

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 Ice milk; identity; label statement
- 8:21-7.4 Sherbet; identity; label statement
- 8:21-7.5 Water ice; identity; label statement
- 8:21-7.6 Mellorine; identity; label statement
- 8:21-7.7 Goat's milk ice cream; identity; label statement
- 8:21-7.8 Goat's milk ice milk; identity; label statement
- 8:21-7.9 Frozen yogurt; identity; label statement
- 8:21-7.10 Frozen yogurt or lowfat frozen yogurt; identity; label statement
- 8:21-7.11 Frozen nonfat yogurt or nonfat frozen yogurt; identity; label statement
- 8:21-7.12 Quiescently frozen confection; identity; label statement
- 8:21-7.13 Quiescently frozen dairy confection; identity; label statement

- 8:21-7.14 Frozen dietary dairy dessert; identity; label statement
- 8:21-7.15 Dietary frozen dessert or lowfat frozen dairy dessert; identity; label statements
- 8:21-7.16 Non-fruit (imitation) sherbet; identity; label statement
- 8:21-7.17 Non-fruit (imitation) water ice; identity; label statement
- 8:21-7.18 Manufactured desserts mix; identity; label statement
- 8:21-7.19 Freezer made shake; freezer made milk shake; freezer made lowfat milk shake; identity; label statement
- 8:21-7.20 Parevine; identity; label statement
- 8:21-7.21 Lo-mel; identity; label statement
- 8:21-7.22 Frozen pudding; identity; label statement
- 8:21-7.23 Lactose reduced ice cream; identity; label statement
- 8:21-7.24 Lactose reduced ice milk; identity; label statement
- 8:21-7.25 Lowfat parevine; identity; label statement
- 8:21-7.26 Temporary marketing permit
- 8:21-7.27 Generic frozen dessert; identity; label statement
- 8:21-7.28 Other standards of identity
- 8:21-7.29 through 8:21-7.30 (Reserved)
- 8:21-7.31 Plant records
- 8:21-7.32 Plant buildings and surroundings
- 8:21-7.33 Plant construction
- 8:21-7.34 Plant cleanliness
- 8:21-7.35 Construction and repair of containers and equipment
- 8:21-7.36 Cleaning and sanitizing of containers and equipment
- 8:21-7.37 Protection from contamination
- 8:21-7.38 Pasteurization and cooling
- 8:21-7.39 Bacterial standards
- 8:21-7.40 Plant sanitary facilities
- 8:21-7.41 Plant personnel
- 8:21-7.42 Supply of milk and fluid milk products
- 8:21-7.43 Packaging and labeling
- 8:21-7.44 Self service frozen desserts manufacturing machines
- 8:21-7.45 Frozen desserts; mobile units
- 8:21-7.46 Mobile unit depots

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.

“Retail establishment” means any place used in the production, preparation, processing, manufacture, packing, storage, or handling of cosmetics for sale or distribution directly to the consumer.

“Wholesale establishment” means any place used in the production, preparation, processing, manufacture, packing, storage, or handling of cosmetics for sale or distribution to a person other than the consumer.

8:21-1.2 General labeling requirements

The general labeling requirements of 21 CFR 1.1, 1.3, 1.4, 1.20, 1.21, 1.23, 1.24 are incorporated herein by reference.

8:21-1.3 Food labeling

The food labeling requirements of 21 CFR 101, 102, 104, and 105 are incorporated herein by reference.

8:21-1.4 Drug labeling

The drug labeling requirements of 21 CFR 201 are incorporated herein by reference.

8:21-1.5 Cosmetic labeling

The cosmetic labeling requirements of 21 CFR 701 are incorporated herein by reference.

8:21-1.6 Labeling, sale, and distribution of cosmetics for professional use only

(a) For the purposes of this section, a cosmetic labeled for professional use only which is offered for sale or distribution to a consumer shall be deemed to be misbranded within the meaning of N.J.S.A. 24:5-18.1 at the time such cosmetic is offered for such sale or distribution.

(b) No person shall distribute or sell, or have in his or her possession with intent to distribute or sell, any cosmetic labeled for professional use only except to professional barbers, professional beauticians, licensed beauty salons, licensed schools of beauty culture, other beauty culture professions, or licensed wholesale establishments.

(c) Any person who offers a cosmetic labeled for professional use only for sale or distribution shall make reasonable inquiries regarding a person's professional status or affiliation as necessary to determine their qualifications to purchase such products so that the retail sale or distribution of such cosmetic may be prevented. This requirement shall not apply to the sale or distribution of cosmetics labeled for professional use only between wholesale establishments.

(d) Cosmetics labeled for professional use only when displayed for sale in a combined retail-wholesale establishment shall be kept separate and apart from retail merchandise. Where such cosmetics are accessible to the general public, posters measuring at least 8½ by 11 inches with lettering measuring at least one-half inch in height shall be conspicuously displayed in all such display areas and contain the following statement, “NOTICE—FOR SALE ONLY TO LICENSED PROFESSIONALS.”

(e) A cosmetic labeled for professional use only shall be exempt from all the provisions of this section if it can be shown through factual and scientific evidence in the possession of the person offering such product for sale or distribution prior to such offering that:

1. Such cosmetic does not require professional skill or knowledge for its safe or effective use;
2. Such cosmetic does contain necessary warnings, cautions, and directions for its safe and effective use in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use; and
3. Such cosmetic is labeled in compliance with all State and Federal requirements for retail sale.

(f) A cosmetic labeled for professional use only which has a retail counterpart identical in name, chemical composition, packaging (size, etc.) and labeling (directions, cautions, etc.) shall be exempt from all provisions of these rules.

8:21-1.7 Cosmetic product warning statements

The requirements that apply to feminine deodorant sprays, cosmetics in self-pressurized containers, and coal tar hair dyes posing a risk of cancer of 21 CFR 740, Cosmetic Product Warning Statements are incorporated herein by reference.

8:21-1.8 Definition of soap

(a) “Soap,” as quoted in N.J.S.A. 24:1-1h(2), shall apply only to products that meet all of the following conditions:

1. More than 50 percent of the nonvolatile matter in the product consists of a salt resulting from an alkali-fatty acid chemical reaction commonly known as saponification and detergent properties of the product are due to the alkali-fatty acid salt; and
2. The product is labeled, sold and represented only as soap.

8:21-1.9 Device labeling

The device labeling requirements of 21 CFR 801 are incorporated herein by reference.

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.

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

“Department” means the State Department of Health.

“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, ice milk, sherbet, water ice, mellorine, goat’s milk ice cream, goat’s milk ice milk, frozen yogurt, frozen lowfat yogurt or lowfat frozen yogurt, frozen nonfat yogurt or nonfat frozen yogurt, quiescently frozen confection, quiescently frozen dairy confection, frozen dietary dairy dessert, dietary frozen dessert or lowfat frozen dairy dessert, whipped cream confection, bisque tortoni, nonfruit sherbet, nonfruit water ice, manufactured dessert mixes, lactose reduced ice cream, lactose reduced ice milk, frozen pudding, freezer made shake and freezer made milk shake, lowfat parevine, 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.

“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 desserts 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 at the wholesale level.

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.”

SUBCHAPTER 6. (RESERVED)

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.

8:21-7.2 Ice cream and frozen custard

(a) Rules concerning descriptions of ice cream and frozen custard are as follows:

1. Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in (b) below, and may contain one or more of the optional caseinates specified in (c) below subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with nutritive carbohydrate sweeteners or other sweetening agents approved by the U.S. Food and Drug Administration for use in frozen desserts and may or may not be characterized by the addition of flavoring ingredients.

2. Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than ten percent milkfat, nor less than ten percent nonfat milk solids, except that when it contains milkfat at one percent increments above the ten percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

| Percent Milkfat | Minimum Percent Nonfat Milk Solids |
|-----------------|------------------------------------|
| 10..... | 10 |
| 11..... | 9 |
| 12..... | 8 |
| 13..... | 7 |
| 14..... | 6 |

i. Except that when one or more bulky flavors are used, the weights of milkfat and total milk solids are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat or total milk solids less than eight percent and 16 percent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard shall contain 1.4 percent egg yolk solids by weight of the finished food: Provided, however, that when bulky flavors are added the egg yolk solids content of frozen custard may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by (e)1. below.

3. When calculating the minimum amount of milkfat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) The optional dairy ingredients referred to in (a) above are: cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate and whey and those modified whey products (for example reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by the Food and Drug Administration (F.D.A.) to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any whey products and modified whey used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of nine percent is substantially free of lactic acid as determined by titration with 0.1N NaOH, and it has a pH value in the range of 8.0 to 8.3.

