**216-RICR-50-10-4**

# TITLE 216 – DEPARTMENT OF HEALTH

## CHAPTER 50 – ENVIRONMENTAL HEALTH

## SUBCHAPTER 10 - FOOD PROTECTION

PART 4 – Good Manufacturing Practices for Food

# 4.1 AUTHORITY AND PURPOSE

### 4.1.1 AUTHORITY

These regulations are promulgated pursuant to the authority conferred by R.I. Gen. Laws Chapters 21-27, 21-31, and 23-1, as amended, and are established for the purpose of adopting minimum safety standards for manufacturing, packing, holding or distributing human food for sale in Rhode Island.

### 4.1.2 SCOPE

A. These regulations apply to every person who grows, manufactures, packs, repacks, cans, bottles, keeps, exposes, stores, handles, sells, transports or distributes food in Rhode Island, whether or not for profit. It applies to wholesale food processing operations within food establishments licensed by RIDOH, but does not apply to food prepared in the home for family consumption, or activities regulated by the Rhode Island Department of Health Food Code, Part 1 of this Subchapter and Processing and Distribution of Shellfish, Part 6 of this Subchapter.

B. The requirements of these regulations include but are not limited to every person who:

1. Operates as a wholesale seafood dealer or a wholesale seafood truck;

2. Cooks, smokes or otherwise processes seafood or combines seafood with non-seafood ingredient(s), for sale at wholesale;

3. Engages in the business of slaughtering livestock or poultry or processing meat or poultry for sale at wholesale;

4. Operates a milk pasteurization plant;

5. Manufactures butter or cheese for sale at wholesale;

6. Manufactures frozen desserts or frozen dessert mix;

7. Manufactures or bottles non-alcoholic beverages, whether carbonated or non-carbonated, for human consumption;

8. Manufactures juice or apple cider for sale at wholesale;

9. Operates a cold storage or refrigerating warehouse, or a food warehouse;

10. Manufactures, processes or distributes any food not specifically named in this section, including dietary supplements, for sale at wholesale.

### 4.1.3 INCORPORATION BY REFERENCE

A. These regulations hereby adopt and incorporate the FDA Food Safety Modernization Act (FSMA) Final Rule on Preventive Controls for Human Food 21 C.F.R. § 117 (2015) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

B. These regulations hereby adopt and incorporate the FDA FSMA Final Rule on Sanitary Transportation of Human and Animal Food 21 C.F.R. § 1 (2016) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

C. These regulations hereby adopt and incorporate the FDA FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration rule 21 C.F.R. § 121 (2016) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

D. These regulations hereby adopt and incorporate the Grade “A” Pasteurized Milk Ordinance (2015) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

## 4.2 DEFINITIONS

A. The following definitions shall apply in the interpretation and application of these Regulations:

1. "Administrative penalty" means a civil monetary fine that RIDOH may assess pursuant to statutory authority.

2. "Adulterated food" means the definition in R.I. Gen. Laws § 21-31-10 and as described below.

3. "Air temperature" means that steady temperature determined by allowing the probe of an accurate thermometer or other appropriate means of temperature measurement to equilibrate to the temperature of a representative area of the air environment in question.

4. "Approved laboratory" means a laboratory approved by the Director or certified by the EPA or certified by the primary enforcement authority in any state which has been granted primacy by EPA or certified (accredited) by a third-party organization acceptable to a primacy state.

5. "Approved source," when used in reference to a bottled water plant's product water or water used in the plant's operation, means the source of the water whether it be from a spring, artesian well, drilled well, public or community water system or any other source that has been inspected and the water sampled, analyzed and found to be of a safe and sanitary quality, per standards approved by the Director.

6. "Bottled water" means bottled water as defined in 21 C.F.R. § 129.3(b).

7. "Bottled water plant" means any place or establishment in which bottled water is prepared for sale.

8. "Bulk water" means water intended for potable uses, which is transported via tanker truck or an equivalent means from one area to another for the purposes of treatment, processing, packaging and/or human consumption, including bottling purposes.

9. "Carbonated non-alcoholic beverage" means a carbonated beverage of any flavor containing no alcohol and includes but is not limited to soda water, sparkling water made with added carbon dioxide, seltzer water, carbonated water and tonic water.

10. "Carbonated water" or "Sparkling water" means bottled water containing carbon dioxide.

11. "Center" means the Center for Food Protection of the Rhode Island Department of Health.

12. "C.F.R." means the Code of Federal Regulations.

13. "Critical violation" means any violation by a facility or any other occurrence or condition in a facility that has the potential to pose a threat to public health.

