4000 Division of Public Health

4457 Regulations Governing the Manufacture and Sale Of Ice

1.0 Preamble

1.1 These Regulations are adopted by the Division of Public Health pursuant to the authority invested in the Board by 16 **Del.C.** §122(1), (3)(a,b,c,f and j). It is hereby declared that it is the purpose of this section to protect, preserve and promote the public health and well-being of the people, to minimize the incidence of communicable diseases, and to regulate the manufacture of ice and to provide for the examination and labeling of ice for the purpose of maintaining minimal adequate sanitation standards.

1.2 These Regulations adopted April 27, 1990 by the Division of Public Health have an effective date of May 15, 1990.

2.0 Application

2.1 These Regulations shall be liberally construed and applied to promote their underlying purpose of protecting the public health. They establish minimum standards and those facilities that choose to require more stringent standards are encouraged to do so.

2.2 These Regulations shall apply to the construction, alteration, addition to and maintenance and/or operation of all ice plants in the State of Delaware, to those ice plants located in states where no ice manufacturing regulations presently exist, and to the ice products originating from outside of the State that are sold in Delaware when Delaware has established reciprocity agreements with such jurisdictions.

3.0 Scope

3.1 These Regulations are written with the intent of impacting upon those persons by whom ice is manufactured or processed, and offered for wholesale or retail sale to the public.

4.0 Severability

4.1 If any provision or application of these Regulations is held invalid, that invalidity shall not affect provisions or applications of these Regulations.

General Provisions

5.0 Definitions

5.1 For purposes of these Regulations:

"**Adequate**" shall mean that which is needed to accomplish the intended purpose in keeping with good public health practice.

"**Approved**" shall mean acceptable to the regulatory authority.

"**Contamination**" shall mean the condition whereby ice or the water used in its manufacture has been or may have been exposed to or may have come in contact with foreign or injurious substances or matter including but not limited to microorganisms.

"**Coring**" shall mean the process of pumping off or removing that portion of a block of ice which has not solidified during the freezing process.

"**Critical Control Point**" shall mean a point in the processing of ice where there is a high probability that improper control may cause, allow or contribute to a hazard or to filth in the final product.

"**Easily Cleanable**" shall mean those surfaces that are readily accessible and made of such materials and finish and so fabricated that residue may be effectively removed by normal cleaning methods.

"**Employee**" shall mean any person working in an ice plant who transports ice or ice containers, who engages in ice manufacture, processing, packaging, storage or distribution, or who comes into contact with any ice equipment.

"**Food Contact Surfaces**" shall mean those surfaces, including a water line, that is touched by a product or ingredient during processing. The term includes those surfaces from which water may drain, drip or splash back.

"**Hazardous Chemical**" shall mean any element, chemical, compound or mixture of elements and/or compounds which is a physical hazard or health hazard.

"**Ice**" shall mean the product, in any form, obtained as a result of freezing water by mechanical or artificial means.

"**Ice Plant**" shall mean any commercial establishment, together with the necessary appurtenances in which ice is manufactured, or processed and stored, packaged, or distributed and offered for sale for human consumption.

"**Person**" shall mean an individual, or a firm, partnership, company, corporation trustee, association, other business organizations or any public or private entity.

"**Potable Water**" shall mean water which is in compliance with all of the required applicable drinking water regulations.

"**Processing**" shall mean the act or acts of grinding, crushing, flaking, cubing or any other operation which changes the physical characteristics of ice.

"**Product**" shall mean any and all areas where the product, ingredients, or packaging materials are handled or stored, including any area related to the manufacturing, packaging, handling, and storage of ice intended for sale for human consumption.

"**Regulatory Authority**" shall mean the official enforcement agency responsible for ice plant sanitation.

"**Sanitization**" shall mean the adequate treatment of food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumers.

"**Single-service Article**" shall mean those articles which are intended by the manufacturers, and are generally recognized by the public as being for one usage only, then to be discarded.

"**Treatment"** shall mean a mechanism which demonstrated to the satisfaction of the regulatory authority will lead to a reduction in the level of any contaminant.

"**Utensil**" shall mean any multi-use cans, buckets, tubs, pails, vats, containers, covers, tongs, picks and similar items used in the manufacture and handling of ice.

6.0 Pre-operational Requirements

6.1 General

6.1.1 An ice plant must comply with these Regulations if it manufactures or processes, and offers ice for wholesale or retail sale to the public.

6.1.2 No person shall operate an ice plant, within the definition set forth in Section 5.0, who does not have a valid permit issued to him by the regulatory authority. Only a person who complies with the requirements of these Regulations shall be entitled to receive or retain such a permit. Permits shall not be transferable from person to person, nor from location to location. The valid permit shall be posted in a location easily observed by the consumers.

6.1.3 When an ice plant changes either ownership, management firm, or lessee, both the facility and its operation shall be brought into full compliance with these Regulations prior to the issuance of a permit. Variances may be issued by the Division of Public Health for reasons stated in Section 17.18.2 of these Regulations.

6.1.4 Sections 1.0 through 16.0 of these Regulations outline requirements for facilities with permanent or provisional permits. Section 17.0 provides compliance procedures applicable to all ice plants issued permits in accordance with Section 6.4.

6.2 Out of State Compliance Verification

6.2.1 In order for any out-of-state ice plant to obtain a permit to ship ice into Delaware, plans and specifications must be submitted in accordance with Section 6.3 to: Bureau of Environmental Health, P. O. Box 637, Dover, DE 19903.

6.2.2 In order for a permit to be issued to a firm located in a state where no ice regulations exist and no recognized certifying laboratory exists, approval can only be achieved by:

6.2.2.1

6.2.2.1.1 Reciprocity approval with that state's regulatory authority; or

6.2.2.1.2 An on-site approval by a designated representative of the Delaware Division of Public Health.

6.2.2.1.3 Certification by an approved nationally recognized certifying body.

6.3 Classification of Ice Plant Permits

6.3.1 Permanent Permits

6.3.1.1 A permanent permit shall be issued as delineated in Section 6.4 and 6.5.

6.3.2 Provisional Permits

6.3.2.1 When no health hazards are present, as determined by the regulatory authority, in an existing ice plant, and the new owner or operator demonstrates proof of intention to correct, within a specified time period, those items which do not meet permit requirements, a provisional permit may be issued. Plans, as required, and a written statement delineating changes to be made and completion dates must be presented to the regulatory authority before a provisional permit shall be issued for a 30-day period, with possible extension to a maximum of 60 days, and shall be non-renewable. After satisfactory compliance with permit requirements, a permanent permit shall be issued.

6.4 Issuance of Permits

6.4.1 Any person desiring to operate an ice plant shall make written application for a permit on forms provided by the regulatory authority. Such application shall include the name and address of each applicant, the location of the ice plant and the signature of each applicant.

6.4.2 Prior to approval of an application for a permit, the regulatory authority shall inspect the proposed ice plant to determine compliance with the requirements of these Regulations.

6.4.3 The regulatory authority shall issue a permit to the applicant if its inspection reveals that the proposed ice plant complies with the requirements of these Regulations.

