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ADOPTIONS SECTION

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL AND OCCUPATIONAL HEALTH

CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE

Notice of Readoption

Food and Drugs

Readoption with Technical Changes: N.J.A.C. 8:21

Authorized By: Judith M. Persichilli, R.N., B.S.N., M.A., Commissioner, Department of Health, in consultation with the Public Health Council.

Authority: N.J.S.A. 24:2-1, 24:5-1 et seq., 24:6B-1 et seq., 24:10-57.20, 24:10-73.1, and 24:12-12.

Effective Dates: November 17, 2021, Readoption;
December 20, 2021, Technical Changes.

New Expiration Date: November 17, 2028.

Take notice that, pursuant to N.J.S.A. 52:14B-5.1, the Commissioner of the Department of Health (Department) hereby readopts N.J.A.C. 8:21, Food and Drugs, with technical changes.

N.J.A.C. 8:21 was scheduled to expire September 13, 2021. Pursuant to Executive Order Nos. 127 (2020) and 244 (2021) and P.L. 2021, c. 103, any chapter of the New Jersey Administrative Code that would otherwise have expired during the Public Health Emergency originally declared in Executive Order No. 103 (2020) is extended through January 1, 2022. Therefore, this chapter has not yet expired and the

30-day filing date pursuant to N.J.S.A. 52:14B-5.1.c has not yet occurred, therefore, pursuant to Executive Order No. 244 (2021), and P.L. 2021, c. 103, this notice of readoption is timely filed.

Chapter 21 establishes standards for wholesale food, drug, cosmetics, and devices that are manufactured or distributed for wholesale in New Jersey. Subchapter 1, Food, Drug, Cosmetic, and Device Labeling, establishes standards for food, drug, cosmetic, and device labeling. Subchapter 2, Foods, establishes food standards. Subchapter 3, Drugs, Devices and Cosmetics, establishes standards for drugs, devices, and cosmetics. Subchapter 3A, Registration of Wholesale Distributors of Drugs, establishes standards for registration of wholesale drug distributors. Subchapter 4, New Drugs, establishes standards for new drugs. Subchapter 5, Manufacturing, Storage, Distribution, and Handling Standards for Bottled Water, establishes standards for manufacturing, storage, distribution, and handling bottled water. Subchapter 6 is reserved. Subchapter 7, Frozen Desserts establishes standards for frozen desserts. Subchapter 8, Imitation Milk, Imitation Low Fat Milk, and Imitation Fluid Milk Products, establishes standards for imitation milk, low-fat milk, and fluid milk products. Subchapter 9, Licensing of Food and Cosmetic Manufacturing and Wholesale Establishments, establishes standards for licensing establishments that manufacture, and/or function as wholesalers of, food and cosmetics. Subchapter 10, Designated Fluid Milk Products establishes standards for designated fluid milk products. Subchapter 11, Dented Cans; Salvage or Distressed Foods, Alcohol and Nonalcoholic Beverages and Industrial Mishandling, establishes standards governing disposition of dented cans, and salvage or distressed food and beverages, and industrial mishandling.

Subchapter 12 is reserved. Subchapter 13, Rules Governing Wholesale Food Establishments, contains standards governing wholesale food establishments.

The Department is developing rulemaking that would update Chapter 21 to conform to changes to Federal law, including those arising from the enactment of the FDA Food Safety Modernization Act, P.L. 111–353 (approved January 4, 2011). However, that rulemaking will not be concluded before the existing rules would have expired. Therefore, subject to the technical changes described below, the Commissioner of the Department of Health (Department) has determined that the existing rules remain necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which they were promulgated, and should be readopted, until the rulemaking that is in development can be concluded.

The Department is making technical changes to reflect the change in the name of the Department pursuant to N.J.S.A. 26:1A-2.1, and to correct cross-references and spelling.

Full text of the technical changes follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. FOOD, DRUG, COSMETIC, AND DEVICE LABELING

8:21-1.1 Definitions

The following words and terms shall have the following meanings, when used in this subchapter:

“Certificate of Free Sale” is a document completed and issued by the Department of Health [and Senior Services] certifying that a company is in compliance with State

and Federal standards. The certificate also attests that a specific food, drug, cosmetic**,** or medical device product regulated under Title 24 of the New Jersey Statutes and manufactured, distributed**,** and offered for sale in this State is labeled in conformance with the applicable food, drug, cosmetic**,** or medical device laws. Such documents shall include Certificates to Foreign Government, Certificates of Exportability, Good Manufacturing Practices (GMP) Certificates, Letters of Free Sale, Certificates of Free Sale and Free Use, Health Certificates for Food/Feed, origin certificates and other documents meeting the requirements [of] **at** N.J.A.C. 8:21-1.10. Issuance of the Certificate of Free Sale attests to the results of the most recently conducted sanitary inspection of the manufacturer or distributor of the product or products.

