

**CHAPTER 21  
FOOD AND DRUGS**

**Authority**

N.J.S.A. 24:2-1, 24:5-1, 24:10-57.1, 24:10-73.1 and 24:12-12

**Source and Effective Date**

R.1995 d.588, effective October 23, 1995.  
See: 27 N.J.R. 3535(a), 27 N.J.R. 4700(b).

**Executive Order No. 66(1978) Expiration Date**

Chapter 21, Food and Drugs, expires on October 23, 2000.

**Chapter Historical Note**

All provisions of this chapter became effective prior to September 1, 1969.

1970 Revisions: Subchapter 7 became effective May 20, 1970 as R.1970 d.58. See: 2 N.J.R. 31(a), 2 N.J.R. 54(d).

1972 Revisions: Subchapter 9 became effective May 1, 1972 as R.1972 d.81. See: 4 N.J.R. 24(d), 4 N.J.R. 125(a). Amendments to this chapter became effective December 15, 1972 as R.1972 d.209. See: 4 N.J.R. 215(a), 4 N.J.R. 26(b).

1973 Revisions: Subchapter 10 became effective January 10, 1973 as R.1973 d.17. See: 4 N.J.R. 302(d), 5 N.J.R. 42(a). Amendments became effective March 13, 1973 as R.1973 d.74. See: 5 N.J.R. 40(a), 5 N.J.R. 107(b). Further revisions became effective March 30, 1973 as R.1973 d.89. See: 5 N.J.R. 81(b), 5 N.J.R. 143(a).

1974 Revisions: Amendments became effective July 9, 1974 as R.1974 d.184. See: 6 N.J.R. 232(a), 6 N.J.R. 310(a). Further amendments became effective July 24, 1974 as R.1974 d.204. See: 6 N.J.R. 179(a), 6 N.J.R. 311(a).

1975 Revisions: Revisions concerning the former N.J.A.C. 8:21-4.44 were filed on December 30, 1974 as R.1974 d.361 effective January 1, 1975. See: 7 N.J.R. 56(b). Further revisions became effective April 22, 1975 as R.1975 d.103. See: 6 N.J.R. 431(a), 7 N.J.R. 21(b). The text of Subchapters 4 and 5 was deleted and Subchapter 10 was amended effective October 22, 1975 as R.1975 d.320. See: 7 N.J.R. 153(b), 7 N.J.R. 503(b).

1976 Revisions: Amendments became effective January 21, 1976 as R.1976 d.19. See: 7 N.J.R. 355(b), 8 N.J.R. 65(b). Further revisions became effective February 18, 1976 as R.1976 d.50. See: 8 N.J.R. 15(c), 8 N.J.R. 118(b). Further revisions became effective April 21, 1976 as R.1976 d.123. See: 8 N.J.R. 117(b), 8 N.J.R. 227(b).

1977 Revisions: Amendments became effective May 26, 1977 as R.1977 d.192. See: 9 N.J.R. 219(d), 9 N.J.R. 269(b). Further amendments became effective September 21, 1977 as R.1977 d.357. See: 9 N.J.R. 362(c), 9 N.J.R. 467(a). Revisions changing the mandatory effective date to July 1, 1979 became effective December 15, 1977 as R.1977 d.472. See: 9 N.J.R. 515(a), 10 N.J.R. 12(b).

1978 Revisions: New rules for Subchapter 4 became effective March 14, 1978 as R.1978 d.93. See: 10 N.J.R. 148(a). Subchapter 11 was adopted effective March 17, 1978 as R.1978 d.100. See: 10 N.J.R. 62(a), 10 N.J.R. 149(a). Amendments to this chapter became effective May 22, 1978 as R.1978 d.167. See: 10 N.J.R. 147(a), 10 N.J.R. 249(b). Further amendments became effective May 27, 1978 as R.1978 d.167. See: 10 N.J.R. 147(a), 10 N.J.R. 249(b). Further amendments became effective July 24, 1978 as R.1978 d.246. See: 10 N.J.R. 238(b), 10 N.J.R. 341(a).

1979 Revisions: Revisions became effective April 12, 1979 as R.1979 d.143. See: 11 N.J.R. 236(a). Further amendments became effective

August 6, 1979 as R.1979 d.299. See: 11 N.J.R. 327(b), 11 N.J.R. 440(c). Further amendments became effective August 16, 1979 as R.1979 d.322. See: 11 N.J.R. 277(b), 11 N.J.R. 441(d). Further amendments became effective November 13, 1979 as R.1979 d.454. See: 11 N.J.R. 504(b), 11 N.J.R. 622(d).

