

Section 2.1 of 1 NYCRR is amended to add thereto a new subdivision (e), to read as follows:

(e) The provisions of subpart A, subpart C, section 117.206 of subpart D, subpart F, and subpart G of Part 117 of Title 21 of the Code of Federal Regulations shall apply to a milk plant or transfer station that is not an interstate milk shipper listed in the document entitled *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers*, published by the U.S. Department of Health and Human Services. The terms set forth in the provisions of Part 117 of Title 21 of the Code of Federal Regulations, incorporated by reference herein, shall have the meaning ascribed to such terms therein except that:

(1) FDA shall be deemed to be a reference to the Department of Agriculture and Markets;

(2) FDA District Director and to Director and to Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition shall be deemed

to be a reference to the Director of the Division of Milk Control and Dairy

Services of the Department of Agriculture and Markets;

(3) Secretary, and to Commissioner of Food and Drugs, shall be deemed

to be a reference to the Commissioner of the Department of Agriculture and

Markets unless the context clearly indicates that each such term should have the

meaning ascribed to it in Title 21 of the Code of Federal Regulations section

117.3.

Section 2.29 of 1 NYCRR is repealed and a new Section 2.29 is added thereto,

to read as follows:

2.29 Definitions. The definitions in section 2.2 of this Part shall apply to all of the
sections of this Part, except that the definitions set forth herein shall apply to sections
2.30 through 2.65 of this Part and shall supersede the definitions for the same words set
forth in section 2.2.

(a) Adequate means that which is needed to accomplish the intended purpose in
keeping with good public health practice.

(b) Allergen cross-contact means the unintentional incorporation of a food allergen into a food.

(c) Defect action level means a level of a non-hazardous, naturally occurring, unavoidable defect at which the Department may regard a food as “adulterated” and subject to enforcement action.

(d) Food means (1) milk and milk products, melloreum, and frozen desserts, (2) articles used for food or drink by humans and animals, and (3) articles used for components of any such article, and includes raw materials and ingredients.

(e) Food allergen means milk, shellfish, eggs, fish, tree nuts, peanuts, wheat, soybeans, and all ingredients derived from such foods, except that a food or an ingredient is not a food allergen if it is, exclusively, a highly-refined oil derived from a food allergen or an ingredient derived from such highly-refined oil.

(f) Food-contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces

that contact the food ordinarily occurs during the normal course of operations. “Food contact surfaces” include utensils and food-contact surfaces of equipment.

(g) *Frozen desserts* means ice cream, frozen custard, French ice cream, French custard ice cream, artificially sweetened ice cream, ice milk, freezer made shakes, fruit sherbet, water ice, quiescently frozen confection, quiescently frozen dairy confection, manufactured desserts mix, frozen confection, mellorine frozen dessert as all such products are commonly known, together with any mix used in such frozen desserts, and any products which are similar in appearance, odor or taste to such products, or are prepared or frozen as frozen desserts are customarily prepared or frozen, whether made with dairy products or non-dairy products.

(h) *Holding* means storage of food and also includes activities performed incidental to storage of a food.

(i) *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food.

(j) *Melloream* means any substance, mixture or compound regardless of the name by which it is represented, which contains vegetable fats or oils and proteins derived from animal or vegetable sources, and whose appearance, odor and taste is similar to cream, half and half, milk or a mixture of milk and cream, to the point of rendering these products difficult to differentiate from each other.

(k) *Milk* means milk and/or prepasteurized milk as defined in subdivisions (y) and (mm), respectively, of Section 2.29 of this Part, as the context requires.

(l) *Milk products* means goat milk products, milk products, and/or sheep milk products, as defined in subdivisions (r,) (cc), and (vv), respectively, of section 2.2 of this Part, as the context requires.

(m) *Packing* means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food.

(n) Pasteurized milk means milk, lowfat milk and skim milk, goat milk and/or sheep milk as defined in subdivisions (y), (w), (ww), (q) and (uu), respectively, of section 2.2 of this Part, as the context requires.

(o) Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

(p) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.

(q) Raw milk, except as used in section 2.60 of this Part, means prepasteurized milk as defined in section 2.2(mm) of this Part.