6.4.4 A permanent permit, after issuance, remains valid indefinitely, or until such time as the ice plant is closed, "out of business," a new owner, management firm or lessee takes possession, or the permit is revoked by the Health Authority for violation(s) of these Regulations.

6.5 Submission of Plans

6.5.1 Whenever an ice plant is constructed or undergoes physical alterations, and whenever an existing structure is converted to use as an ice plant, properly prepared plans and specifications for such conversion shall be submitted to the applicable County Health Unit, Division of Public Health, for review and approval before construction, alteration or conversion is begun. The plans and specifications shall indicate the proposed layout, arrangement, mechanical plans, and construction materials of work areas, and the type and model of proposed fixed equipment and facilities. The applicable County Health Unit shall approve plans and specifications if they meet the requirements of these Regulations. No ice plant shall be constructed or undergo physical alterations, nor shall a structure be converted to an ice plant except in accordance with plans and specifications approved by the applicable County Health Unit.

6.6 Post-construction Inspection

6.6.1 Whenever plans and specifications are required by Section 6.5 of these Regulations, the regulatory authority shall inspect the ice plant prior to the start of ice manufacturing or processing, to determine compliance with approved plans and specifications and with the requirements of these Regulations. The post-construction inspection report shall indicate compliance with the plans and specifications as approved by the regulatory authority.

6.7 Pre-operational Inspection

6.7.1 The regulatory authority shall inspect an ice plant prior to the start of operations to determine compliance with the requirements of these Regulations, as follows:

6.7.1.1 Following completion of a satisfactory post-construction inspection, a newly converted or physically altered facility shall be in a minimum of 90% compliance with these Regulations in order to be approved for a permanent operating permit.

6.7.1.2 When there is a change of ownership, management firm, or lessee of an existing operating facility:

6.7.1.2.1 A new operating permit will be issued.

6.7.1.2.2 The facility shall be in a minimum of 90% compliance with these Regulations to be approved for a permanent operating permit.

6.7.1.2.3 The new owner, management firm, or lessee may be granted a provisional permit to operate in accordance with Section 6.3.2, pending completion of the requirements for a permanent operating permit.

6.7.1.2.4 The new owner, management firm, or lessee may be granted a variance from certain requirements in accordance with Section 17.18.2.

6.7.1.3 When reopening an ice plant which has been closed for 60 or more consecutive days. The facility shall be in a minimum of 90% compliance with these Regulations in order to be approved for a permanent operating permit, or to resume operations under a currently valid permit.

Quality Standards

7.0 Water Source

7.1 Ice-Contact and Ingredient - Potability Requirements

7.1.1 All water used in ice plants, including that used in preparing brine solutions, shall be of safe and sanitary quality and drawn from an approved public or private water supply system which is constructed, protected, operated, and maintained in conformance with applicable Federal, State and local laws, ordinances, and regulations, and in compliance with “State of Delaware Regulations Governing Public Drinking Water Systems” and the U.S. Environmental Protection Agency Drinking Water Standards. Only potable water shall be used in sprays and in filling dipping wells for the removal of ice cakes from ice cans or tanks. Ice shall not come into direct contact with water in dipping wells.

7.2 Potability Exception

7.2.1 If specifically approved by the regulatory authority, a non-potable water supply may be permitted within the plant for purposes of fire protection, cooling of refrigeration equipment, use in boilers or flushing toilets.

7.3 Water Treatment

7.3.1 If water is treated at the ice plant, the facilities and treatment shall be approved by the regulatory authority. Use of chemicals and additives shall be in accordance with regulations promulgated under the food additives amendment to the Federal Food, Drug and Cosmetics Act (52 Stat. 1040, 21 U.S.C. §301, et seq.).

7.4 Ice Quality

7.4.1 Ice intended for human consumption and for use in direct contact with water, beverage, food, food equipment or utensils shall meet the same bacteriological, chemical and physical standards as are required of the water from which it is made.

7.5 Testing and Analysis Requirements

7.5.1 Frequency of source water testing and analytical procedures shall conform with the requirements as specified in the "State of Delaware Regulations Governing Drinking Water Systems."

7.5.2 Product ice shall be sampled for bacteriological analysis on a monthly basis during the peak period of production, from May 1 through September 30. Sampling during the remainder of the year shall be conducted on a quarterly basis. Said sample collection requirement shall be satisfied by any routine samples collected at the time of annual regular inspection.

7.5.3 Both source water and ice product samples shall be collected by a representative of the regulatory authority having jurisdiction in the matter or by a representative of a recognized certified laboratory.

Water/Ice Protection

8.0 Water Protection

8.1 All water storage shall have suitable watertight covers which exclude birds, animals, insects and excessive dust. All openings shall be screened.

8.2 Ice Protection

8.2.1 Ice, while being manufactured, processed, packaged, stored and transported~~,~~ shall be protected from contamination. As such, these activities must be conducted in an enclosed building and maintained in sanitary condition. Such ice shall not be processed, packaged, or stored on open platforms or transported or in trucks or delivery vehicles, or in any manner which would permit contamination from overhead drip, dust, dirt, rodents, insects or any other sources of contamination.

Personnel

9.0 Employee Health

9.1 No person, while infected with a disease in a communicable form that can be transmitted by ice, or who is a carrier of organisms that cause such a disease, or while afflicted with a boil, an infected wound, or an acute respiratory infection, shall work in an ice plant in any capacity in which there is a likelihood of such a person contaminating ice or ice-contact surfaces with pathogenic organisms or transmitting disease to other persons.

9.2 Personnel Hygiene

9.2.1 Persons working in direct contact with ice or ice-contact surfaces:

9.2.1.1 Shall thoroughly wash their hands and the exposed portions of their arms with soap and warm water in an approved handwashing 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;

9.2.1.2 Shall not resume work after visiting the toilet room without washing hands;

9.2.1.3 Shall wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices to the extent necessary to prevent contamination of the product;

9.2.1.4 Shall wear hair nets, headbands, caps or other effective hair restraints;

9.2.1.5 Take necessary precautions to prevent contamination of ice and ice-contact surfaces with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals and medications; and

9.2.1.6 Shall not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in areas of manufacturing, processing, packaging and storage.

Process Controls

10.0 Supplies Storage

10.1 Storage of paper and packaging supplies shall be on pallets or raised above floor level, and all partially used supplies shall be kept in closed containers.

10.2 Single-service supplies shall be stored, dispensed and handled in a sanitary manner and shall be used only once.

10.3 Hazardous Chemicals. Hazardous chemicals consist of the following categories:

10.3.1 Insecticides and rodenticides;

10.3.2 Detergents, sanitizers, related cleaning agents;

10.3.3 Refrigerants particular to the ice industry such as anhydrous ammonia and chlorinated fluorocarbon (freon).

10.4 Chemicals Permitted

10.4.1 There shall be present in the ice plant only those hazardous chemicals necessary for maintaining the establishment and the grounds, cleaning and sanitizing equipment and utensils and controlling insects and rodents.

10.4.2 The presence and storage of necessary hazardous chemical shall be reported in accordance with State and Federal law.