1980 Revisions: Revisions became effective April 10, 1980 as R.1980 d.320. See: 12 N.J.R. 315(a), 12 N.J.R. 467(e). Previous rules to section 1.32 and 1.33 were codified to 8:12-1.13 by N.J.S.A. 24:5-18(b). Amendments became effective February 28, 1980 as R.1980 d.96. See: 12 N.J.R. 186(a). Further amendments became effective May 15, 1980 as R.1980 d.218. See: 12 N.J.R. 11(a), 12 N.J.R. 317(a). Subchapter 6 entitled "Production, Distribution and Sale of Certified Milk, Cream and Skim Milk" was substantially amended effective September 18, 1980 as R.1980 d.403. See: 12 N.J.R. 181(d), 12 N.J.R. 579(d). Further amendments became effective December 11, 1980 as R.1980 d.539. See: 12 N.J.R. 643(c), 13 N.J.R. 13(f).

1981 Revisions: Amendments became effective April 10, 1981 as R.1980 d.320. See: 12 N.J.R. 315(a), 12 N.J.R. 467(e).

1982 Revisions: Amendments became effective April 19, 1982 as R.1982 d.123. See: 14 N.J.R. 79(a), 14 N.J.R. 389(a). Further amendments became effective December 20, 1982 as R.1982 d.451. See: 14 N.J.R. 1029(a), 14 N.J.R. 1456(a).

1983 Revisions: Amendments became effective February 22, 1983 as R.1983 d.41. See: 14 N.J.R. 1190(a), 15 N.J.R. 244(b). Further amendments became effective April 18, 1983 as R.1983 d.115. See: 14 N.J.R. 1265(a), 15 N.J.R. 623(a). Subchapter 12 became effective April 18, 1983 (operative June 1, 1983) as R.1983 d.115. See: 14 N.J.R. 1265(a), 15 N.J.R. 623(a), 15 N.J.R. 809(a). Subchapter 9 was readopted pursuant to Executive Order 66(1978) effective August 8, 1983 as R.1983 d.345. See: 15 N.J.R. 609(a), 15 N.J.R. 1475(a). Amendments became effective October 17, 1983 as R.1983 d.456. See: 15 N.J.R. 1317(a), 15 N.J.R. 1762(b).

1984 Revisions: Section 2.40 was amended (originally adopted as an emergency rule R.1984 d.60 effective February 22, 1984) effective April 23, 1984 as R.1984 d.171. See: 16 N.J.R. 436(a), 16 N.J.R. 1089(a). Subchapter 13 became effective June 18, 1984 as R.1984 d.246. See: 15 N.J.R. 1318(a), 16 N.J.R. 1499(a). Subchapter 7 expired September 6, 1984 and a new rule was adopted pursuant to Executive Order 66(1978) effective November 18, 1985 as R.1985 d.591. See: 17 N.J.R. 1986(b), 17 N.J.R. 2756(b).

1985 Revisions: Amendments became effective February 19, 1985 as R.1985 d.42. See: 16 N.J.R. 2897(a), 17 N.J.R. 449(a). Subchapter 6, Production, Distribution and Sale of Certified Milk, Cream and Skim Milk expired on September 18, 1985. Subchapter 7 was adopted as a new rule pursuant to Executive Order 66(1978) effective November 18, 1985 as R.1985 d.591. See: 17 N.J.R. 1986(b), 17 N.J.R. 2756(b). Subchapter 10 expired December 10, 1985 pursuant to Executive Order 66(1978).

1986 Revisions: Subchapter 10 became effective April 7, 1986 (adopted as a new rule) as R. 1986 d.96. See: 18 N.J.R. 59(b), 18 N.J.R. 660(a).

1987 Revisions: Subchapter 4 became effective May 18, 1987 (Adopted as a new rule. The subchapter had expired July 21, 1983 pursuant to Executive Order 66(1978).) with amendments to sections 5, 26, 31 and 32 as R.1987 d.227. See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).

1990 Revisions: Pursuant to Executive Order No. 66(1978), Chapter 21 was readopted as R.1990 d.563, effective November 19, 1990. See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a). As part of the re-adoption, Subchapter 1, Food, Drug, Cosmetic, and Device Labeling was adopted as new rules, replacing former Subchapter 1, Names; Labels, which expired on May 15, 1985; Subchapter 5, Manufacturing, Storage, Distribution, and Handling of Bottled Water, was adopted as new rules; and Subchapter 12, Manufacturing, Storage, Distribution and Handling of Nonalcoholic Beverages and Bottled Water, was repealed.

1992 Revisions: Subchapter 3A, Registration of Wholesale Distributors of Prescription Drugs, was adopted as new rules by R.1992 d.354, effective September 8, 1992. See: 24 N.J.R. 2410(b), 24 N.J.R. 3100(a).

Pursuant to Executive Order No. 66(1978), Chapter 21 was readopted as R.1995 d.588, effective October 23, 1995. See: Source and Effective Date. See, also, section annotations.