14. "Dedicated" means equipment used exclusively for the bottling, manufacturing for water and food.

15. "Denature" means to use a material to render an article unfit for human consumption.

16. "DEM" means the Rhode Island Department of Environmental Management.

17. "Director" means the Director of RIDOH.

18. "Embargo" means action taken pursuant to R.I. Gen. Laws § 21-31-6.

19. "EPA" means the U.S. Environmental Protection Agency.

20. "Equipment" means items used in the storage, preparation, display, or transportation of food such as stoves, ovens, hoods, slicers, grinders, mixers, scales, cutting blocks, tables, food shelving, reach-in refrigerators and freezers, sinks, ice makers, dishwashers, steam tables, utensils and similar items used in the operation of a food processing operation.

21. "Facility" means the premises or parts thereof, and delivery or other vehicles used for or in connection with the slaughtering, preparing, processing, manufacturing, packaging, repackaging, canning, bottling, keeping, exposing, storing, handling, distributing, transporting or holding of food. It does not include a food establishment as defined in the Rhode Island Food Code.

22. "Farm warehouse (meat products)" means a frozen storage area on a farm used to hold meat that has been slaughtered and packaged in a USDA facility.

23. "Fluoridated water" means bottled water containing fluoride. The label shall specify whether the fluoride is naturally occurring or added. Any water which meetings the definition of this subsection shall contain not less than 0.8 milligrams per liter fluoride ion and otherwise comply with the FDA quality standards in 21 C.F.R. Part 165.110(b)(4)(ii).

24. "FDA" means the U.S. Food and Drug Administration.

25. "Food" means articles used for food or drink for man or other animals; chewing gum; articles used for components of any such article; includes raw materials and ingredients; as defined in the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(f). Food includes dietary supplements as defined in the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(ff).

26. "Food-contact surfaces" means 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.

27. "Freezing" means the removal of latent heat from the product, so that it enters a solid state.

28. "Frozen" means the temperature of the product (except frozen desserts) has reached 0°F (-18°C) or lower at the thermal center, after thermal stabilization.

29. "Frozen dessert mix" means any unfrozen mixture to be used in the manufacture of frozen desserts or milk shakes.

30. "Frozen food" means articles in package form used for food or drink for man or other animals, which have been preserved by freezing.

31. "FSIS" means the Food Safety and Inspection Service of the U.S. Department of Agriculture.

32. "Grade A" means the standard of quality which may be attached to all those products which meet the requirements of and have been processed in accordance with the requirements of the RIDOH's administrative regulations based on the Grade "A" Pasteurized Milk Ordinance (PMO).

33. "Hermetically sealed container" means a container designed and intended to be secure against the entry of microorganisms and to maintain the commercial sterility of its contents after processing.

34. "Imminent danger to the public health" means any occurrence or condition which has the potential to pose a serious threat to public health and shall include, but not be limited to:

    a. A loss of water supply that may result in adulteration of food;

    b. The use of an unapproved source of water within the facility;

c. A failed sewer system or a sewage backup into the facility;

d. A power outage that may result in adulteration of food;

e. Information that indicates that food may have been intentionally adulterated;

f. The facility has been subject to one or more of the following: flood, fire, chemical exposure, natural disaster and/or catastrophic event;

g. An employee is found to be infected with a communicable disease;

h. A food-borne illness outbreak that appears to be associated with the facility;

i. Severe unsanitary conditions that threaten to contaminate the facility, a part of the facility, or a particular product;

j. Failure to comply with an order to correct a critical deficiency immediately;

k. Failure to submit an approved correction plan for a critical deficiency in timely manner;

l. Failure to comply with an approved correction plan for a critical deficiency in a timely manner; or

m. Failure to carry out a product recall.

n. The failure to include other violations, occurrence or conditions in Imminent Danger to the Public Health shall not be construed as a determination that such other violations, occurrences or conditions are not or may not be considered an imminent danger to the public health.

35. "Inedible" means adulterated or not intended for use as human food.

36. "Inspector" means an agent of the Rhode Island Department of Health, as defined in R.I. Gen. Laws § 21-31-21.

37. "Juice" means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one of more fruits or vegetables, or any concentrates of such liquid or puree.

38. "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under

authority of these Regulations that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper, as defined in the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(k).

39. "Labeling" means all labels and other written, printed, or graphic matter:

    a. upon any article or any of its containers or wrappers, or

    b. accompanying such article, as defined in the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(m).

40. "Landing" means that point in time when seafood has been brought on-shore after harvesting.