10.5 Labeling of Chemicals

10.5.1 Containers of hazardous chemicals shall be prominently and distinctly labeled in accordance with 29 CFR 1910.1200, “Hazard Communication Standard.”

10.6 Storage of Chemicals

10.6.1 Hazardous chemicals must be stored in accordance with applicable Federal and State requirements.

10.7 Filtration System

10.7.1 Filter beds and filtering equipment shall be designed to protect ice from contamination and shall be subject to periodic treatment and cleaning as required for good sanitation practices.

10.8 Agitator

10.8.1 Air intakes shall be located and maintained in an approved manner.

10.8.2 Filters shall be located upstream from the compressor and shall be easily removable for cleaning or replacement.

10.9 Agitation Air

10.9.1 Air used for water agitation shall be filtered or otherwise treated to render it free of dust, dirt, insects, and extraneous material.

10.10 Blower/Compressor

10.10.1 The blower or compressor for supplying air for water agitation shall be designed so it will deliver oil-free air. Oil-free air may be produced by one of the following methods or its equivalent:

10.10.1.1 Use of a carbon ring compressor; or

10.10.1.2 Use of an oil-lubricated compressor with effective provision for removal of any oil vapor; or

10.10.1.3 Use of high-pressure water lubricated or non-lubricated blowers.

10.11 Restricted Operations

10.11.1 Ice for human consumption shall be processed and packaged only in rooms used solely for those operations necessary to the processing and packaging of food products.

10.12 Restricted Access

10.12.1 Unauthorized Personnel.

10.12.1.1 Unauthorized personnel shall not be permitted in any room where ice is manufactured, processed, packaged, or stored.

10.13 Animals

10.13.1 No live animals shall be allowed in any production, packaging or storage areas of the plant.

Packaging and Labeling

11.0 Packaging

11.1 The immediate ice-contact surface of any product packaging material shall be foodgrade in quality, and therefore meet the food safety requirements of 16 **Del.C.,** Ch. 33, Pure Food & Drug Act of the State of Delaware.

11.2 Labeling

11.2.1 Ice packaging shall clearly and accurately display the following information:

11.2.1.1 Product common name;

11.2.1.2 Net weight;

11.2.1.3 Processing Plant/Distributor Name, Address and Zip Code; and

11.2.1.4 Production lot number/code.

Liquid Waste Disposal

12.0 Sewage Disposal

12.1 All sewage and waste water shall be disposed of by means of a public sewerage system or an approved sewage-disposal system which is constructed, operated and maintained in conformance with applicable State and local laws, ordinances, and regulations.

12.2 Waste Processing Water

12.2.1 Water used for washing or rinsing shall not be reused and shall be disposed of as liquid waste.

Plumbing

13.0 General

13.1 All plumbing shall be sized, installed and maintained in accordance with applicable State and local plumbing laws, ordinances, and regulations. Plumbing shall be of adequate size and design and installed and maintained to carry sufficient quantities of water to required locations throughout the ice plant.

13.2 Cross-Connections

13.2.1 The potable water supply piping shall not be connected with any non-potable water supply system whereby the non-potable water can be drawn or discharged into the potable water supply system.

13.3 Backflow

13.3.1 The potable water system shall be installed in such a manner as to preclude the possibility of backflow into the system.

13.4 Marking/Identification

13.4.1 The piping of any non-potable water system shall be adequately and durably identified, such as by distinctive colored paint, so that it is readily distinguished from piping which carries potable water; and non-potable water shall not be connected to equipment, except as specified in Section 7.2, or have outlets in the brine circulation tanks. Fire protection outlets shall be so designed or protected as to discourage their use for any other purpose.

13.5 Drain Lines

13.5.1 Drain lines from equipment shall not discharge waste water in such a manner as to permit flooding of floors or the flowing of water across working or walking areas, or in difficult to clean areas, or otherwise create a nuisance.

13.5.2 Soil, waste or discharge pipes shall be so located, installed and maintained as not to constitute a source of contamination for ice equipment, or utensils, or to create an insanitary condition or nuisance.

Toilet and Handwashing Facilities

14.0 Toilet Facilities

14.1 Toilet Installation.

14.1.1 Toilet facilities shall be installed according to law, shall be adequate and conveniently located, and shall be accessible to the employees at all times. Applicable laws include the "State of Delaware Regulations Governing a Detailed Plumbing Code", and specific county/city building and plumbing codes. These facilities shall contain or be located adjacent to adequate handwashing facilities.

14.2 Toilet Fixtures.

14.2.1 Toilets and urinals shall be designed to be easily cleanable.

14.3 Toilet Rooms.

14.3.1 The walls, ceilings and floors of these facilities shall be of a material that is easy to clean. These rooms and their fixtures shall be kept clean and in good repair.

14.3.2 Toilet rooms shall be completely enclosed, properly ventilated, and shall have tight-fitting, self-closing doors. Windows, when provided in rest rooms and capable of being opened, shall be equipped with screens in good repair. Toilet room doors shall not be left open except during cleaning or maintenance, nor shall they open directly into the manufacturing, processing or packaging areas. If vestibules are provided, they shall be kept clean and in good repair.

14.3.3 Each toilet shall be furnished with toilet tissue at all times.

14.3.4 Signs shall be posted requiring employees to wash hands with soap or detergent before returning to work.

14.4 Handwashing Facilities.

14.4.1 Handwashing facilities shall have hot and cold running water, hand-cleaning soaps or detergents, and sanitary paper towels or other approved sanitary hand-drying device. If provided, mechanical hand dryers shall be maintained in good repair. Adequate trash receptacles with covers shall be provided for disposal of waste.

Design, Construction and Maintenance

15.0 Ice Plant Structure - General

15.1 Plant buildings and structures for ice manufacture shall be suitable in size, construction, design, and of sound repair to facilitate maintenance and sanitary operations including the effective exclusion of vermin.

15.2 Sufficient space shall be provided for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe ice.

15.3 Housekeeping operations shall be sufficiently frequent and thorough to maintain all parts of the plant in a clean condition.

15.4 Contamination Exclusion

15.4.1 Ice manufacturing, processing, packaging and storage operations shall be conducted in an enclosed building designed to protect the ice, ingredients, equipment and utensils from contamination. Adequate screening and tight-fitting closures shall be provided at

openings to ice manufacturing, processing, packaging and storage areas to effectively exclude dust, dirt, rodents, birds or insects and other sources of contamination

15.5 Floors, Walls and Ceilings

15.5.1 The floors, walls and ceilings of all rooms in which ice is manufactured, processed, packaged, and stored shall be of such material, and so constructed as to facilitate cleaning and good repair. They shall be maintained in a clean and sanitary condition.

15.5.2 Adequate floor drainage shall be provided in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste onto the floor.

15.6 Lighting

15.6.1 Illumination Requirements.

15.6.1.1 Adequate lighting shall be provided in areas where ice is manufactured, processed, packaged or stored to facilitate handling and inspection of the product and cleanup and repair of the building, equipment and utensils. Sources or artificial light shall be provided and used to the extent necessary to provide illumination on those surfaces and in those areas when in use and when being cleaned. The following minimum intensities, as measured 30 inches from the floor, shall be fulfilled:

15.6.1.1.1 At least 10 foot-candles of light shall be required on surfaces in all rooms or areas in which ice is manufactured, processed or packaged,

15.6.1.1.2 At least 10 foot-candles of light shall also be required in utensil-washing areas, toilet rooms, handwashing areas and dressing and locker rooms.