(c) The optional caseinates referred to in (a) above may be added to ice cream mix containing not less than 20 percent total milk solids are: casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

(d) Fat content shall be determined by the following methods contained in the current edition of "Official Methods of Analysis of the Association of Official Analytical Chemists."

1. Fat content shall be determined by the method: "Fat; Roesse-Gottlieb Method—Official Final Action."

(e) Rules concerning nomenclature of ice cream and frozen custard are as follows:

1. The name of the food is "ice cream," except that when the egg yolk solids content of the food is in excess of that specified for ice cream by (a) above, the name of the food is "frozen custard" or "French ice cream" or "French custard ice cream."

2. If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, for example, "vanilla," in letters not less than one-half the height of the letters used in the words "ice cream."

i. If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream," followed by the word "flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, for example, "Vanilla flavored," or "Peach flavored," or "Vanilla flavored and Strawberry flavored."

ii. If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream," preceded by "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor, for example, "artificial Vanilla," or "artificially flavored Strawberry" or "artificially flavored Vanilla and artificially flavored Strawberry."

3. If the food is subject to the requirements of 2ii above or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial flavor added," the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

i. Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than six-point on packages containing less than one pint, not less than eight-point on packages containing at least one pint but less than one-half gallon, not less than ten-point on packages containing at least one-half gallon but less than one gallon and not less than 12-point on packages containing one gallon or over. Provided, however, that where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required

words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: And provided further, that if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, for example, "Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added."

4. If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, for example, "strawberry and artificial strawberry flavor."

5. An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

i. In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than one ounce per unit of vanilla constituent, as that term is defined in 21 CFR 169.3(c).

ii. In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than two percent in the case of citrus ice cream, six percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

iii. In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than two percent.

iv. In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in ii or iii above. For example, if a combination ice cream contains less than five percent of bananas and less than one percent of almonds, it would be "artificially flavored banana-almond ice cream." However, if it contains more than five percent of bananas and more than one percent of almonds, it would be "banana-almond flavored ice cream."

6. If two or more flavors of ice cream are distinctively combined in one package, for example, "Neapolitan" ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(f) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of 21 CFR 101, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in 21 CFR 101.4(b)(3), (4), (8), and (9) are used or alternatively as permitted in 21 CFR 101.4, Pursuant to Section 403(k) of the Federal Food, Drug, and Cosmetic Act. Artificial color need not be declared in ice cream except as provided in 21 CFR 74.705. Voluntary declaration of such color in ice cream is recommended.

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.

8:21-7.3 Ice milk; identity; label statement

(a) Ice milk is the food prepared from the same ingredients and in the same manner prescribed for ice cream and complies with all the provisions of N.J.A.C. 8:21-7.2 (including the requirements for label statement of optional ingredients), except that:

1. Its content of milkfat is more than two percent but not more than seven percent;
2. Its content of total milk solids is not less than 11 percent;
3. Caseinates may be added when the content of total milk solids is not less than 11 percent;
4. The provision for reduction in milkfat and nonfat milk solids content from the addition of bulky flavors in N.J.A.C. 8:21-7.2 applies, except that in no case will the milkfat content be less than two percent, nor the nonfat milk solids content be less than four percent. When the milkfat content increases in increments of one percent above the two percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

| Percent Milkfat | Minimum Percent Nonfat Milk Solids |
|-----------------|------------------------------------|
| 2..... | 9 |
| 3..... | 8 |
| 4..... | 7 |
| 5..... | 6 |
| 6..... | 5 |
| 7..... | 4 |

5. The quantity of food solids per gallon is not less than 1.3 pounds;
6. When any artificial coloring is used in ice milk, directly or as a component of any other ingredients, the label shall bear the statement "artificially colored," "artificial coloring added," "with added artificial color," or "..... an artificial color added," the blank being filled in with the common or usual name of the artificial color; or in lieu thereof, in case the artificial color is a component of another ingredient, "..... artificially colored;"

7. If both artificial color and artificial flavoring are used, the label statements may be combined.

(b) The name of the food is "ice milk". Ice milk may be offered for sale, sold or served in properly labeled factory-filled containers, from a dispensing freezer or may be dipped from a factory-filled container.

(c) When ice milk is sold at retail, direct from a frozen dessert dispensing freezer or hand-dipped from a factory-filled container, as provided in (b) above, a sign must be prominently and conspicuously displayed not more than 18 inches above each dispensing freezer, where it can be clearly read by customers under normal condition of purchase, stating "ICE MILK SOLD HERE". The letters on such sign shall be bold face capitals in contrasting color to the background. When ice milk is sold at retail, only in properly labeled factory-filled containers, no such sign shall be required.

1. In addition, if items containing ice milk are listed on a menu board the statement "Ice Milk Served Here" shall be included on the menu board in reasonable proximity to the items containing ice milk. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing ice milk 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 a menu furnished to the customer. In such case the menu shall contain the statement "Ice Milk Served Here." Such statement shall be in reasonable proximity to the menu items containing Ice Milk and the letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing Ice Milk.

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.

8:21-7.4 Sherbet; identity; label statement

(a) Rules concerning descriptions of sherbet are as follows:

1. Sherbet is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in (b) below, and may contain one or more of the optional caseinates specified in (c) below subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Sherbet is sweetened with nutritive carbohydrate sweeteners and is characterized by the addition of one or more of the characterizing fruit ingredients specified in (d) below or one or more of the nonfruit characterizing ingredients specified in (e) below.

2. Sherbet weighs not less than six pounds to the gallon. The milkfat content is not less than one percent nor more than two percent, the nonfat milk-derived solids content not less than one percent, and the total milk or milk-derived solids content is not less than two percent nor more than five percent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than 0.35 percent.

(b) The optional dairy ingredients referred to in (a) above are: cream, dried cream, plastic cream, (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate and whey and those modified whey products (for example, reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by F.D.A. to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. The modified skim milk, when adjusted with water to a total solids content of nine percent is substantially free of lactic acid as determined by titration with 0.1N NaOH, and it has a pH value in the range of 8.0 to 8.3.

(c) The optional caseinates referred to in (a) above may be added to sherbert mix are: casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali. Such caseinates are not considered to be milk solids.

(d) The optional fruit characterizing ingredients referred to in (a) above are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices from which part of the water is removed, substances contributing flavor volatilized during water re-

moval may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbert, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruit or fruit juices to their original moisture content), is not less than two percent in the case of citrus sherbets, six percent in the case of berry sherbets and ten percent in the case of sherbets prepared with other fruits. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruits.

(e) The optional nonfruit characterizing ingredients referred to in (a) above include but are not limited to the following:

1. Ground spice or infusion of coffee or tea;
2. Chocolate or cocoa, including syrup;
3. Confectionery;
4. Distilled alcoholic beverage, including liquors or wine, in an amount not to exceed that required for flavoring the sherbet;
5. Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

(f) Rules concerning nonmenclature of sherbet are as follows:

1. The name of each sherbet is as follows:
 - i. The name of each fruit sherbet is "..... sherbet," the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredient used.
 - ii. The name of each nonfruit sherbet is "..... sherbet," the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, "peppermint," except that if the characterizing flavor used is vanilla, the name of the food is "..... sherbet," the blank being filled in as specified by N.J.A.C. 8:21-7.2(e)2 and 5i.
2. When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:
 - i. If the flavoring ingredient or ingredients consist exclusively of artificial flavoring, the label designation shall be "artificially flavored."

ii. If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be "artificial and natural flavoring added."

iii. The label shall designate artificial coloring by the statement "artificially colored," "artificial coloring added," "with added artificial coloring," or "..... an artificial color added," the blank being filled in with the name of the artificial coloring used.

(g) Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by (f)2i and ii, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word "sherbet" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than six-point on packages containing less than one pint, not less than eight-point on packages containing at least one pint but less than one-half gallon, not less than ten-point on packages containing at least one-half gallon but less than one gallon, and not less than 12-point on packages containing one gallon or over.

(h) Except as specified in (g) above, the statements required by (f)2 above shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(i) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of 21 CFR Part 101.

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.

8:21-7.5 Water ice; identity; label statement

(a) Water ices are the foods each of which is prepared from the same ingredients and in the same manner prescribed in N.J.A.C. 8:21-7.4 for sherbets except that the mix need not be pasteurized and complies with all provisions of N.J.A.C. 8:21-7.4 (including the requirements for label statement of optional ingredients) except that no milk or milk-derived ingredient and no egg ingredient, other than pasteurized egg white, is used.

(b) The name of the food is "..... ice," the blank being filled in, in the manner as specified in N.J.A.C. 8:21-7.4(f)1i and ii as appropriate.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Pasteurized egg white required in (a).

