CHAPTER 21

FOOD AND DRUGS

Authority

N.J.S.A. 24:2–1 et seq., N.J.S.A. 24:10–57.1 et seq., specifically 24:10–57.1, 24:10–57.20 and 24:10–57.24b.

Source and Effective Date

R.1990 d.563, effective October 23, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

Executive Order 66(1978) Expiration Date

Chapter 21, Food and Drugs, expires on October 23, 1995.

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 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).

Pursuant to Executive Order No. 66(1978), Chapter 21 was readopted as R.1990 d.563. See: Source and Effective Date.

See section annotations for specific rulemaking.

CHAPTER TABLE OF CONTENTS

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

Authority

N.J.S.A. 24:2–1, 24:10–57.20, 24:10–57.24(b), 24:10–73.1 and 24:12–12.

Source and Effective Date

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

Historical Note

Previous subchapter 1, "Names; Labels", was adopted pursuant to the Authority of N.J.S.A. 24:2–1 and became effective prior to September 1, 1969. This subchapter expired May 15, 1985, pursuant to Executive Order 66 (1978).

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.

SUBCHAPTER 2. FOODS

8:21–2.1 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on objectives deleted.

8:21–2.2 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on inspection of food establishments deleted.

8:21–2.3 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on special inspection deleted.

8:21–2.4 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on recalling foods deleted.

8:21–2.5 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on standards for sanitarians deleted.

8:21–2.6 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on food establishment surveys deleted.

8:21–2.7 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on food product evaluations deleted.

8:21–2.8 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on reciprocity programs deleted.

8:21–2.9 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on food service training courses deleted.

8:21–2.10 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on licenses deleted.

8:21–2.11 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on promotion of standardized code adoption deleted.

8:21–2.12 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on preparation, handling and service of food deleted.

8:21–2.13 Use of textile bags as containers for flour

No person, firm, or corporation shall sell, offer or expose for sale, distribute or have in possession with intent to sell or to distribute or to manufacture into food for human consumption in this State, any flour in textile bags that have been used previously.

8:21–2.14 Frozen food locker plants

(a) The refrigeration system for a locker plant or branch locker storage plant shall be equipped with adequate and reliable automatic controls for the maintenance of uniform temperatures as required in the various rooms and shall be of adequate capacity to provide these temperatures under peak load conditions in the normal operation of the plant with extreme conditions of outside temperature.

(b) Each locker plant shall have thermometers so placed as to be readily accessible to public view in the various low temperature rooms.

(c) All food products offered for storage shall be placed in clean containers or wrappings suitable for freezing and proper storage, and clearly marked with the date of storage. Persons or firms operating locker or locker storage plants shall not place in a locker storage plant or allow to be received for processing, chilling, freezing, or storage in a locker or locker storage plant, any food articles in a state of decomposition or putrefaction, or in any other condition which renders them unfit for food, or in any condition which may cause deterioration in other food products.

(d) When articles of food, held in a locker plant, are removed from the packages in which they were contained and placed in other packages, the date of original entry into the locker plant of such articles shall be placed upon the containers into which they have been transferred; and if articles of food which have been placed in a locker or locker storage plant on different dates are packed in the same container, the date of storage of the article longest stored shall be placed upon the container to which such articles have been transferred.

(e) Any article of food, if intended for use other than human consumption shall be plainly and legibly labeled or marked with the words "Not for Human Consumption".

(f) All rooms in which food products are stored shall be provided with smooth, water-tight floors which can be readily cleansed. Floors must be kept in a clean condition at all times.

(g) The sidewalls and ceilings of all rooms shall be of smooth material, free from crevices and must be kept clean at all times.

(h) Waste materials shall not be permitted to accumulate in or around buildings in an insanitary manner. Waste materials shall be placed in clean metal containers.

(i) Adequate toilet facilities shall be provided for employees. All toilets shall be kept clean at all times.

(j) Adequate lavatory facilities shall be provided. All persons engaged in handling foods shall be required to wash hands before handling food after visiting toilet.

(k) No employer shall require, permit or allow any person to work in a cold storage warehouse, who is afflicted with any communicable disease.

(*l*) The license granted by the Department of Health to operate locker plant shall be displayed in the plant.

8:21–2.15 Sale of enriched white flour and unenriched white flour

(a) All flour, excepting that sold under a certificate as provided in N.J.S.A. 24:11A–4, intended for sale for human consumption in New Jersey shall be held in containers which are marked in a plain and conspicuous manner with the words, "Enriched Flour" and with the name and address of the manufacturer, packer or distributor.

(b) All flour sold to distributors, bakers or other processors under the proviso contained in N.J.S.A. 24:11A–4, which allows the sale of unenriched flour under certain conditions, shall be held in containers which are marked in a plain and conspicuous manner with the words, "Unenriched Flour", and the name and address of the manufacturer, packer or distributor.

(c) All persons purchasing flour which has not been enriched and which is to be resold or used as outlined in the proviso contained in N.J.S.A. 24:11A–4 shall furnish a certificate to the seller on the form adopted by the Board of Health of the State of New Jersey, and this certificate shall be kept on file by the seller for a period of two years. The purchaser shall keep a copy of each certificate for a period of two years.

(d) One certificate shall be furnished the seller by the purchaser covering all the flour purchased from him during the first half of the calendar year and one new certificate shall be furnished the seller by the purchaser for each following six-month period. Certificates issued during the first six months of the year shall expire on June 30 and certificates issued during the last six months of the year shall expire on December 31.

8:21–2.16 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on egg-breaking establishments deleted.

8:21–2.17 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on canned tomatoes, identity deleted.

8:21–2.18 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on canned tomatoes, quality deleted.

8:21–2.19 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on canned tomatoes, label statement of substandard quality deleted.

8:21–2.20 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on tomato puree and pulp identity deleted.

8:21–2.21 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on tomato paste deleted.

8:21–2.22 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on tomato juice identity deleted.

8:21–2.23 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on yellow tomato juice identity deleted.

8:21–2.24 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on catsup identity deleted.

8:21–2.25 (Reserved)

Repealed 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 egg yolks identity deleted.

8:21–2.26 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on dried egg yolks identity deleted.

8:21–2.27 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on liquid egg yolks identity deleted.

8:21–2.28 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on dried eggs identity deleted.

8:21–2.29 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on liquid eggs identity deleted.

8:21–2.30 (Reserved)

Repealed 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 eggs identity deleted.

8:21–2.31 (Reserved)

R.1984 d.246, effective June 18, 1984.
See: 15 N.J.R. 1318(a), 16 N.J.R. 1499(a).
Repealed.

8:21–2.32 (Reserved)

R.1984 d.246, effective June 18, 1984.
See: 15 N.J.R. 1318(a), 16 N.J.R. 1499(a).
Repealed.

8:21–2.33 (Reserved)

R.1984 d.246, effective June 18, 1984.
See: 15 N.J.R. 1318(a), 16 N.J.R. 1499(a).
Repealed.

8:21–2.34 (Reserved)

R.1983 d.115, effective April 18, 1983, operative June 1, 1983.
See: 14 N.J.R. 1265(a), 15 N.J.R. 623(a).
This section formerly contained rules concerning bottling water and nonalcoholic drinks.

8:21–2.35 Public posting of inspection reports

(a) The operator of every food establishment shall post on forms approved by the New Jersey State Department of Health the most recent inspection report, subsequent to December 15, 1972, the effective date of this regulation, made by a licensed municipal county, regional, or State health department employee.

(b) Each such report shall be presented to the owner or manager of the establishment inspected at the completion of each inspection by the inspector with instructions that such report shall be posted in a conspicuous place near the public entrance of the establishment in such manner that the public may review the report.

(c) The detailed supporting data serving as the basis of each inspection report shall be maintained by the operator of each food establishment on the premises for review by the public.

R.1972 d.209, effective December 15, 1972.
See: 4 N.J.R. 215(a), 4 N.J.R. 26(b).

Authority

N.J.S.A. 24:2–1

8:21–2.36 Public availability of inspection records

Records of inspections of food establishments subsequent to December 15, 1972, the effective date of this regulation, shall be made available to the public.

R.1972 d.209, effective December 15, 1972.
See: 4 N.J.R. 215(a), 4 N.J.R. 266(b).

Authority

N.J.S.A. 24:2–1

8:21–2.37 (Reserved)

8:21–2.38 Bacteriological standards for potentially hazardous foods

(a) Bacteriological standards shall be applied to the following ready-to-eat products sold in New Jersey:

1. Chicken salad;
2. Chopped chicken liver;
3. Coleslaw;
4. Egg salad;
5. Macaroni salad;
6. Potato salad;
7. Shrimp salad;
8. Tuna salad;
9. Turkey salad.

(b) No sample of these foods shall, by bacteriological analysis, contain any of the following:

1. More than 100,000 per gram in total aerobic bacteria plate count;

2. More than 100 per gram of total coliform organisms;

3. More than 100 per gram of coagulase positive staphylococcus aureus;

4. Any salmonella, shigella or enteropathogenic strains of E. coli.

(c) However, if these standards are not met for the potentially hazardous foods specified due to the addition of otherwise wholesome foods having naturally high total bacteria plate counts, the onus of demonstrating that this is indeed the case rests with the food establishment at the point of sampling.

(d) Penalty action shall not be taken on the basis of a single sample violating the standard included in subsection (b)1 or 2 of this Section, unless such sample was obtained during an inspection in which existing sanitary conditions

constitute a potential hazard to public health. Whenever two of the last four consecutive bacteria counts or coliform determinations taken on separate days exceeds the limit of the standard for potentially hazardous food, the health authority or representative so designated shall send a written warning notice thereof to the person concerned. This warning notice shall be effective so long as two of the last four consecutive samples exceeds the limit of the standard. An additional sample shall be taken within 14 days of the sending of such warning notice, but not before the lapse of three days. Immediate penalty action shall be instituted whenever the standard is violated by three of the last five bacteria counts or coliform determinations.

(e) Any potentially hazardous food sample which violates the provisions of subsection (b)3 or 4 of this Section shall be subject to immediate administrative and/or penalty action by the health authority.

(f) Samples of potentially hazardous foods collected at an establishment other than the manufacturer or processor and which products have not been further processed, and violate subsections (b)1 or (b)2 of this Section shall result in action by the health authority to collect additional samples of the product from the original unopened container at the time of delivery from the manufacturer or processor in order to determine whether the cause of the high bacteria count is due to faulty handling in production, distribution and/or storage.

(g) Nothing in subsections (a), (b), (c), (d), (e) and (f) of this Section shall preclude the right of the State or local health authority from embargoing foods which are or are suspected of being adulterated within the meaning of N.J.S.A. 24:5.8.