15.6.1.1.3 Storage rooms shall have at least 5 foot-candles of light.

15.7 Protective Shielding.

15.7.1 Effective shielding to protect against broken glass falling onto ice or equipment shall be provided on all light bulbs, fixtures, skylights or other glass suspended over, by or within, ice manufacturing, processing, packaging and storage areas.

15.8 Ventilation.

15.8.1 Rooms in which hazardous chemicals are stored or used shall be ventilated in accordance with applicable Federal, State, and local requirements.

15.8.2 Adequate ventilation shall be provided, and the equipment kept clean, to minimize odors, noxious fumes or vapors, and condensate in manufacturing, processing, and storage rooms.

15.8.3 Toilet rooms and fixtures shall be ventilated in accordance with applicable State and local plumbing laws, ordinances, and regulations.

15.9 Vehicles

15.9.1 Vehicles used for transporting or delivering unpackaged ice shall be of closed construction with tight-fitting covered bodies. All vehicles hauling unpackaged ice shall be thoroughly washed immediately prior to loading with ice.

15.9.2 The ice compartment of vehicles used in transporting or delivery of ice shall be of cleanable construction and shall be kept clean and in good repair. If the vehicles are of open construction, they shall have tight floors and sides and shall be equipped with clean tarpaulins.

15.10 Grounds

15.10.1 The grounds around the ice plant under the control of the operator shall be free from conditions, which may result in the contamination of ice including, but not limited to~~,~~ the following:

15.10.1.1 Improperly stored or discharged equipment, litter, waste, refuse, and uncut weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for rodents, insects, and other pests;

15.10.1.2 Excessively dusty roads, yards, or parking lots that may constitute a source of contamination; or

15.10.1.3 Inadequately drained areas that may contribute contamination to the ice through seepage or foot-borne filth, by providing a breeding place for insects or microorganisms.

Equipment and Utensils

16.0 General

16.1 All equipment and utensils used in ice plants shall be of easily cleanable construction and shall be kept clean, in good repair, and shall be handled and stored in a sanitary manner. Materials used as ice-contact surfaces shall be smooth, non-toxic, and corrosion resistant and non-absorbent.

16.2 Ice-contact surfaces, including loading platforms, conveyors, and chutes, shall be easily cleanable and shall be kept clean and in good repair.

16.3 Equipment Lubrication.

16.3.1 Equipment lubrication shall not cause contamination and only food grade lubricants shall be used.

16.4 Ice Cans

16.4.1 Ice cans shall be leak-proof and the inner surfaces shall be free of corrosion.

16.4.2 Canvas containers shall not be used unless such use is with a sanitary single-service liner that completely protects the ice from contamination.

16.5 Tank Covers.

16.5.1 Freezing tank covers shall be designed and constructed of acceptable and easily cleanable materials to protect ice containers from contamination. They shall be kept clean and in good repair and shall be equipped with rings or similar devices when hooks are used for pulling. Can or tank covers and the ledges or sides of the tank upon which the cover rests shall be cleaned as often as necessary to keep them in a sanitary condition.

16.6 Conveyors.

16.6.1 Conveyor surfaces shall be of impervious material and shall protect ice from contaminants that may result from shredding, flaking, peeling or fragmentation of the conveyor surface.

16.7 Equipment Cleaning and Sanitization

16.7.1 Ice contact surfaces, including storage bins, conveyors, packaging equipment and hand utensils shall be kept clean. Ice contact surfaces shall be cleaned, using acceptable cleansers and cleaning methods, as often as necessary to insure that no contamination of the product occurs.

16.7.2 Equipment that is used to store or deliver water or that is in contact with the ice in the freezing process should be regularly sanitized. All process water-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the surfaces may have become contaminated. Any time portable equipment or utensils contact the floor or are otherwise subjected to contamination, they shall be cleaned and sanitized, before use or storage in a sanitary manner.

16.7.3 Cleaning and sanitization operations shall be conducted in a manner to preclude contamination of product and product contact surfaces. When chemicals are used for sanitization, they shall not exceed concentrations permitted under 21 CFR 178.1010. An approved means for measuring the solution concentration shall be provided and used.

16.8 Utensil and Equipment Storage.

16.8.1 Utensils and portable equipment shall be maintained in a sanitary condition. When not in use, they shall be stored in a clean cabinet or other suitable enclosure which provides protection from contamination. When equipment or utensils contact the floor or are otherwise subjected to contamination, they shall be thoroughly sanitized before reuse.

16.9 Tarpaulins

16.9.1 If transporting or delivery vehicles are of such design as to require them, tarpaulins shall meet the following criteria. Tarpaulins shall:

16.9.1.1 Cover the entire load and reach all the way to the floor in back of the load; and

16.9.1.2 They shall be thoroughly cleaned after each usage.

Compliance Procedures

17.0 General

17.1 No person shall operate an ice plant who does not possess a valid permit issued to him by the Division of Public Health in accordance with Section 6.0 of these Regulations. Only a person who complies with the requirements of these Regulations shall be entitled to receive or retain such a permit.

17.2 A valid Delaware Division of Public Health permit shall be posted in a conspicuous location, in every ice plant.

17.3 The Division of Public Health, or its designated authority, for just reasons of non-compliance with the requirements of these Regulations, may: Refuse to issue a permit, deny the reissuance of a permit; or suspend/revoke a permit.

17.4 Enforcement authority for the assurance of a safe source of water supply and the microbiological, chemical and physical standards of both the water and the ice product shall be vested concomitantly in these Regulations and in ***State of Delaware Regulations Governing Drinking Water Supplies.***

17.5 Change of Ownership, Management Firm or Lessee

17.5.1 A valid permit is not transferable from person to person or location to location. Therefore, it is the responsibility of the new owner/operator to apply for an operating permit prior to commencing operations.

17.5.2 If any renovation(s) of the physical structure of the transferred facility is(are) required, based on previous inspection reports of the regulatory authority, the new owner/operator will be held responsible for this(these) renovation(s).

17.5.3 Compliance with these Regulations shall be achieved prior to the start of business unless the new owner/operator is either granted a variance in accordance with Section 17.18.2, or is granted a provisional permit in accordance with Section 6.3.2 of these Regulations. Upon compliance with these Regulations, a permanent permit shall be issued to the operator as described in Section 6.3.1.

17.6 Inspections

17.6.1 Inspection Frequency.

17.6.1.1 An inspection of an ice plant shall be performed at least once every twelve (12) months. Additional inspections of the ice plant shall be performed as often as necessary for the enforcement of these Regulations.