8:21-7.6 Mellorine; identity; label statement

(a) Rules concerning descriptions of mellorine are as follows:

1. Mellorine is a food produced by freezing, while stirring, a pasteurized mix consisting of safe and suitable ingredients including, but not limited to, milk-derived nonfat solids and animal or vegetable fat, or both, only part of which may be milkfat. Mellorine is sweetened with nutritive carbohydrate sweetener and is characterized by the addition of flavoring ingredients.

2. Mellorine contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Mellorine contains not less than six percent fat and 2.7 percent protein having a protein efficiency ratio (PER) not less than that of whole milk protein (108 percent of casein) by weight of the food, exclusive of the weight of any bulky flavoring ingredient used. In no case shall the fat content of the finished food be less than 4.8 percent of the protein content be less than 2.2 percent. The protein to meet the minimum protein requirements shall be provided by milk solids, not fat and/or other milk-derived ingredients.

3. When calculating the minimum amount of milkfat and protein required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruits or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) Mellorine shall be fortified so that Vitamin A is present in a quantity which will ensure that 40 international units (IU) (8 μ g of retinol equivalence), are available for each gram of fat in mellorine, within limits of good manufacturing practice.

(c) Fat and protein content, and the PER shall be determined by the following methods contained in the current edition of "Official Methods of Analysis of the Association of Official Analytical Chemists."

1. Fat content shall be determined by the method: "Fat, Roes-Gottlieb Method—Official Final Action;"

2. Protein content shall be determined by one of the following methods: "Nitrogen—Official Final Action," Kjeldahl Method or Dye Binding Method;

3. PER shall be determined by the method: "Biological Evaluation of Protein Quality—Official Final Action."

(d) The name of the food is "mellorine." The name of the food on the label shall be accompanied by a declaration indicating the presence of characterizing flavoring in the same manner as is specified in N.J.A.C. 8:21-7.2(e).

(e) The common or usual name of each of the ingredients used shall be declared on the label as required by the applicable sections of 21 CFR 101, except that sources of milkfat or milk solids not fat may be declared in descending order or predominance, either by the use of the terms "milkfat, and nonfat milk" when one or any combination of two or more ingredients listed in 21 CFR 101.4(b)(3), (4), (8), and (9) are used, or alternatively as permitted in 101.4. Mellorine shall be sold, held, offered for sale by any manufacturer, wholesaler, retailer, or any seller only in factory-filled containers except in the following instances:

1. Mellorine may be sold from a dispensing freezer or dipped from a properly labeled bulk container. When mellorine is sold in this manner from a dispensing freezer or dipped from a bulk container a sign shall be displayed in such a location as it can be easily read by customers under normal conditions of sale, stating "Mellorine Served Here." Such sign shall be in bold face capitals on a contrasting background. In addition, if items containing mellorine are listed on a menu board the statement "Mellorine Served Here" shall be included on the menu board in reasonable proximity to the items containing mellorine. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing mellorine 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 a menu furnished to the customer. In such case the menu shall contain the statement "Mellorine Served Here." Such statement shall be in reasonable proximity to the menu items containing mellorine and the letters on such statement shall be bold face capitals at least as large as the letters used in listing items containing mellorine. Any menu listing mellorine or items prepared with mellorine shall conform to the provisions of this paragraph.

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).

8:21-7.7 Goat's milk ice cream; identity; label statement

(a) Goat's milk ice cream is the food prepared in the same manner prescribed in N.J.A.C. 8:21-7.2 for ice cream, and complies with all the provisions of N.J.A.C. 8:21-7.2 except that the only optional dairy ingredients that may be used are those in (b) below; caseinates may not be used; and paragraphs (e)(1) and (f) of N.J.A.C. 8:21-7.2 shall not apply.

(b) Optional dairy ingredients. The optional dairy ingredients referred to in (a) above are goat's skim milk, goat's

milk, and goat's cream. These optional dairy ingredients may be used in liquid, concentrated, and/or dry form.

(c) The name of the food is "goat's milk ice cream" or, alternatively, "ice cream made with goat's milk," except that when the egg yolk solids content of the food is in excess of that specified for ice cream in N.J.A.C. 8:21-7.2, the name of the food is "goat's milk frozen custard" or, alternatively "frozen custard made with goat's milk," or "goat's milk french ice cream," or, alternatively "french ice cream made with goat's milk," or "goat's milk french custard ice cream," or, alternatively "french custard ice cream made with goat's milk."

(d) Each of the optional ingredients used shall be declared on the label by the applicable section of 21 CFR 101.

8:21-7.8 Goat's milk ice milk; identity; label statement

(a) Goat's milk ice milk is the food prepared in the same manner prescribed in N.J.A.C. 8:21-7.7 for goat's milk ice cream, except that paragraph (c) shall not apply, and which complies with all the requirements of N.J.A.C. 8:21-7.3(a)1, 2, 4, 5, 6, and 7 for ice milk.

(b) The name of the food is "goat's milk ice milk" or, alternatively "ice milk made with goat's milk."

(c) The provisions for serving ice milk from a dispensing freezer as required by N.J.A.C. 8:21-7.3 shall apply, except the required statement shall read "goat's milk ice milk served here."

8:21-7.9 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. Sweeten-

er(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. Frozen yogurt, before addition of bulky characterizing ingredient(s) or sweetener(s) shall contain not less than 3.25 percent milkfat and 8.25 percent milk solids not fat. Frozen yogurt shall contain not less than 1.3 pounds of total solids per gallon, and shall weigh not less than 4.0 pounds per gallon.

(b) The name of the food is "frozen yogurt." The name of the food shall be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in 21 CFR 101.22.

(c) Each of the ingredients used in the food shall be declared on the label as required by 21 CFR 101.

(d) Frozen yogurt may be sold from a dispensing freezer or may be dipped from a properly labeled bulk container. When frozen yogurt is sold as provided above, a sign shall be displayed in such a location as it can be easily read by customers under normal conditions of sale, stating "Frozen Yogurt Sold Here."

1. Such sign shall be in bold face capitals on a contrasting background. In addition, if items containing frozen yogurt are listed on a menu board the statement "Frozen Yogurt Served Here" shall be included on the menu board in reasonable proximity to the items containing frozen yogurt. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing frozen yogurt and on a contrasting background.

2. No such sign or menu board declaration shall be required if the only method of advising customers of what items are being offered for sale is a menu furnished to the customer. In such case, the menu shall contain the statement "Frozen Yogurt Served Here." Such statement shall be in reasonable proximity to the menu items containing frozen yogurt and the letters on such statement shall be bold face capitals at least as large as the letters used in listing items containing frozen yogurt. Any menu listing frozen yogurt or items prepared with frozen yogurt shall conform to the provisions of this paragraph.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Text deleted and replaced with latest FDA standard.

8:21-7.10 Frozen yogurt or lowfat frozen yogurt; identity; label statement

(a) Frozen lowfat yogurt is the food which is prepared from the same ingredients and in the same manner prescribed in N.J.A.C. 8:21-7.9 for frozen yogurt, and complies with all of the provisions of N.J.A.C. 8:21-7.9, including the requirements for customer notification of product sale by posting, menu board or menu; except that the milkfat level is not less than 0.5 percent nor more than 2.0 percent.

(b) The name of the food is "frozen lowfat yogurt" or, alternatively, "lowfat frozen yogurt".

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Text deleted and replaced with latest FDA standard.

8:21-7.11 Frozen nonfat yogurt or nonfat frozen yogurt; identity; label statement

(a) Frozen nonfat yogurt is the food which is prepared from the same ingredients and in the same manner prescribed in N.J.A.C. 8:21-7.9 for frozen yogurt, and complies with all the provisions of N.J.A.C. 8:21-7.9, including the requirements for customer notification by posting, menu board or menu; except that the milkfat level is less than 0.5 percent.

(b) The name of the food is "frozen nonfat yogurt" or, alternatively, "nonfat frozen yogurt".

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Text deleted and replaced with latest FDA standard.

8:21-7.12 Quiescently frozen confection; identity; label statement

(a) Quiescently frozen confection means the frozen product made from sweetening agent(s), harmless natural or artificial flavoring, water, and it may contain milk solids, harmless coloring, organic acids, and any safe and suitable functional ingredient approved by the Department. The finished product shall contain not less than 17 percent by weight of total food solids.

(b) The name of the food is "quiescently frozen confection."

(c) In the manufacture of this product, freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing).

(d) In the production of this quiescently frozen confection, no processing or mixing prior to quiescent freezing shall be used that develops in the finished confection mix any physical expansion in excess of ten percent.

(e) The confection must be manufactured in the form of servings, individually packaged, bagged or otherwise wrapped, properly labeled and purveyed to the consumer in its original factory-filled package. The individually wrapped confection need not be labeled if it is contained in a multiple package which is properly labeled and is purveyed unopened to the consumer.