41. "Law" means any applicable federal, state or local statute, ordinances and regulations.

42. "License" means any license or permit issued by RIDOH pursuant to these regulations and applicable statutes.

43. "Licensee" means any person who holds a license or permit issued by RIDOH pursuant to these regulations and applicable statutes.

44. "Livestock" means any animal raised commercially or privately, excluding poultry, which can or may be used in and for the preparation of meat or meat food products. In these regulations, livestock includes so-called non-amenable animals raised for sale as food, including but not limited to buffalo, rabbits, frogs and turtles.

45. "Major food allergen" means a major food allergen as defined by 21 U.S.C. § 321(qq).

46. "Meat" except as used in § 4.6 of this Part, means the edible portion of livestock or wild-caught animals after slaughter.

47. "Meat food product" means any article used as human food which is made wholly or in part from any meat or other portion of the carcass of any livestock, except those exempted from definition as a meat food product pursuant to 9 C.F.R. Part 317.

48. "Misbranded food" means the definition of R.I. Gen. Laws § 21-31-11.

49. "Noncompliance," "Failure to comply," and "Violation" each mean any act or failure to act that constitutes or results in one or more of the following:

    a. Engaging in any operation subject to these regulations or applicable statute, without a license, permit, or approval whenever engaging in such an operation requires a license, permit or approval;

    b. Engaging in any activity prohibited by, or not in compliance with these regulations or other applicable statute or regulation, or prohibited by or not in compliance with any order, license, permit, approval, certification, guideline, policy or protocol issued by RIDOH pursuant to these regulations or applicable statute.

    c. Failing to do, or failing to do in a timely manner, anything required by these regulations or other applicable statute or regulation, or required by any order, license, permit, approval, certification, guideline, policy or protocol issued by RIDOH pursuant to these regulations or applicable stature.

50. "Pasteurization plant" means a facility for the pasteurization of milk.

51. "Person" means any individual, partnership, corporation, association or other legal entity.

52. "Person in charge" means the individual present in the facility who has actual or apparent authority to supervise the activities of the facility and the employees at the time of the inspection.

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

54. "Potentially hazardous food" or "PHF", has the same meaning as "Time Temperature Control for Safety Food" or "TCS".

55. "Poultry" means any bird, whether live or dead, intended for use as food.

56. "Poultry food product" means any product capable of use as human food which is made wholly or in part from any poultry carcass or part thereof, except those exempted from definition as a poultry product pursuant to 9 C.F.R. § 381.15.

57. "Public water system" means a system for the provision to the public of water for human consumption, as defined by 42 U.S.C. § 300(f), the Safe Drinking Water Act, in compliance with R.I. Gen. Laws or comparable

standards of the state or foreign country where the public water system is located.

58. "Reduced oxygen packaging" or "ROP" means the removal or partial removal of oxygen from a package with or without replacing it with a gas mixture, to control food spoilage. ROP includes controlled atmospheric packaging (CAP), modified atmospheric packaging (MAP), straight vacuum packaging (VP), sous vide and cook-chill.

59. "Refrigeration" means mechanical lowering of the temperature of food to, at a maximum, 41°F (5°C), or to a temperature required by other applicable law, regulation or ordinance.

60. "Regulatory agency" means the Rhode Island Department of Health, Center for Food Protection.

61. "Remodel" means to make a material change to the facility.

62. "Retail" means sale to the ultimate consumer.

63. "Retail seafood dealer" means a person who sells raw, fresh or frozen seafood directly to the consumer.

64. "RIDOH" means the Rhode Island Department of Health.

65. "R.I. Gen. Laws" means the General Laws of Rhode Island, as amended.

66. "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.

67. "Seafood" means all fish and/or fishery products.

68. "Sell" means to sell, offer or expose for sale, barter, trade, deliver, give away, possess with intent to sell, or dispose of in any other commercial manner.

69. "Shelf life" means a period after the date of packaging during which a food product has no significant risk of spoilage, loss of nutritional value, or loss of palpability, given compliance with recommended conditions of storage and handling as disclosed on the label of such product.

70. "These regulations" shall mean all parts of the rules and regulations for the Rhode Island Department of Health Good Manufacturing Practices for Food (216-RICR-50-10-04).

71. "Time temperature control for safety food" "TCS" means any food or food ingredient, natural or synthetic, in a form capable of supporting a) the rapid and progressive growth of infectious or toxigenic microorganisms or b) the slower growth of Clostridium botulinum.

72. "USDA" means the United States Department of Agriculture.