…

8:21-1.10 Certificate of Free Sale application process, fees, appeal process

(a) An entity desiring to obtain a Certificate of Free Sale shall make application to the Commissioner **of the Department of Health** for a Certificate of Free Sale or any other certificate or affidavit, on forms approved by the Department, in accordance with the requirements of this section. Certificate of Free Sale application forms may be obtained by writing to the following address:

[Food and Drug Safety] **Public Health and Food Protection** Program

Consumer, Environmental, and **Occupational** Health Service[s]

Department of Health [and Senior Services]

PO Box 369

Trenton, NJ 08625-0369

(b) (No change.)

(c) Applicants for a Certificate of Free Sale shall:

1. - 4. (No change.)

5. Submit the nonrefundable fee specified [in] **at** (f) below by means of certified check or money order, made payable to the Department of Health [and Senior Services];

6. - 7. (No change.)

(d)-(f) (No change.)

SUBCHAPTER 2. FOODS

8:21-2.3 Inspection reports

A copy of the last inspection report shall be maintained by the operator of each food establishment licensed under applicable provisions of Title 24 of the Revised Statutes and made available for inspection by a representative of the Department **of Health** upon request.

8:21-2.5 Prohibition of sale of striped bass

No person may expose for sale, offer for sale, or sell striped bass ([Morone saxatilis] ***Morone saxatilis***) in this State.

8:21-2.6 Prohibition of sale of channel [cat fish] **catfish**

No person may expose for sale, or sell channel [cat fish] **catfish** ([Ictalurus punctatus] ***Ictalurus punctatus***) harvested from the Delaware River between the

Interstate 276 Highway Bridge in Burlington Township, Burlington County and Birch Creek, which flows into the Delaware River at Logan Township, Gloucester County.

SUBCHAPTER 3. DRUGS, DEVICES**,** AND COSMETICS

8:21-3.2 Rulings on dangerous cosmetics

(a) (No change.)

(b) The toxic effect of paratoluylenediamine is well known. There is no doubt that preparations containing this dye are in violation of the Food, Drug**,** and Cosmetic Act. Based upon a serious consideration of the injurious effects of paratoluylenediamine, eyelash and eyebrow dyes containing paratoluylenediamine in any amount will be considered adulterated [under] **pursuant to** N.J.S.A. 24:5-11.1(a) and appropriate action taken. It has also been noted that substances such as oils, argyrol, magnesium carbonate, paper shields, and the like are customarily included in packages of eyelash and eyebrow dye preparations to be used to prevent the introduction of the dye into the eyes. It is the opinion of the [department] **Department of Health** that the use of these precautionary measures cannot guarantee protection of the eyes against such dangerous product as paratoluylenediamine. This notice should not be interpreted as indicating that other dyes used for eyelash and eyebrow dyeing are to be accepted as meeting the requirements [of] **at** N.J.S.A. 24:5-11.1(a).

8:21-3.5 Compressed air used in [self contained] **self-contained** underwater breathing apparatus (SCUBA)

Components of compressed air shall not exceed the following limits:

CARBON MONOXIDE

10 parts/million (PPM) 0.001%

CARBON DIOXIDE

1000 PPM 0.1%

OIL

0.02 mg/liter

WATER

Saturation

ODOR

Free from objectionable odors

OTHER

Contaminants deleterious to health shall not be present

8:21-3.6 SCUBA recommendations

(a) The [following] recommendations **in this section** are primarily directed to purveyors of SCUBA air to protect public health.

[(a)] **(b)** (No change in text.)

[(b)] **(c)** Preparation of compressed air. Uncontaminated air may be compressed by means of suitable equipment and the compressed air should not exceed the limits set forth in [the regulations] **this section**. The following sampling, testing**,** and test procedures may be used to determine the quantitative composition of the compressed air.

1. (No change.)