R.1974 d.204, effective July 24, 1974.
See: 6 N.J.R. 179(a), 6 N.J.R. 311(a).

8:21–2.39 Sale of ground meat and similar products

(a) The following Federal standards of identity as currently promulgated and hereafter amended shall apply to the processing and retail sale of ground meat, sausage, and similar products in this State. The quality standards of 9 CFR 319.15, 319.140, 319.141, 319.142, 319.143, 319.144, 319.145, 319.160, 319.180, 319.181, and 319.182 are incorporated herein by reference.

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

Historical Note

This rule was filed with the office of the Secretary of State on July 26, 1965, to become effective October 4, 1965, but was not included in the initial printing of Title 8 in error.

8:21–2.40 (Reserved)

As amended, R.1984 d.171, eff. April 23, 1984 originally adopted as emergency rule R.1984 d.60, eff. February 22, 1984.
See: 16 N.J.R. 436(a), 16 N.J.R. 1089(a).
Amended by R.1985 d.42, effective February 19, 1985.
See: 16 N.J.R. 2897(a), 17 N.J.R. 449(a).
(a)1: "900" deleted and "300" substituted; (a)4 added.
Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on maximum tolerance of EDB deleted.

8:21–2.41 Prohibition of sale of striped bass

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

New Rule R.1987 d.127, effective March 2, 1987.
See: 18 N.J.R. 2174(a), 19 N.J.R. 409(a).

8:21–2.42 Prohibition of sale of channel cat fish

No person may expose for sale, or sell channel cat fish (Ictalurus punctatus) harvested from the Delaware River between the Interstate 276 Highway Bridge in Burlington Township, Burlington County and Birch Creek, which flows into the Delaware River at Logan Township, Gloucester County.

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

SUBCHAPTER 3. DRUGS, DEVICES AND COSMETICS

8:21–3.1 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on objectives deleted.

8:21–3.2 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on adulterated or misbranded drugs deleted.

8:21–3.3 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on wild marijuana inspections deleted.

8:21–3.4 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on SCUBA deleted.

8:21–3.5 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on control of certain drugs deleted.

8:21–3.6 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on inspection of hazardous substance labeling deleted.

8:21–3.7 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on illegal drug activity control deleted.

8:21–3.8 Warning statements for drug labels

The warning statements listed in this Section, or their adequate equivalents, should appear on the labels of preparations containing the following drugs:

(a) Cathartic or laxative drugs (except castor oil and phenolphthalein) which act as irritants to the gastro-intestinal tract or stimulate intestinal peristalsis.

"Warning: Not to be used when abdominal pain (stomachache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present."

"Frequent or continued use of this preparation may result in dependence on laxatives."

(b) Castor oil.

"Warning: Not to be used when abdominal pain (stomachache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present."

"Frequent or continued use of this preparation may result in dependence on laxatives."

"Do not use during pregnancy except on competent advice."

(c) Phenolphthalein:

"Warning: Not to be used when abdominal pain (stomachache, cramps, colic), nausea, vomiting (stomach sickness) or other symptoms of appendicitis are present."

"Frequent or continued use of this preparation may result in dependence on laxatives."

"Important: If a skin rash appears, discontinue use."

(d) Preparations containing so-called roughage materials and intended for use in constipation:

"Important: All varieties of constipation are not benefited by this preparation. It should be particularly avoided in cases such as spastic constipation in which abdominal discomfort or pain may be present."

(e) Preparations containing mineral oil for administration:

"Warning: Do not take directly before or after meals."

(f) Preparations containing sodium perborate as an active ingredient and intended for local use in the mouth and throat:

"Warning: This preparation may cause irritation and inflammation of the gums, tongue and mucous membranes of the mouth. It should be discontinued at the first sign of irritation or soreness. In case of doubt, consult your physician or dentist."

(g) Nose drops, inhalants and sprays:

1. Those that contain oil as a vehicle or base:

"Caution: The use of excessive amounts of this preparation may be dangerous. Do not use at all in infants and younger children except on competent advice."

2. Those that contain ephedrine, epinephrine, amphetamine (benzedrine), propadrine, neosynephrin and other vaso-constricting drugs of similar activity:

"Caution: frequent or continued use may cause nervousness, restlessness or sleeplessness. Individuals suffering from high blood pressure, heart disease, diabetes, or thyroid trouble should not use this preparation except on competent advice."

(h) Preparations containing volatile oils, aromatics, or drugs of an oleoresinous nature and intended for their effect upon the urinary tract.

"Warning: If disturbance of the stomach or bowels, or skin rash is noticed, discontinue use."

(i) Atropine and pharmacologically related drugs:

"Caution: Frequent or continued use of this preparation should be avoided. Discontinue if dryness of the throat, excessively rapid pulse or blurring of vision appears."

"Warning: This preparation should not be taken by elderly people except on competent advice."

(j) Iodine or iodides:

"Warning: Do not use in cases of lung disease or chronic cough, goiter or thyroid disease, except upon the advice of a physician."

"If a skin rash appears, discontinue use."

(k) Preparations containing carbolic acid as a therapeutically active ingredient:

Note: Products containing more than two per cent of carbolic acid are not considered safe for indiscriminate distribution.

"Warning: When applied to fingers and toes, do not use a bandage."

"Apply according to directions for use, and in no case to large areas of the body."

(*l*) Cresols, creosote, guaiacol or coal-tar derivatives intended for use as douches:

Note: Preparations intended for use after dilution should bear adequate directions for preparing solution and thorough mixing before pouring into douche bag.

"Warning: The use of solutions stronger than those recommended may result in severe local irritation or burns or serious poisoning."

(m) Cresols, creosote, guaiacol, or coal-tar derivatives intended for surface application:

"Warning: Apply according to directions for use and in no case to large areas of the body."

(n) Strychnine:

"Warning: Do not take more than the dosage recommended. Frequent or continued use is to be avoided and its use for children and elderly persons may be especially dangerous."

(*o*) Anthelmintics: The following preparations in therapeutically potent doses are not safe for indiscriminate distribution and should only be used under the direct supervision of a physician:

1. *Carbon tetrachloride:*

Note: Specific adequate directions for administration of a saline cathartic after use of this drug should be given.

"Warning: Avoid taking castor oil or other preparations or foods containing oil or fat while this drug is being administered. The use of this preparation in debilitated children and persons addicted to alcohol is dangerous."

2. *Tetrachlorethylene:*

Note: Specific adequate directions for the administration of a saline cathartic should be given.

3. *Aspidium (Male fern):*

Note: Specific adequate directions for administration of a saline cathartic should be given.

"Warning: Avoid taking castor oil or other preparations or foods containing oil or fat while this drug is being administered."

4. *Santonin:*

Very important: Shake vigorously before using. Failure to do so may result in serious injury.

Caution: The use of more than the prescribed dose is dangerous.

"Do not take castor oil or other preparations or foods containing oil or fat while this drug is being administered."

"The prescribed dose should not be repeated within seven days."

5. *Chenopodium oil:*

Note: Specific adequate directions for administration of a cathartic, preferably castor oil, should be given.

6. *Thymol:*

Note: Specific adequate directions for administration of a saline cathartic should be given.

"Warning: Avoid taking alcohol or any preparation containing alcohol before, after or during administration of this drug."

(p) Acetanilid:

"Warning: Frequent or continued use may be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug. Do not take more than the dose recommended. Not to be given to children."

(q) Acetophenetidin:

"Warning: Frequent or continued use may be dangerous, causing serious blood disturbances."

"Do not take more than the dosage recommended."

(r) Antipyrine:

"Warning: Frequent or continued use may be dangerous, causing serious blood disturbances."

"Do not take more than the dosage recommended."

(s) Bromides:

"Warning: Frequent or continued use may lead to mental derangement, skin eruptions or other serious effects."

"Do not take more than the dosage recommended."

"Not to be taken by those suffering from kidney disease."

(t) Mouth washes and gargles containing chlorates:

"Caution: Avoid swallowing."

(u) Preparations containing arsenic except those employed as chemotherapeutic agents for specific diseases such as syphilis, amebic dysentery, and so forth.

"Caution: Continued or prolonged use may result in serious injury."

(v) Quinine, cinchonine and cinchonidine:

"Caution: Discontinue use if deafness, skin rash, visual disturbances (eye trouble) or other serious symptoms appear."

(w) Preparations containing silver salts:

"Caution: Prolonged or frequent use of this preparation may result in permanent discoloration of the skin and mucous membranes."

(x) Preparations sold under representations relating to coughs due to colds:

"Important: Persistent coughs may indicate the presence of a serious condition. Do not use this preparation when the cough has persisted for 10 days without securing competent advice."

(y) Preparations containing mercury intended for administration by mouth or as douches:

"Warning: The prolonged or frequent use of this preparation or the use of amounts in excess of the prescribed directions may cause serious mercury poisoning."

(z) Rubifacients, or irritants such as ammonia, arnica, cantharides, capsicum, chloroform, ether, methyl salicylate, pepper, mustard, or turpentine oil intended for surface application:

"Caution: This preparation may irritate the skin, particularly if applied with rubbing. Avoid getting it into the eyes or on mucous membranes."

(aa) Chrysarobin or goa powder:

"Caution: The use of this product over large skin areas may cause kidney irritation."

"Warning: Keep away from the eyes."

(bb) Digitalis, squill, strophanthus, or other pharmacologically related drugs in therapeutically effective proportions:

Note: Potent doses of these drugs have an accumulative action and may lead to disastrous effects upon the heart and circulation. They should be used only under the direct supervision of a qualified physician.

"Caution should be exercised in using this preparation, particularly if the patient has had digitalis, squill, strophanthus, oubain or similar drug within the preceding three weeks."

"The appearance of anorexia (loss of appetite), nausea, vomiting, headaches or heart irregularities (palpitation) is often an early sign of full digitalization or overdosage. When such symptoms appear do not continue the use of this preparation without consulting a physician."

8:21–3.9 Restrictions on sales of dangerous drugs

The following drugs may not be sold within the limits of this State except upon the prescription of a physician:

Aconite;

Aminopyrine;

Barbiturates;

Benzedrine sulfate (for internal use);

Cantharides (for internal use);

Chrysarobin or goa powder;

Chrysophanic acid;

Cinchophen, Neocinchophen, and other cinchophen derivatives;

Colchicine;

Colchicum;

Emetine;

Phenol and Camphor (in undiluted eutectic mixture);

Phosphides;

Phosphorus;

Radium;

Sulfadiazine (includes preparations and related compounds);

Sulfaguanidine;

Sulfanilamide;

Sulfapyridine;

Sulfathiazole;

Tansy oil;

Thiocyanates;

Thyroid;

Carbon tetrachloride—for internal use;

Tetrachlorethylene;

Male fern (aspidium);

Santonin and preparations of Santonin;

Wormseed oil (chenopodium oil);

Thymol—for internal use;

and the following drugs shall not be sold for medicinal use within this State:

Dinitrophenol, Dinitrocresol, and their derivatives;

Diethylene Glycol;

Ethylene Glycol;

Carbitol;

Cellosolve, and all other Glycols except Glycerin and Propylene Glycol;

The latter if present in drug products in appreciable quantities.