## CHAPTER TABLE OF CONTENTS

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

- 8:21-1.1 Definitions
- 8:21-1.2 General labeling requirements
- 8:21-1.3 Food labeling
- 8:21-1.4 Drug labeling
- 8:21-1.5 Cosmetic labeling
- 8:21-1.6 Labeling, sale, and distribution of cosmetics for professional use only
- 8:21-1.7 Cosmetic product warning statements
- 8:21-1.8 Definition of soap
- 8:21-1.9 Device labeling

### SUBCHAPTER 2. FOODS

- 8:21-2.1 through 8:21-2.12 (Reserved)
- 8:21-2.13 Use of textile bags as containers for flour
- 8:21-2.14 Frozen food locker plants
- 8:21-2.15 Sale of enriched white flour and unenriched white flour
- 8:21-2.16 through 8:21-2.34 (Reserved)
- 8:21-2.35 Public posting of inspection reports
- 8:21-2.36 Public availability of inspection records
- 8:21-2.37 (Reserved)
- 8:21-2.38 Bacteriological standards for potentially hazardous foods
- 8:21-2.39 Sale of ground meat and similar products
- 8:21-2.40 (Reserved)
- 8:21-2.41 Prohibition of sale of striped bass
- 8:21-2.42 Prohibition of sale of channel cat fish

### SUBCHAPTER 3. DRUGS, DEVICES AND COSMETICS

- 8:21-3.1 through 8:21-3.7 (Reserved)
- 8:21-3.8 Warning statements for drug labels
- 8:21-3.9 Restrictions on sales of dangerous drugs
- 8:21-3.10 Other dangerous drug regulations
- 8:21-3.11 Rulings on dangerous drugs
- 8:21-3.12 Rulings on dangerous cosmetics
- 8:21-3.13 Keeping of records by drug manufacturing businesses and wholesale drug businesses
- 8:21-3.14 through 8:21-3.18 (Reserved)
- 8:21-3.19 Paregoric
- 8:21-3.20 Compressed air used in self contained underwater breathing apparatus (SCUBA)
- 8:21-3.21 SCUBA recommendations
- 8:21-3.22 (Reserved)
- 8:21-3.23 Animal repellants
- 8:21-3.24 List of ingredients for human self-defense sprays
- 8:21-3.25 Permit for nitrous oxide

### SUBCHAPTER 3A. REGISTRATION OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

- 8:21-3A.1 Scope
- 8:21-3A.2 Purpose
- 8:21-3A.3 Definitions
- 8:21-3A.4 Application requirements; reciprocity
- 8:21-3A.5 Evaluation criteria
- 8:21-3A.6 Denial of application
- 8:21-3A.7 Personnel requirements
- 8:21-3A.8 Facility
- 8:21-3A.9 Security
- 8:21-3A.10 Storage
- 8:21-3A.11 Examination of materials

- 8:21-3A.12 Returned, damaged and outdated prescription drugs
- 8:21-3A.13 Recordkeeping
- 8:21-3A.14 (Reserved)
- 8:21-3A.15 Availability of records and inventories
- 8:21-3A.16 Policies and procedures
- 8:21-3A.17 List of responsible persons
- 8:21-3A.18 Inspection and auditing
- 8:21-3A.19 Salvage; reprocessing
- 8:21-3A.20 Suspension; revocation
- 8:21-3A.21 Penalties
- 8:21-3A.22 Appeals

### SUBCHAPTER 4. NEW DRUGS

- 8:21-4.1 Statement of policy
- 8:21-4.2 Combination drugs
- 8:21-4.3 General provisions; definitions
- 8:21-4.4 Exemptions from section 505(a)
- 8:21-4.5 General provisions; new drug applications
- 8:21-4.6 through 8:21-4.24 (Reserved)
- 8:21-4.25 Amygdalin (Laetrile); generally
- 8:21-4.26 Amygdalin; testing
- 8:21-4.27 Amygdalin; subject to other administrative rules
- 8:21-4.28 Use and distribution of amygdalin; forms
- 8:21-4.29 Failure to comply with provisions
- 8:21-4.30 Use of amygdalin; treatment of cancer
- 8:21-4.31 Filing of affidavit
- 8:21-4.32 Written orders; prescriptions; dispensing
- 8:21-4.33 Patient's medical history
- 8:21-4.34 Information; confidentiality
- 8:21-4.35 through 8:21-4.49 (Reserved)
- 8:21-4.50 Approved new drugs

### SUBCHAPTER 5. MANUFACTURING, STORAGE, DISTRIBUTION, AND HANDLING OF BOTTLED WATER

- 8:21-5.1 Separability
- 8:21-5.2 Definitions
- 8:21-5.3 Water source protection
- 8:21-5.4 Springs
- 8:21-5.5 Bottled water labeling requirements
- 8:21-5.6 Facilities for the storage, distribution, handling, and bottling of bottled water
- 8:21-5.7 Production, equipment, and packaging requirements
- 8:21-5.8 Sanitation and maintenance requirements
- 8:21-5.9 Storage and handling of chemicals
- 8:21-5.10 Personnel requirements
- 8:21-5.11 Sanitizing requirements for multi-use bottles or containers
- 8:21-5.12 Bulk water requirements
- 8:21-5.13 Recordkeeping requirements
- 8:21-5.14 Water standards and sampling requirements
- 8:21-5.15 Bulk and bottled water registration (out-of-State) requirements