2. Carbon dioxide. Determination of carbon dioxide may be made by using:

i.- ii. (No change.)

iii. Any other device or method acceptable to the [New Jersey State] Department [of Health].

3. (No change.)

4. Water. Compressed air may be saturated with water vapor but should not contain water in separated form. This may be determined by using:

i. (No change.)

ii. Any other device or method acceptable to the [New Jersey State] Department [of Health].

5. (No change.)

[(c)] **(d)** (No change in text.)

8:21-3.9 Permit for nitrous oxide

(a) Every person or firm desiring to use or distribute nitrous oxide, except a duly licensed physician, dentist, veterinarian, nurse, hospital, sanitarium, or other medical institution, or a resident physician or intern of a hospital, sanitarium, or medical

institution, and those buying or selling nitrous oxide for use in food preparation equipment or registered pursuant to N.J.S.A. 24:6G-1 et seq.**,** shall complete a permit application provided by the Department [of Health and Senior Services] and provide the following information:

1.-9. (No change.)

10. Any other information as may be requested by the Department [of Health and Senior Services].

(b) The applicant shall submit with the permit application a nonrefundable fee of $25.00 by means of certified check or money order made payable to the Department of Health [and Senior Services].

(c) Upon approval of the application, the Department [of Health and Senior Services] shall issue a permit that shall expire two years from the date the permit is issued. A copy of the permit issued to the user shall be maintained by the distributor of the nitrous oxide for a period of two years.

(d)-(e) (No change.)

(f) Every permit issued by the Department [of Health and Senior Services] for the use or sale of nitrous oxide shall be valid only for the location listed in that permit and shall not be transferable.

(g)-(h) (No change.)

SUBCHAPTER 3A. REGISTRATION OF WHOLESALE DISTRIBUTORS OF DRUGS

8:21-3A.10 Storage

(a) All drugs shall be stored at appropriate temperature and conditions, in accordance with the requirements set forth in the labeling of such drugs or with the requirements of the current edition of an official compendium, such as the United **States** Pharmacopeia/National Formulary (USP/NF).

(b)-(d) (No change.)

SUBCHAPTER 4. NEW DRUGS

8:21-4.1 Statement of policy

(a) The following “new drug” regulations as adopted by the [department] **Department of Health (Department)** are to provide guidance in the administration of the provisions of N.J.S.A. 24:6A-1 et seq.

(b) To ensure that a complete and comprehensive review for safety is provided to a new drug application submitted pursuant to the State act, it has been deemed proper and expeditious to adopt by reference such procedures, records, reports, sampling, toxicology, pathology**,** and clinical testing measures afforded to new drugs by the United States Food and Drug Administration as provided in 21 C.F.R. 300, 310, 312**,** and 314.

(c) It is the intent and policy of the [department] **Department** to implement and administer those provisions of the Federal new drug regulations adopted by this [department] **Department** that pertain to or are concerned with the safety of the product subject of a State new drug application.

8:21-4.3 General provisions; definitions

(a) (No change.)

(b) The definitions set forth in subpart A (General provisions), section 21 [C.F.R.] **CFR** 310.3 pursuant to the intent and policy of the Department [of Health and Senior Services] as set forth in a preamble to new drug regulations, mean the following:

1. (No change.)

2. The term “department” means the New Jersey Department of Health [and Senior Services] **(Department)**.

3. The term “secretary” means the New Jersey Commissioner of Health [and Senior Services].

4. (No change.)

SUBCHAPTER 5. MANUFACTURING, STORAGE, DISTRIBUTION, AND HANDLING STANDARDS FOR BOTTLED WATER

8:21-5.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

…

“Certified laboratory” means a laboratory approved by the New Jersey [State] Department of Environmental Protection in accordance with N.J.A.C. 7:18, Regulations Governing Laboratory Certification and Standards of Performance.

…

"Department" means the New Jersey Department of Health [and Senior Services].

…

8:21-5.6 Facilities for the storage, distribution, handling, and bottling of bottled water

(a)-(b) (No change.)

(c) Every plant and facility shall be provided with effective screening, rodent proofing, or other protective methods against animals and vermin.

1.-2. (No change.)

3. The use of pesticides is permitted only under precautions and restrictions that will prevent contamination of the water. Pesticides shall be applied in an approved manner and by a certified applicator in conformance with [the New Jersey Department of Environmental Protection Regulations,] N.J.A.C. 7:30, Pesticide Control Regulations.