8:21–3.10 Other dangerous drug regulations

(a) *Bromides.* It is the opinion of the authorities that preparations containing bromides should not be sold without prescription if the dosage provided involves the consumption of more than 30 grains per day or more than 15 grains during any three-hour period.

(b) *Acetanilid.* The same is true of acetanilid, in the case of medicines that provide a total daily intake or more than 5 grains or more than 2½ grains during any three-hour period.

(c) *Bromide-acetanilid combinations.* For Bromide-acetanilid combinations, it has been suggested that preparations for lay use should not provide more than a total daily dose of 15 grains of sodium bromide and 5 grains of acetanilid, or more than 7½ grains of sodium bromide and 2½ grains of acetanilid during any three-hour period. Comparable amounts of other bromide preparations should, of course, be subject to the same restriction.

(d) *Acetophenetidin-antipyrine.* There is ample scientific evidence to support the view that preparations providing a daily dose of more than 15 grains of acetophenetidin or more than 15 grains of antipyrine are dangerous within the meaning of Federal and State Drug Laws when distributed for indiscriminate lay use. Investigations which are currently in progress strongly suggest the probability that somewhat smaller daily doses of these drugs may likewise be dangerous when consumed indiscriminately. After public notice, the regulatory program will, of course, include actions based on sales of acetophenetidin and antipyrine under circumstances providing for a somewhat smaller daily dose if scientific opinion becomes available to establish the illegality of such sales.

(e) *Epinephrine, ipecac, strychnine.* In the judgment of the authorities, epinephrine in solution of one per cent or stronger cannot safely be indiscriminately used, and the same is true of ipecac in daily dosage greater than 10 grains, as well as of strychnine, in a daily dose greater than 1/30 grain.

(f) *Digitalis, squill, strophantus.* The opinion has also been expressed that products containing therapeutically effective proportions of digitalis, squill, strophanthus, or other pharmacologically related drugs may not be safe for indiscriminate distribution.

Pharmacists should guide themselves in accordance with the regulations and views expressed by the authorities.

8:21–3.11 Rulings on dangerous drugs

(a) *Sulfanilamide and related drugs.* It is the consensus of qualified experts that sulfanilamide is a valuable aid in the treatment of several serious disease conditions when the dosage is properly adjusted to the requirement of the individual patient and frequency of dosage and duration of treatment are intelligently and expertly directed. It is further the consensus of such experts that, when used under other conditions, it is a dangerous drug, capable of causing serious injury and even death. In the light of these facts, careful consideration has been given to the status of sulfanilamide under the provisions of the Food, Drug and Cosmetic Act which deals with traffic in dangerous drugs. Sulfanilamide and drug preparations containing sulfanilamide or related compounds offered for sale to the public without a physician's prescription are actionable, in the opinion of the Department of Health of the State of New Jersey.

(b) *Cinchophen, neocinchophen, and related drugs.* Since the introduction of cinchophen as a therapeutic agent some 30 years ago, many reports of its toxic manifestations have been reported in medical literature. These include numerous cases of acute yellow atrophy and cirrhosis of the liver which result in permanent damage and not infrequently in death. The dangerous potentialities of this drug are now generally recognized by informed physicians. The toxic properties of neocinchophen are generally similar to those of cinchophen. In the light of these facts, careful consideration has been given to the status of cinchophen and neocinchophen under the currently effective provisions of the Food, Drug and Cosmetic Act which deal with traffic in dangerous drugs. In the opinion of the Department of Health of the State of New Jersey, cinchophen, neocinchophen, and drug preparations containing them, when offered for sale to the public without a physician's prescription, are actionable.

(c) *Aminopyrine and related drugs.* Although aminopyrine has been employed as a drug for more than 40 years and although agranulocytosis has been recognized as a clinical entity for the past 16 years, the role of aminopyrine as probably the most important causative factor in agranulocytosis was not recognized until about six years ago. Once the causal relationship between the drug and the disease was suspected confirmatory evidence rapidly accumulated and was reported in medical literature. There is now no doubt that this drug has been responsible for numerous deaths in the United States. In the light of these facts, careful consideration has been given to the status of aminopyrine under the currently effective provisions of the Food, Drug and Cosmetic Act which deal with traffic in dangerous drugs. In the opinion of the Department of Health of the State of New Jersey, aminopyrine and drug preparations containing it, when offered for sale to the public without a physician's prescription, are actionable.

Authority

N.J.S.A. 24:5–18.

8:21–3.12 Rulings on dangerous cosmetics

(a) The toxic effect of paraphenylenediamine is well known. A number of persons have suffered severe injury, and in some cases blindness has resulted from the application of this dye to the eyelashes and eyebrows. There is no doubt that preparations containing this dye are in violation of the Food, Drug and Cosmetic Act. The Department of Health of the State of New Jersey has obtained very definite evidence of injury from this dye. Based upon a serious consideration of the injurious effects of paraphenylenediamine, eyelash and eyebrow dyes containing paraphenylenediamine in any amount will be considered adulterated under N.J.S.A. 24:5–11.1(a) and appropriate action taken. It has also been noted that substances such as oils, argyrol, magnesium carbonate, paper shields, and the like are customarily included in packages of eyelash and eyebrow dye preparations to be used to prevent the introduction of the dye into the eyes. It is the opinion of the Department that the use of these precautionary measures cannot guarantee protection of the eyes against such dangerous product as paraphenylenediamine. This notice should not be interpreted as indicating that other dyes used for eyelash and eyebrow dyeing are to be accepted as meeting the requirements of N.J.S.A. 24:5–11.1(a).

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

8:21–3.13 Keeping of records by drug manufacturing businesses and wholesale drug businesses

(a) Drug manufacturing businesses shall maintain records identifying the source of each ingredient used in the manufacture or processing of a drug. Records identifying the source of each ingredient shall include the date of receipt of the ingredient, vendor's name and address, the name of the ingredient and the vendor's batch number, lot number, control number or other identifying symbol, if any, used by the vendor to identify the ingredient as well as the grade (such as U.S.P., N.F., reagent, technical or crude) and quantity of said ingredient.

(b) Drug manufacturing businesses shall maintain a system of record keeping that will permit the identification for purposes of recall of any lot or batch of a drug from the market when such is found to be unsafe for use. As part of this system, the manufacturer shall insure that the container of any drug at any stage in the process of manufacture and distribution bears an identifying name and number, commonly known as "lot" or "control" number, to make it possible to determine the complete manufacturing history of the package of the drug. This Section shall not require that the manufacturer keep a record of the control number of any given shipment of drugs if the manufacturer's overall records are such as to enable the manufacturer to recall an unsafe drug.

(c) Wholesale drug businesses shall maintain records identifying each drug received. Records of receipt shall include the date the drug was received, the vendor's name and address, the drug name and the quantity of the drug received. Such records in the form of vendors' invoices shall suffice for compliance with this regulation.

(d) Wholesale drug businesses shall maintain records of shipments which identify the recipient of the drug by name, street address, city and state, date of shipment, the drug name and the quantity of the drug shipped. Such records in the form of customers' invoices shall suffice for compliance with this regulation.

(e) Records required by this Section shall be maintained for not less than 24 consecutive months.

(f) The provisions of this section shall not apply to "commercial feeding stuff" as these articles are defined and administered under the provisions of N.J.S.A. 4:4–1 et seq.

8:21–3.14 (Reserved)

As amended, R.1979 d.454, eff. November 13, 1979.
See: 11 N.J.R. 504(b), 11 N.J.R. 622(d).

Historical Note

Current rules on good drug manufacturing are now cited as N.J.A.C. 8:21A–1.1 et seq.

8:21–3.15 through 8:21–3.18 (Reserved)

As amended, R.1979 d.451, eff. November 13, 1979.
See: 11 N.J.R. 504(c), 11 N.J.R. 622(a).

Historical Note

Rules concerning controlled dangerous substances are now located in chapter 65 of this Title.

8:21–3.19 Paregoric

Paregoric, as defined in the United States Pharmacopoeia XVII, shall be henceforth regarded as a narcotic drug and

subject to the provisions of the Controlled Dangerous Substances Act, N.J.S.A. 24:21–1 et seq., of this State requiring a prescription except when sold or dispensed in compounds containing not more than one fluid drachm of Paregoric in each fluid ounce.

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

8:21–3.20 Compressed air used in self contained underwater breathing apparatus (SCUBA)

Components of compressed air shall not exceed the following limits:

CARBON MONOXIDE	10 parts/million (PPM) 0.001%
CARBON DIOXIDE	1000 PPM 0.1%
OIL	0.02 mg/liter
WATER	Saturation
ODOR	Free from objectionable odors
OTHER	Contaminants deleterious to health shall not be present

8:21–3.21 SCUBA recommendations

The following recommendations are primarily directed to purveyors of SCUBA air to protect public health.

(a) Compressed air containers. No compressed air container used for self-contained underwater breathing apparatus should be filled or refilled unless it shows evidence of a recent I.C.C. hydrostatic test.

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

1. Carbon monoxide. Determination of carbon monoxide may be made by using:

i. Mine Safety Appliance Detector Co., Carbon Monoxide Tester No. Ds–47133;

ii. U.S. Safety Services Detector, model 300 "Saf–Co–Meter";

iii. Kitagawa Precision Gas Detection Unico Model No. 400, with the cartridge No. 106A; or its equivalents;

iv. Any other device or method acceptable to the Department of Health.

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

i. Kitagawa Precision Gas Detection Unico Model No. 400;

ii. Davis Emergency Co., Gas Detector Kit;

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

3. Oil. Determination of oil may be made by passing 100 liters of air at atmospheric pressures and room temperature through a Number 41 Whatman Filter and measuring the increase in weight over the original weight of the filter. Air contamination with 0.02 milligrams of oil per liter of air will add two milligrams to the weight of the filter. Other forms of particulate matter may be similarly assayed. Assays may be made by this or by any other device or method acceptable to the Department of Health.

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

i. Dew point equipment as manufactured by Mine Safety Appliance Co., Foxboro Co., or American Instrument Co.;

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

5. Odor. Compressed air may be tested for odor by cracking the valve and smelling the escaping air. Filled cylinders having any objectionable odors should be rejected.