73. "Water Source" means any ground or surface water body and the site from which water is withdrawn.

74. "Wholesale" means sale to other than the ultimate consumer.

75. "Wholesale seafood dealer" means a person who in a facility does any or all of the following: handling, storing, preparing, heading, eviscerating, shucking, freezing, manufacturing, preserving, packing, labeling or shipping raw fish and/or shellfish, whether frozen or unfrozen, for sale at wholesale.

76. "Wild game" means an animal that is used for food, that is not domesticated and that is harvested in the wild, including but not limited to wild deer, elk, moose, rabbits, squirrels and raccoons, and wild birds such as ducks, pheasants, quail and turkeys.

### 4.2.1 ADULTERATED FOOD

A. The criteria and definitions in these Regulations shall apply in determining whether a food is adulterated:

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

2. Within the meaning of R.I. Gen. Laws § 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.

B. 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).

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

D. For the purposes of these Regulations, a food shall be deemed to be adulterated:

1. Poisonous, Insanitary or Deleterious Ingredients

a. If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but if the substance is not an added substance such food shall not be considered adulterated under § 4.2.1(D)(1)(a) of this Part if the quantity of such substance in such food does not ordinarily render it injurious to health; or

b. 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 § 408(a) of the Federal Food, Drug and Cosmetic Act; or

c. 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

d. If it is or if it bears or contains:

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

(2) 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

e. If it consists in whole or in part of any filthy, putrid or decomposed substance, or it is otherwise unfit for food; or

f. If it has been prepared, packaged or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health; or

g. 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

h. 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

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

2. Absence, Substitution or Addition of Constituents

a. If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

b. If any substance has been substituted wholly or in part therefore; or

c. If damage or inferiority has been concealed in any manner; or

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

3. Color Additives

a. 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.

4. Confectionary Containing Alcohol or Nonnutritive Substance. If it is confectionary, and:

a. 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 confectionary product and would not render the product injurious or hazardous to health;

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

c. Bears or contains any nonnutritive substance, except that this requirement shall not apply to a safe nonnutritive substance which is in or on confectionery due to 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.

5. Oleomargarine Containing Filthy, Putrid, etc., Matter.

a. 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.

6. Dietary Supplement or Ingredient: Safety. If it is a dietary supplement or contains a dietary ingredient that:

   a. Presents a significant or unreasonable risk of illness or injury under:

      (1) conditions or use recommended or suggested in labeling, or

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

   b. 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

   c. The FDA declares that it poses an imminent hazard to public health or safety; or

   d. Is or contains a dietary ingredient that renders it adulterated under § 4.2.1(D) of this Part under the conditions of use recommended or suggested in the labeling of such dietary supplement.

7. Dietary Supplement: Manufacturing Practices.

   a. If it is a dietary supplement and it has been prepared, packed or held under conditions that do not meet current good manufacturing practices standards established by these Regulations or regulations promulgated by the FDA, including, when necessary, expiration date labeling.

8. Unsanitary Transport

   a. 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.

## 4.3 ADOPTION OF FEDERAL REGULATIONS

A. All licensees and permit holders shall comply with all federal regulations that are applicable to the type of food processing that they conduct. Such regulations include but are not necessarily limited to the following.

1. Food Processing

a. 21 C.F.R. Part 106 (except § 106.120): Infant Formula Quality Control Procedures;

b. 21 C.F.R. Part 109: Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Materials;

c. 21 C.F.R. Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food;

d. 21 C.F.R. Part 111: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements;

e. 21 C.F.R. Part 113: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers;

f. 21 C.F.R. 108.35: Emergency Permit Control - Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers;

g. 21 C.F.R. Part 114: Acidified Foods;

h. 21 C.F.R. 108.25: Emergency Permit Control - Acidified Foods;

i. 21 C.F.R. Part 115: Shell Eggs;

j. 21 C.F.R. Part 117: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food;

k. 21 C.F.R. Part 118: Production, Storage and Transportation of Shell Eggs;

l. 21 C.F.R. Part 120: Hazard Analysis and Critical Control Point (HACCP) Systems;

m. 21 C.F.R. Part 123: Fish and Fishery Products;

n. 21 C.F.R. Part 129: Processing and Bottling of Bottled Drinking Water.