(d) (No change.)

8:21-5.12 Bulk water facility requirements

(a) (No change.)

(b) All sources of water for bulk water shipment must be approved by the [New Jersey Health] Department or the governmental regulatory agency having jurisdiction over the source water location outside the State or in a foreign country. Before bulk water is delivered to any bottling plant, an analysis of the water indicating that it meets bacteriological, chemical, and radiological standards set forth in this subchapter shall be submitted to the plant owner or operator.

(c)-(e) (No change.)

(f) The Department [of Health] shall be notified by telephone by the management of the water establishment anytime a tank truck or load of water is rejected at the time of pickup or delivery with the reason for rejection. This notification shall take place no later than the next business day.

SUBCHAPTER 7. FROZEN DESSERTS

8:21-7.1 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

…

"Department" means the New Jersey Department of Health [and Senior Services].

…

8:21-7.7 Frozen yogurt; identity; label statement

(a) Rules concerning description of frozen yogurt are as follows:

1. Frozen yogurt is the food produced by freezing, while stirring, a mix containing safe and suitable ingredients, including, but not limited to, dairy ingredients, but excluding chemical preservatives. The mix may be homogenized and all of the dairy ingredients shall be pasteurized or ultra-pasteurized. All or a portion of the dairy ingredients shall be cultured with a characterizing live bacterial culture that shall contain the lactic acid-producing bacteria [Lactobacillus bulgaricus] ***Lactobacillus bulgaricus***

and [Streptococcus thermophilus] ***Streptococcus thermophilus***, and may contain other lactic acid-producing bacteria. The culturing of all or a portion of the dairy ingredients must take place to the extent that the finished, unflavored mix has an increased titratable acidity, calculated as lactic acid, and a decreased pH as a result of the fermentation process. The titratable acidity of the finished, unflavored frozen yogurt mix shall have been increased by a minimum of 0.15 percent, calculated as lactic acid, as a result of the fermentation process. Food grade acids or other acidogens may not be used for the purpose of raising the titratable acidity of the mix or lowering the pH. The frozen yogurt mix shall contain the characterizing live yogurt culture organisms. Sweetener(s), flavoring(s), color additive(s)**,** and/or other characterizing food ingredients may be added to the mix before or after pasteurization or ultra-pasteurization, provided that any ingredient addition after pasteurization or ultra-pasteurization is done in accordance with good manufacturing practices. Any dairy ingredients added after culturing shall have been pasteurized or ultra-pasteurized. The standard plate count requirement for frozen desserts shall apply only to the dairy ingredients prior to culturing.

2. (No change.)

(b)-(d) (No change.)

8:21-7.16 Frozen pudding; identity; label statement

(a)-(c) (No change.)

(d) If not frozen promptly after pasteurization, it shall be cooled to 45 [degree F] **degrees Fahrenheit** or lower and maintained thereat.

I-(g) (No change.)

8:21-7.25 Cleaning and sanitizing of containers and equipment

(a) (No change.)

(b) The sanitizing of containers, utensils and equipment shall be accomplished by exposing them to one of the following methods:

1. A flow of steam at a temperature of 200 degrees [F] **Fahrenheit** for at least five minutes; [or]

2. A flow of hot water at a temperature of 170 degrees [F] **Fahrenheit** for at least five minutes; [or]

3. A flow of chlorine solution testing 50 [p.p.m.] **parts per million** for at least one minute; [or]

4. A flow of iodine solution testing 12.5 [p.p.m.] **parts per million** for at least one minute; or

5. (No change.)

(c) (No change.)

8:21-7.27 Pasteurization and cooling

(a) All mixtures used in the manufacture of frozen desserts, except as noted in the standards of identity above, shall be pasteurized in a plant and in properly designed and operated equipment, to one of the following temperatures and held continuously at or above that temperature for at least the corresponding specified time:

1. To a temperature of at least 155 degrees [F] **Fahrenheit** for at least 30 consecutive minutes by the batch (vat) process; [or]

2. To a temperature of at least 175 degrees [F] **Fahrenheit** for at least 25 consecutive seconds by a high-temperature-short-time process; [or]

3. To a temperature of at least 180 degrees [F] **Fahrenheit** for at least 15 consecutive seconds by the high-temperature-short-time process; [or]

4. To a temperature of at least 280 degrees [F] **Fahrenheit** for at least [2] **two** consecutive seconds by the ultra-high-temperature process; or

5. (No change.)