(c) Equipment. Equipment for compressing air should be of suitable design, size, construction and location to facilitate maintenance and operation for its intended purpose in a manner that is orderly and clean. Such equipment should be:

1. So constructed that any surface that comes in contact with the air be nonreactive, nonadditive, or nonabsorptive to the finished product;

2. So constructed that any substances required for its operation, such as lubricants or coolants, may be employed without hazard or without becoming additive to the finished compressed air;

3. So constructed to facilitate maintenance to assure reliability of the finished product within the limits as set forth in section 20 of this subchapter.

8:21–3.22 (Reserved)

Repealed by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Text on locomotion control systems deleted. The rules were formerly cited as N.J.A.C. 8:64–1.1.

8:21–3.23 Animal repellants

(a) The list of animal repellants which are non-injurious to canines or other animals and which immobilize only temporarily and produce only temporary physical discomfort covered by the exemptions pursuant to the provisions of N.J.S.A. 2C:39–6(h) shall include, but not be limited to, the following trade products:

1. Dog Chaser;
2. Guardian;
3. Halt;
4. Sentinel;
5. Stinger;
6. Stop Dog.

(b) The following list of active and inactive ingredients can be used in animal repellants that are non-injurious to canines or other animals and immobilize only temporarily and produce only temporary physical discomfort covered by the exemptions pursuant to the provisions of N.J.S.A. 2C:39–6(h).

1. Active ingredient:
   i. Oleoresin Capsicum.
2. Inactive ingredient:
   i. Mineral Oil;
   ii. Nitrogen Propellant.

(c) The Department shall add to or delete from the above list those active and inactive ingredients and products to be consistent with the provisions of the Act.

R.1982 d.123, effective April 19, 1982.
See: 14 N.J.R. 79(a), 14 N.J.R. 389(a).

8:21–3.24 List of ingredients for human self-defense sprays

(a) The following list of active and inactive ingredients can be used in devices which contain and release chemical substances which cause temporary physical discomfort covered by the exemptions pursuant to the provisions of N.J.S.A. 2C:39–6(i):

1. Active ingredients:
   i. Chloroacetophenone
   ii. Ortho-chlorobenzalmalonitrile
2. Inactive ingredients:
   i. 1,1,1–trichloroethane
   ii. Trichlorotriflouroethane
   iii. Kerosene
   iv. Mineral oil

R.1982 d.451, effective December 20, 1982.
See: 14 N.J.R. 1029(a); 14 N.J.R. 1456(a).

8:21–3.25 Permit for nitrous oxide

(a) Every person or firm, except a duly licensed physician, dentist, veterinarian, nurse, hospital, sanitarium or other medical institution, or a resident physician or intern of a hospital, sanitarium or other medical institution, desiring to use nitrous oxide shall request a permit from the Department of Health. Such permit shall include but not be limited to:

1. Name of the firm or person requesting the permit;
2. Address of the firm or person;
3. Telephone number of person or firm;
4. Location at which nitrous oxide is to be used;
5. Signature of person in charge of the location where the nitrous oxide is to be used;
6. Purpose for such use;
7. Name and address of the distributor from whom nitrous oxide is to be obtained; and
8. Any other information as may be requested by the Department.

(b) Every person or firm distributing nitrous oxide shall cause the same to be supplied on the permit enumerated in (a) above except where the firm is registered pursuant to N.J.S.A. 24:6B–1 et seq. A copy of the permit completed in compliance with this subsection shall be given to the user listed in the permit. A copy of the permit shall be maintained by the distributor of nitrous oxide for a period of two years.

(c) Every permit issued by the Department for the use or sale of nitrous oxide shall be valid only for the location listed in that permit and may not be transferable.

(d) Every person or firm distributing or using nitrous oxide for either manufacturing or research purposes shall allow inspection of such permit by a public officer or employee engaged in the enforcement of this Act.

(e) A permit shall be issued for a period of two years.

R.1983 d.41, effective February 22, 1983.
See: 14 N.J.R. 1190(a), 15 N.J.R. 244(b).

SUBCHAPTER 3A. REGISTRATION OF WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

Subchapter Historical Note

New Rules, R.1992 d.354, effective September 8, 1992. See: 24 N.J.R. 2410(b), 24 N.J.R. 3100(a). Rules adopted with portions not adopted, but still pending.

8:21–3A.1 Scope

This subchapter sets forth standards for the registration and operation of any person, partnership, corporation or

business firm engaging in the wholesale distribution of human prescription drugs.

8:21–3A.2 Purpose

The purpose of this subchapter is to implement the requirements of the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. 351, 353, 371 and 374, and 21 C.F.R. 205, and for the benefit of the health and safety of the ultimate consumers of prescription drugs.

8:21–3A.3 Definitions

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

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Department" means the New Jersey Department of Health.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Manufacturer" means anyone who is engaged in the manufacturing of drugs or devices, as defined in N.J.S.A. 24:6B–12, or engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

"Non-prescription" or "Non-legend" or "O.T.C." drugs mean drugs directly available to the consumer over the counter, without a physician's prescription.

"Prescription drug" means any human drug required by Federal law or regulation to be dispensed only by a prescription, including dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

"Wholesale distribution" means the distribution of drugs or devices to persons other than a consumer or patient, but does not include:

1. Intracompany sales;

2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization, of a drug or device for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

3. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

4. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device among hospitals or other health care entities that are under common control; for purposes of this definition "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

5. The sale, purchase or trade of a drug or device or an offer to sell, purchase, or trade a drug or device for emergency medical reasons; for purposes of this definition, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

6. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

7. The distribution of drug or device samples by manufacturers' representatives or distributors' representatives; or

8. The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means anyone engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; and independent wholesale drug traders, but does not include a retail pharmacy whose sales of prescription drugs to other than the ultimate user, including physicians for office use, nursing homes, institutions, etc. does not exceed five percent of the total gross annual sales of prescription drugs of the pharmacy.

8:21–3A.4 Application requirements; reciprocity

(a) The Department may permit an out-of-State wholesale distributor to satisfy the registration requirements of this subchapter on the basis of reciprocity provided that:

1. Such out-of-State wholesale distributor possesses a valid license or registration granted by another state pursuant to legal standards comparable to those which must be met by a registrant of this State as prerequisites for satisfying the registration requirements under the laws of this State; and

2. Such other state extends reciprocal treatment under its own laws to wholesale distributors of this State.

(b) Every wholesale distributor of prescription drugs shall apply to the Department in accordance with the provisions of N.J.S.A. 24:6B–2 using forms supplied by the Department. In addition, every applicant shall complete the appropriate sections of the application, which shall include:

1. Name, full business address and telephone number of the applicant;

i. All trade or business names used by the registrant;

ii. Addresses, telephone numbers and name of the contact person for all facilities used by the registrant for the storage, handling and distribution of prescription drugs;

2. The type of ownership or operation (that is, partnership, corporation, or sole proprietorship);

3. The name(s) of the owner and/or operator of the applicant, including:

i. If a person, the name of the person;

ii. If a partnership, the name of each partner, and the name of the partnership;

iii. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation, and

iv. If a sole proprietorship, the full name of the proprietor and the name of the business entity;

4. The address of each location in New Jersey at which the business is to be conducted. If an applicant's business is not to be conducted within the State, the application shall give the name and address of an agent resident of this State on whom process against the applicant may be served;

5. If the business is to be conducted at more than one location in this State, the name and address of the individual in charge of each such location;

6. A description of the business;

7. The name and address of the individual or individuals on whom orders of the Commissioner may be served; and

8. A statement as to whether the registrant engages in the manufacturing, compounding, processing, wholesaling, jobbing, distribution of any controlled dangerous substances as defined pursuant to N.J.S.A. 24:21–2.

8:21–3A.5 Evaluation criteria

(a) In considering any application for registration, the Department shall consider, at a minimum, the following factors in reviewing the qualifications of those persons applying for registration as a wholesale prescription drug distributor:

1. Any convictions of the applicant under any Federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of a controlled substance;

2. Any felony conviction under Federal laws, or the equivalent (under whatever statutory term) conviction under state or local laws;

3. The applicant's past experience in the manufacturing or distribution of prescription drugs or controlled substances;

4. The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

5. Suspension or revocation by Federal, state or local government of any registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

6. Compliance with license and/or registration requirements under any previously granted license or registration, if any;

7. Compliance with requirements to maintain and/or make available to the Department or Federal or local law enforcement officials those records required by this subchapter; and

8. Any other factors or qualifications the Department considers relevant to and consistent with the public health and safety.

(b) Wholesale drug distributors shall operate in compliance with applicable Federal, State and local laws and regulations and where the wholesale drug distributor also deals in controlled dangerous substances, it shall also register with the Department and Drug Enforcement Administration (DEA) and also comply with all applicable State rules and DEA regulations.

(c) A retail pharmacy wishing to conduct a wholesale business shall operate the wholesale business under a separate name and at a separate location, other than that of the pharmacy name and address and the wholesale business will be subject to all of the requirements of a wholesale distributor.

8:21–3A.6 Denial of application

The Department shall have the right to deny an application for registration if it determines the granting of such registration would not be in the public interest. *Public* interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety as delineated in N.J.A.C. 8:21–3A.5.

8:21–3A.7 Personnel requirements

Personnel employed by a wholesale distributor shall have appropriate education and/or experience to assume responsibility for positions that would affect compliance with registration requirements.

8:21–3A.8 Facility

(a) All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

2. Provide storage areas which include adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3. Provide a quarantine area for storage of outdated, damaged, deteriorated, misbranded or adulterated prescription drugs, or drugs that are in immediate or sealed secondary containers that have been opened;

4. Be maintained in a clean and orderly condition; and

5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

8:21–3A.9 Security

(a) All facilities used for wholesale distribution shall be secure from unauthorized entry and shall provide the following additional security measures:

1. Access from outside the premises shall be kept at a minimum and shall be well controlled;

2. The outside perimeter of the premises shall be well-lighted; and

3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours.

(c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion, and shall provide, when appropriate, protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

8:21–3A.10 Storage

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

(b) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(c) Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices and/or logs shall be utilized to document proper storage of prescription drugs.

8:21–3A.11 Examination of materials

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution, and such examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(b) Each outgoing shipment of prescription drugs shall be carefully examined for the identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

8:21–3A.12 Returned, damaged and outdated prescription drugs

(a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(b) Prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality and purity. The wholesale distributor of prescription drugs shall consider, among other things, the conditions under which the drugs were held, stored, or shipped before or during their return and the condition of the drug and its container, carton, or labeling as a result of storage and shipping when considering that there is any doubt of the drug's safety, identity, strength, quality or purity.