### SUBCHAPTER 6. (RESERVED)

### SUBCHAPTER 7. FROZEN DESSERTS

- 8:21-7.1 Definitions
- 8:21-7.2 Ice cream and frozen custard
- 8:21-7.3 Sherbet
- 8:21-7.4 Water ice
- 8:21-7.5 Mellorine
- 8:21-7.6 Goat's milk ice cream
- 8:21-7.7 Frozen yogurt; identity; label statement
- 8:21-7.8 Quiescently frozen confection; identity; label statement
- 8:21-7.9 Quiescently frozen dairy confection; identity; label statement
- 8:21-7.10 Non-fruit (imitation) sherbet; identity; label statement
- 8:21-7.11 Non-fruit (imitation) water ice; identity; label statement
- 8:21-7.12 Manufactured desserts mix; identity; label statement
- 8:21-7.13 Freezer-made shake; freezer-made milk shake; identity; label statement
- 8:21-7.14 Parevine; identity; label statement

- 8:21-7.15 Lo-mel; identity; label statement
- 8:21-7.16 Frozen pudding; identity; label statement
- 8:21-7.17 Temporary marketing permit
- 8:21-7.18 Generic frozen dessert; identity; label statement
- 8:21-7.19 Other standards of identity
- 8:21-7.20 Plant records
- 8:21-7.21 Plant buildings and surroundings
- 8:21-7.22 Plant construction
- 8:21-7.23 Plant cleanliness
- 8:21-7.24 Construction and repair of containers and equipment
- 8:21-7.25 Cleaning and sanitizing of containers and equipment
- 8:21-7.26 Protection from contamination
- 8:21-7.27 Pasteurization and cooling
- 8:21-7.28 Bacterial standards
- 8:21-7.29 Plant sanitary facilities
- 8:21-7.30 Plant personnel
- 8:21-7.31 Supply of milk and fluid milk products
- 8:21-7.32 Packaging and labeling
- 8:21-7.33 Self service frozen desserts-manufacturing machines
- 8:21-7.34 Frozen desserts; mobile units
- 8:21-7.35 Mobile unit depots
- 8:21-7.36 Procedures for reconstituting dry frozen desserts mix
- 8:21-7.37 License fees
- 8:21-7.38 Suspension, revocation or nonrenewal of license
- 8:21-7.39 to 8:21-7.46 (Reserved)

**SUBCHAPTER 8. IMITATION MILK, IMITATION LOW FAT MILK AND IMITATION FLUID MILK PRODUCTS**

- 8:21-8.1 Definitions and standards of identity
- 8:21-8.2 Misbranding of imitation milk, imitation low fat milk and imitation fluid milk products
- 8:21-8.3 Misbranding of foods made in semblance of imitation milk, imitation low fat milk or any imitation fluid milk product
- 8:21-8.4 Adulteration of imitation milk, imitation low fat milk and foods made in semblance of such products

**SUBCHAPTER 9. LICENSING OF FOOD AND COSMETIC MANUFACTURING AND WHOLESALE ESTABLISHMENTS**

- 8:21-9.1 Definitions
- 8:21-9.2 Scope of regulations
- 8:21-9.3 Exemptions
- 8:21-9.4 License requirement
- 8:21-9.5 License fees
- 8:21-9.6 Expiration of license; nontransferability of license
- 8:21-9.7 Revocation of license

**SUBCHAPTER 10. DESIGNATED FLUID MILK PRODUCTS**

- 8:21-10.1 Definitions and product standards
- 8:21-10.2 Labeling
- 8:21-10.3 Inspection of dairy farms and milk plants
- 8:21-10.4 Examination of milk and fluid milk products
- 8:21-10.5 Animal health
- 8:21-10.6 Standards for milk and fluid milk products
- 8:21-10.7 Transferring; delivery containers; cooling
- 8:21-10.8 Milk and milk products from points beyond the limits of routine inspections
- 8:21-10.9 Personnel health
- 8:21-10.10 Procedure when infection is suspected
- 8:21-10.11 Future dairy farms and milk plants
- 8:21-10.12 Dating of milk and fluid milk products
- 8:21-10.13 Temporary marketing permit

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

- 8:21-11.1 Scope
- 8:21-11.2 Definitions

- 8:21-11.3 Damaged cans unsuitable for sale
- 8:21-11.4 Damaged food containers suitable for sale
- 8:21-11.5 Salvage of food, drugs, devices or cosmetics associated with natural or local disasters or distressed food conditions or industrial mishandling
- 8:21-11.6 Disposal of distressed foods

**SUBCHAPTER 12. (RESERVED)**

**SUBCHAPTER 13. RULES GOVERNING WHOLESALE FOOD ESTABLISHMENTS**

- 8:21-13.1 Scope
- 8:21-13.2 Separability
- 8:21-13.3 Definitions
- 8:21-13.4 Facilities and procedures for the storage, distribution, handling and processing of food and nonalcoholic drinks
- 8:21-13.5 Sanitary facilities and controls
- 8:21-13.6 Sanitary operations
- 8:21-13.7 Equipment and procedures
- 8:21-13.8 Personnel
- 8:21-13.9 Production and process controls
- 8:21-13.10 Emergency occurrences

**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:

“Consumer” means an individual who secures a cosmetic for his or her self application and has not received any special training or experience in its use.