(b) After pasteurization, all milk and milk products, whether unmixed or mixed with any other ingredient, shall be maintained at a temperature of not more than 45 degrees [F] **Fahrenheit** until subject to freezing. This requirement on maintaining temperature of mix shall be construed:

1.-2. (No change.)

8:21-7.31 Supply of milk and fluid milk products

(a) All milk and fluid milk products used in the manufacture of frozen desserts for sale or distribution in New Jersey shall be obtained from milk plants holding permits from the Department [of Health]; except frozen dessert plants located outside the geographical boundaries of New Jersey shall receive their dairy ingredients, which are used in the manufacture of frozen desserts, from plants holding a current satisfactory Interstate Milk Shippers rating.

(b)-(c) (No change.)

8:21-7.34 Frozen desserts; mobile units

(a) Mobile units shall comply with all applicable provisions of this subchapter exclusive of toilet facilities, pasteurization and storage facilities, and in addition thereto, shall comply with the following:

1. -5. (No change.)

6. A refrigerated box to maintain a temperature of 45 degrees [F] **Fahrenheit** or below shall be provided. The box shall be of ample capacity, of stainless steel or other noncorrosive material, the floor of which shall be pitched towards a center drain. It shall be provided with metal racks or platforms or shelves on which to store products or ingredients and shall be equipped with an indicating thermometer which is accurate to [+/- 3] **plus or minus three** degrees [F] **Fahrenheit**;

7.- 9. (No change.)

10. A refrigerated syrup rail with holding plate to maintain a temperature not higher than 45 degrees [F] **Fahrenheit** shall be provided. Use of syrup pumps is prohibited unless the type of pump has been found to be acceptable to the Department;

11.- 15. (No change.)

SUBCHAPTER 10. DESIGNATED FLUID MILK PRODUCTS

8:21-10.1 Pasteurized Milk Ordinance (PMO) adopted

The **National Conference on Interstate Milk Shipments,** Grade “A” Pasteurized Milk Ordinance (PMO) [1978 Recommendations of the United States Public Health Service/Food and Drug Administration, Publication No. 229,] **2019,** is [adopted and]

incorporated herein by reference, as amended and supplemented, as the legal requirements for the production and processing of milk and milk products in the State of New Jersey, provided, however, that certain sections of the PMO as identified in this subchapter are not adopted and that certain additional requirements as set forth in this subchapter are promulgated. [Copies of the] **The** PMO [may be obtained] **is available** from the Food and Drug Administration (FDA), **Grade "A"** Milk Safety **Program, Milk and Milk Products** Branch [. HFS-626, HFS, 200 "C" Street S.W., Washington, DC 20204 or reviewed at the offices of the New Jersey Department of Health and Senior Services] **, HFS-316, Division of Dairy, Eggs and Meat Products, 5001 Campus Drive College Park, MD 20740-3835 (240) 402-1700, and online at https://www.fda.gov/food/milk-guidance-documents-regulatory-information/national-conference-interstate-milk-shipments-ncims-model-documents#PMO.**

8:21-10.2 Definitions

(a) (No change.)

(b) The following words and terms, as used in this subchapter and in the PMO as incorporated by reference herein, shall have the following meanings:

…

"Commissioner" [shall] mean**s** the Commissioner of the Department of Health [and Senior Services or his/her duly appointed agent].

…

"Department" means the Department of Health [and Senior Services].

…

"Health [Authority] **authority**" means [the duly authorized] **an** agent of the Department [of Health and Senior Services] **that the Department duly authorizes** to act in the enforcement of the sanitary laws of the State.

…

8:21-10.8 Standards for milk and fluid milk products

(a) Section 7. "Standards for Milk and Milk Products" of the Pasteurized Milk Ordinance is adopted with the following additional requirements:

1. (No change.)

2. The following requirements are added to Item 1r. Abnormal Milk:

i. (No change.)

ii. Whenever a herd milk sample exceeds any of the following screening test results, a confirmatory count, using a Direct Microscopic, Electronic, Membrane Filter DNA or Optical Somatic Cell counting technique, shall be made on that sample and the results of this count shall be the official result. Pyronine Y-methyl green stain shall be used in the confirmatory test for direct microscopic somatic cell counts in goat's milk.

