning of §408(a) of the Federal Food, Drug, and Cosmetic Act; or

(iii) If it is or if it bears or contains:

(a) any food additive that is unsafe within the meaning of §409 of the Federal Food, Drug, and Cosmetic Act; or

(b) a new animal drug (or conversion product thereof) that is unsafe within the meaning of §512 of the Federal Food, Drug, and Cosmetic Act; or

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) If it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to §409 of the Federal Food, Drug, and Cosmetic Act.

(b) **Absence, Substitution, or Addition of Constituents.**

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) If any substance has been substituted wholly or in part therefore; or

(3) If damage or inferiority has been concealed in any manner; or

(4) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) **Color Additives.** If it is, or it bears or contains, a color additive which is unsafe within the meaning of §721(a) of the Federal Food, Drug, and Cosmetic Act.

(d) **Confectionery Containing Alcohol or Nonnutritive Substance.** If it is confectionery, and:

(1) Has partially or completely imbedded therein any nonnutritive object, except that this requirement shall not apply in the case of any nonnutritive object where the FDA has determined that such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) Bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum (0.5%) by volume derived solely from the use of flavoring extracts, except that this requirement shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the state in which such confectionery is intended to be offered for sale; or

(3) Bears or contains any nonnutritive substance, except that this requirement shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of these Regulations.

(e) **Oleomargarine Containing Filthy, Putrid, etc., Matter.** If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) **Dietary Supplement or Ingredient: Safety.**

(1) If it is a dietary supplement or contains a dietary ingredient that:

(i) Presents a significant or unreasonable risk of illness or injury under:

(a) conditions of use recommended or suggested in labeling, or

(b) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use; or

(ii) Is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury; or

(iii) The FDA declares to pose an imminent hazard to public health or safety; or

(iv) Is or contains a dietary ingredient that renders it adulterated under §2.4(a)(1) of these Regulations under the conditions of use recommended or suggested in the labeling of such dietary supplement.

(g) **Dietary Supplement: Manufacturing Practices.** If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice standards established by these Regulations or regulations promulgated by the FDA, including, when necessary, expiration date labeling.

(h) **Unsanitary Transport.** If it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under §416 of the Federal Food, Drug, and Cosmetic Act.

Section 3.0 *Personnel*

3.1 The plant management shall take all reasonable measures and precautions to ensure the following:

(a) **Disease Control.** 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 their supervisors.

(b) **Cleanliness.** 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:

(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.

(2) Maintaining adequate personal cleanliness.

(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.

(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.

(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 nonlatex material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(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 the Rhode

Island *Rules and Regulations Pertaining to Smoke-free Public Places and Workplaces* [*R23-20.10-SMOKE*][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.

(c) **Education and training.** Personnel 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 and supervisors should 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.

(d) **Supervision.** Responsibility for assuring compliance by all personnel with all requirements of these Regulations shall be clearly assigned to competent supervisory personnel.

Section 4.0 *Plant and Grounds*

4.1 **Grounds.** The grounds about 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:

(a) 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.

(b) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(c) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(d) 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.

(e) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in §§4.1(a)-(c) of these Regulations, 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.

4.2 **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:

(a) 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.

(b) 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

[2] Current copies of all regulations issued by the RI Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: http://www.sos.ri.gov/rules/

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.

(c) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(1) Using protective coverings.

(2) Controlling areas over and around the vessels to eliminate harborages for pests.

(3) Checking on a regular basis for pests and pest infestation.

(4) Skimming the fermentation vessels, as necessary.

(d) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept 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.

(e) 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.

(f) 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.

(g) Provide tight fitting doors and outer openings and, where necessary, adequate screening or other protection against pests.

Section 5.0 ***Sanitary Operations***

5.1 **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.

5.2 **Substances Used in Cleaning and Sanitizing - Storage of Toxic Materials**.

(a) 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:

(1) Those required to maintain clean and sanitary conditions;

(2) Those necessary for use in laboratory testing procedures;

(3) Those necessary for plant and equipment maintenance and operation; and

(4) Those necessary for use in the plant's operations.

(b) 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.

5.3 **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.

5.4 **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.

(a) 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.

(b) 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.

(c) 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.

(d) 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.

(e) 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.

5.5 **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.

Section 6.0 ***Sanitary Facilities and Controls***

6.1 Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) **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 as specified in RIGL Chapter 46-13 (*Public Drinking Water Supply*) and the *Rhode Island Rules and Regulations Pertaining to Public Drinking Water* [*R-46-13-DWQ*].

(1) Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality.

(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.

(b) **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:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) **Sewage Disposal.** Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) **Toilet Facilities.** Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) **Hand-Washing Facilities.** Hand-washing facilities shall be adequate and convenient and be furnished with running water at a temperature of at least 100°F (38°C). Hand-washing sinks shall be designated for hand-washing only and shall not be used for other purposes. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unproteced food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

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

(f) **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.

Section 7.0 *Equipment and Utensils*

7.1 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.

(a) 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.

(b) All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

(c) 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.

7.2 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.

7.3 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.

7.4 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.

7.5 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 should 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.

7.6 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.

7.7 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.

Section 8.0 ***Production and Process Controls***

8.1 All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.

(a) 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. Foods shall also be produced and labeled to comply with 21 CFR Part 101 *Food Labeling* and the Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

(b) Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function.

(c) 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.

(d) All food that has become contaminated to the extent that it is adulterated within the meaning of these Regulations shall be rejected, or if permissible, treated or processed to eliminate the contamination.

8.2 **Raw Materials and Other Ingredients**

(a) 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.

(1) Raw materials shall be washed or cleaned as necessary to remove soil or other contamination.

(2) Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality.

(3) Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.

(4) Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(b) 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.

(c) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with RIGL §21-31-13, these Regulations 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.