8:21–3A.13 Recordkeeping

(a) Wholesale distributors of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. Such records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs.

8:21–3A.14 (Reserved)

8:21–3A.15 Availability of records and inventories

(a) Records and inventories, including those related to any prescription drug salvage or reprocessing procedure, shall be made available for inspection and photocopying by Federal, State or local law enforcement agencies and shall be maintained for a period of two years following the disposition of the drugs.

(b) The records that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period, and records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a Federal, state or local enforcement agency.

8:21–3A.16 Policies and procedures

(a) Wholesale prescription drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventory. Wholesale drug distributors shall include in their policy and procedures the following:

1. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for, and which shall be adequate for, handling recalls and withdrawals due to:

i. Any action initiated by the request of the Food and Drug Administration or other Federal, state, local law enforcement or other government agency, including the State registering agency;

ii. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

iii. Any action undertaken to promote public health, and safety by replacing existing merchandise with an approved product or new package design.

3. A procedure to ensure that a wholesale distributor prepares for, protects against, and handles any crisis that affects security or the operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of a local, State or national emergency; and

4. A procedure to ensure that outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. Such procedure shall provide for written documentation of the disposition of the outdated prescription drugs and shall be maintained for two years after disposition of the outdated drugs.

8:21–3A.17 List of responsible persons

Wholesale drug distributors shall establish and maintain a list of officers, directors, managers, and other persons in charge of wholesale distribution, storage, and handling of prescription drugs that shall include a description of their duties and a summary of their qualifications.

8:21–3A.18 Inspection and auditing

Wholesale drug distributors shall permit the Department and authorized Federal, State and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

8:21–3A.19 Salvage; reprocessing

Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State or local laws, rules or regulations that relate to prescription drug product salvaging or reprocessing.

8:21–3A.20 Suspension; revocation

The Department shall suspend or revoke any registration granted under this subchapter upon conviction of the registrant of a violation of applicable Federal, State or local drug laws, rules or regulations and may suspend or revoke any registration granted hereunder if the registrant willfully and seriously violated the requirements of this chapter.

8:21–3A.21 Penalties

The Department may provide for fines, imprisonment, or civil penalties as set forth in N.J.S.A. 24:6B–11 or 24:17.1.

8:21–3A.22 Appeals

Prior to the suspension or revocation of a registration issued in accordance with this subchapter, the registrant shall have a right to prior notice and a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules N.J.A.C. 1:1.

SUBCHAPTER 4. NEW DRUGS

8:21–4.1 Statement of policy

(a) The following "new drug" regulations as adopted by the department are to provide guidance in the administration of the provisions of N.J.S.A. 24:6A–1 et seq.

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

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

8:21–4.2 Combination drugs

21 C.F.R. 300.50, Fixed combinations prescription drugs for humans, is hereby adopted by reference.

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

8:21–4.3 General provisions; definitions

(a) 21 C.F.R. 310.3 (Definitions and interpretations), 21 C.F.R. 310.4 (Biologics, products subject to license control) and 21 C.F.R. 310.9 (Designated journals) are hereby adopted by reference, with the following modifications.

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

1. The term "act" means the Title 24, New Jersey Statutes Annotated.

2. The term "department" means the New Jersey Department of Health.

3. The term "secretary" means the New Jersey State Commissioner of Health.

4. Where administrative procedures are set forth in the Federal regulations, the provisions of N.J.S.A. 52:14B–1 et seq. shall apply.

Amended by R.1987 d.227, effective May 18, 1987.
See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).
Added 21 C.F.R. to (b).

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.

8:21–4.4 Exemptions from section 505(a)

(a) 21 C.F.R. 312.1 (Conditions for exemption of new drugs for investigational use), 21 C.F.R. 312.5 (Confidentiality of data and information in an investigational new drug notice, IND), and 21 C.F.R. 312.9 (New drugs for investigational use in laboratory research animals or in vitro tests) are hereby adopted by reference.

(b) Regarding subpart B (Controlled substances), 21 C.F.R. 312.10, Availability of records, is hereby adopted by reference.

(c) Regarding subpart C (International research), 21 C.F.R. 312.20, Clinical data generated outside the United States and not subject to a "Notice of Claimed Investigational Exemption of a New Drug", is hereby adopted by reference.

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

8:21–4.5 General provisions; new drug applications

(a) 21 C.F.R. 314.1 (Applications), 21 C.F.R. 314.60 (Amended applications), 21 C.F.R. 314.65 (Withdrawal of applications without prejudice), 21 C.F.R. 314.70 (Supplemental applications), 21 C.F.R. 314.90 (Insufficient information in application), 21 C.F.R. 314.105 (New drug application approvals; notification to applicant of approval of application; availability of information), 21 C.F.R. 314.420 (Master files), 21 C.F.R. 314.12 (Untrue statements in application), 21 C.F.R. 314.104 (New drugs with potential for abuse) and 21 C.F.R. 314.140 (Confidentiality of data and information in a new drug application, NDA, file) are hereby adopted by reference.

(b) Regarding subpart B (Administrative actions on applications), 21 C.F.R. 314.102 (Comment on application), 21 C.F.R. 314.125 (Reasons for refusing to file applications), 21 C.F.R. 314.125 (Reasons for refusing to file applications), 21 C.F.R. 314.120 (Refusal to approve the application), 21 C.F.R. 314.150 (Withdrawal of approval of an application), 21 C.F.R. 314.152 (Notice of withdrawal of approval of application), 21 C.F.R. 314.160 (Revocation of order refusing to approve application, or suspending or withdrawing approval of an application), and 21 C.F.R. 314.162 (Notices and orders) are hereby adopted by reference.

(c) Full text of Federal regulations pertaining to new drugs, incorporated herein by reference, may be found in sections 310, 312 and 314 of 21 C.F.R., parts 300 through 499, revised as of April 11, 1989 and may be purchased from:

Superintendent of Documents
United States Government Printing Office

Washington, D.C. 20402
Price—$28.00 per copy.

(d) The complete text of those sections adopted by the Department may be reviewed in the:

Office of Drug Control
Alcoholism and Drug Abuse
New Jersey Department of Health
CN 362 (129 East Hanover Street)
Trenton, New Jersey 08625–0362

Amended by R.1987 d.226, effective May 18, 1987.
See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).
21 C.F.R. numbers changed; price raised from $5.00 to $25.00 and address changed.
Correction: Text was omitted from (a) "notification to applicant of approval of application".
See: 19 N.J.R. 1342(b).
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.

8:21–4.6 through 8:21–4.24 (Reserved)

8:21–4.25 Amygdalin (Laetrile); generally

Amygdalin, also known as Laetrile or vitamin B–17, pursuant to the provisions of N.J.S.A. 24:6F–4 has been deemed to be a substance subject to the provisions of N.J.S.A. 24:6A–1 et seq.

8:21–4.26 Amygdalin; testing

(a) As a substance subject to a new drug application (FD form 356H), amygdalin, also known as Laetrile or vitamin B–17, shall not be available for testing on humans until such time as the sponsor identified in FD form 356H provides to the department the information specified in a "Notice of Claimed Investigational Exemption for a New Drug" (form FD 1571, 1572 and 1573), known as an IND. Copies of these IND forms may be obtained from:

Office of Drug Control
Alcoholism and Drug Abuse
New Jersey Department of Health
CN 362 (129 E. Hanover Street)
Trenton, New Jersey 08625–0362

Amended by R.1987 d.227, effective May 18, 1987.
See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).
Address change.
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.

8:21–4.27 Amygdalin; subject to other administrative rules

Amygdalin, also known as Laetrile or vitamin B–17, shall be subject to the provisions of N.J.A.C. 8:21–4.1 et seq.

8:21–4.28 Use and distribution of amygdalin; forms

(a) In addition to the requirements of N.J.A.C. 8:21–4.1 et seq., an investigator shall have completed or have caused to be completed, by the patient or person signing for the patient, a form DDC–L5, "Written Informed Request for Prescription of Amygdalin (Laetrile) for Medical Treatment".

(b) Distribution and filing of form DDC–L5 shall be in accordance with instructions which accompany the form.

(c) Copies required to be filed with the department shall be received by the department on or before the seventh day following the date as attested to, and signed by the prescribing physician.

8:21–4.29 Failure to comply with provisions

Failure to comply with the provisions of N.J.A.C. 8:21–4.28 may require the department to request the sponsor to withhold or withdraw approval of the investigator to continue the clinical investigation of amygdalin.

8:21–4.30 Use of amygdalin; treatment of cancer

(a) Additional clinical investigations, records, reports and any other clinical data relating to the efficacy of the use of amygdalin in the treatment of cancer shall be required of the sponsor where amygdalin is used as a primary treatment of cancer, or as an adjunct to or in conjunction with other modalities of treatment of cancer.

(b) Such information shall be in the form and manner as shall be required by the department.

8:21–4.31 Filing of affidavit

Any physician who makes or witnesses an affidavit which authorizes the importation of Amygdalin, Laetrile or Vitamin B–17 (hereinafter Laetrile) for any person or who prescribes Laetrile for any person shall immediately file with the Office of Drug Control in the Department of Health at CN 362, Trenton, New Jersey 08625–0362, a copy of the "Written Informed Request for Prescription of Amygdalin (Laetrile) for Medical Treatment" established by N.J.S.A. 24:6F–1. Forms may be obtained at no cost from the Department of Health.

R.1978 d.246, effective July 24, 1978.
See: 10 N.J.R. 238(b), 10 N.J.R. 341(a).
As amended, R.1979 d.299, effective August 6, 1979.
See: 11 N.J.R. 327(b), 11 N.J.R. 440(c).
Amended by R.1987 d.227, effective May 18, 1987.
See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).
Address change.

8:21–4.32 Written orders; prescriptions; dispensing

(a) Any prescription or order which authorizes the dispensing or administration of Laetrile to any person shall be written and shall contain the following information: the name and address of the prescriber; the prescriber's professional license number; the name, address, age and sex of the person for whom the drug is being prescribed; the name of the drug; the name and address of the manufacturer of the drug; the strength of the drug; full directions for its use, including the number and type of dosage forms to be dispensed or administered; the date the prescription or order is issued, and the written signature of the prescriber.

(b) Laetrile is dispensed by other than the prescriber, it shall be dispensed in a container to which a label shall be affixed containing all of the information required in the written order or prescription except for the written signature of the prescriber and shall in addition contain the supplier's name, address and license number.