(f) In addition to all other required information, the label shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of 21 CFR 101.22.

8:21-7.13 Quiescently frozen dairy confection; identity; label statement

(a) Quiescently frozen dairy confection means the frozen product made from milk products, sweetening agent(s), harmless natural or artificial flavoring, water, and it may contain harmless coloring, and any safe and suitable functional ingredient approved by the Department. The finished product contains not less than 13 percent by weight of total milk solids, not less than 33 percent by weight of total food solids.

(b) The name of the food is "quiescently frozen dairy confection."

(c) In the manufacture of this product, freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing).

(d) In the production of this quiescently frozen dairy confection, no processing or mixing prior to quiescent freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10 percent.

(e) The confection must be manufactured in the form of servings, individually packaged, bagged or otherwise wrapped, properly labeled and purveyed to the consumer in its original factory-filled package. The individually wrapped confection need not be labeled if it is contained in a multiple package which is properly labeled and is purveyed unopened to the consumer.

(f) In addition to all other required information, the label shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4, and comply with the provisions of 21 CFR 101.22.

8:21-7.14 Frozen dietary dairy dessert; identity; label statement

(a) Frozen dietary dairy dessert means a frozen dessert prepared for persons who wish to restrict their intake of ordinary sweetening ingredients. It is produced by freezing while stirring a pasteurized mix consisting of the ingredients permitted for ice cream in N.J.A.C. 8:21-7.2 with the exception of nutritive carbohydrate sweeteners. The minimum fat content shall be three percent. It shall contain no sugars

other than those naturally present in the milk solids or flavoring agents which have been added thereto and it may contain edible carbohydrates other than sugars. The edible carbohydrates must be approved by the Department. The name of the food is "frozen dietary dairy dessert."

(b) The label on frozen dietary dairy dessert in addition to other required information shall:

1. Contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4;
2. Contain a statement as follows:
 - i. (Diabetics: This product may be useful in your diet on the advice of a physician. The food is not a reduced calorie food);
3. Immediately preceding or following the name of the product, contain a statement as follows: "Contains% milkfat." the blank to be filled in with the percentage of milkfat in the product;
4. Comply with the provisions of 21 CFR 101.9 and 21 CFR 101.22.

(c) The product shall not be sold in any manner other than in sealed or unbroken packages or containers except that it may be sold from a dispensing freezer or dipped from a properly labeled bulk container. The container in which it is served shall contain the information required in (b) above, or identical information shall be supplied in printed form to the customer at the time of service.

8:21-7.15 Dietary frozen dessert or lowfat frozen dairy dessert; identity; label statements

(a) Dietary frozen dessert or lowfat frozen dairy dessert is a food prepared by freezing, while stirring, a pasteurized mix consisting of the ingredients permitted for ice cream in N.J.A.C. 8:21-7.2. The finished product contains less than two percent by weight of ether extractable fat: its content of total milk solids consisting of ingredients listed in N.J.A.C. 8:21-7.2(b) is not less than seven percent by weight. The product weighs no less than 4.5 pounds per gallon and the quantity of food solids per gallon is not less than 1.1 pounds nor more than 1.9 pounds, exclusive of any microcrystalline cellulose used as an ingredient.

(b) One or more vitamins and/or minerals listed in 21 CFR 101.9(c)(7)(iv) may be added to the product. If vitamins and/or minerals are added, the name of the food on the principal display panel shall be immediately preceded or followed by the word "fortified" in the same style and at least one-half the size of the type used for the name "dietary frozen dessert" or "lowfat frozen dairy dessert" and on the same contrasting background. If vitamins and/or minerals are added, then each four fluid ounce serving of finished product shall provide no less than eight percent nor more than 20 percent of the U.S. recommended daily allowance of such vitamins and/or minerals.

(c) The name of the food is "dietary frozen dessert" or "lowfat frozen dairy dessert."

(d) The label on dietary frozen dessert or lowfat frozen dairy dessert, in addition to all other required information shall:

1. Contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4;
2. Comply with the provisions of 21 CFR 101.9 and 21 CFR 101.22.

(e) Dietary frozen dessert or lowfat frozen dairy dessert may be sold from a dispensing freezer or may be dipped from a properly labeled bulk container. When dietary frozen dessert or lowfat frozen dairy dessert is sold directly from a dispensing freezer or dipped from a bulk container, the name of the food, nutrition information in compliance with 21 CFR 101.9, and a complete listing of dairy ingredients in accordance with the provisions of 21 CFR 101.4 shall appear on the container used or identical information shall be supplied in printed form at the time of service.

(f) When dietary frozen dessert or lowfat frozen dairy dessert is sold in such manner from a dispensing freezer as provided in (e) above, a sign shall be displayed in such a location as it can be easily read by customers under normal conditions of sale. Such sign shall be in bold face capitals on a contrasting background.

1. In addition, if items containing dietary frozen dessert or lowfat frozen dairy dessert are listed on a menu board, the statement "Dietary Frozen Dessert or Lowfat Frozen Dairy Dessert Served Here" shall be included on the menu board in reasonable proximity to the items containing dietary frozen dessert or lowfat frozen dairy dessert. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing dietary frozen dessert or lowfat frozen dairy dessert 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 a menu furnished to the customer. In such case the menu shall contain the statement "Dietary Frozen Dessert or Lowfat Frozen Dessert Served Here." Such statement shall be in reasonable proximity to the menu items containing dietary frozen dessert or lowfat frozen dairy dessert and the letters on such statement shall be bold face capitals at least as large as the letters used in listing items containing dietary frozen dessert or lowfat frozen dairy dessert. Any menu listing dietary frozen dessert or lowfat frozen dairy dessert or items prepared with dietary frozen dessert or lowfat frozen dairy dessert shall conform to the provisions of this paragraph.

8:21-7.16 Non-fruit (imitation) sherbet; identity; label statement

(a) Rules concerning descriptions of non-fruit sherbet are as follows:

1. Non-fruit sherbet is a food having a characteristic fruit-like flavor but shall not contain any fruit or fruit juice. Non-fruit sherbet is prepared by freezing while stirring a pasteurized mix consisting of one or more of the optional dairy ingredients specified in (b) below, one or more of the optional caseinates specified in (c) below subject to the conditions hereinafter set forth, and any other safe and suitable non-milk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions. Non-fruit sherbet is sweetened with nutritive carbohydrate sweeteners and contains characteristic fruit-like flavor.

2. Sherbet weighs not less than six pounds to the gallon. The milkfat content is not less than one percent nor more than two percent, the nonfat milk-derived solids content not less than one percent, and the total milk or milk derived solids content is not less than two percent nor more than five percent by weight of the finished food.

(b) The optional dairy ingredients referred to in (a) above are: cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, sweetened condensed skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate and whey and those modified whey products (for example, reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by F.D.A. to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk.

(c) The optional caseinates referred to in (a) above that may be added to non fruit sherbet are: casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali. Such caseinates are not considered to be milk solids.

(d) In addition to all other required information, the label shall:

1. Contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4;
2. Comply with the provisions of 21 CFR 101.22;
3. Contain the following statement ("Imitation Sherbet.") The blank to be filled in by the characterizing flavor used. The letters in the word imitation shall be the same size, type and color and on the same contrasting background as the name of the characterizing flavor and the word sherbet;
4. The statement required in 3 above shall be followed immediately by the words "contains no fruit or fruit juice" in letters at least half the size of those used in statement three above;
5. When a sign is used at the point of purchase to advertise non-fruit sherbet, it shall contain the same information as required in 3 and 4 above;
6. When non-fruit sherbet is sold other than in properly labeled factory-filled containers, a sign must be conspicuously displayed on the sale premises or vehicle where it can be clearly read by customers under normal conditions of purchase stating the name of the food and the information required in 3 and 4 above. The letters on such sign shall be bold face capitals in contrasting color to the background;
7. The sign required in 6 above need not be used if the only method of advising customers on what items are being offered for sale is a menu furnished to the customer. In such case, the menu shall contain the name of the food and the information required in 3 and 4 above. Such statements shall be in reasonable proximity to the menu items containing non-fruit sherbet and the letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing non-fruit sherbet. Any menu listing non-fruit sherbet or items prepared with non-fruit sherbet shall conform to the provisions of this paragraph.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Superheated condensed milk and modified whey products added.

8:21-7.17 Non-fruit (imitation) water ice; identity; label statement

(a) Non-fruit water ice is an ice having a characteristic fruit-like flavor, but shall not contain any fruit or fruit juice. Non-fruit water ice is prepared while stirring a mix composed of:

1. Characteristic fruit-like flavors;
2. One or more nutritive sweeteners;
3. Any other safe and suitable ingredient approved by the Department.