2. Food Labeling

a. 21 C.F.R. Part 1: General Enforcement Regulations:

(1) Subpart B: General Labelling Requirements;

b. 21 C.F.R. Part 100: General:

(1) Subpart G: Specific Administrative Rulings and Decisions;

c. 21 C.F.R. Part 101: Food Labeling (except § 101.69 and § 101.108);

d. 21 C.F.R. Part 102 (except § 102.19): Common or Usual Name for Nonstandardized Foods;

e. 21 C.F.R. Part 104: Nutritional Quality Guidelines for Foods;

f. 21 C.F.R. Part 105: Foods for Special Dietary Use;

g. 21 C.F.R. Part 107 (except § 107.200-107.280): Infant Formula;

h. 21 C.F.R. Part 190: Dietary Supplements;

i. 9 C.F.R. Part 317: Labeling, Marking Devices and Containers.

3. Standards of Identity

a. 21 C.F.R. Part 130: Food Standards: General (except 130.5-6, 130.17);

b. 21 C.F.R. Part 131: Milk and Cream;

c. 21 C.F.R. Part 133: Cheeses and Related Cheese Products;

d. 21 C.F.R. Part 135: Frozen Desserts;

e. 21 C.F.R. Part 136: Bakery Products;

f. 21 C.F.R. Part 137: Cereal Flours and Related Products;

g. 21 C.F.R. Part 139: Macaroni and Noodle Products;

h. 21 C.F.R. Part 145: Canned Fruits;

i. 21 C.F.R. Part 146: Canned Fruit Juices;

j. 21 C.F.R. Part 150: Fruit Butters, Jellies, Preserves and Related Products;

k. 21 C.F.R. Part 152: Fruit Pies;

l. 21 C.F.R. Part 155: Canned Vegetables;

m. 21 C.F.R. Part 156: Vegetable Juice;

n. 21 C.F.R. Part 158: Frozen Vegetables;

o. 21 C.F.R. Part 160: Eggs and Egg Products;

p. 21 C.F.R. Part 161: Fish and Shellfish;

q. 21 C.F.R. Part 163: Cacao Products;

r. 21 C.F.R. Part 164: Tree Nut and Peanut Products;

s. 21 C.F.R. Part 165: Beverages;

t. 21 C.F.R. Part 166: Margarine;

u. 21 C.F.R. Part 168: Sweeteners and Table Syrups;

v. 21 C.F.R. Part 169: Food Dressings and Flavorings;

w. 9 C.F.R. Part 319: Definitions and Standards of Identity or Composition.

4. Food Additives

a. 21 C.F.R. Part 170: Food Additives (except § 170.6, 170.15, 170.17);

b. 21 C.F.R. Part 172: Food Additives Permitted for Direct Addition to Food for Human Consumption;

c. 21 C.F.R. Part 173: Secondary Direct Food Additives Permitted in Food for Human Consumption;

d. 21 C.F.R. Part 174: Indirect Food Additives: General;

e. 21 C.F.R. Part 175: Indirect Food Additives: Adhesives and Components of Coatings;

f. 21 C.F.R. Part 176: Indirect Food Additives: Paper and Paperboard Components;

g. 21 C.F.R. Part 177: Indirect Food Additives: Polymers;

h. 21 C.F.R. Part 178: Indirect Food Additives: Adjuvants, Production Aids and Sanitizers;

i. 21 C.F.R. Part 180: Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study;

j. 21 C.F.R. Part 181: Prior-Sanctioned Food Ingredients;

k. 21 C.F.R. Part 182: Substances Generally Recognized as Safe;

l. 21 C.F.R. Part 184: Direct Food Substances Affirmed as Generally Recognized as Safe;

m. 21 C.F.R. Part 186: Indirect Food Substances Affirmed as Generally Recognized as Safe;

n. 21 C.F.R. Part 189: Substances Prohibited from Use in Human Food.

5. Color Additives

a. 21 C.F.R. Part 70: Color Additives (only § 70.20-70.25);

b. 21 C.F.R. Part 73: Listing of Colors Exempt from Certification (only § 73.1-73.615);

c. 21 C.F.R. Part 74: Listing of Color Additives Subject to Certification (only § 74.101-706);

d. 21 C.F.R. Part 81: General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics;

e. 21 C.F.R. Part 82: Listing of Certified Provisionally Listed Colors and Specifications (only § 82.3-82.706).

6. Sanitary Transportation

a. 21 C.F.R. Part 1: Subpart O: Sanitary Transportation of Human and Animal Food;

b. 21 C.F.R. Part 11: Electronic Records; Electronic Signatures.

7. Intentional Adulteration

    a. 21 C.F.R. 121: Mitigation Strategies to Protect Food Against Intentional Adulteration.