“Cosmetic” means “cosmetic” as defined in N.J.S.A. 24:1-1h.

“Label” means “label” as defined in N.J.S.A. 24:1-1j.

“Labeling” means “labeling” as defined in N.J.S.A. 24:1-1k.

“Person” means an individual or firm, partnership, company, corporation, trustee, association, or any public or private entity.

“Professional” means an individual qualified through special training and experience and licensed by the State to perform beauty culture services.

“Professional use only” means for use only by a professional, or words of similar import.

“Retail” means sale or distribution directly to the consumer.

**8:21-5.12 Bulk water requirements**

(a) Tank trucks, loading and unloading facilities, storage tanks, and other equipment used to store or transport bulk water shall be maintained in a clean and sanitary condition. All previously cited rules and regulations which pertain to equipment, construction, maintenance, cleaning, and sanitizing shall also apply to transporting and handling of bulk water.

(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) Tank trucks previously used to transport toxic substances, petroleum products, or other deleterious substances shall not be used to transport bulk water.

(d) Tank trucks and related equipment used to transport or handle bulk water shall be used for no other purpose and shall be thoroughly cleaned and sanitized prior to filling in accordance with the provisions of N.J.A.C. 8:21-5.8 and shall comply with the following:

1. Storage tanks and tank trucks shall be free of deep pits, excessive scale, dents or poorly welded seams which may tend to hold standing water;
2. Inlets, outlets, piping hose and other appurtenances associated with storage tanks and tank trucks shall be constructed and handled to prevent contamination of product water;
3. All tank trucks shall be tagged identifying the time and place of cleaning and sanitization. These records shall be available at all times for inspection by the regulatory authority; and
4. All hoses, connections and fittings used in conjunction with the coupling of the tank truck to the bulk water delivery line shall be sanitized with 100 parts per million chlorine solution at 75 degrees Fahrenheit or any other approved sanitizer of equivalent concentration. The solution shall be brushed on all exposed parts to assure proper sanitization.

(e) The physical water quality in the tank truck shall be determined in the following manner:

1. At the time of filling of a tank with bulk water for transport, the tank truck shall be visually inspected and initially be filled with approximately 50 gallons of water. The discharge valve shall then be opened and several gallons of water discharged and checked for odor, clarity and particulates. If the water has an unsatisfactory odor, clarity or other detectable problem the tank truck shall be rejected. If satisfactory, the tank truck may be loaded for transport;

2. At time of delivery of bulk water to the bottling plant, the discharge valve of the tank truck shall be opened and several gallons shall be discharged and checked for odor, clarity and particulate matter. If the water has an unsatisfactory odor, clarity or other detectable problem the load shall be rejected;

3. The dome cover shall be opened at the time of filling and discharge of bulk water from the tank truck. The dome screen filter shall be in place and properly sealed during loading and unloading of tank trucks. Tank trucks shall be loaded and unloaded through the tail pipe discharge valve whenever possible; and

4. The dome cover and tail pipe valve cover and doors shall be closed prior to transport of water.

(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.

**8:21-5.13 Recordkeeping requirements**

(a) Each bottling plant shall keep true and accurate records of all water processed. Such records shall show:

1. Source, type, and volume of water processed daily; and
2. Records indicating the physical inspection of bulk water delivered.

(b) Each bottling plant shall keep true and accurate records of finished product. Such records shall show:

1. The amount bottled;
2. Dates of bottling; and
3. Expiration date.

(c) Records of the required water analysis on both raw and finished product water as specified in N.J.A.C. 8:21-5.12 and 5.14 shall be forwarded to the Department. Upon completion, the certified laboratory conducting the required tests may, upon written approval of the Department, submit the test results on behalf of the plant owner or operator. The weekly microbiological test results may be consolidated and reported on a monthly basis.

(d) Records shall be kept of the cleaning and sanitizing of multipurpose fillers and bottle washing equipment, if applicable.

(e) All records shall be maintained at the plant for 30 months from the date of processing of the raw water and shall be available for review by the inspecting agency upon request.