(b) The finished non-fruit water ice weighs not less than six pounds per gallon.

(c) In addition to all other required information the label shall:

1. Contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4;
2. Comply with the provisions of 21 CFR 101.22;
3. Contain the following statement: ("Imitation Ice"). The blank to be filled in by the characterizing flavor used. The letters in the word imitation shall be the same size, type and color and on the same contrasting background as the name of the characterizing flavor and the word ice;
4. The statement required in 3 above shall be followed immediately by the words "contains no fruit or fruit juice" in letters at least half the size of those used in 3 above;
5. When a sign is used at the point of purchase to advertise non-fruit water ice, it shall contain the same information as required in 3 and 4 above;
6. When non-fruit water ice is sold other than in properly labeled factory-filled containers a sign must be conspicuously displayed on the sale premises or vehicle where it can be clearly read by customers under normal conditions of purchase, stating the name of the food and the information required in 3 and 4 above. The letters on such sign shall be bold face capitals in contrasting color to the background;
7. The sign required in 6 above need not be used if each customer is provided with a menu stating the name of the food and the information required in paragraphs three and four above in bold face capitals as large as those used in listing items containing non-fruit water ice.

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.

8:21-7.18 Manufactured desserts mix; identity; label statement

(a) "Manufactured desserts mix," whipped cream confection or bisque tortoni means a frozen dessert made with milk products, sweetening agents, flavoring agents, with or without harmless coloring or any other safe and suitable ingredients approved by the Department. It contains not less than 18 percent by weight of milk fat, and not more than 12 percent of milk solids not fat, and may be packaged with harmless gas causing it to fluff upon ejection from the package or container.

(b) In addition to all other required information, the label shall contain a complete list of ingredients in accordance with the provisions of 21 CFR 101.4.

8:21-7.19 Freezer made shake; freezer made milk shake; freezer made lowfat milk shake; identity; label statement

(a) Freezer made milk shake means a pure, clean, wholesome semi-viscous drink prepared by stirring while freezing in a dispensing freezer a pasteurized mix consisting of the ingredients prescribed for ice milk in N.J.A.C. 8:21-7.3 except that:

1. It shall contain not less than 3.25 percent and not more than six percent milk fat;
2. Its content of milk solids not fat shall not be less than ten percent;
3. Freezer made milk shake may only be sold or served from a dispensing freezer and may not be sold hard frozen.

(b) Freezer made lowfat milk shake means the same product as (a) above, except that it shall contain not less than 0.5 percent and not more than 2.0 percent milkfat.

(c) Other freezer made shakes including jumbo shake, thick shake, T.V. shake, or any coined or trade name containing the word "shake" shall meet the requirements of (a) above except that the minimum percent of milk fat may be less than 3.25 percent.

(d) "Shakes" not meeting the requirement for "milk shakes" shall not be advertised, sold or served as milk shake.

(e) When any freezer made milk shake or other freezer made shake purports to be or is represented for any special dietary use by man, it shall be sold only in a container labeled in accordance with all applicable provisions of the regulations of the Federal Food and Drug Administration.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Freezer-made lowfat milk shake added at (b).

8:21-7.20 Parevine; identity; label statement

(a) Parevine is the food which is prepared by freezing while stirring a pasteurized mix composed of one or more edible vegetable oils or fats; protein and carbohydrate food ingredients from other than milk or meat sources; nutritive sweeteners other than lactose; characterizing ingredients except any containing meat or milk; and any other safe and suitable ingredient which is not milk or meat or a product or derivative of milk or meat. This product shall not contain any milk, milk product, meat or meat products or any of their derivatives of any kind.

(b) Its fat content shall not be less than ten percent, except that when bulky optional characterizing ingredients are used, the fat content may be reduced, as a result of the addition of such ingredients, but shall in no case be less than eight percent.

(c) Its content of food solids shall not be less than 1.3 pounds per gallon of finished product.

(d) The name of the product is "parevine."

(e) Parevine may be sold from a dispensing freezer or dipped from a properly labeled bulk container. When parevine is sold in such manner from a dispensing freezer or dipped from a bulk container, a sign shall be displayed in such a location as it can be easily read by customers under normal conditions of sale, stating "Parevine Served Here".

1. Such sign shall be in bold face capitals on a contrasting background. In addition, if items containing parevine are listed on a menu board the statement "Parevine Served Here" shall be included on the menu board, in reasonable proximity to the items containing parevine. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing parevine 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 a menu furnished to the customer. In such case, the menu shall contain the statement "Parevine Served Here". Such statement shall be in reasonable proximity to the menu items containing parevine and the letters of such statement shall be bold face capitals at least as large as the letters used in listing items containing parevine. Any menu listing parevine or items prepared with parevine shall conform to the provisions of this paragraph.

(f) The label on packages of parevine shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4.

8:21-7.21 Lo-mel; identity; label statement

(a) "Lo-mel" means a pure, clean, wholesome semi-viscous drink prepared by stirring while freezing in a dispensing freezer a pasteurized mix composed of edible fats or oils other than milkfat, milk solids not fat, water, optional sweetening ingredients as approved by the Department, with or without egg or egg products, with or without harmless flavoring, with or without harmless coloring, and with or without stabilizer or emulsifier as approved by the Department. It shall contain not more than six percent edible fats or oils. It shall contain not less than ten percent milk solids not fat. It may contain any other safe and suitable ingredients approved by the Department. It shall contain not more than one-half percent by weight of stabilizer and not more than one-fifth of one percent of emulsifier.

(b) Lo-mel may only be served or sold directly from a dispensing freezer and may not be sold hard frozen.

(c) When Lo-mel is sold a sign must be displayed which shall read "Lo-mel Served Here," in bold faced capitals on a contrasting background. No such sign shall be required if the only method of advising the customers of what items are being offered for sale is a menu furnished to the customer, in such case, the menu shall contain the statement "Lo-mel Served Here."

(d) When any Lo-mel purports to be or is represented for any special dietary use, it shall be sold only in a labeled container. The label shall include the name of the food, a complete list of ingredients in accordance with the provisions of 21 CFR 101.4 and nutrition information as required by 21 CFR 101.9.

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.

8:21-7.22 Frozen pudding; identity; label statement

(a) Frozen pudding is a product made from a pasteurized mix, intended to be eaten in the frozen state. The mix may be composed of:

1. Milk and milk products;
2. Modified or unmodified food starch;
3. Sweetening agent(s);
4. Harmless natural and/or artificial flavoring;
5. Harmless natural and/or artificial color;
6. Any other safe or suitable functional ingredient approved by the Department.

(b) The finished product shall contain:

1. Not less than five percent by weight of milk solids not fat;
2. Not less than twenty-five percent total solids.

(c) The weight of the finished product shall not be less than 4.5 pounds per gallon.

(d) If not frozen promptly after pasteurization, it shall be cooled to 45°F or lower and maintained thereat.

(e) The name of the product is "Frozen Pudding".

(f) The label on packages of frozen puddings shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4 and 101.22.

(g) Frozen pudding may be sold from a dispensing freezer or dipped from a properly labeled bulk container. When frozen pudding is sold in such a manner from a dispensing freezer or dipped from a bulk container, a sign shall be displayed in such a location as it can be easily read by customers under normal conditions of sale, stating "Frozen Pudding Served Here".

1. Such sign shall be in bold face capitals in a contrasting background. In addition, if items containing frozen pudding are listed on a menu board the statement "Frozen Pudding Served Here" shall be included on the menu board in reasonable proximity to the items containing frozen pudding. The letters in such statement shall be bold face capitals at least as large as the letters used in listing items containing frozen pudding and on a contrasting background.

2. No such sign or menu board declaration shall be required if the only method of advising customers of what items are being offered for sale is a menu furnished to the customer. In such case, the menu shall contain the statement "Frozen Pudding Served Here". Such statement shall be in reasonable proximity to the menu items containing frozen pudding and the letters on such statement shall be in bold face capitals at least as large as the letters used in listing items containing frozen pudding. Any menu listing frozen pudding or items prepared with frozen pudding shall conform to the provisions of this paragraph.

8:21-7.23 Lactose reduced ice cream; identity; label statement

(a) Lactose reduced ice cream is the product resulting from the treatment of ice cream as defined in N.J.A.C. 8:21-7.2 by the addition of safe and suitable enzyme(s) so that the lactose remaining is thirty percent or less than lactose in ice cream.

(b) The name of the food is "Lactose Reduced Ice Cream".

(c) The package label shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4 and contain nutrition information as required by 21 CFR 101.9.