(1) (No change.)

(2) Wisconsin mastitis t—t--18 [mm.] **millimeters** applicable to goat's milk only.

iii. Whenever the confirmatory count indicates the presence of greater than 750,000 somatic cells per [ml.] **milliliter** on cow's milk or 1,000,000 somatic cells per [ml.] **milliliter** on goat's milk, the following procedure shall be followed:

(1) (No change.)

(2) Whenever two of the last four consecutive somatic cell counts exceed 750,000 cells per [ml.] **milliliter** on cow's milk or 1,000,000 cells per [ml.] **milliliter** on goat's milk, written notice thereof shall be sent to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples exceed 750,000 cells per [ml.] **milliliter** on cow's milk or 1,000,000 somatic cells per [ml.] **milliliter** on goat's milk. In addition to the written notice, an inspection should be made by certified personnel. This inspection should be made at milking time to be the most effective.

(3) An additional milk sample shall be taken within 21 days of the written notice and inspection required above, but not before the lapse of three days. If three of the last five samples within any consecutive six months indicate a confirmatory count greater than 750,000 cells per [ml.] **milliliter** on cow's milk or 1,000,000 somatic cells per ml. on goat's milk, the receipt of milk from the producer shall be discontinued for a period of at least two days or until such time as additional samples show correction of the condition.

3.-4. (No change.)

SUBCHAPTER 11. DENTED CANS; SALVAGE OR DISTRESSED FOODS, ALCOHOL AND NONALCOHOLIC BEVERAGES AND INDUSTRIAL MISHANDLING

8:21-11.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

…

"Department" [or "State department"] means the New Jersey [State] Department of Health.

…

"Health officer" means the duly appointed official in charge of the local board of health who holds a currently effective health officer's license issued by the [department] **Department**.

…

"Inspector" means a duly appointed official of the [State department] **Department** or the local health authority who holds a currently effective sanitary inspector license, grade 1, issued by the [department] **Department**.

…

"Salvage food" means food which has been subjected to a "natural" or "local disaster" or suspected of being adulterated, misbranded, or otherwise unsafe for human consumption. The term also applies to "distressed foods". Foods in this category are subject to complete and thorough examination and/or sampling by the [State department] **Department** or the local board of health to determine if they are fit for consumption.

“Sanitize” means effective bactericidal treatment of clean surfaces by a process which has been approved by the [department] **Department** as being effective in destroying microorganisms, including pathogens.

…

8:21-11.3 Damaged cans unsuitable for sale

(a)-(j) (No change.)

Notes: A pictorial guide entitled “Visual Aids for Inspection of Damaged Food Containers” has been developed to correspond to the requirements contained in sections 2 and 3 of this subchapter and will serve to clarify some of the terminology used in the regulations. This guide is available from the [New Jersey State] Department [of Health].

8:21-11.5 Salvage of food, drugs, devices**,** or cosmetics associated with natural or local disasters or distressed food conditions or industrial mishandling

(a) General provisions are as follows:

1. (No change.)

2. Complete instructions should be issued to local health authorities by the [department] **Department** regarding [our] **the** policy and procedures to be used during the disaster.

3. (No change.)

4. All articles [which] **that** have lost their identity and cannot be re-identified shall be destroyed or disposed of in a manner approved by the [department] **Department** or local health authority.

5. Inventory lists should be made of all embargoes and destroyed materials as soon as possible under the supervision of the [department] **Department** or local health authority representative. If quantities of affected articles are such that inventory cannot be taken immediately, a blanket embargo shall be placed on the contents of the room, building**,** or other place affected.

6. Complete instructions shall be issued to the establishment operator with special emphasis on maintaining embargoes until articles are released by the [department] **Department** or local health authority.

7. (No change.)

(b) Rules concerning sanitizing hermetically sealed containers are as follows.

1. Food, drugs, devices**,** and cosmetics in hermetically sealed containers may be salvaged if **they are**:

i. [They are thoroughly] **Thoroughly** washed in a solution of soap or detergent and clean water;

ii.-iii. (No change.)

iv. Upon expiration of the [15 or 30 day] **15- or 30-day** holding period, reconditioned goods should be examined by [department] **Department** or local health authority personnel and may be released if found in satisfactory condition.

(c)-(e) (No change.)

(f) Rules concerning utensils, equipment**,** and work surfaces are as follows.