(r) 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.

(s) Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing

numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(t) *Unlawful indirect food additives* means food additives not listed in 21 CFR

Parts 175 – 178.

(u) *Unpasteurized milk* means prepasteurized milk as defined in section 2.2(mm) of this Part.

(v) *21 CFR* means Title 21 of the Code of Federal Regulations, revised as of April 1, 2016, published by the U.S. Government Printing Office, Washington, D.C. A copy of 21 CFR is maintained in a file at the Department of Agriculture and Markets, 10B Airline Drive, Albany, New York 12235, and at the Department of State, 99 Washington Avenue, Suite 650, Albany, New York 12231, and is available for public inspection and copying during normal business hours.

Section 2.30 of 1 NYCRR is amended to read as follows:

(a) *Floors.*

(1) The floors of all rooms in which milk is handled, processed, or stored, or in which milk containers or utensils are washed, [are] shall be constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.

(2) The floor surface [is] shall be smooth and sloped[,] so that there are no pools of standing water after flushing; and the joints between the floor and the walls [are] shall be impervious.

(3) The floors [are] shall be provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exists. Storage rooms for dry ingredients and/or packaging materials need not be provided with drains.

(4) The floors shall be constructed in such a manner to ensure that they can be adequately cleaned, kept clean, and kept in good repair.

(b) *Walls and ceilings.*

(1) Walls and ceilings [are] shall be finished with smooth, washable, light-colored painted wood, tile, smooth-surface concrete, cement plaster, brick, or other equivalent materials with washable, light-colored surfaces.

(2) [Walls, partitions, windows and ceilings are kept in good repair and refinished as often as the finish wears off or becomes discolored.] Walls and ceilings shall be constructed in such a manner to ensure that they can be adequately cleaned, kept clean, kept in good repair.

Subdivision (c) of section 2.31 of 1 NYCRR is repealed and a new subdivision (c) is added thereto, to read as follows:

(c) All openings shall be adequately screened or otherwise configured to protect against the entry of pests.

Subdivision (a) of section 2.32 of 1 NYCRR is repealed and a new subdivision (a) is added to thereto, to read as follows:

(a) Adequate lighting in hand-washing areas, dressing and locker rooms, toilet rooms, and all areas where food is manufactured, processed, packed, or held, and where equipment or utensils are cleaned, shall be provided.

Subdivisions (b) and (c) of section 2.32 of 1 NYCRR are relettered to be subdivisions (c) and (d) respectively, and a new subdivision (b) is added thereto, to read as follows:

(b) Adequate ventilation or control equipment to minimize dust, odors, and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food shall be provided; fans and other air-blowing equipment shall be provided, located, and operated in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

Subdivision (f) of section 2.33 of 1 NYCRR is repealed and a new subdivision (f) is added thereto, to read as follows:

(f) The milk plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The milk plant must:

(1) Provide adequate space for placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

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

Subdivision (a) of section 2.34 of 1 NYCRR is repealed and a new subdivision (a) is added thereto, to read as follows:

(a) Each milk plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities shall be kept clean and shall not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

Subdivisions (f) and (g) of section 2.34 of 1 NYCRR are amended to read as follows:

(f) All plumbing [is] shall be installed to meet the applicable provisions of the State or local plumbing code. Plumbing shall be of adequate size and design and adequately installed and maintained to ensure 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.

(g) Sewage and other liquid wastes [are] shall be disposed of in a sanitary manner. Plumbing shall be of adequate size and design and adequately installed and

maintained to properly convey sewage and liquid disposable waste from the milk plant.

Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

Subdivision (a) of section 2.35 of 1 NYCRR is amended to read as follows:

(a) Water for milk plant purposes shall be adequate for the operations intended and from an adequate supply, properly located, protected and operated. [It] Any water that contacts food, food-contact surfaces, or food-packaging materials shall be easily accessible and of a safe[,] and sanitary quality, and shall not cause allergen cross-contact or increase the level of contamination of the food. 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.

(1) When ice is used in contact with food, it must 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 set forth in this Part.