17.7 Official Access.

17.7.1 Representatives of the regulatory authority, after proper identification, shall be permitted to enter any ice plant or gain access to product stored in vending machines at any reasonable time for the purpose of making inspections to determine compliance with these Regulations. These inspections may include any room, area or vehicle associated with the ice plant operation. In addition, the representatives shall be permitted to examine the records of any ice plant to obtain information pertaining to required water and ice product analysis, bulk ice product purchase receipts and supplies used. The Deputy State Health Officer, or his/her designee may, after providing the opportunity for a hearing, suspend for a period not to exceed ninety (90) days, the permit to operate an ice plant for refusing access to representatives of the regulatory authority.

17.8 Inspection Report Form

17.8.1 A co-signed copy of the completed inspection report form adopted by the regulatory authority shall be furnished to the person in charge of the ice plant at the conclusion of the inspection. Inspectional remarks on the completed inspection form shall refer to the

item(s) violated, give the time period for correcting the violation(s), and shall state the corrections to be made. The inspection report form shall summarize the requirements of these Regulations and shall set forth a weighted point value for each requirement.

17.8.2 The post-construction/pre-permitting inspection report form shall be used to record the post-construction inspections of ice plants as specified in Section 17.9 below. This form shall contain the statement: "Items whose number and weight value are circled have not been completed." The Regulations Governing the Manufacture and Sale of Ice require that compliance with approved plans and specifications be obtained prior to a pre-opening inspection.

17.8.3 The completed inspection report form is a public document that shall be made available for public disclosure to any person who requests it, in accordance with the Freedom of Information Act.

17.9 Types of Inspections

17.9.1 Inspections of ice plants are performed for a wide range of purposes. All inspections shall be categorized by type, classified by purpose and shall include, but not be limited to, the following:

17.9.1.1 Regular Inspections.

Regular inspections are performed on a routine basis in permanent, operating, permitted facilities. These inspections shall address all items on the inspection report form. Items in violation shall be recorded by item number and the weighted point value given to that item. The rating score of the ice plant shall be the total of the weighted point values for all violations subtracted from 100.

17.9.1.2 Follow-up Inspections.

17.9.1.2.1 Follow-up inspections shall be performed when a regular inspection score of less than 85 and greater than 69 is received, or when one or more 4 or 5-point weighted items are in violation. When the regular inspection score is 85 or above, the follow-up inspection shall address only items of "C" value or 4 or 5-point weighted items in violation. A rating score shall not be determined for these inspections. When the regular inspection score is less than 85, a complete inspection shall be performed and a follow-up rating score shall be determined.

17.9.1.2.2 Follow-up inspections may also be performed after complaint and investigation inspections, or after administrative hearings. Rating scores may or may not be determined for these inspections.

17.9.1.3 Complaint Inspections.

17.9.1.3.1 Complaint inspections are performed in response to formal or informal complaints against permitted facilities. A complete inspection may be performed by the regulatory authority in the interest of the public's health.

17.9.1.4 Investigation Inspections.

17.9.1.4.1 Investigation inspections are performed on non-permitted ice plants for determining compliance with these Regulations.

17.9.1.5 Other Inspections.

17.9.1.5.1 These inspections include post-construction, pre-operational and other inspections not included above. (See Sections 6.6 and 6.7 of the Regulations).

17.10 Rating Score.

Rating scores of ice plants are kept on file by the regulatory authority and may be used to determine inspection frequencies. The receipt of any "C" value items, an overall rating score below 70 (excluding the presence of any critical violative items) during a regular inspection, a follow-up rating score below 85, or two successive regular inspection scores below 85, shall

indicate the need for action by the regulatory authority as specified in Section 17.12 of these Regulations.

17.11 Response to Violations

17.11.1 Official and/or operator response to citing of violative items shall be in accordance with the below stated procedures:

17.11.1.1 Closure Items (denoted “17.11.1.3”).

When an inspection results in the finding of any violative items denoted “17.11.1.3”, the permit shall be immediately suspended in accordance with Section 17.12.

17.11.1.2 Critical Items (4 or 5-point weighted items)

17.11.1.2.1 When the rating score of an ice plant is determined to be 85 or above by regular inspection, all violations of 4 or 5-point weighted items shall be corrected, or written proof of intention to correct shall be provided as soon as possible, but in any event, within 48 hours following inspection.

17.11.1.2.2 When the rating score of an ice plant is determined to be less than 70 by regular inspection, the permit shall be suspended in accordance with Section 17.13. All violations of 4 or 5-point weighted items shall be corrected or written proof of intention to correct prior to resuming operations.

17.11.1.2.3 Follow-up inspections shall be conducted at reasonable time intervals to assure corrections are completed according to schedule.

17.11.1.3 Non-critical Items (1 or 2-point weighted items). All 1 or 2-point weighted items shall be corrected as soon as possible, but in any event, by the time of the next regular inspection.

17.12 Procedure for Administrative Action

17.12.1 Administrative action is required if any of the following conditions are found to exist:

17.12.1.1 The inspection discloses any immediate health hazards (described below) constituted by violation of any “17.11.1.3” value items; or

17.12.1.2 the Deputy State Health Officer or his/her designee determines that an imminent health hazard (described below) exist(s) in an ice plant which represents a threat to life; or

17.12.1.3 there exists a serious risk of damage to health or safety of the public; or

17.12.1.4 critical or repeat violations; or

17.12.1.5 general insanitary conditions are found to exist.

17.12.2 Immediate Health Hazard

17.12.2.1 An immediate health hazard shall include, but is not limited to, any one of the following:

17.12.2.1.1 An unapproved source of water for product (ice) manufacture;

17.12.2.1.2 Source water or ice product fails to meet microbiological, chemical and physical standards for drinking water; or

17.12.2.1.3 Cross-connections are found between potable and non-potable water systems.

17.12.3 Imminent Health Hazard(s)

17.12.3.1 An imminent health hazard shall include, but is not limited to, any one of the following:

17.12.3.1.1 An ongoing outbreak of an infectious, pathogenic or toxic agent capable of being transmitted to consumers; or

17.12.3.1.2 The absence of potable water, supplied under pressure, in quantities capable of meeting the needs of the facility; or

17.12.3.1.3 A sewage backup into the facility or into equipment containing ice; or

17.12.3.1.4 An infestation of vermin to the extent that ice or ice-contact surfaces cannot be protected from contamination; or

17.12.3.1.5 Receipt of an overall rating score of less than 70 following an inspection by a representative of the regulatory authority.

17.13 Suspension of Permit

17.13.1 If some condition(s) is/are determined to exist in an ice plant which present(s) an imminent health hazard to the public, the Deputy State Health Officer or his/her designee in the county in which the ice plant operates, may suspend the operating permit of the ice plant without a hearing or written notice for a period not to exceed ten (10) days. Further enforcement action shall be taken in accordance with Section 17.19.

17.13.2 The suspension shall be effective upon receipt of written notice by the person in charge of the ice plant. A suspension statement recorded on the inspection report by the inspecting regulatory representative constitutes a written notice. The Deputy State Health Officer, or his/her designee, shall be notified of the suspension by the close of the following business day. Service of written notice of suspension by the Deputy State Health Officer, or his/her designee stating the reason(s) for the suspension shall be made by the close of the following business day. The person in charge shall be requested to yield the permit to the representative of the regulatory authority. The permit shall not be suspended for a period longer than ten (10) days without a hearing.