(d) Wherever the name of the food appears on the container, the words "lactose reduced" shall be in the same type, style, and size and in the same color and contrasting background as the words "ice cream".

(e) Lactose reduced ice cream may be sold from a dispensing freezer or dipped from a properly labeled bulk container. When lactose reduced ice cream is sold in such a manner from a dispensing freezer, a sign shall be displayed where it can be easily read by customers under normal conditions of sale stating, "Lactose Reduced Ice Cream Served Here." Such sign shall be in bold face capitals on a contrasting background.

8:21-7.24 Lactose reduced ice milk; identity; label statement

(a) Lactose reduced ice milk is the product resulting from the treatment of ice milk, as defined in N.J.A.C. 8:21-7.3, by the addition of safe and suitable enzyme(s), so that the lactose remaining is thirty percent or less than lactose in ice milk.

(b) The name of the food is "Lactose Reduced Ice Milk".

(c) The package label shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4 and contain nutrition as required by 21 CFR 101.9.

(d) Wherever the name of the food appears on the container, the words "lactose reduced" shall be in the same type, style and size and in the same color and contrasting background as the words "ice milk".

(e) Lactose reduced ice milk may be sold from a dispensing freezer or dipped from a properly labeled bulk container. When lactose reduced ice milk is sold in such a manner from a dispenser, a sign shall be displayed where it can be easily read by customers under normal conditions of sale stating, "Lactose Reduced Ice Milk Served Here." Such sign shall be in bold face capitals on a contrasting background.

8:21-7.25 Lowfat parevine; identity; label statement

(a) Lowfat parevine is a food which meets all of the requirements of N.J.A.C. 8:21-7.20 except that its fat content shall be not more than six percent.

(b) The name of the food is "Lowfat Parevine".

(c) The provisions of N.J.A.C. 8:21-7.20(e) shall apply, except the required statement shall read "Lowfat Parevine Served Here".

8:21-7.26 Temporary marketing permit

Any person holding a current New Jersey frozen dessert license who wishes to manufacture a frozen dessert product for which a standard of identity has not been promulgated, may make application to the Department for a temporary marketing permit to market such a product. The application shall be on a form furnished by the Department and shall contain such information as the Department may require. Such permit shall be for a period not to exceed one year, however it may be renewed pending action by the Department.

8:21-7.27 Generic frozen dessert; identity; label statement

(a) A generic frozen dessert is a food that in its unfrozen form or state is recognized by consumers by an established common or usual name or, in the absence thereof, by an appropriate descriptive term. The unfrozen food becomes a frozen dessert when it is frozen, with or without agitation, and when the food, in its frozen form, is designed and intended to be consumed in a frozen state. Generic frozen desserts shall be made from safe and suitable ingredients. A generic frozen dessert, whose unfrozen counterpart is subject to a definition and standard of identity, shall comply with that definition and standard of identity, and ingredient provisions, except that safe and suitable ingredients may additionally be used that are necessary in the manufacture of the frozen dessert.

(b) The name of the frozen dessert shall be: "Frozen ...". The blank shall be filled in with the common or usual name of the unfrozen counterpart of the food or, in the absence thereof, an appropriate descriptive term.

(c) The label on packages of generic frozen dessert shall, in addition to all other required information, include a complete list of all ingredients in accordance with the provisions of 21 CFR 101.4 and 101.22.

New Rule, R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

8:21-7.28 Other standards of identity

Frozen desserts standards of identity as adopted or amended by the U.S. Food and Drug Administration and published in the latest edition of the Code of Federal Regulations (CFR) shall apply in the State of New Jersey.

New Rule, R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

8:21-7.29 through 8:21-7.30 (Reserved)

8:21-7.31 Plant records

(a) Each licensee shall keep a true and correct record showing the milk and milk products received and the frozen desserts and special dietary foods manufactured. Such record shall show:

1. Source, date of receipt, and volume of milk products received;
2. Type of frozen dessert products manufactured;
3. Date and volume of each class of product manufactured; and
4. Results of bacterial analysis of frozen dessert samples.

(b) When applicable the plant shall also maintain records of pasteurization processes and cleaning procedures (CIP charts).

(c) The records shall be legibly written in English and shall be retained at said plant for a period of not less than one year from the date of manufacture and at the plant or other reasonably accessible location for an additional year. Records shall be available at all times for examination by the Department.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Record requirements added at (a)4, (b) and (c).

8:21-7.32 Plant buildings and surroundings

Frozen dessert plants, stations and depots shall be so located as to insure proper shelter and drainage. Sewage and industrial wastes shall be disposed of in accordance with pertinent laws and regulations. Premises shall be kept clean and unless properly retained, no refuse shall be allowed to accumulate on or about the same. Roads, driveways, yards and parking areas adjacent thereto should be paved or otherwise treated to prevent dust. No person shall be allowed to live or sleep in any room where frozen desserts or special frozen dietary foods are manufactured, packed, stored, distributed or sold.

8:21-7.33 Plant construction

(a) The floors of all rooms in which frozen desserts are processed, handled, or stored, or in which containers, equipment, and utensils are washed shall be constructed of concrete or other equally impervious and easily cleaned material and shall be smooth, properly sloped, provided with trapped drains, kept in good repair; provided, hardening room floors need not be provided with floor drains when the floors are sloped to drain to one or more exits; provided further, that rooms for storing dry ingredients and/or packaging materials need not be provided with drains; and the floors may be constructed of tightly joined wood.

(b) Walls and ceilings of rooms in which frozen desserts are handled, processed, or stored, or in which containers, utensils, and equipment are washed shall have a smooth, washable, light-colored surface, in good repair.

(c) All openings to the outer air shall be effectively protected against the entrance of insects by self-closing doors, closed windows, screening, controlled air currents, or other effective means. Screen doors to the outer air shall be self-closing and screens for windows, doors, skylights, transoms, and other openings to the outer air shall be tight-fitting and free of breaks.

(d) All rooms in which frozen desserts are handled, processed, or stored and/or in which containers, equipment, and utensils are washed shall be well lighted and well ventilated. A minimum of 30 foot candles of light shall be provided in all working areas and ten foot candles of light in dry storage and cold storage rooms.

(e) There shall be separate rooms for:

1. The pasteurizing, processing, cooling, hardening and packaging of frozen desserts;
2. Cleaning and sanitizing facilities for milk tank trucks;
3. The cleaning and storage of frozen dessert containers and cases.

(f) Rooms in which frozen desserts are handled, processed, or stored, or in which containers, utensils, and equipment are washed or stored, shall not open directly into any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

8:21-7.34 Plant cleanliness

All rooms in which frozen desserts are handled, processed, or stored and/or in which containers, utensils, or equipment are washed or stored shall be kept clean, neat, and free of evidence of insects and rodents. Pesticides shall be safely used. Only equipment directly related to processing operations or to the handling of containers, utensils, and equipment, shall be permitted in the pasteurizing, processing, cooling and packaging rooms.

8:21-7.35 Construction and repair of containers and equipment

(a) All single service and multiuse containers and equipment which come in contact with frozen desserts shall be of smooth, impervious, corrosion resistant, nontoxic material shall be constructed for ease of cleaning and shall be kept in good repair. Single service containers, closures, gaskets, and other articles which come in contact with frozen desserts shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single service use shall not be reused.

(b) All sanitary piping, fittings, and connections which are exposed to frozen desserts shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be maintained in good repair. Frozen desserts shall be conducted from one piece of equipment to another only through sanitary piping.

8:21-7.36 Cleaning and sanitizing of containers and equipment

(a) The product contact surfaces of all multiuse containers, utensils and equipment used in the transportation, processing, handling, and storage of frozen desserts shall be effectively cleaned and shall be sanitized before each use.

(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 for at least five minutes; or
2. A flow of hot water at a temperature of 170 degrees F for at least five minutes; or
3. A flow of chlorine solution testing 50 p.p.m. for at least one minute; or
4. A flow of iodine solution testing 12.5 p.p.m. for at least one minute; or
5. By such other method as may be acceptable to the Department.

(c) After cleaning and sanitizing all product contact surfaces of containers, equipment and utensils, they shall be so stored and handled as to be protected from contamination.

8:21-7.37 Protection from contamination

(a) Frozen desserts plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of frozen dessert products, ingredients, equipment, containers, and utensils. All frozen dessert products or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than frozen desserts in the plant shall be performed to preclude the contamination of such frozen desserts and its ingredients and the product-contact surfaces of all equipment, containers and utensils.

(b) Novelty type frozen desserts which employ the use of non-food grade brine solution as a freezing medium shall add a brilliant blue or green food dye to the brine solution in such quantity that the dye would be observable if the frozen dessert product has become contaminated with brine.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Blue dye required at (b).