(c) Any physician who prescribes or orders the administration or dispensing of Laetrile shall file with the Office of Drug Control in the Department of Health at CN 362, Trenton, New Jersey 08625–0362, a clear copy of the order as described in (a) above.

R.1978 d.246, effective July 24, 1978.
See: 10 N.J.R. 238(b), 10 N.J.R. 341(a).
As amended, R.1979 d.299, effective August 6, 1979.
See: 11 N.J.R. 327(b), 11 N.J.R. 440(c).
Amended by R.1987 d.227, effective May 18, 1987.
See: 18 N.J.R. 2363(a), 19 N.J.R. 873(a).
Address change.

8:21–4.33 Patient's medical history

Any physician who makes or witnesses an affidavit which authorizes the importation of Laetrile for any person, who prescribes Laetrile for any person, or who treats any person for whom Laetrile has been authorized or prescribed, shall maintain a complete record of his treatment of any such person, including but not limited to the results of physical examination and laboratory studies, and make same available to the Department upon presentation of a medical records release completed by the individual whose records are involved.

R.1978 d.246, effective July 24, 1978.
See: 10 N.J.R. 238(b), 10 N.J.R. 341(a).
As amended, R.1979 d.299, effective August 6, 1979.
See: 11 N.J.R. 327(b), 11 N.J.R. 440(c).

8:21–4.34 Information; confidentiality

(a) The Epidemiology Program within the Department of Health shall use the information supplied to the Department in accordance with the provisions of N.J.A.C. 8:21–4.31 through N.J.A.C. 8:21–4.34 to implement its study of the efficacy of Laetrile in cancer therapy, providing the protocol for any such study is first approved by the New Jersey Public Health Council.

(b) All information supplied to the Department of Health in accordance with the provisions of N.J.A.C. 8:21–4.31 through N.J.A.C. 8:21–4.34 or voluntarily made available to the Department in the course of its efforts to study the efficacy of Laetrile, including the names or physicians who make or witness affidavits which authorize the importation of Laetrile or who prescribe, dispense or administer Laetrile, shall be kept in the confidence of the Department.

(c) The information supplied to the Department of Health in accordance with the provisions of N.J.A.C. 8:21–4.31 through N.J.A.C. 8:21–4.34 shall not be revealed or disclosed in any manner or under any circumstances by any person connected with such research by the Department or any person therein without the consent of the individual for whom the laetrile has been authorized or prescribed and to whom the information pertains except:

1. To persons within the Department; or

2. To other persons participating in such research studies; or

3. To other appropriate law enforcement agencies; or

4. In such impersonal form that the individual to whom the information or data relates cannot be identified therefrom.

R.1978 d.246, eff. July 24, 1978.
See: 10 N.J.R. 238(b), 10 N.J.R. 341(a).
As amended, R.1979 d.299, eff. August 6, 1979.
See: 11 N.J.R. 327(b), 11 N.J.R. 440(c).

8:21–4.35 through 8:21–4.49 (Reserved)

8:21–4.50 Approved new drugs

(a) Amygdalin, also known as Laetrile or vitamin B–17, which has complied with the provisions of N.J.S.A. 24:6A–1 et seq. and N.J.A.C. 8:21–4.1 et seq. and N.J.A.C. 8:21–4.25 et seq., and said new drug application has been approved by the New Jersey Department of Health, shall be prohibited for use pursuant to N.J.S.A. 24:6F–5, unless such substance is prescribed by a physician on the form set out in N.J.S.A. 24:6F–1.

(b) All copies of the required form DDC–L5 shall be filed pursuant to the provisions of N.J.A.C. 8:21–4.28.

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

Authority

N.J.S.A. 24:2–1, 24:10–57.20, 24:10–57.24(b), 24:10–73.1 and 24:12–12.

Source and Effective Date

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

Subchapter Historical Note

Revisions, which deleted the text of this subchapter, were filed and became effective on October 22, 1975, as R.1975 d.320. See: 7 N.J.R. 153(b), 7 N.J.R. 473(a).

8:21–5.1 Separability

If any provision or application of any provision of this subchapter is held invalid, that invalidity shall not affect other provisions or applications of this subchapter.

8:21–5.2 Definitions

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

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practices.

"Adulteration" means the term "adulteration" as defined in N.J.S.A. 24:5–8.

"Approved" means acceptable to the Department, local health authority, or other appropriate administrative agency based on its determination as to the conformance with applicable standards and good public health practices.

"Approved source" means the source of water from a spring, artesian well, drilled well, municipal water supply, or any other source which has been evaluated and found to be of satisfactory sanitary quality as determined by the governmental regulatory agency having primary jurisdiction for that source.

"Aquifer" means a water bearing stratum used as a source of potable water supply.

"Artesian well water" means water that comes from a deep well where water is forced up by underground pressure.

"Bottled water" means all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water.

"Bulk water" means water intended for potable uses which is transported by means of tank trucks.

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

"CFR" means the Code of Federal Regulations.

"Department/State Department" means the New Jersey State Department of Health.

"Drilled well" means a system whereby water is taken from below the ground through a pipe or piping system or similar installed device utilizing external force or vacuum.

"Expiration date" means the date established by N.J.S.A. 24:12–2 as two years from the date the product was bottled.

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

"Lot" means a collection of primary containers or units of the same size, type, and style containing a finished product produced under conditions as nearly uniform as possible and designated by a common container, code or marking; and, in any event, "lot" means no more than one day's production.

"Misbranded" means the term "misbranded" as defined in N.J.S.A. 24:5–16 and 17.

"Multi-use containers" means containers intended for use more than one time.

"Nontoxic materials" means materials for product water contact surfaces utilized in the transporting, processing, storing, or packaging of bottled drinking water which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor or bacteriological quality of the water.

"Operations water" means water which is delivered under pressure to a plant for container washing, hand washing, plant and equipment clean up and for other sanitary purposes.

"Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, storage, processing, packaging, labeling or handling of bottled water.

"Product contact surfaces" means those surfaces that contact product and those surfaces from which drainage onto product or onto surfaces that contact product ordinarily occurs during the normal course of operations.

"Product water" means processed water used by a plant for bottled drinking water.

"Sanitize" means adequate treatment of surfaces by a process that is effective in destroying the vegetative cell of microorganisms of public health significance and in substantially reducing numbers of other microorganisms.

"Source water" means water from a spring, artesian well, drilled well, community water supply or any other approved source which is used for or in connection with bottled water.

"Spring" means water that is taken from a natural orifice in the ground without external force or vacuum. It may be collected from the natural orifice and transported by pipes, tunnels, or similar devices.

"Spring house" means a structure approved by the Department that is constructed over a spring so as to provide complete protection for the source from all types of external sources of contamination.

"Total Trihalomethanes (TTHM)" means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane dibromochloromethane, bromochloromethane, bromodichloromethane and tribromomethane).

"Water hauler" means any person who causes bulk water to be transported for bottling for human consumption or other consumer uses from the source to the bottling plant.

8:21–5.3 Water source protection

(a) The source water supply for bottled water shall be from an approved source which is properly located, protected, and operated and shall be easily accessible, adequate, and of safe, sanitary quality. The water quality and sampling frequency shall be in conformance at all times with the applicable laws and rules and regulations of the Department or other governmental agencies having jurisdiction. Examples of source water supplies which may be used for bottled water upon approval by the Department are as follows:

1. Approved public community water systems;

2. Drilled and driven wells when constructed and protected in accordance with applicable standards set forth in N.J.A.C. 7:10–12, Standards for the Construction of Public Non-community and Non-public Water Systems; and

3. Springs inspected for development as a water source and constructed in accordance with the applicable standards established by the Department of Environmental Protection and set forth in N.J.A.C. 7:10–12.24, Standards for the Construction of Public Non–Community and Non–Public Water Systems (springs) and shall meet the standards for springs set forth under N.J.A.C. 8:21–5.4.

8:21–5.4 Springs

(a) The spring shall be properly protected from the entry of insects, birds, rodents and other vermin.

(b) Adequate ventilation shall be provided.

(c) Sufficient protection shall be provided at the intake end of the draw pipe to prevent the introduction of stone, gravel, sand and other particulate matter.

(d) The overflow shall be free-flowing and shall be constructed in a manner to prevent flooding of the springhouse and surrounding area.

(e) The minimum distance from a spring to a building sewer line, septic tank, and a distribution box shall be 50 feet. The minimum distance from a spring to a disposal field or seepage pit shall be 100 feet.

(f) Plumbing shall be sized, installed and maintained in accordance with applicable State and local standards. Also, plumbing shall be properly designed and protected from contamination and damage.

(g) Walls and ceilings shall be smooth, easily cleanable, free of cracks and crevices and constructed of materials that are not adversely affected by moisture, algae, or mold.

(h) Proper cleaning and sanitization equipment and facilities shall be available and used whenever a spring is damaged, repaired and/or contaminated.

8:21–5.5 Bottled water labeling requirements

(a) The type of source water shall be clearly and prominently identified on the principal display panel as defined under 21 CFR 101.1 according to the following criteria. Additional types of bottled water may be distributed by petitioning the Department to establish additional standards of identity. A product meeting more than one standard of identity is permitted to be identified by any of the applicable product names, for example, demineralized drinking water. Commingling different source water supplies as specified in N.J.A.C. 8:21–5.3 is prohibited.

1. For "artificially carbonated water," the source of the carbon dioxide gas being used for carbonation of the water shall not come naturally from the same source the water being bottled or packaged was obtained.

2. "Demineralized water," "distilled water," or "purified water" means water which has been treated by deionization, distillation, reverse osmosis, or other approved processes and contains no more than 10 parts per million total dissolved solids.

3. "Drinking water" means water which is derived from either approved public community or public non-community water systems.

4. "Mineral water" means water containing at least 500 parts per million of naturally impregnated mineral solids which is derived from an underground source.

5. "Naturally carbonated" or "naturally sparkling water" means any water which contains carbon dioxide as it emerges from the source and is bottled directly with its entrapped gas, or, the carbon dioxide is mechanically separated from the water and later reintroduced into the water at time of bottling.

6. "Spring water" means water which is derived from an approved spring, that is a gravity spring, artesian spring, seepage spring, tubular spring, or fissure spring.

7. "Well water" means water which is derived from either an approved driven or a drilled well.

(b) The principal display panel as defined under 21 CFR 101.1 shall bear a statement indicating the specific location at which the water was obtained, including the municipality, state, and country, if not the United States. If the water source is a public community water system, the label shall state "public water supply." If more than one water source is used in the final product, the label shall clearly state the locations of all sources used.

(c) Sodium labeling shall be in accordance with 21 CFR 101.9, 21 CFR 101.13, and 21 CFR 105.69. Mineral water and mineralized water labeling requirements shall include a declaration of the total sodium content stated in milligrams per eight fluid ounce serving.