(2) Plumbing must be of adequate size and design, and shall be adequately installed and maintained, to carry adequate quantities of water to required locations throughout the milk plant.

Subdivision (a) of section 2.36 of 1 NYCRR is amended to read as follows:

(a) Hand-washing facilities [are] shall be provided[,] that are conveniently located and are designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials. [including hot] Adequate hot and cold and/or warm running water, and soap and individual sanitary towels or other approved hand-drying devices, shall be provided.

Section 2.37 of 1 NYCRR is amended by relettering subdivisions (a), (b), (c), and (d) to be subdivisions (b), (c), (d), and (e), respectively, and adding thereto a new subdivision (a) to read as follows:

(a) The milk plant, and all fixtures and structures therein, shall be maintained in a clean and sanitary condition and kept in repair adequate to prevent food from becoming adulterated.

Subdivisions (b) and (c) of section 2.37 of 1 NYCRR, relettered to be subdivisions (c) and (d), respectively, are amended to read as follows:

[(b)] (c) All piping, floors, walls, ceilings, fans, shelves, tables, and the nonproduct-contact surfaces of other facilities and equipment [are clean] shall be maintained in a clean and sanitary condition and shall be kept in a condition adequate to prevent food from becoming adulterated. Non-food-contact surfaces of equipment used in the operation of a milk plant shall be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

[(c)] (d) No trash or solid waste [is] shall be stored within the plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during operation of such equipment. Rubbish and any waste shall be so

conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

Subdivision (a) of section 2.39 of 1 NYCRR is amended to read as follows:

(a) All multiuse containers and equipment used in manufacturing, processing, packing, or holding of [with which] milk or milk products shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be adequately maintained to protect against allergen cross-contact and contamination. [come into contact are] Equipment shall be made of smooth, impervious, corrosion-resistant, and non-toxic material.

(1) Equipment and utensils shall be designed, constructed, and used in such a manner in order to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(2) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, food in process, rework, or other food shall be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(3) Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

Paragraph (1) of subdivision (a) of section 2.40 of 1 NYCRR is amended to read as follows:

(1) All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food. All multiuse containers and utensils [are] shall be thoroughly cleaned after each use, and all equipment [is] shall be thoroughly cleaned at least once each day used; provided, that storage tanks shall be cleaned when emptied and shall be emptied at least every 72 hours, except that in the

case of milk plants at which frozen desserts or storable milk products are manufactured, such tanks shall be emptied at least every 96 hours. Storage tanks which are used to store raw milk longer than 24 hours and silo tanks used for the storage of raw milk shall be equipped with a seven-day temperature recording device complying with the specifications of Appendix 3 of this Title.

Subdivision (a) of section 2.40 of 1 NYCRR is amended by adding thereto new paragraphs (3), (4), (5), and (6), to read as follows:

(3) All utensils and equipment shall be cleaned and sanitized in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(4) Food-contact surfaces used in the manufacturing/processing, packing, or holding low-moisture food shall be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they shall be sanitized and thoroughly dried before subsequent use.

(5) In wet processing, when cleaning is necessary to protect against allergen cross-contact or 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 must be cleaned and sanitized as necessary.

(6) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be both free from undesirable microorganisms and safe and adequate under the conditions of use. Compliance with this requirement shall be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination.

Subdivision (a) of section 2.41 of 1 NYCRR is amended to read as follows:

(a) All multiuse containers, equipment and utensils, after cleaning, [are] shall be transported and/or stored on [metal] racks or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively non-absorbent, corrosion-resistant, non-toxic materials, or otherwise protected from contamination. All portable equipment with food-contact surfaces, and all utensils, that have been cleaned and sanitized shall be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

Subdivision (a) of section 2.42 of 1 NYCRR is amended to read as follows:

(a) Single-service caps, cap stock, parchment paper, containers, gaskets and other single-service articles [for use in contact with milk and milk products are] shall be:

(1) purchased and stored in sanitary tubes, wrappings or cartons; [are]

(2) kept in a clean, dry place until used; and [are].

(3) handled in a sanitary manner.