8:21-7.38 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 for at least 30 consecutive minutes by the batch (vat) process; or
2. To a temperature of at least 175 degrees F for at least 25 consecutive seconds by a high-temperature-short-time process; or
3. To a temperature of at least 180 degrees F for at least 15 consecutive seconds by the high-temperature-short-time process; or
4. To a temperature of at least 280 degrees F for at least 2 consecutive seconds by the ultra-high-temperature process; or
5. To such equivalent temperature and holding periods demonstrated to accomplish the same results which are acceptable to the Department.

(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 until subject to freezing. This requirement on maintaining temperature of mix shall be construed:

1. To require the use of refrigerated or insulated vehicles or approved insulated containers in transporting frozen desserts mix from the manufacturing plant to retail manufacturers; and
2. To apply the conveying mix from coolers or refrigerated tanks in the manufacturing plant to freezers by means of piping or tubing.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Exception added to (a).

8:21-7.39 Bacterial standards

(a) Frozen desserts, special frozen dietary foods or their mixes shall not contain in excess of ten coliform organisms per gram and/or in excess of fifty thousand bacteria per gram. When fruit, nuts or bulky flavoring is added after pasteurization, the coliform count shall not exceed twenty per gram.

(b) Tests to determine whether the bacteria standards for frozen desserts, special frozen dietary foods, or their mixes are being complied with shall be made following the procedures set forth in the current edition of "Standard Methods for the Examination of Dairy Products" published by the American Public Health Association, Inc.

(c) During any consecutive six months, each wholesale frozen desserts manufacturer shall collect and have analyzed at least four samples of each frozen desserts product classification as defined in this subchapter. Records of these samples shall be maintained in accordance with N.J.A.C. 8:21-7.31.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Four samples required every six months.

8:21-7.40 Plant sanitary facilities

(a) The water supply shall be adequate as to quantity, of a safe, sanitary quality, and from an approved water supply system which is constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act (N.J.S.A. 58:12A-1 et seq.) and regulations (N.J.A.C. 7:10) and local laws, ordinances, and regulations; provided, that if approved by the Department of Environmental Protection, a nonpotable water supply system may be permitted within the establishment for purposes such as air conditioning and fire protection, only if such system complies fully with N.J.A.C. 8:24-6.6 (Size, installation and maintenance of plumbing), and the nonpotable water supply is not used in such a manner as to bring it into contact either directly or indirectly with food, food equipment or utensils.

(b) Hot and cold running water, under pressure, shall be provided in all areas where frozen desserts are prepared, and where equipment, utensils or containers are washed.

(c) Each plant shall be provided with adequate, conveniently located toilet facilities and dressing rooms accessible to the employees at all times which meet the following criteria:

1. Toilet facilities and dressing rooms shall be installed in accordance with applicable State and local standards;
2. Doors to toilet rooms and dressing facilities shall be self closing and shall not open directly into areas where products are exposed to airborne contamination; except where alternate means have been taken to prevent such contamination;
3. Toilet facilities and dressing rooms including toilet rooms and fixtures shall be kept clean and in good repair and free from objectionable odors;

4. Toilet rooms shall be equipped with lavatory fixtures which shall be located therein or immediately adjacent and shall be supplied with soap, running hot and cold water, single service towels or an approved hand drying device;

5. Handwashing signs directing employees to wash their hands before returning to work, shall be posted conspicuously in all toilet rooms and at each separate lavatory in the plant;

6. Handwashing facilities shall be conveniently located in processing rooms, and shall include a lavatory supplied with soap, running hot and cold water, single service towels or an approved hand drying device.

(d) All sewage and waste water shall be disposed of by means of a public sewage system or disposal system which is constructed and maintained in conformance with applicable State and local requirements.

(e) Garbage and refuse shall be so stored and disposed of as to minimize the development of odors, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food or food contact surfaces, ground surfaces, ground surfaces and water supplies.

8:21-7.41 Plant personnel

(a) No person, while affected with a disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, acute respiratory infection, nausea, vomiting, diarrhea which could cause foodborne diseases such as staphylococcal intoxication, salmonellosis, shigellosis or hepatitis, shall work in any area of a frozen desserts plant in any capacity in which there is a reasonable possibility of such person contaminating food, food ingredients, or food contact surfaces with pathogenic organisms, or transmitting disease to other individuals.

(b) Employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic practices during all working periods to prevent contamination of food products.

(c) Employees shall not use tobacco, eat food or drink beverages in areas where food or food ingredients are exposed or in areas used for washing and/or sanitizing of equipment or utensils. Smoking and eating areas may be designated by management where no contamination of food, equipment or utensils will result.

(d) Employees shall wear light colored, clean, washable uniforms and adequate hair restraints while engaged in handling frozen desserts, equipment and utensils.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Diseases specified at (a).

8:21-7.42 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) Milk and fluid milk products, including frozen desserts mix, which have overflowed, leaked, been spilled, or improperly handled shall be discarded.

(c) Milk and milk products including frozen desserts mix from damaged, punctured or otherwise contaminated containers, products from out of code containers or packaged milk and milk products which have physically left the control of a milk processing plant shall not be repasteurized for use in frozen desserts mix. However, the repasteurization of milk and milk products shipped in transport tankers which have been pasteurized at another plant and have been handled in a sanitary manner and maintained at 45 degrees Fahrenheit or less is permitted.

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

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

Discard and repasteurization requirements added at (b) and (c).

8:21-7.43 Packaging and labeling

(a) Frozen desserts shall be packaged in commercially acceptable containers and packaging material that will protect the quality of the product and protect it from possible contamination in regular channels of trade. The packaging, cutting, molding, dispensing and other handling or preparation of frozen desserts and their ingredients shall be done in a sanitary manner.

(b) Multiuse containers used for transporting frozen desserts shall be rinsed immediately after emptying, shall be cleaned upon return to the plant and shall be protected from contamination during storage. Metal cans and containers shall be free from rust and corrosion.

(c) All packages of frozen desserts shall be labeled in accordance with the applicable provisions of this subchapter (N.J.A.C. 8:21-7) and the Code of Federal Regulations, Title 21, Chapter 1. Frozen desserts packaged in accordance with a customer's request and in the presence of such customer shall be exempt from the labeling requirements, except as provided in the regulations.

8:21-7.44 Self service frozen desserts manufacturing machines

(a) Retail frozen desserts manufacturing plants which permit the self service of frozen desserts by the customer shall comply with the following provisions to protect the product from contamination by the public:

1. Hoppers, reservoirs and similar frozen dessert mix holding devices to which the public has easy access shall be secured by a method acceptable to the Department to prevent entry by the public.

2. Dispensing nozzles on dispensing freezers shall be protected from incidental contact by the customer by installation of a barrier or shield in front of the nozzle.

New Rule, R.1990 d.563, effective November 19, 1990.

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

Text on Frozen desserts; mobile units recodified to 7.45; text on Self service frozen desserts manufacturing machines added.

8:21-7.45 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. Truck interior shall be of sufficient size with equipment and fixtures conveniently located so as to eliminate needless steps for operation of equipment and serving of customers;

2. A potable water supply shall be provided, to be kept in a supply tank having a capacity of at least 40 gallons, heated electrically or otherwise. The tank shall be tilted sufficiently to permit complete drainage and a suitable drain cock shall be provided. The water inlet pipe shall be of removable flexible copper or other approved tubing, with nozzle for hose connection capped when not being used. Hose for connection to potable water supply shall be provided and it shall be equipped with an approved check valve;

3. A seamless double compartment sink supplied with running hot and cold water, which shall have a swivel faucet, shall be provided and it shall be large enough to accommodate the largest piece of equipment to be cleaned therein;

4. A hand wash sink, with running hot and cold water, soap and single service or individual towels or mechanical hand dryer shall be provided;

5. A suitable waste water tank with a capacity at least fifteen percent greater than the water supply tank shall be provided. The tank shall be tilted sufficiently to permit complete drainage and shall be provided with a suitable drain cock. It shall be provided with some means of gauging the contents and shall be emptied and flushed as often as necessary and shall be maintained in a sanitary condition;

6. A refrigerated box to maintain a temperature of 45 degrees F 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 degrees F;

7. Floors shall be of metal or similar approved material and properly sloped. Junctures of floors, walls and adjoining fixtures shall be water-tight and coved;

8. The truck interior shall be well lighted with a minimum of 30 foot candles on all working surfaces;

9. Flavors, syrups, fruits, and other ingredients used in making sundaes, shakes, etc., shall be kept in single service containers or other type of container acceptable to the Department;

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

11. A refuse container with cover must be available for deposit of papers and other solid wastes by customers and operators, so constructed, designed and placed so it can be readily used, cleaned and kept clean, and shall be located so as not to create a nuisance;

12. Persons handling frozen desserts shall wear light colored, clean, washable uniforms and adequate hair restraints;

13. There shall be a partition or self-closing doors between the driver's seat and the manufacturing and serving area, unless the vehicle is air conditioned;

14. Frozen dessert mix shall be packaged in single service containers at the place of manufacture and shall remain in the original container until used;

15. The original frozen desserts license shall be displayed on each vehicle and a photocopy shall be posted in the depot from which the mobile unit is operated.