17.14 Reinstatement of Permit

17.14.1 If a follow-up inspection by a representative of the regulatory authority shows that the immediate health hazard(s) or the imminent health hazard(s) no longer exist(s), the suspension shall be lifted immediately and the permit returned. If there is no evidence that the immediate health hazard(s) and/or the imminent health hazard(s) has/have been corrected by the end of the ten (10) day suspension, the Deputy State Health Officer or his/her designee must schedule a hearing to determine if the suspension should be extended. Failure to hold a hearing within the ten (10) day period shall automatically terminate the suspension.

17.14.2 The owner/operator of the ice plant may request, in writing, a hearing before the Deputy State Health Officer or his/her designee at any time during the period of suspension, for the purpose of demonstrating that the immediate health hazard(s) and/or imminent health hazard(s) no longer exist(s). The request for hearing shall not stay the suspension.

17.15 Administrative Hearings.

17.15.1 Whenever conditions in an ice plant warrant, the Deputy State Health Officer or his/her designee shall schedule an administrative hearing to consider suspension or recommend revocation of a permit. The Deputy State Health Officer or his/her designee shall neither suspend nor recommend revocation of a permit of an ice plant for serious or repeated violations, which do not present an imminent health hazard, without having first held a hearing to determine whether the permit should be suspended or revoked. The holder of the permit or the person in charge of the ice plant must be informed at least ten (10) days prior to the hearing, of the date, time, and place of the hearing and the specific charges against the ice plant. The notification of the hearing shall be sent by certified mail or by hand delivery. The Deputy State Health Officer or his/her designee, after providing the opportunity for a hearing, may suspend for a period not to exceed ninety (90) days, or may recommend revocation of a permit to operate an ice plant for serious or repeated violations of any of the requirements of these Regulations.

17.16 Records of Administrative Proceedings.

(Number needed) Written minutes shall be made of all hearing proceedings and shall become documents of record. A written report of the hearing decision shall be furnished to the Division of Public Health, the Bureau of Environmental Health and the owner/operator by the Deputy State Health Officer or his/her designee within ten (10) days following the hearing.

17.17 Right of Appeal to the Division of Public Health.

(Number needed) The owner/operator of the ice plant may appeal to the Division of Public Health for reconsideration of the decision of the Deputy State Health Officer or his/her designee. In order to appeal for reconsideration, written notice of appeal must be received by the Division of Public Health within forty-eight (48) hours after announcement of the decision of the Deputy State Health Officer, or his/her designee. The notice of appeal may be sent via certified mail or hand delivered to the Division of Public Health. If a notice of appeal is timely filed, the decision of the Deputy State Health Officer or his/her designee in regard to ice plant suspension or revocation for serious or repeat violations, or for general insanitary conditions will be stayed until that decision is confirmed by the Division of Public Health. If a notice of appeal is not filed within the required time period, the permit suspension or revocation recommendation shall be upheld and other enforcement action taken in accordance with Section 17.19. If the notice of appeal is timely filed, the Division of Public Health shall hold a hearing at the next scheduled Division of Public Health meeting.

17.18 Division of Public Health Action

17.18.1 The Division of Public Health, at its next scheduled meeting, shall consider the Deputy State Health Officer's recommendation for permit revocation or hear an appeal by the owner/operator whose permit to operate an ice plant stands suspended. The Division of Public Health shall, at each scheduled meeting, release the name(s) of those ice plants not meeting the following criteria:

17.18.1.1 Permit revoked; or

17.18.1.2 Permit suspended due to imminent health hazard; or

17.18.1.3 Permit suspended due to repeat violation(s) of critical items; or

17.18.1.4 Operating without a valid ice plant permit.

17.18.2 Variance

17.18.2.1 The Division of Public Health may, from time to time, grant written permission to vary from particular provisions of these Regulations when the extent of the variation is clearly specified and such variation is:

17.18.2.1.1 In conformance with the variance requirements of the ***State of Delaware Regulations Governing Public Drinking Water Systems;***

17.18.2.1.2 Necessary to obtain a beneficial use of an existing facility; and

17.18.2.1.3 Appropriate alternative measures have been taken to protect the health and safety of the public and to assure that the purpose of the provisions from which the variation is sought will be observed.

17.18.3 Written applications for such variances shall be filed with the Director, Division of Public Health. No such variance shall be effective until granted by the Division of Public Health.

17.19 Agency Emergency Actions

17.19.1 Condemnation/Embargo.

(Number needed) Ice and/or water may be sampled by the regulatory authority as often as necessary for enforcement of these Regulations. All product water and ice shall meet the quality standards set forth in quality standards of these Regulations. Ice failing to meet the quality standards shall not be kept on the premises. The established administrative procedures for the implementation and enforcement of the provisions of 16 **Del.C.,** Ch. 33 (Volume 63, Chapter 148, Laws of Delaware), relating to the embargo of misbranded or adulterated food and penalties shall be applicable to this section.

17.19.2 Procedure When Infection is Suspected

17.19.2.1 When the regulatory authority has reasonable cause to suspect possible disease transmission by an ice plant or an employee thereof, it may conduct an epidemiological investigation which can indicate morbidity histories of suspected employees or make any other investigations as indicated and shall take appropriate action. The regulatory authority may require any or all of the following:

17.19.2.1.1 The immediate exclusion of an employee from the ice plant;

17.19.2.1.2 The immediate closing of the ice plant until, in the opinion of the regulatory authority, no further danger of disease outbreak exists;

17.19.2.1.3 Restriction of an employee(s) services to some area of the ice plant where there is no danger of transmitting disease;

17.19.2.1.4 Adequate medical and laboratory examination of the employee and of other employees and of his and their body discharges;

17.19.2.1.5 Any other action deemed necessary and feasible by the Deputy State Health Officer or his/her designee or the State Epidemiologist to protect the health of the public and other employees of the ice plant.

17.20 Recall Plan

17.20.1 The ice plant management must:

17.20.1.1 Prepare and maintain a current written contingency plan for use in initiating and affecting a recall;

17.20.1.2 Use sufficient coding of regulated products to make possible positive identification and to facilitate effective recall of all violative lots; and

17.20.1.3 Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the expected use of the product and is at least the length of time specified in other applicable regulations governing records retention.

17.21 Penalties

17.21.1 Any person (or responsible officer of that person) who violates a provision of these Regulations and any responsible person (or responsible officer to that person) who is the holder of a permit or who otherwise operates an ice plant that does not comply with the requirements of these Regulations shall be subject to the provisions of 16 **Del.C.** §107.

17.21.2 The regulatory authority may seek to enjoin violations of these Regulations.

17.21.3 A conspicuous, colored placard shall be prominently displayed at all entrances to ice plants meeting the following requirements:

17.21.3.1 Failure to obtain a valid permit; or

17.21.3.2 whose permit stands suspended; or

17.21.3.3 whose permit stands revoked.

APPENDIX A

Sanitizing Solutions

Sanitizing solutions may be safely used on ice-processing equipment and utensils, and on other ice-contact articles as specified in this section, within the following prescribed conditions:

(a) Such sanitizing solutions are used, followed by adequate draining, before contact with ice.