8. Federal Food, Drug and Cosmetic Act

    a. Definitions: 21 U.S.C. § 321(f), (k), (m) and (ff);

    b. Prohibited Acts: 21 U.S.C. § 331(a), (b), (c), (d), (e), (f), (k) and (v);

    c. Penalties: 21 U.S.C. § 333;

    d. Seizure: 21 U.S.C. § 334;

    e. Definitions and Standards for Food: 21 U.S.C. § 341;

    f. Adulterated Food: 21 U.S.C. § 342;

    g. Misbranded Food: 21 U.S.C. § 343;

    h. New Dietary Ingredients: 21 U.S.C. § 350(b);

    i. Regulations and Hearings: 21 U.S.C. § 371;

    j. Records of Interstate Shipments: 21 U.S.C. § 373;

    k. Factory Inspection: 21 U.S.C. § 374.

## 4.4 NATURAL OR UNAVOIDABLE DEFECTS IN FOOD FOR HUMAN USE THAT PRESENT NO HEALTH HAZARD-DEFECT ACTION LEVELS

A. Compliance with defect action levels does not excuse violation of the requirement of R.I. Gen. Laws 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 always utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

B. 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.

## 4.5 SUPPLEMENTAL REGULATIONS FOR FISH AND FISHERY PRODUCTS

No person shall operate as a wholesale seafood dealer, retail seafood dealer or wholesale seafood truck without a valid permit issued by RIDOH. No person shall operate as such a dealer in violation of applicable laws or in violation of any of the requirements specified in these Regulations.

## 4.6 SUPPLEMENTAL REGULATIONS FOR MEAT AND POULTRY SLAUGHTER AND PROCESSING

A. All persons operating within Rhode Island for the purpose of slaughtering any animal for human consumption, or for canning, curing, smoking, salting, packing, rendering, or handling the carcass of any animal or part of the carcass, or for the manufacturing of any meat product or meat food product, must obtain a permit from RIDOH.

B. All persons who operate a meat or poultry slaughter and/or processing facility shall comply with R.I. Gen. Laws Chapter 21-11 and these Regulations.

### 4.6.1 SPECIAL REQUIREMENTS PERTAINING TO A FARM WAREHOUSE (Meat Products)

A. A farm warehouse shall not further process any meat items. This includes, but is not limited to, opening packages and handling exposed product, relabeling product, applying net weights or repackaging product.

B. A farm warehouse shall:

1. Register with the Food Safety and Inspection Service (FSIS) of the USDA as a meat handler pursuant to 9 C.F.R. § 320.5 and comply with all applicable USDA requirements;

2. Register with RIDOH as a food business;

3. Utilize only slaughtering and processing facilities approved by the USDA and operated in compliance with 21 U.S.C. §§ 601 through 695;

4. Ensure that all meat products are handled and stored under acceptable conditions/ practices which will prevent unsanitary conditions and the misbranding and/or adulteration of the meat products;

5. Ensure that storage units, such as coolers or freezers, are:

   a. Dedicated for the meat products that will be offered for sale; and

   b. Indoors, clean, in good repair and can keep meat products frozen or below 41°F (5°C);

6. Ensure that vehicles, refrigerators and/or chest type freezers used for transport of fresh or frozen meat products are in good working condition, able to keep meat products frozen or below 41°F (5°C), designed to prevent unsanitary conditions and capable of maintaining all meat products in a safe, wholesome condition.

C. Notwithstanding the requirements of these Regulations, a farm warehouse shall only be required to ensure that any water that contacts food-contact surfaces is safe and of adequate sanitary quality.

## 4.7 SUPPLEMENTAL REGULATIONS FOR GRADE A MILK AND MILK PRODUCTS

A. All pasteurization plants in Rhode Island, as well as all facilities in Rhode Island that produce or transport milk products must comply with the Grade "A" Pasteurized Milk Ordinance incorporated by reference in § 4.1.3(D) of this Part.

B. No person shall operate a pasteurization plant without a valid license granted by RIDOH or in violation of any of the requirements specified in these regulations.

## 4.8 SUPPLEMENTAL REGULATIONS FOR NON-ALCOHOLIC BEVERAGES, DRINKS AND JUICES

A. All persons manufacturing or bottling for sale or to sell or offer for sale any carbonated or nonalcoholic beverage, soda water, fruit juice, syrup, bottled drinking water either plain or carbonated, or any other so-called soft drink, must obtain a permit from RIDOH.