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

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

Text on Frozen desserts; mobile units recodified from 7.44; accuracy requirement added at (a)6; text on mobile unit depots recodified to 7.46.

8:21-7.46 Mobile unit depots

(a) All mobile units, other than those operated exclusively at fairs, outings, carnivals and other fairs of short duration, shall operate from a depot as authorized on license. Such depot shall be large enough to accommodate one or more mobile units for cleaning and sanitizing. Mobile units shall return to their respective depots at least once a day for cleaning and sanitizing. Such depots shall be maintained and operated in accordance with the following requirements:

1. Walls shall be reasonably smooth and clean;

2. There shall be no openings in the walls or at the base of doors where vermin or rodents may enter;

3. The floor must be constructed of cement or other impervious material, must be provided with a drain, sloped to such drain, and the juncture of the floor and walls shall be coved;

4. There shall be provisions for adequate ventilation. Ventilation facilities shall be screened or otherwise protected to prevent the entrance of flies, other insects, vermin or rodents;

5. There shall be adequate lighting, suitable toilet facilities, hand washing facilities equipped with hot and cold running water, soap and single service towels or air dryers, clothes lockers, and garbage cans provided;

6. A sufficient supply of hot and cold running water shall be provided and there must be at least two large sinks, each of which is large enough to accommodate the largest piece of equipment to be washed. Drain boards of impervious material shall be provided;

7. Hose and hose connections for supplying potable water to the mobile units shall be provided. Such hose shall be equipped with a check valve or other device to eliminate possible contamination from return flow. There shall be facilities for hanging the hose for complete drainage and to avoid contamination;

8. There shall be a metal pipe drying rack or its equivalent for utensils and equipment;

9. There shall be suitable covered storage facilities or containers for all refuse and waste which shall be removed daily from the depot;

10. A physical separation between the area where the trucks are located and the area where food is stored is required.

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

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

Text on mobile unit depots recodified from 7.45.

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

8:21-8.1 Definitions and standards of identity

For the purposes of these regulations the following definitions and standards of identity shall obtain:

(a) Imitation milk is a fluid product in which there is combined one or more edible fats or oils with not less than 8¼ percent milk solids-not-fat derived from fluid or dry products. Above the minimum level for milk solids-not-fat, edible food solids other than milk solids-not-fat may be used. Imitation milk shall contain not less than 3¼ percent by weight of edible fats or oils. If only one fat or oil is used in any such combination, one of them may be milk fat.

Imitation milk may contain one or more of the optional ingredients specified in Regulation 1 (b) in amounts necessary to accomplish its or their intended purpose; except that if Vitamin A is used, it is used in such quantity that eight fluid ounces of the finished product contains not less than 500 USP units and, when Vitamin D is used, it is used in such quantity that eight fluid ounces of the finished product contains not less than 100 USP units.

(b) Optional ingredients referred to in subsection (a) of this Section are: stabilizers, emulsifiers, diacetyl and other like flavors, vitamins, minerals, edible food solids other than milk solids and other similar ingredients approved by the Department.

(c) Imitation low fat milk conforms in all respects to the definition and standard of identity for imitation milk including the provisions relating to the use of optional ingredients, except that it shall contain not less than 0.5 percent and not more than 2.0 percent by weight of edible fats or oils.

(d) Imitation fluid milk products mean and include any combination of edible fats and oils with milk solids-not-fat so that the resulting product is in semblance or imitation of one or another of the following fluid milk products: milk, cream, half-and-half, flavored milk, dairy drink, cultured buttermilk, cultured milk, cultured sour cream, cultured salad cream, yogurt, cultured half-and-half; and such other fluid milk products as may be designated by the Department, but shall not include evaporated milk, condensed milk or dry milk products, nor imitation fluid milk products which are sterilized and packaged in hermetically-sealed containers.

With respect to each particular imitation fluid milk product, edible fats and oils shall be present in the same minimum proportion as the minimum butterfat requirement for the fluid milk product in semblance or imitation of which it is made. If only one fat or oil is used it shall be a fat or oil other than milk fat. If more than one edible fat or oil is used in any such combination, one of them may be milk fat. Each particular product shall contain not less than the minimum proportion of milk solids-not-fat as is present in the fluid milk product in semblance of which the imitation fluid milk product is made. Above the minimum level for milk solids-not-fat, edible food solids other than milk solids-not-fat may be used.

Imitation fluid milk products may contain one or more of the following optional ingredients in amounts not in excess of the amount necessary to accomplish the intended purpose of its use: flavorings, sweeteners, stabilizers, emulsifiers, acidifiers, vitamins, minerals, edible food solids other than milk solids, and similar ingredients approved by the Department.

(e) The name of each imitation fluid milk product shall be "Imitation _____", the blank to be filled by the

name of the fluid milk product in semblance or imitation of which the imitation fluid milk product is made.

8:21-8.2 Misbranding of imitation milk, imitation low fat milk and imitation fluid milk products

(a) Its label bears the name under which any such product is defined in N.J.A.C. 8:21-8.1 (Definitions and standards of identity).

(b) Its label bears a list of ingredients, identified by their specific common, or usual names, which were used in fabricating the product. If any artificial flavor is used, the label shall bear a statement such as "artificially flavored" or "artificial flavor added". Nothing in this section shall prevent the use of a brand or fanciful name or mark to further identify the product.

8:21-8.3 Misbranding of foods made in semblance of imitation milk, imitation low fat milk or any imitation fluid milk product

(a) A food which is made in semblance of imitation milk, imitation low fat milk or any imitation fluid milk product as those products are defined herein but which does not meet the edible fats and oils, or milk solids-not-fat minimum requirements prescribed in Section 8.1(d) (Definitions and standards of identity) of this Chapter, or which contains no dairy ingredient shall be deemed to be misbranded if:

1. There appears on the label of any such food the word milk or the name of any of the fluid milk products identified in or under authority of 9:40-150(d) thereof, even if preceded by the word "Imitation". Such products shall be labeled by using a fanciful or brand name only;

2. There appears on the label of any such product any representation made or suggested by statement, word, grade, designation, design, symbol, picture, device or any combination thereof that such food is a dairy product, or is imitation milk, imitation low fat milk, or imitation fluid milk product as those terms are defined herein.

8:21-8.4 Adulteration of imitation milk, imitation low fat milk and foods made in semblance of such products

(a) For the purpose of this regulation imitation milk, imitation low fat milk or any imitation fluid milk products or any food made in semblance of any such product shall be deemed to have been produced under sanitary conditions, if the plant in which such products are produced is subject to the provisions of the State statutes or regulations relating to plant sanitation for milk and milk products including temperature, bacteriological and chemical standards, and such provisions are complied with and the requirements hereinafter set forth in subsection (c) are met.

(b) When imitation milk, imitation low fat milk or imitation fluid milk products or any of them is produced in a plant not now subject to the provisions of the State milk and milk products statutes or regulations relating to milk plant sanitation, such imitation products shall be produced under the same sanitary conditions as is provided for in subsection (a) above.

(c) The requirements referred to in subsection (a) above are as follows.

Imitation milk plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of imitation milk or imitation fluid milk products, ingredients, equipment, containers, and utensils. All imitation milk or imitation fluid milk products or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than imitation milk and imitation fluid milk products in the pasteurization plant shall be performed to preclude the contamination of such imitation milk and imitation fluid milk products.

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

8:21-9.1 Definitions

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

"Person" shall mean an individual or firm, partnership, company, corporation, trustee, association or any public or private entity.

"Retail establishment" means any place engaged in the production, preparation, processing, manufacture, packing, storage or handling of food or cosmetics for sale or distribution directly to the consumer.

"Wholesale establishment" means any place engaged in the production, preparation, processing, manufacture, packing, storage or handling of food or cosmetics for sale or distribution to any other person other than the ultimate consumer.

As amended, R.1973 d.89, eff. March 30, 1973.

See: 5 N.J.R. 81(b), 5 N.J.R. 143(a).

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

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

Definition of wholesale establishment added.

8:21-9.2 Scope of regulations

(a) Every wholesale establishment falling within the definitions of N.J.S.A. 24:15-1, must obtain a license from the Department except as hereinafter exempted.