**8:21-5.14 Water standards and sampling requirements**

(a) Bottled water which is manufactured, distributed, or sold within this State shall comply with the microbiological, physical, chemical, hazardous contaminants, and radiological standards set forth in this section. Bottlers and bulk water handling facilities which derive their water from a public community water system as defined under N.J.A.C. 7:10-1.3 are exempt from sampling the source (raw) water. Analysis shall be conducted in accordance with procedures set forth in N.J.A.C. 7:18, Rules Governing Laboratory Certification and Standards of Performance, and the following:

1. Microbiological Standards: A weekly analysis for total coliform is required for finished product water. A weekly analysis for total coliform shall be required for source (raw) water. Bottled water should be examined for standard aerobic plate count. Standards for total coliform are contained in Table 1 below;

2. Physical Standards: An annual analysis shall be required for both source (raw) and bottled water. Standards for physical quality are contained in Table 2 below;

3. Chemical Standards: An annual analysis shall be required for both source (raw) and bottled water. Standards for chemical quality are contained in Tables 3 and 4 below;

4. Radiological Standards: A radiological analysis shall be required once every four years for both source (raw) and bottled water. Radiological standards are contained in Table 5 below; and

5. Hazardous Contaminant Standards: A semiannual analysis shall be required for selected hazardous contaminants as specified in N.J.A.C. 7:10-14.1, Maximum Contaminant Levels for Hazardous Contaminant Levels. The current list of hazardous contaminants and maximum contaminant levels is contained in Table 6 below. This list may be updated periodically by the New Jersey State Department of Environmental Protection. Individual bottlers may petition the Department in writing requesting a reduction in frequency of testing for these selected contaminants from semiannually to annually. In order for the Department to consider this request, the bottler's petition shall include the last three consecutive semiannual analyses which shall not show detectable levels for these contaminants. If a detectable level is identified for any of the selected hazardous contaminants on any subsequent analyses, the requirement for semiannual testing shall be reinstated by the bottler.

(b) Samples Exceeding Standards: If any bottled water standard for physical, chemical, radiological quality is exceeded, the product shall be labeled with a statement indicating substandard quality as follows:

1. "Excessively Turbid," "Abnormal Color," and/or "Abnormal Odor;"

2. "Contains Excessive Chemical Substance," if the bottled water fails to meet any of the chemical quality standards set forth in this section. The specific chemical(s) may be declared in lieu of the words "Chemical Substances" in the statement "Contains Excessive Chemical Substances." When a specific chemical is declared, that name by which the chemical(s) is designated in this section shall be used. Example: "Contains Excessive Copper;" and

3. "Excessively Radioactive" if the bottled water fails to meet the requirements of this section;

(c) Bottled water containing a substance at a level considered injurious to health shall be deemed adulterated, regardless of whether or not the bottled water bears a label statement of substandard quality prescribed in this section.

(d) The statement of substandard quality shall appear on the principal display panel or panels and shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the type of bottled water.

(e) The Department may require the owner/operator of the bottled water facility to institute additional treatment in order to meet bottled water standards when a maximum contaminant level is exceeded. If contamination is excessive and the best available treatment will not result in meeting the maximum contaminant level, the water supply shall be deemed adulterated and its use prohibited.

**TABLE 1  
MICROBIOLOGICAL STANDARDS  
FOR BOTTLED WATER**

Determination	Methods	Standard
Total Coliform	Membrane Filter (MF)	<1 per 100 milliliters
	Most Probable Number (MPN)	<2.2 per 100 milliliters

**TABLE 2  
PHYSICAL REQUIREMENTS  
FOR BOTTLED WATER**

Determination	Standard
Color	15 units
Odor	8 threshold odor number
Turbidity	5 nephelometric turbidity units

**TABLE 3  
CHEMICAL STANDARDS FOR BOTTLED WATER**

Determination	Maximum Contaminant Level
Arsenic	0.05 mg/l
Barium	1.0 mg/l
Cadmium	0.01 mg/l
Chloride	250.05 mg/l
Chromium	0.05 mg/l

Determination	Maximum Contaminant Level
Copper	1.0 mg/l
Fluoride	2.2 mg/l
Iron	0.3 mg/l
Lead	0.05 mg/l
Manganese	0.05 mg/l
Mercury	0.002 mg/l
Nitrate	10.0 mg/l
Selenium	0.01 mg/l
Silver	0.05 mg/l
Sulfate	250.0 mg/l
Total dissolved solids	500.0 mg/l
Zinc	5.0 mg/l
ABS/LAS (foaming agents)	0.5 mg/l
Total Trihalomethanes	0.1 mg/l
ph	+ 6.5 to 8.5 units
Sodium	++ mg/l

+ Recommended range. (Not applicable to distilled or purified water.)