(b) The solutions consist of one of the following, to which may be added components generally recognized as safe and components which are permitted by prior sanction or approval:

(1) An aqueous solution containing potassium, sodium or calcium hypochlorite, with or without the bromides of potassium, sodium or calcium.

(2) An aqueous solution containing dichloroisocyanuric acid, trichloroisocyanuric acid, or the sodium or potassium salts of these acids, with or without the bromides of potassium, sodium or calcium.

(3) An aqueous solution containing potassium iodide, sodium p-toluenesulfonochloramide, and sodium lauryl sulfate.

(4) An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol having a cloudpoint of 90°C-100°C in 0.5 percent aqueous solution and an average

molecular weight of 3,300, and ethylene glycol monobutyl ether. Additionally, the aqueous solution may contain diethylene glycol monoethyl ether as an optional ingredient.

(5) An aqueous solution containing elemental iodine, hydriodic acid, alpha-(p-nonylphenyl)-omega-hydroxy-poly(oxyethylene) complying with the identity prescribed in '178.3400(c)CFR and having a maximum average molecular weight of 748) and/or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 1,900). Additionally, the aqueous solution may contain isopropyl alcohol as an optional ingredient.

(6) An aqueous solution containing elemental iodine, sodium iodide, sodium dioctylsulfosuccinate, and polyoxyethylene-polyoxpropylene block polymers (having a minimum average molecular weight of 1,900).

(7) An aqueous solution containing dodecylbenzenesulfonic acid and either isopropyl alcohol or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800).

(8) An aqueous solution containing elemental iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene gluycol having a minimum average molecular weight of 2,400 and a-lauroyl-omega-hydroxypoly (oxyethylene) with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. Rinse water treated with this solution can be recirculated as a preliminary rinse. It is not to be used as a final rinse.

(9) An aqueous solution containing n-alkyl (C12-C18) benzyldimethylammonium chloride compounds having average molecular weights of 351 to 380. The alkyl groups consist principally of groups with 12 to 16 carbon atoms and contain not more than 1 percent each of groups with 8 and 10 carbon atoms. Additionally, the aqueous solution may contain either ethyl alcohol or isopropyl alcohol as an optional ingredient.

(10)An aqueous solution containing trichloromelamine and either sodium lauryl sulfate or dodecyl-benzenesulfonic acid.

(11) An aqueous solution containing equal amounts of n-alkyl (C 12-C18) benzyl dimethyl ammonium chloride and n-alkyl (C12-C18) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 384).

(12)An aqueous solution containing the sodium salt of sulfonated oleic acid, polyoxyethylene-polyoxypropylene block polymers (having an average molecular weight of 2,000 and 27 to 31 moles of polyoxypropylene).

(13)An aqueous solution containing elemental iodine and alkyl (C12-C15) monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud point of 70°C-77°C in 1 percent aqueous solution and an average molecular weight of 807.

(14)An aqueous solution containing iodine, butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol, having a cloud point of 90°C-100°C in 0.5 percent aqueous solution and an average molecular weight of 3,300, and polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,000).

(15)An aqueous solution containing lithium hypochlorite.

(16)An aqueous solution containing equal amounts of n-alkyl (C12-C18) benzyl dimethyl ammonium chloride and n-alkyl (C12-C14) dimethyl ethylbenzyl ammonium chloride (having an average molecular weight of 377 to 384), with the optional adjuvant substances tetrasodium ethylenediaminetetraacetate and/or a-(p-nonylphenol)-omega-hydroxy poly(oxyethylene) having an average poly(oxyethylene) content of 11 moles.

Alpha-hydro-omega-hydroxypoly-(oxyethylene) poly(oxypropylene) (15 to 18 mole minimum) poly(oxyethylene) block copolymer, having a minimum molecular weight of 1,900 (CAS Registry No. 9003-11-6) may be used in lieu of alpha- (p-nonylphenol)-omega-hydroxy poly(oxyethylene) having an average poly(oxyethylene) content of 11 moles.

(17)An aqueous solution containing di-n-alkyl (C8-C10)dimethyl ammonium chlorides having average molecular weights of 332-361 and either ethyl alcohol or isopropyl alcohol.

(18)An aqueous solution containing n-alkyl(C12-C18) benzyldimethylammonium chloride, sodium metaborater, a[p-(1,1,3,3,-tetramethylbutyl)phenyl] Bomega-hydroxy-poly (oxethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide.

(19)An aqueous solution containing sodium dichloroisocyanurate and tetrasodium ethylenediaminetetraacetate.

(20)An aqueous solution containing ortho-phenylphenol, ortho-benzyl-para-chlorophenol, para-tertiaryamylphenol, sodium-a-alkyl(C12-C15)-omega-hydroxypoly(oxyethylene) sulfate with the poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.

(21)An aqueous solution containing sodium dodecylbenzenesulfonate.

(22)An aqueous solution containing (1) di-n-alkyl(C8-C10) dimethylammonium chloride compounds having average molecular weights of 332-361, (2) n-alkyl (C12-C18) benzyldimethylammonium chloride compounds having average molecular weights of 351-380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

(23)An aqueous solution containing n-alkyl (C12-C16) benzyl-dimethylammonium chloride and didecyldimethylammonium chloride.

(24)An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), a-[p-(1,1,3,3-tetramethylbutyl)-phenyl]-omega-hydroxypoly(oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and a-alkyl(C12-C15)-omega-hydroxy[poly(oxyethylene) poly(oxypropylene)] (having an average molecular weight of 965).

(25)An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), potassium iodide (CAS Reg. No. 67-63-0).

(26)An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), and sodium 1-octanesulfonate (CAS Reg. No. 5324-84-5). Additionally, the aqueous solution may contain isopropyl alcohol (CAS Reg. No. 67-63-0) as an optional ingredient.

(27)An aqueous solution containing sulfonated 9-octadecenoic acid (CAS Reg. No. 68988-76-1) and sodium xylenesulfonate (CAS Reg. No. 1300-72-7).

(28)An aqueous solution containing dodecyldiphenyloxidedisulfonic acid (CAS Reg. No. 30260-73-2), sulfonated tall oil fatty acid (CAS Reg. No. 68309-27-3), and neo-decanoic acid (CAS Reg. No. 26896-20-8).

(29)An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1), peracetic acid (CAS Reg. No. 79-21-0), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4).

(30)An aqueous solution containing elemental iodine, a-alkyl(C10-C14)-omega-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and a-alkyl (C12-C18)-omega-hydroxypoly(oxyethylene)poly(oxpropylene) of average molecular weight between 950 and 1,120.

(31)An aqueous solution containing (I) di-n-alkyl(C8-C10)dimethyl ammonium chloride compounds having average molecular weights of 332-361, (ii) n-alkyl-(C12-C18)benzyldimethylammonium chloride compounds having average molecular weights of 351-380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of groups with 8 and 10, (iii) ethyl alcohol, and (iv) a-(p-nonylphenyl)-omega-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p-nonylphenol with 9 to 12 moles of ethylene oxide. The ratio of compound (i) to (ii) is 3 to 2.