(d) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with the provisions of §10.0 of these Regulations 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.

(e) 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.

(f) 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.

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

8.3 **Manufacturing Operations.**

(a) 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.

(b) 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, 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.

(c) 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 within the meaning of these Regulations. Compliance with this requirement may be accomplished by any effective means, including:

(1) Maintaining refrigerated foods at 41°F (5°C) or below as appropriate for the particular food involved.

(2) Maintaining frozen foods in a frozen state.

(3) Maintaining hot foods at 140°F (60°C) or above.

(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.

(d) 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.

(e) Work-in-process shall be handled in a manner that protects against contamination.

(f) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.

(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.

(2) Food transported by conveyor shall be protected against contamination as necessary.

(g) 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.

(h) 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.

(i) 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.

(j) 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.

(k) 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 (from 135°F (57°C) to 70°F (21°C) within two (2) hours, and from 135°F (57°C) to 41°F (5°C) within a total of six (6) hours) or passing it to subsequent manufacturing without delay.

(1) Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.

(2) Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(l) 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 may be accomplished by any effective means, including one or more of the following:

(1) Using ingredients free of contamination and verified by testing.

(2) Employing adequate heat processes where applicable.

(3) Using adequate time and temperature controls minimizing time food is in temperature danger zone of 41°F (5°C) to 140°F (60°C).

(4) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(5) Cooling to an adequate temperature within an appropriate time frame [from 135°F (57°C) to 70°F (21°C) within two (2) hours, and from 135°F (57°C) to 41°F (5°C) within a total of six (6) hours] during manufacturing.

(6) Disposing of batters at appropriate intervals to protect against the growth of micro-organisms.

(m) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(1) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(2) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(3) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in these Regulations.

(4) Providing physical protection from contamination, particularly airborne contamination.

(5) Using sanitary handling procedures.

(n) 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 may be accomplished by any effective means, including employment of one or more of the following practices:

(1) Monitoring the a_w of food.

(2) Controlling the soluble solids-water ratio in finished food.

(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.

(o) 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 may be accomplished by any effective means, including employment of one or more of the following practices:

(1) Monitoring the pH of raw materials, food in process, and finished food.

(2) Controlling the amount of acid or acidified food added to low-acid food.

(p) 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.

(q) Food-manufacturing areas and equipment used for manufacturing human food should 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.

Section 9.0 ***Warehousing and Distribution***

9.1 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.

Section 10.0 ***Natural or Unavoidable Defects In Food For Human Use That Present No Health Hazard - Defect Action Levels***

10.1 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[3].

10.2 Defect action levels are established 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.

10.3 Compliance with defect action levels does not excuse violation of the requirement of RIGL Chapter 21-31 that food not be prepared, packed, or held under unsanitary conditions or the requirements of these Regulations that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of these Regulations, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

10.4 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.

[3] The current Defect Action Levels handbook may be downloaded from the FDA Center for Food Safety and Applied Nutrition website: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm.

Section 11.0 ***Adoption by Reference***

11.1 Federal Food, Drug, and Cosmetic Act : §201(ff) [21 USC §321 *Definitions*], §301(e), (v) [21 USC §331 *Prohibited Acts*], §304 [21 USC §334 *Seizure*], §401 [21 USC §341 *Definitions and Standards for Food*], §403 [21 USC §343 *Misbranded Food*], §413 [21 USC §350b - *New Dietary Ingredients*], §701 [21 USC §371 – *Regulations and Hearings*], §703 [21 USC §373 - *Records of Interstate Shipment*] and §704 [21 USC §374 – *Factory Inspection*] are adopted by reference except where provisions of these Regulations may specify different requirements.

11.2 Code of Federal Regulations: 21 CFR Parts 1.20-1.24, 7.1-7.13, 7.40-7.59, 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 107.200-280), 108.25-108.35, 109-130 (except 130.5-6 and 130.17), 131-170 (except 170.6, 170.15, and 170.17), 172-178, and 180-190 are adopted by reference, except where provisions of these Regulations may specify different requirements.

Section 12.0 ***Compliance and Enforcement***

12.1 **Enforcement Options**

(a) The Director may pursue any combination of the following administrative and judicial enforcement actions, depending upon the circumstances and gravity of each case:

(1) Confiscation of food pursuant RIGL §21-27-4;

(2) Notice to cease business pursuant RIGL §21-27-5;

(3) Penalties for violations pursuant to RIGL §21-27-9 and/or RIGL §21-31-5;

(4) Administrative fines pursuant RIGL §21-27-11.11;

(5) Embargo, condemnation and destruction of adulterated food pursuant RIGL §21-31-6;

(6) Penalties for obstruction of inspections or examinations pursuant to RIGL §23-1-19;

(7) Compliance orders pursuant to RIGL §23-1-20;

(8) Immediate compliance orders pursuant to RIGL §23-1-21;

(9) Enforcement of compliance orders pursuant to RIGL §23-1-23;

(10) Criminal penalties pursuant to RIGL §23-1-25; and

(11) Revocation, suspension, or other disciplinary action pursuant to RIGL §21-27-10(c) regarding a registration issued in accordance with RIGL §21-27-10.

(b) The imposition of one or more remedies and/or penalties provided in §12.1(a) of these regulations shall not prevent the Director from jointly exercising any other remedy or penalty available to him or her by statute or regulation.

(c) **Consent Agreement/Order**. Nothing in these Regulations shall preclude the Director from resolving outstanding violations or penalties through a Consent Agreement or Consent Order at any time he or she deems appropriate.

12.2 All hearings and reviews required under the provisions of RIGL §21-31-7, RIGL §22-1-22 or these Regulations shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health* (*R42-35-PP*).

Section 13.0 ***Severability***

13.1 If any provision of these Regulations or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.

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