B. No carbonated or nonalcoholic beverage, soda water, fruit juice, syrup, bottled drinking water either plain or carbonated, or any other so-called soft drink, which has been manufactured outside of this state shall be sold or offered for sale within this state unless the person, firm, or corporation manufacturing or bottling it for sale holds a permit to do so from RIDOH.

C. Any person applying for a permit to bottle or manufacture apple cider shall certify that he or she does not manufacture or bottle any carbonated or nonalcoholic beverage, soda water, fruit juice, syrup, bottled drinking water, either plain or

carbonated, or any other so-called soft drink, other than apple cider. Permits shall not apply to any person who manufactures and bottles during any one calendar year not exceeding five hundred (500) gallons of cider.

D. All persons who operate with non-alcoholic beverages, drinks and juices and/or processing facility shall comply with R.I. Gen. Laws Chapter 21-23 and these Regulations.

## 4.9 SUPPLEMENTAL REGULATIONS FOR BOTTLED WATER

A. The sources of all bulk or bottled drinking water located in Rhode Island must be approved by the Director. Sources of all bottled drinking water located outside of Rhode Island must be approved by the agency having jurisdiction.

B. New sources of all bottled drinking water located in Rhode Island shall comply with those requirements found in the Rhode Island Department of Health rules and regulations for the Public Drinking Water, Subchapter 05 Part 1 of this Chapter.

C. Licensed sources of all bottled drinking water located in Rhode Island, following termination for any reason of their license to manufacture bottled drinking water, shall meet the requirements for new sources of bottled drinking water prior to reactivation of their bottled water license.

### 4.9.1 EQUIPMENT

A. All tanks, pipelines and equipment used to store, handle and transport water for bottled water purposes shall be inspected, maintained, cleaned and sanitized per the following requirements.

1. Storage Tanks

    a. Inspected for cleanliness monthly and shall be kept free of scale, evidence of oxidation and residue;

    b. Cleaned monthly by sanitizing and flushing with product water.

2. Product Water Pipelines

    a. Must be kept free of scale, evidence of oxidation and residue;

    b. Cleaned daily by sanitizing with chlorine water of two hundred (200) ppm for five (5) minutes, followed by product water flushing, or continuous recirculation of at least 0.1 ppm ozonated water.

3. Product Equipment

a. Cappers shall be sanitized daily;

b. Hoppers shall be kept covered, free of residue and contact surfaces shall be sanitized daily;

c. Ozone mixing tanks and equipment; soft water tanks and other associated equipment shall be inspected monthly, disassembled, if necessary cleaned and sanitized as needed;

d. Bottle washing equipment shall be checked daily to assure proper timing and adequate washing of bottles;

e. Fillers shall be kept free from residue and shall be sanitized daily. Filling and capping operations shall be conducted as to prevent contamination of water being bottled. The filler reservoir shall be kept covered at all times.

### 4.9.2 CONTENTS OF LABEL

A. Each label shall indicate:

1. Type of Source Water

a. Water coming from springs may be labeled "Spring Water" or "Natural Spring Water;"

b. Artesian or pumped water taken from the ground, from drilled wells may be labeled, "Well Water," "Artesian Water," or "Natural Water;"

c. For water containing carbon dioxide that emerges from the source and is bottled directly with its entrapped gas or from which the gas is mechanically separated and later reintroduced at a level not higher than naturally occurring in the water may be labeled "Naturally Carbonated" or "Naturally Sparkling." Bottled water which contains carbon dioxide other than that naturally occurring in the source of the product shall be labeled "Carbonated," "Carbonation Added" or "Sparkling;"

d. Mineral water may be labeled "Mineral Water" or "Natural Mineral Water." Bottled water to which minerals are added shall be labeled to disclose that minerals are added and may not be labeled "Natural Mineral Water;"

e. For a municipal water supply source, the name of the municipal water supply must be stated.

2. Supplemental printed information and graphics concerning recognized uses of the water may appear on the label but shall not imply properties of the product or preparation methods which are not factual.

3. Location of water source must be stated.

4. Sodium Labeling

    a. Certain descriptive terms about the quantitative sodium content of bottled water may be used on the label, provided such statements indicate the number of milligrams of sodium per measured volume of bottled water.

5. Additional Label Statements

    a. Whenever any term such as "no fluorides," "no chlorides," "no bromides," etc., is used in labeling, quantitative information shall be provided, which includes milligrams per liter or milligrams per measured serving. All label statements are subject to review and approval by the Director.

### 4.9.3 SAMPLING REQUIREMENTS, METHODS AND ANALYSIS

A. When determined to be necessary by the director, more frequent sampling or additional monitoring may be required by the Director.