(32)An aqueous solution containing (i) di-n-alkyl-(C8-C108)dimethylammonium chloride compounds having average molecular weights of 332 to 361; (ii) n-alkyl-(C12-C18)-benzyldimethylammonium chloride compounds having molecular weights of 351 to 380 and consisting principally of alkyl groups with no more than 1 percent of the groups with 12 to 16 carbon atoms with no more than 1 percent of the groups with 8 to 10; and (iii) tetrasodium ethylenediamine tetraacetate.

(33)An aqueous solution of an equilibrium mixture of oxychloro species (predominantly chlorite, chlorate, and chlorine dioxide) generated either (i) by directly metering a concentrated chlorine dioxide solution, prepared just prior to use, into potable water to provide the concentration of available chlorine

dioxide stated in paragraph (c)(27) of this section, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominantly chlorite and chlorate) followed by dilution with potable water to provide the concentration of available chlorine dioxide described in paragraph (c)(27) of this section.Additionally, the aqueous solution contains either a-(p-nonylphenyl)-ometa-hydroxypoly-(oxyethylene) or a-alkyl(C11-C15)-omega-hydroxypoly(oxyethylene), each produced with 9 to 13 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(c) The solutions identified in paragraph (b) of this section will not exceed the following concentrations:

(1) Solutions identified in paragraph (b)(1) of this section will provide not more that 200 parts per million of available halogen determined as available chlorine.

(2) Solutions identified in paragraph (b)(2) of this section will provide not more than 100 parts per million of available halogen determined as available chlorine.

(3) Solution identified in paragraph (b)(3) of this section will provide not more than 25 parts per million of titratable iodine. The solutions will contain the components potassium iodide, sodium p-toluenesulfonchloramide and sodium lauryl sulfate at a level not in excess of the minimum required to produce their intended functional effect.

(4) Solutions identified in paragraph (b)(4), (5), (6), (8), (13), and (14) of this section will contain iodine to provide not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(5) Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million dodecylbenzenesulfonic acid and not more than 80 parts per million of polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800) or not more than 40 parts per million of isopropyl alcohol.

(6) Solutions identified in paragraph (b)(9) of this section shall provide, when ready to use, no more than 200 parts per million of the active quaternary compound.

(7) Solutions identified in paragraph (b)(10) of this section shall provide not more than sufficient trichloromelanine to produce 200 parts per million of available chlorine and either sodium lauryl sulfate at a level not in excess of the minimum required to produce its intended functional effect or not more than 400 parts per million of dodecylbenzenesulfonic acid.

(8) Solutions identified in paragraph (b)(11) of this section shall provide, when ready to use, not more than 200 parts per million of active quaternary compound.

(9) The solution identified in paragraph (b)(12) of this section shall provide not more than 200 parts per million of sulfonated oleic acid, sodium salt.

(10)Solutions identified in paragraph (b)(15) of this section will provide not more than 200 parts per million of available chlorine and not more than 30 ppm lithium.

(11)Solutions identified in paragraph (b)(16) of this section shall provide not more than 200 parts per million of active quaternary compound.

(12)Solutions identified in paragraph (b)(17) of this section shall provide, when read to use, a level of 150 parts per million of the active quaternary compound.

(13)Solutions identified in paragraph (b)(18) of this section shall provide not more than 200 parts per million of active quaternary compound and not more than 66 parts per million of a-[p-(1,1,3,3-tetramethylbutyl)phenyl]-omega-hydroxypoly(oxyethylene).

(14)Solutions identified in paragraph (b)(19) of this section shall provide, when ready to use, a level of 100 parts per million of available chlorine.

(15)Solutions identified in paragraph (b)(20) of this section are for single-use applications only and shall provide, when ready to use, a level of 800 parts per million of total active phenols consisting of 400 parts per million ortho-phenylphenol, 320 parts per million ortho-benzyl-para-chlorophenol and 80 parts per million para-tertiaryamylphenol.

(16)Solution identified in paragraph (b)(21) of this section shall provide not more than 430 parts per million and not less than 25 parts per million of sodium dodecylbenzenesulfonate.

(17)Solutions identified in paragraph (b)(22) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compound.

(18)Solutions identified in paragraph (b)(23) of this section shall provide at least 150 parts per million and not more than 200 parts per million of the active quaternary compound.

(19)Solutions identified in paragraphs (b)(24) and (b)(25) of this section shall provide at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine shall not be in excess of the minimum required to accomplish the intended technical effect.

(20)Solutions identified in paragraph (b)(26) of this section shall provide, when ready to use, at least 109 parts per million and not more than 218 parts per million of total active fatty acids and at least 156 parts per million and not more than 312 parts per million of the sodium 1-octanesulfonate.

(21)Solutions identified in paragraph (b)(27) of this section shall provide, when ready to use, at least 156 parts per million and not more than 312 parts per million of sulfonated 9-octadecenoic acid, at least 31 parts per million and not more than 62 parts per million of sodium xylenesulfonate.

(22)Solutions identified in paragraph (b)(28) of this section will provide at least 237 parts per million and not more than 474 parts per million dodecyldiphenyloxideddisulfonic acid, at least 33 parts per million and not more than 66 parts per million sulfonated tall oil fatty acid, and at least 87 parts per million and not more than 174 parts per million neo-decanoic acid.

(23)Solutions identified in paragraph (b)(29) of this section shall provide, when ready to use, not less than 550 parts per million and not more than 1,100 parts per million hydrogen peroxide, not less than 100 parts per million and not more than 200 parts per million peracetic acid, not less than 150 parts per million and not more than 300 parts per million acetic acid, and not less than 15 parts per million and not more than 30 parts per million 1-hydroxyethylidene-1,1-diphosphonic acid.

(24)Solutions identified in paragraph (b)(30) of this section shall provide, when ready to use, at least 12.5 parts per million and not more than 25 parts per million of titratable iodine. The adjuvants used with the iodine will not be in excess of the minimum amounts required to accomplish the intended technical effect.

(25)Solutions identified in paragraph (b)(31) of this section shall provide, when ready to use, at least 150 parts per million and no more than 400 parts per million of active quaternary compounds in solutions containing no more than 600 parts per million water hardness. The adjuvants used with the quaternary compounds will not exceed the amounts required to accomplish the intended technical effect.

(26)Solutions identified in paragraph (b)(32) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compounds. The adjuvants used with the quaternary compounds shall not exceed the amounts required to accomplish the intended technical effect. Tetrasodium ethylenediamine tetraacetate shall be added at a minimum level of 60 parts per million. Use of these sanitizing solutions shall be limited to conditions of water hardness not in excess of 300 parts per million.

(27)Solutions identified in paragraph (b)(33) of this section should provide, when ready to use, at least 100 parts per million and not more than 200 parts per million available chlorine dioxide as determined by the method titled, AIodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available CIO2),@ which is incorporated by references. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. S.W., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 100 L St. N.W., Washington, DC 20408.

(d) Sanitizing agents for use in accordance with this section will bear labeling meeting the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act.