1. Food, drug**,** and cosmetic establishments affected by a natural or local disaster shall not resume operations until all utensils, equipment**,** and work surfaces have been thoroughly cleaned and subjected to sanitization procedures acceptable to the [department] **Department** or local health authority and permission to resume operations has been granted by the [department] **Department** or the local health authority.

(g)-(i) (No change.)

8:21-11.6 Disposal of distressed foods

(a) All disaster or distressed food shall be disposed of in the following manner.

1. All foods and food containers [which] **that** have been subject to a natural or local disaster or industrial mishandling shall be embargoed until such time that the [department] **Department** or the local health authority has determined that the foods are safe, wholesome**,** and free from adulteration. Every effort shall be made to provide proper security for embargoed food during the entire period of the embargo.

2. Upon completion of the sorting and reconditioning process, the [department] **Department** or the local health authority shall examine the embargoed food and determine if the foods are safe for consumption or are condemned for use as food.

3. Upon determination by the [department] **Department** or the local health authority that the embargoed foods are safe, wholesome**,** and free from adulteration, an embargo release shall be issued and the foods released for sale. No embargoed foods shall be moved or otherwise disposed without permission of the [department] **Department**, the local health authority**,** or the court.

4. Upon determination that foods under embargo are unfit for consumption, the [department] **Department**, local health authority**,** or the court shall condemn such foods and cause or order the foods to be destroyed for food purposes.

5. Condemned foods shall be destroyed under the direct observation of the [department] **Department** or the local health authority.

6. Condemned foods shall be disposed of in a manner satisfactory to the [department] **Department** or the local health authority.

7. (No change.)

8. Large lots of foods shall be disposed of by incineration or disposal in a sanitary landfill. The condemned foods shall be under constant observation of the [department] **Department** or the local health authority during loading, transportation**,** and eventual disposition at the incinerator or sanitary landfill. Condemned foods to be disposed of in a sanitary landfill shall be discharged upon a hard surface, thoroughly crushed by a bulldozer or similar type of equipment, pushed into the active part of the landfill**,** and covered with soil to a depth which would preclude the possibility of scavaging.

9. Distressed embargoed foods may be disposed of in any other manner acceptable to the [department] **Department** or the local health authority.

10. (No change.)

SUBCHAPTER 13. RULES GOVERNING WHOLESALE FOOD ESTABLISHMENTS

8:21-13.3 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

…

"Department" means the New Jersey [State] Department of Health.

…

"Local [Health Authority] **health authority**" means the local board or local board of health of any municipality or the boards, body, or officers in such a municipality lawfully exercising any of the powers of the local board of health under the laws governing such municipality, and includes any consolidated board of health, local or county board of health created and established pursuant to law.

…

8:21-13.5 Sanitary facilities and controls

(a)-(e) (No change.)

(f) Toilet facilities: Each plant shall provide its employees with adequate toilet and associated hand-washing facilities within the plant. The facilities shall be maintained in a sanitary condition and kept in good repair at all times. Doors to toilet rooms shall be self-closing and shall not open directly into areas where food is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination (such as double doors, positive air-flow systems, etc.).

1. - 2. (No change.)

3. Hot and cold water under suitable pressure shall be provided in toilet facilities. (90 [degree F-] **degrees Fahrenheit to** 105[degree F] **degrees Fahrenheit**)

(g)-(h) (No change.)

8:21-13.7 Equipment and procedures

(a) General: All plant equipment and utensils shall be suitable for their intended use, so designed and of such material and workmanship as to be adequately cleanable and properly maintained. The design, construction, and use of such equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces.

1.-5. (No change.)

6. Each freezer and cold storage compartment used for storing and holding raw materials or products capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device and/or temperature recording device so installed as to show the temperature accurately within the compartment. Thermometers and other temperature recording devices shall be accurate to [+/- 2 degree] **plus or minus two degrees** Fahrenheit.

7.-11. (No change.)

8:21-13.12 Emergency occurrences

(a) In the event of a fire, flood, power outage, or similar event that might result in the contamination of food, or that might prevent potentially hazardous food from being held at safe temperatures, the person in charge shall immediately take necessary remedial action so as to prevent the adulteration of food. A fire, flood, or power outage of such duration or similar event [which] **that** jeopardizes food safety shall be reported promptly to the [department] **Department** and the local health authority.

(b) (No change.)