(d) Each container of bottled water shall contain on its principal display panel or informational panel as defined under 21 CFR 101.1 and 101.2 an expiration date of two years from the date the water was bottled. Bottled water can no longer be offered for sale, distributed, or given to the public for consumption after the expiration date.

(e) If a bottled water exceeds any of the chemical standards as set forth in the tables listed under N.J.A.C. 8:21–5.12, such water shall be labeled as outlined in that section.

(f) Label claims of medicinal or health-giving properties are prohibited. In addition, references to bacteriological purity or laboratory examination which may have been made by a governmental agency are also prohibited.

(g) Products which are not in conformance with the above referenced bottled drinking water labeling requirements shall be deemed misbranded within the meaning of N.J.S.A. 24:5–16 and 17.

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

(a) The grounds surrounding the plant shall be kept in a condition that will not cause the bottled water to be contaminated and/or adulterated.

1. Equipment storage, litter, waste, and excessive weeds or grass within the immediate vicinity of the plant buildings or structures shall not constitute an attractant, breeding place or harborage for rodents, insects or other pests.

2. Roads, yards, and other parking lots shall be maintained so that they do not constitute a source of contamination to the bottled water.

3. Areas surrounding the plant shall be properly drained in order to prevent contamination of the bottled water by seepage, by foot-borne filth, or by providing a breeding place for rodents, insects or other pests.

(b) Plant buildings shall be of suitable size, construction, and design to facilitate maintenance and sanitary operations for processing purposes.

1. The bottle filling operations shall be separated from the balance of plant operations and storage areas by tight walls, ceilings, and self-closing doors or other appropriate barriers. No loading or unloading of trucks or other vehicles shall take place within an establishment unless acceptable segregation or isolation is accomplished.

2. Sufficient space shall be provided for such placement of equipment and storage of materials as is necessary for sanitary operations.

3. The plant shall be designed to reduce the potential for contamination of end products, raw materials, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by any effective means including the separation by location, partition, air flow, enclosed systems or other effective means, of the plant operations to include receiving; raw material storage; processing operations; packaging and packing; finished product storage and shipping; portable equipment and utensil cleaning and sanitizing; and equipment and vehicle maintenance.

4. Floors, walls, and ceilings shall be constructed to be easily cleanable and shall be kept clean and in good repair. Fixtures, ducts, pipes shall be installed in such a manner that drip or condensation does not contaminate the bottled water, raw materials, or product contact surfaces. Aisles or walking spaces between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of the bottled water or product contact surfaces.

i. Floors, walls, and ceilings in the bottling room(s) shall be constructed of smooth, nonabsorbing, easily cleanable, light colored surface material and maintained in a clean and sanitary condition at all times.

ii. The floors in the bottling rooms shall be adequately drained in order to prevent pooling of water and to facilitate cleaning procedures. In addition, drain lines from equipment shall not discharge wastewater or product in such a manner as will permit flooding of floors or the flowing of water across working or walking areas or in difficult to clean areas or otherwise create a nuisance. Wastewater disposal shall be provided and have a discharge to a municipal wastewater system or an approved individual wastewater disposal system.

5. Adequate lighting shall be provided throughout the plant to facilitate cleaning and inspection procedures.

i. At least 30 foot candles of light shall be provided in the processing, bottling, equipment, and utensil washing areas. All other areas shall have a minimum

of 10 foot candles of light at a distance of 30 inches from the floor surfaces.

ii. Light fixtures which are located in processing, equipment/utensil washing areas or other areas where bottled drinking water may be exposed shall be of the safety type, or otherwise protected to prevent contamination/adulteration in case of breakage.

6. Ventilation in every room of a plant or facility shall be adequate to minimize condensation, odors, vapors, noxious fumes, dust, and other potential airborne contaminants.

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

1. No vermin or animal shall be permitted in the areas of a bottled water plant.

2. Effective measures shall be taken to exclude pests from processing areas and to protect against the contamination of the bottled water products.

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

(d) The establishment shall be provided with adequate sanitary facilities and control measures to protect the purity and quality, of the bottled water. Facilities and controls shall include, but not be limited to:

1. The water supply shall be adequate as to quantity, of a safe, sanitary quality, and from a public or private 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., 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 the above referenced regulations and the nonpotable water supply is not used in such a manner as to bring it into contact, either directly or indirectly, with water processing or handling equipment.

i. Hot and cold running water, under sufficient pressure, shall be provided in all areas where bottled drinking water is processed and filled and where equipment, utensils, or containers are washed.

2. All plumbing shall be sized, installed and maintained in accordance with N.J.A.C. 5:23, New Jersey Uniform Construction Code and shall:

i. Carry adequate quantities of water to required locations throughout the establishment;

ii. Prevent contamination of the water supply;

iii. Properly convey sewage and liquid wastes from the establishment to the sewer or sewage disposal system; and

iv. Not constitute a source of contamination of water, equipment or utensils, or create an unsanitary condition or nuisance.

3. Nonpotable water shall not be connected to water related equipment or have outlets in the water processing areas. The potable water supply piping shall not be directly connected with any nonpotable water supply system whereby the nonpotable water can be drawn or discharged into the potable water supply system, provided, that an exception would be an approved physical connection conforming to N.J.A.C. 7:10–10, Safe Drinking Water regulations. The piping of any nonpotable system shall be adequately and durably identified, such as by a distinctive yellow colored paint, so that it can be readily distinguished from piping which carries potable water; and such piping shall not be connected to equipment or have outlets in the processing and bottling area.

4. All sewage and waste water shall be disposed of by means of:

i. A public sewerage system; or

ii. A disposal system which is constructed and operated in conformance with N.J.A.C. 7:9–2, Standards for the Construction of Individual Subsurface Sewage Disposal Systems, the New Jersey Water Pollution Control Act Regulations, N.J.A.C. 7:14, and local laws, ordinances, and regulations.

5. Each plant shall be provided with adequate, conveniently located toilet facilities accessible to the employees at all times.

i. Toilet facilities and dressing rooms, when provided, shall be installed in accordance with N.J.A.C. 5:23, New Jersey Uniform Construction Code.

ii. Doors to toilet rooms and dressing facilities shall be self-closing and shall not open directly into areas where product is exposed to airborne contamination, except where alternate means have been taken to prevent such contamination.

iii. Toilet facilities and dressing rooms, including toilet rooms and fixtures, shall be kept clean and in good repair and free from objectionable odors.

iv. A supply of toilet tissue shall be provided at each toilet at all times.

v. Handwashing signs stating "Wash Hands Before Resuming Work" shall be posted conspicuously in all toilet rooms and at each separate lavatory facility in a bottling plant.

vi. Easily cleanable receptacles shall be provided for waste materials and such receptacles in toilet rooms for women shall be covered. Such receptacles shall be emptied at least once a day, and more frequently when necessary, to prevent excessive accumulation of waste material.

vii. Hot or cold or tempered (90 degrees to 105 degrees Fahrenheit) water under pressure shall be provided in toilet facilities.

6. Lavatories shall be adequate in size and number and shall be so located as to permit convenient and expeditious use by all employees.

i. Lavatories shall be installed in accordance with N.J.A.C. 5:23, New Jersey Uniform Construction Code.

ii. Each lavatory shall be designed to provide hot and cold or tempered (90 degrees to 105 degrees Fahrenheit) running water.

iii. An adequate supply of hand cleansing soap, detergent, or other sanitizing solution shall be available at each lavatory. Also, an adequate supply of sanitary towels, or an approved drying device, shall be available and conveniently located near the lavatory. Common towels are prohibited. Where disposable towels are used, waste receptacles shall be located conveniently near the handwashing facilities.

iv. Lavatories, soap dispensers, hand drying devices, and all other components of the handwashing facilities shall be kept clean and in good repair.

8:21–5.7 Production, equipment, and packaging requirements

(a) All bottled water production, including transporting, packaging, and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxic formations, deterioration or contamination of the processed product, production equipment, and product packaging materials and shall be in conformance with 21 CFR 129.1, 129.20, 129.30, 129.35, 129.37, 129.40, and 129.80, incorporated herein by reference.

(b) All water that is bottled shall receive a final disinfectant treatment that ensures a minimum 0.1 milligram per liter ozone residual or utilize other effective microbial control procedures at time of packaging. Test kits or other appropriate equipment shall be used to measure the disinfectant residual at least daily, or more frequently, if deemed appropriate by the Department.

(c) Water storage tanks shall be designed to exclude all foreign matter and all ports, hatches, and other openings shall be provided with tight fitting covers and shall be vented only through the use of inverted air filters or other approved venting device(s).

(d) Product water pipelines shall be constructed with seams and pipe connections that are smoothly bonded or connected to minimize the accumulation of scale residue or other contaminants.

1. Pipe connections shall be constructed for easy breakdown for inspection and cleaning.

2. Transport pipelines charging the storage tanks and transporting water to the filling lines shall be used only for bottled water products.

(e) All treatment and processing of bottled drinking water by distillation, ion-exchange, filtration, reverse osmosis, mineral addition, and ultraviolet treatment or any other process shall be done in a manner so as to be effective in accomplishing its intended purpose and in conformance with Section 409 of the Federal Food, Drug, and Cosmetic Act.

(f) Filling and closing of bottled water containers shall be done in a sanitary manner by approved mechanical filling and capping equipment, provided that other sanitary methods may be approved by the Department.

1. Fillers shall have a charging inlet designed as to prevent the entrance of condensation and contaminants. All filling valves shall be equipped with a condensation diverting apron.

2. All closure hoppers and product reservoirs or filling machines along with any other type of hopper or conveying system used in the production and filling of bottled water products shall be equipped with covers. These covers shall adequately protect closures and bottled water from dust, dirt, and other contaminants and shall be used at all times during and after operations.

3. Fillers and other processing, filling and capping equipment used in the production of bottled drinking water shall be constructed of smooth, impervious, corrosion resistant nontoxic materials. All fillers shall be constructed for ease of cleaning and kept in good repair.

4. Fillers, filling line piping, pumps, and other processing, filling, and capping equipment used in the production of bottled water may not be used for the production of milk, fruit drinks, and/or any other food products, unless adequate written washing and sanitizing procedures have been established and followed that will prevent microbiological contamination or adulteration of the bottled water. Non-food products shall not be processed, filled, and/or capped on lines used for bottling water products.

5. Only sanitary, nontoxic, food grade lubricants shall be used on container contact surfaces.

(g) Containers and closures for bottled water shall conform to the requirements of 21 CFR 177, incorporated herein by reference.