++ Maximum contaminant levels have not been established.  
mg/l = milligrams per liter

Determination	Maximum Contaminant Levels
1,1,1,-trichloroethane	26.0 µg/l
1,2-dichloroethane	2.0 µg/l
Vinyl chloride	2.0 µg/l
Methylene chloride	2.0 µg/l
Benzene	1.0 µg/l
Chlorobenzene	4.0 µg/l
Dichlorobenzenes (S)	
Ortho (O)	600.0 µg/l
Meta (M)	600.0 µg/l
Para (P)	75.0 µg/l
Trichlorobenzene	8.0 µg/l
1,1-Dichloroethylene	2.0 µg/l
1,2-Dichloroethylene	10.0 µg/l
Sis and trans	
Polychlorinated Biphenyls (PCB)	0.5 µg/l
Chlordane	0.5 µg/l
Xylenes	44.0 µg/l

µg/l = micrograms per liter

TABLE 4  
ORGANIC CHEMICAL STANDARDS  
FOR BOTTLED WATER

Determination	Maximum Contaminant Levels
Endrin	0.002 mg/l
Lindane	0.004 mg/l
Methoxychlor	0.1 mg/l
Toxaphene	0.005 mg/l
2,4-D	0.1 mg/l
2,4,5-TP, Silvex	0.01 mg/l

mg/l = milligrams per liter

TABLE 5  
RADIOLOGICAL STANDARDS  
FOR BOTTLED WATER

Determination	Maximum Contaminant Level
Gross alpha activity including radium 226; excluding radon and uranium	15 pci/l
Combined radium 226 and radium 228	5 pci/l
If two or more beta or photon emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed four millirems per year.	4 mrem/yr.

pci/l = picocuries per liter  
mrem/yr. = millirems per year

TABLE 6  
STANDARDS FOR SELECTED HAZARDOUS  
CONTAMINANTS IN BOTTLED WATER

Determination	Maximum Contaminant Levels
Trichloroethylene	1.0 µg/l
Tetrachloroethylene	1.0 µg/l
Carbon tetrachloride	2.0 µg/l

#### 8:21-5.15 Bulk and bottled water registration (out-of-State) requirements

(a) Every out-of-State or foreign bottling plant and/or bulk water handling facilities that sell or distribute bottled and bulk water in New Jersey shall have a current valid registration issued by the Department.

(b) In order to obtain a valid registration to sell or distribute bottled water the following requirements shall be met:

1. The applicant shall complete a registration form provided by the Department and provide all information requested. The registration application shall be signed by the owner or operator responsible for the facility.

2. A letter of certification shall be submitted from the appropriate regulatory agency having jurisdiction over the operation verifying that the facility has been inspected and approved.

3. A copy of each product label shall be submitted for each size and type of bottled water that will be sold or distributed. This requirement does not apply to bulk water.

4. A complete microbiological, physical, chemical, radiological, and hazardous contaminants analysis as listed in N.J.A.C. 8:21-5.14 above must be performed on each finished bottled water product to be distributed in New Jersey. A copy of the required analyses shall accompany the application and shall be forwarded to the Department at the frequency prescribed in N.J.A.C. 8:21-5.14 except that microbiological sample results need only be submitted every six months.

5. All analyses required shall be conducted at an approved laboratory certified by the New Jersey Department of Environmental Protection in accordance with N.J.A.C. 7:18, Rules Governing Laboratory Certification and Standards of Performance, and the laboratory shall be certified for the specific method for which the water is being analyzed.

6. All analyses shall be performed within six months prior to the date of application for registration.

(c) In order to obtain a valid registration to sell or distribute bulk water, the following requirements shall be met:

1. The applicant shall comply with (a) and (b) above as they relate to bottled water registration;

2. The establishment shall comply with all of the requirements of N.J.A.C. 8:21-5.12;

3. A complete microbiological, physical, chemical, radiological, and hazardous contaminants analysis must be performed on each source of water that is used in accordance with the standards established under N.J.A.C. 8:21-5.14. Sample results must be submitted initially with the application for registration and annually thereafter; and

4. The bulk water establishment shall submit a new registration form to the Department any time there is a change in the source of bulk water. The establishment shall meet all of the criteria of this section before he can resume bulk shipments of water into New Jersey.

(d) A registration will be issued to the bottled water and/or bulk water facility upon submission, review and approval of all the information required.

(e) Failure to comply with the bulk and bottled water registration requirements may result in the prohibition of the distribution, sale, or offering for sale of the bottled water products in New Jersey.

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## SUBCHAPTER 6. (RESERVED)

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## 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.

“CFR” means the Code of Federal Regulations of the United States Government.

“Department” means the New Jersey Department of Health and Senior Services.

“Dispensing freezer” means the type of equipment which freezes frozen desserts so they are served in a soft condition for sale to the customer.

“Frozen desserts” means ice cream, frozen custard, sherbet, water ice, mellorine, goat’s milk ice cream, frozen yogurt, quiescently frozen confection, quiescently frozen dairy confection, whipped cream confection, bisque tortoni, nonfruit sherbet, nonfruit water ice, manufactured desserts mix, frozen pudding, freezer made shake and freezer made milk shake, parevine, Lo-Mel, as all such products are commonly known, together with any such mix used in frozen desserts and any products which are similar in appearance, odor, or taste to such products or are prepared or frozen as such products are customarily prepared or frozen whether made with dairy or nondairy products.