Single-service articles must be stored, handled, and disposed of in a manner

that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

Subdivision (a) of section 2.43 of 1 NYCRR is repealed and a new subdivision (a) is added thereto, to read as follows:

(a) The milk plant shall operate in a manner to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The milk plant shall:

(1) Provide adequate space for placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Take adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material.

The potential for allergen cross-contact and for contamination shall be reduced by adequate food safety control, operating practices, or effective design,

including the separation of operations in which allergen cross-contact and contamination are likely to occur, or by any affective means including but not limited to: location, time, partition, air flow systems, dust control systems, and/or enclosed systems.

(3) Take adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including but not limited to:

(i) Using protective coverings;

(ii) Controlling areas over and around the vessels to eliminate harborages for pests;

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

(4) Be operated in such a manner 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, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide shatter-resistant 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.

Subdivision (c) of section 2.43 of 1 NYCRR is amended to read as follows:

(c) All milk, [and] milk products, and ingredients [which] that have overflowed, leaked, been spilled, [or] improperly handled, or are otherwise adulterated [are] shall be discarded or, if appropriate, treated or processed to eliminate the contamination. Milk and milk products drained from processing equipment at the end of a run, or collected from a defoamer system and milk solids rinsed from equipment, containers or pipelines, [shall] may be repasteurized only if such milk or milk products are handled in a sanitary manner and maintained at 45°F (7°C) or less. When the handling and/or refrigeration of such milk and milk products are not in compliance with this requirement, they shall be

discarded. Returned packaged milk and milk products, frozen desserts or melloreem shall not be repasteurized for Grade A milk products, frozen desserts or melloreem use; provided, that the repasteurization of milk and milk products shipped in transport tankers which have been pasteurized at another Grade A plant and have been handled in a sanitary manner and maintained at 45°F (7°C) or less is permitted.

Subdivision (e) of section 2.43 of 1 NYCRR is amended to read as follows:

(e) [Whenever air] Air under pressure that is used for the agitation or movement of milk, or is directed at a milk-contact surface, [it is] shall be free of oil, dust, rust, excessive moisture, extraneous materials, and odor. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products, it shall be of culinary quality and shall comply with the applicable standards of quality. 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.

Subdivision (i) of section 2.43 of 1 NYCRR is amended to read as follows:

(i) All ingredients and nonproduct-contact materials used in the preparation or packaging of milk and milk products [are] shall be stored in a clean place and [are] so handled as to prevent their contamination.

(1) Raw materials and other ingredients shall be inspected and segregated or otherwise adequately handled to ensure that they are clean and suitable for processing into food and stored be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with 21 CFR Part 109 for poisonous or deleterious substances before being incorporated into finished food.

(4) Raw materials, other ingredients, and rework that contain an added poisonous or deleterious substance shall not contain an amount any such substance in excess of the applicable defect action level.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination, and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

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

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, shall be identified and held in a manner that prevents allergen cross-contact.

Subdivision (k) of section 2.43 of 1 NYCRR is repealed and a new subdivision (k) is added thereto, to read as follows:

(k) Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

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

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

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

and

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

Subdivision (l) of section 2.43 of 1 NYCRR is amended to read as follows:

(l) Those poisonous or toxic materials that are necessary [are]:

(1) shall not be stored in [any] a room where milk or milk products are received, processed, pasteurized or stored, or where equipment, containers, or utensils are washed or where single-service containers, closures or caps are stored; and

(2) shall be stored in a manner that protects against contamination of food, food-contact surfaces, and food packaging materials.

Subdivision (m) of section 2.43 of 1 NYCRR is amended to read as follows:

(m) Those poisonous or toxic materials that [are necessary are] may be used or stored, pursuant to subdivision (k) of this section, shall be stored in a separate area of the plant in [prominently and distinctly labeled] containers that have labels affixed thereto that prominently and distinctly advise and warn against the use of such

materials in a manner that may cause or contribute to contamination of food, food contact surfaces, or food packaging materials; provided, that this does not preclude the convenient availability of detergents or sanitizers to areas where equipment, containers and utensils are washed and sanitized.