B. All required source water quality analysis must be performed by a laboratory meeting either domestic approval or foreign approval by the appropriate government agency for source water analysis.

### 4.9.4 BULK WATER

A. Tank trucks, loading and unloading facilities and other equipment used to transport bulk water for bottled water purposes shall be maintained in clean and sanitary conditions at all times.

B. Tanks previously used to transport milk or juice products, toxic materials, petroleum products or other deleterious substances shall not be used to haul drinking water.

C. All sources of water for bulk water shipment must be approved by the Director.

D. All source water storage facilities must be maintained in a clean and sanitary condition at all times.

E. Bulk Transport and Transfer Procedure

1. Sanitation

    a. Prior to filling, tank interior shall be cleaned, flushed with potable water, sanitized with no less than one hundred (100) ppm chlorine water solution for a contact period of not less than twenty (20) minutes and rinsed with potable water.

    b. All hoses, connections and fittings shall be sanitized with a concentrated solution of chlorine, three (3) ounces of 5.25% household bleach to two (2) gallons of water by brushing solution on all exposed parts.

    c. The cover shall not be opened after sanitizing.

2. Fluid Transfer

    a. Tank trucks or tank trailers may be filled through the fitting on the inner dome cover when the rear pipe cannot be used.

    b. Water quality in the tank, after 20-30 gallons have been delivered into the tank, shall be checked as follows:

        (1) Stop filling;

        (2) Have discharge valve opened;

        (3) Inspect water as it discharges. If water has unpleasant odor and/or looks dirty, it shall be rejected for use and the tank shall be resanitized.

    c. When these checks indicate satisfactory water quality proceed to fill the tank.

    d. The dome cover shall be closed and sealed after filing to volume desired.

    e. The tank discharge valve cover shall be closed and sealed after filling.

    f. If used a fill connectional shall be constructed in a manner to prevent contamination and shall be capped at all times when not in use.

F. Sampling

1. Analysis of the samples must be performed for the plant by an approved laboratory.

2. When deemed necessary by the Director, sampling of water from bulk water system (i.e. tank truck, water buffalo, storage tank, transfer line, etc.) shall be conducted and analyzed.

G. Records

1. Shall be maintained and include the number of gallons delivered daily, cleansing and sanitizing methods used for tank truck and tank trailer interiors, risers, connections, hoses, etc.

2. Such records shall include date, time and location of delivery, concentration of sanitizing solution, time of contact when applicable, and water quality analysis results as legal evidence of compliance with public health practices and standards.

## 4.10 COMPLIANCE AND ENFORCEMENT

### 4.10.1 VARIANCES

RIDOH may grant a variance by modifying or waiving the requirements of these Regulations if in the opinion of RIDOH a health hazard or nuisance will not result from the variance. If a variance is granted, RIDOH shall retain the information in its records.

### 4.10.2 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 to R.I. Gen. Laws § 21-27-4;

2. Notice to cease business pursuant to R.I. Gen. Laws § 21-27-5;

3. Penalties for violations pursuant to R.I. Gen. Laws §§ 21-27-9 and/or 21-31-5;

4. Administrative fines pursuant to R.I. Gen. Laws § 21-27-11.11;

5. Embargo, condemnation and destruction of adulterated food pursuant to R.I. Gen. Laws § 21-31-6;

6. Penalties for obstruction of inspections or examinations pursuant to R.I. Gen. Laws § 23-1-19;

7. Compliance orders pursuant to R.I. Gen. Laws § 23-1-20;

8. Immediate compliance orders pursuant to R.I. Gen. Laws § 23-1-21;

9. Enforcement of compliance orders pursuant to R.I. Gen. Laws § 23-1-23;

10. Criminal penalties pursuant to R.I. Gen. Laws § 23-1-25; and

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

B. The imposition of one of more remedies and/or penalties provided in § 4.10 of this Part 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.

### 4.10.3 HEARING AND REVIEWS

All hearings and reviews required under the provisions of R.I. Gen. Laws Chapter 21-31 and/or R.I. Gen. Laws Chapter 23-1 and these Regulations shall be held in accordance with the provisions of the Rhode Island Department of Health "Rules and Regulations Pertaining to Practices and Procedures Before the Rhode Island Department of Health."

**216-RICR-50-10-4**

# TITLE 216 - DEPARTMENT OF HEALTH

## CHAPTER 50 - ENVIRONMENTAL HEALTH

## SUBCHAPTER 10 - FOOD PROTECTION

PART 4 - Good Manufacturing Practices for Food (216-RICR-50-10-4)

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