“Label” means any written, printed or graphic matter attached to or on a package.

“Mobile unit” means any vehicle on which frozen desserts are manufactured, prepared, processed or converted in form and which is used for selling and dispensing such products to the consuming public.

“Optional ingredients” means Grade A dry milk products, concentrated milk, concentrated fluid milk products, flavors, sweeteners, stabilizers, emulsifiers, acidifiers, vitamins and minerals. Similar ingredients may be added to frozen desserts when approved by the Food and Drug Administration.

“Package” means any carton, box, jar, bottle, pail, wrapper or other container for frozen desserts.

“Person” means any individual, copartnership, corporation, cooperative association, cooperative corporation or unincorporated association.

“Wholesale frozen dessert manufacturer” means any place, premises or establishment or any part thereof where frozen desserts are assembled, manufactured, processed, frozen, or converted in form, for distribution or sale to a person other than the ultimate consumer.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Added “optional ingredients” and “wholesale frozen desserts manufacturer.”

Amended by R.1998 d.341, effective July 6, 1998.

See: 30 N.J.R. 1361(a), 30 N.J.R. 2516(c).

Rewrote “Department”, “Frozen desserts” and “Wholesale frozen dessert manufacturer” definitions, and added new “Mobile unit” definition.

### 8:21-7.2 Ice cream and frozen custard

(a) Ice cream and frozen custard means the food defined at 21 CFR 135.110, incorporated herein by reference.

(b) When ice cream is formulated to make a nutritional claim including, but not limited to, lowfat ice cream, reduced fat ice cream, nonfat ice cream, light ice cream, reduced calorie ice cream, low calorie ice cream; or purports to be or is represented for special dietary use, and is sold at retail, direct from a frozen dessert dispensing freezer, or hand-dipped from a factory-filled container, a sign shall be prominently and conspicuously displayed. This sign shall be not more than 18 inches above each dispensing freezer where it can be clearly read by customers under normal conditions of purchase and state "\_\_\_\_\_ Sold Here." The blank shall be filled in with the descriptive name of the product(s) being sold. The letters on the sign shall be bold face capitals in contrasting color to the background. When these products are sold at retail in properly labeled factory-filled containers, no such sign shall be required.

1. If items containing the products listed in (b) above are listed on a menu board, the statement "\_\_\_\_\_ Served Here," shall be included on the menu board in reasonable proximity to the items containing these products. The blank shall be filled in with the descriptive name of the product(s) being sold. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing these products and on a contrasting background.

2. No such sign or menu board declaration shall be required if the only method of advising customers on what items are being offered for sale is on a menu furnished to the customer. In such case the menu shall contain the statement "\_\_\_\_\_ Served Here." The blank shall be filled in with the descriptive name of the product(s) being sold. Such statement shall be in reasonable proximity to the menu items containing these products and the letters in such statement shall be bold face capitals at least as large as the letters in listing items containing these products.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Added other sweetening agents approved by FDA.

Repeal and New Rule, R.1998 d.341, effective July 6, 1998.

See: 30 N.J.R. 1361(a), 30 N.J.R. 2516(c).

Section was "Ice Cream and frozen custard".

### 8:21-7.3 Sherbet

Sherbet means the food defined at 21 CFR 135.140, incorporated herein by reference.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Dispensing freezer or factory-filled container permitted.

Repeal and New Rule, R.1998 d.341, effective July 6, 1998.

See: 30 N.J.R. 1361(a), 30 N.J.R. 2516(c).

Section was "Ice milk; identity; label statement".

### 8:21-7.4 Water ice

Water ice is the food defined at 21 CFR 135.160, incorporated herein by reference.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Stylistic changes.

Repeal and New Rule, R.1998 d.341, effective July 6, 1998.

See: 30 N.J.R. 1361(a), 30 N.J.R. 2516(c).

Section was "Sherbet; identity; label statement".

### 8:21-7.5 Mellorine

Mellorine is the food defined at 21 CFR 135.130, incorporated herein by reference.

Amended by R.1990 d.563, effective November 19, 1990.

See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Vitamin A content clarified in (b).

Recodified from N.J.A.C. 8:21-7.6 and amended by R.1998 d.341, effective July 6, 1998.

See: 30 N.J.R. 1361(a), 30 N.J.R. 2516(c).

Former N.J.A.C. 8:21-7.5, Water ice; identity; label statement, repealed.

### 8:21-7.6 Goat's milk ice cream

Goat's milk ice cream means the food defined at 21 CFR 134.115, incorporated herein by reference.

New Rule, R.1998 d.341, effective July 6, 1998.

See: 30 N.J.R. 1361(a), 30 N.J.R. 2516(c).

Former N.J.A.C. 8:21-7.6, Mellorine; identity; label statement, was recodified to N.J.A.C. 8:21-7.5.

### 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* and *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.