Subdivision (n) of section 2.43 of 1 NYCRR is amended to read as follows:

(n) Effective measures shall be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only to the extent that precautions and restrictions are taken that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. Only [insecticides and rodenticides] pesticides approved by the commissioner and/or registered with the U.S. Environmental Protection Agency shall be used for [insect and rodent] pest control. Such [insecticides and rodenticides] pesticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from

contaminating [milk, containers, equipment and utensils] food, food-contact surfaces, or food-packaging materials.

Section 2.43 of 1 NYCRR is amended by adding subdivisions (o), (p), (q), (r), (s), (t), (u), (v), and (w) thereto, to read as follows:

(o) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Adequate precautions shall be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(p) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) shall be conducted in accordance with adequate sanitation principles.

(q) All food manufacturing, processing, packing, and holding shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(r) Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(s) 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 precise, adequately maintained, and adequate in number for their designated uses.

(t) The mixing of adulterated food with another lot of food shall not be permitted and renders the final food adulterated.

(u) The manufacturer, processor, packer, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(v) Storage and transportation of food shall be under conditions that will adequately protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

(w) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor shall be held under conditions that will protect against contamination, including the following:

(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution shall be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food shall be accurately identified.

(4) Labeling that identifies the by-product by the common or usual name shall be affixed to or accompany human food by-products for use as animal food when distributed.

(5) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food shall be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

Subdivision (a) of section 2.44 of 1 NYCRR is repealed and a new subdivision (a)

of section 2.44 is added thereto, to read as follows:

(a) Pasteurization shall be performed as follows: Every particle of prepasteurized milk, milk, lowfat milk, skim milk, milk product, goat milk, goat milk product, sheep milk, sheep milk product, mellorecream and frozen dessert mix, with the exception of water ice mix and flavoring agents used in frozen desserts, shall be heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Batch (Vat) Pasteurization	
Temperature	Time
63°C (145°F)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	Time
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 seconds
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

* If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5°F (3°C): provided, that eggnog and frozen desserts shall be heated to at least the following temperature and time specifications:

Batch (Vat) Pasteurization	
Temperature	Time
69°C (155°F)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	Time
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

Provided further, that nothing shall be construed as barring any other pasteurization process which has been recognized by the FDA to be equally efficient and which is approved by the commissioner.

Subdivision (c) of section 2.49 of 1 NYCRR is amended to read as follows:

(c) Each [refrigerator room] freezer and cold storage compartment [in which milk or milk products are stored is equipped with an indicating thermometer] used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device [which] that complies with the applicable specifications of Appendix 3 of this

Title[.] and shall be installed as to show the temperature accurately within the compartment. Such thermometer shall be located in the warmest zone of the [refrigerator room] freezer and cold storage compartment. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix 3 of this Title[.] and shall be installed as to show the temperature accurately within the compartment.

Section 2.52 of 1 NYCRR is repealed and a new section 2.52 is added thereto, to read as follows:

Section 2.52. Personnel Cleanliness--Item 20p

All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food.

The methods for maintaining cleanliness include:

(a) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(b) Maintaining adequate personal cleanliness.

(c) 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.

(d) 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.

(e) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

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

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

(h) 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.

(i) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials from microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

Section 2.54 of 1 NYCRR is repealed and a new section 2.54 is added thereto, to

read as follows:

(a) The grounds about a milk 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 shall include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

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

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

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

(5) Grading, draining, and keeping free of standing water driveways, lanes, and areas adjacent to the milk plant.

(6) Constructing outdoor areas for milk tank truck unloading from smooth concrete or equally impervious material that are properly sloped to drain and are equipped with trapped drains of sufficient size.

(7) Using only those insecticides and rodenticides that have been approved for use by the Department and/or registered with the U.S. Environmental Protection Agency.

(8) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (7) of this section, care must be exercised in the plant by inspection,

extermination, or other means to exclude pests, dirt, and filth that may be a source of contamination.

(b) Rubbish and any waste shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant, harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

Section 2.65 of 1 NYCRR is amended by relettering subdivisions (a) and (b) to be subdivisions (b) and (c), respectively, and to add thereto a new subdivision (a), to read as follows:

(a) 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 until the

condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.