1. All cleaned bottled water containers and single service containers shall be protected from dust, dirt, insects, debris, and all other forms of contamination while in storage or during the production, filling and capping operations.

2. All closures (screw, snap, or crown caps) shall be new. These closures, while in storage, shall be covered and protected from contamination and/or adulteration at all times.

8:21–5.8 Sanitation and maintenance requirements

(a) All tanks, pipelines, and equipment used to store and transport water shall be inspected, maintained, cleaned, and sanitized. Sanitizing shall be accomplished by one of the following methods followed by a product water flush.

1. Chemical sanitizer shall be equivalent to a chlorine water solution of 50 parts per million for a minimum of two minutes at a temperature of 75 degrees Fahrenheit.

i. If surfaces cannot be reached by the aforementioned soaking treatment, surfaces shall be sprayed with 100 parts per million chlorine water solution at 75 degrees Fahrenheit.

ii. Other chemical sanitizers of equivalent concentration may be used provided they meet the equivalent concentrations as outlined in this subsection.

iii. Steam sanitization in an enclosed system of at least 170 degrees Fahrenheit for at least 15 minutes or 200 degrees Fahrenheit for five minutes.

iv. Hot water in an enclosed system of at least 170 degrees Fahrenheit for at least 15 minutes or at 200 degrees Fahrenheit for at least five minutes.

v. 0.1 parts per million ozone water solution for not less than a five minute contact time period.

(b) The following additional requirements shall apply to the cleaning, sanitizing, and monitoring of equipment.

1. Storage tanks shall be inspected on a monthly basis and shall be kept free of scale, evidence of oxidation, and residue.

i. Tank seams in contact with product water shall be smoothly bonded and maintained to minimize accumulation of possible contaminants.

ii. Tanks shall be cleaned and sanitized before use except that tanks that are used in a continuous production operation shall be cleaned and sanitized on a predetermined schedule with a minimum treatment of at least once a month.

2. Product water pipelines shall be kept free of scale, evidence of oxidation, and residue.

i. Product water pipelines shall be cleaned and sanitized before and after use and sanitizing shall be accomplished according to procedures outlined in this section.

3. Processing equipment, to include water treatment systems, shall be cleaned and sanitized in a manner and at a frequency so as to be effective in accomplishing its intended purpose(s). Cleaned and sanitized equipment and utensils when not in use shall be stored in a location and in a manner that protects product contact surfaces from splash, dust, dirt, and any other type of possible contamination.

i. Water treatment equipment to include ozone mixing tanks and equipment, soft water tanks, and all associated equipment shall be inspected on a monthly basis, disassembled, if necessary; cleaned; and sanitized.

ii. Bottle washing equipment shall be kept free of paper residue and substances which may interfere with the proper operation of the water or air jets. Internal sprays shall be checked on a daily basis to assure proper timing and adequate dispersion of the washing medium to properly clean the containers.

iii. Fillers shall be kept free from scale, evidence of oxidation and residue, and shall be sanitized before and immediately after use.

(1) The filler reservoir shall be kept adequately covered at all times.

(2) Filling and capping operations shall be conducted as to prevent contamination of the water being bottled.

iv. Cappers shall be kept free of residue and washed, rinsed, and sanitized before and after use.

(1) Capper hoppers shall be kept adequately covered to protect the closures from dust, dirt, and other contaminants and shall be emptied when not in use.

(2) Hopper surfaces in contact with product container closures shall be kept free of residue and sanitized before and after use.

8:21–5.9 Storage and handling of chemicals

(a) The following requirements shall apply to the storage and handling of chemicals:

1. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended use.

2. Only toxic materials that are required to maintain sanitary conditions in laboratory testing procedures, for plant and equipment maintenance and operations or in manufacturing or processing operations shall be used and stored in the facility.

3. Poisonous or dangerous cleaning compounds, sanitizing agents, and pest control chemicals shall be applied, stored, and held in a manner that prevents the raw water, bottled water, or water packaging materials and equipment from being contaminated.

4. These materials shall be identified and used only in the manner and under the conditions that will be safe for their intended use.

8:21–5.10 Personnel requirements

(a) All persons, while working in the processing and bottling of water, shall conform to good hygienic practices while those persons are on duty, to the extent necessary to prevent contamination of bottled water. The methods for maintaining cleanliness shall include, but are not limited to:

1. Wearing clean outer garments;

2. Maintaining a high degree of personal cleanliness;

3. Washing hands and exposed arms thoroughly with soap and warm water before starting work, after each absence from work station, after smoking, eating, drinking, or visiting the toilet room and at any other time when the hands may have become soiled or contaminated;

4. Removing all insecure jewelry and during periods in which the latter is manipulated by hand, removing from hands any jewelry that cannot be adequately sanitized;

5. If gloves are used in water bottling operations, they shall be maintained in a clean and sanitary condition;

6. Wearing hair nets, headbands, caps, beard covers, or other effective hair restraints in an effective manner;

7. No storing of clothing or other personal belongings in bottled water processing areas or in areas used for washing equipment or utensils;

8. No eating of food, drinking of beverages, expectorating, or using tobacco in areas where water is being processed or bottled or in areas used for washing of equipment or utensils; and

9. Taking any other necessary precautions to prevent contamination of bottled water with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines.

(b) No person shall be allowed to live or sleep in any room where bottled water is produced, manufactured, packed, stored, bottled, distributed, or sold.

(c) No person affected by disease in a communicable form or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall knowingly be permitted to work in a bottled water plant in any capacity in which there is a reasonable possibility of finished product water becoming contaminated by such person, or of disease being transmitted by such persons or other individuals.

8:21–5.11 Sanitizing requirements for multi-use bottles or containers

(a) Mechanical bottle washers shall be provided when multi-use containers are used. In addition, mechanical washers shall be designed and maintained to thoroughly wash and sanitize all surfaces of containers prior to filling.

(b) Multi-use bottles shall be checked prior to washing by a method acceptable to the Department to assure that containers that may have been used for other purposes are not reused for bottled water. Such containers shall be rendered unusable for rebottling.

(c) Before filling, all multi-use containers shall be thoroughly washed in an effective cleansing agent and water solution, having a temperature not less than 120 degrees Fahrenheit, followed by application of a bactericidal solution, and the inside rinsed with product water to remove traces of sanitizing agents.

(d) The bactericidal procedure as a minimum, shall be one of the following:

1. Sanitize with 100 parts per million chlorine water solution at 75 degrees Fahrenheit for not less than 30 seconds;

2. Sanitize with a 2½ percent caustic solution at a minimum temperature of 120 degrees Fahrenheit followed by a rinse containing not less than 10 parts per million free chlorine. (Note: When caustic is discharged by means of high-velocity jets, this procedure shall be considered to satisfy both cleaning and bactericidal requirements);

3. Sanitize with water at an inside bottle temperature not less than 170 degrees Fahrenheit for not less than 15 seconds;

4. Sanitize by exposing all surfaces to a three percent caustic solution at a minimum temperature of 120 degrees Fahrenheit for five minutes by means of automatic bottle washers utilizing high-velocity jets (hydro type) or by means of soaker washers, followed by a rinse containing not less than 10 parts per million free chlorine;

5. As an alternative to the use of a caustic alkali solution, multi-use containers may be cleaned and sanitized prior to refilling by the use of an alkaline detergent cleaner containing a minimum of 0.35 percent active alkalinity at a minimum temperature of 130 degrees Fahrenheit for not less than one minute (if high velocity jets are used), or for not less than three minutes (if a soaker type washer is used), followed by a rinse of at least one minute with a sanitizing solution containing at least 25 parts per million chlorine or 10 parts per million iodine. All bottles and carboys shall be rinsed until free of any detergent or sanitizing solution residue with product water; or

6. Other methods equally protective of public health as the above, when approved by the Department, may be used.

(e) Only sanitizers listed in 21 CFR 178.1010 shall be acceptable.

8:21–5.12 Bulk water requirements

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

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

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

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

1. Storage tanks and tank trucks shall be free of deep pits, excessive scale, dents or poorly welded seams which may tend to hold standing water;

2. Inlets, outlets, piping hose and other appurtenances associated with storage tanks and tank trucks shall be constructed and handled to prevent contamination of product water;

3. All tank trucks shall be tagged identifying the time and place of cleaning and sanitization. These records shall be available at all times for inspection by the regulatory authority; and

4. All hoses, connections and fittings used in conjunction with the coupling of the tank truck to the bulk water delivery line shall be sanitized with 100 parts per million chlorine solution at 75 degrees Fahrenheit or any other approved sanitizer of equivalent concentration. The solution shall be brushed on all exposed parts to assure proper sanitization.

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

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

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

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

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

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

8:21–5.13 Recordkeeping requirements

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

1. Source, type, and volume of water processed daily; and

2. Records indicating the physical inspection of bulk water delivered.

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

1. The amount bottled;

2. Dates of bottling; and

3. Expiration date.

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

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

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

8:21–5.14 Water standards and sampling requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 1

MICROBIOLOGICAL STANDARDS FOR BOTTLED WATER

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

TABLE 2

PHYSICAL REQUIREMENTS FOR BOTTLED WATER

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

TABLE 3

CHEMICAL STANDARDS FOR BOTTLED WATER

Determination	Maximum Contaminant Level
Arsenic	0.05 mg/l
Barium	1.0 mg/l
Cadmium	0.01 mg/l
Chloride	250.05 mg/l
Chromium	0.05 mg/l
Copper	1.0 mg/l
Fluoride	2.2 mg/l
Iron	0.3 mg/l
Lead	0.05 mg/l
Manganese	0.05 mg/l
Mercury	0.002 mg/l
Nitrate	10.0 mg/l
Selenium	0.01 mg/l
Silver	0.05 mg/l
Sulfate	250.0 mg/l
Total dissolved solids	500.0 mg/l
Zinc	5.0 mg/l
ABS/LAS (foaming agents)	0.5 mg/l
Total Trihalomethanes	0.1 mg/l
ph	+ 6.5 to 8.5 units
Sodium	+ + mg/l

+ Recommended range. (Not applicable to distilled or purified water.)
+ + Maximum contaminant levels have not been established.
mg/l = milligrams per liter

TABLE 4

ORGANIC CHEMICAL STANDARDS FOR BOTTLED WATER

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

mg/l = milligrams per liter

TABLE 5

RADIOLOGICAL STANDARDS FOR BOTTLED WATER

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

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

TABLE 6

STANDARDS FOR SELECTED HAZARDOUS CONTAMINANTS IN BOTTLED WATER

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

ug/l = micrograms per liter

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUBCHAPTER 6. (RESERVED)

Historical Note

The provisions of this subchapter were adopted pursuant to N.J.S.A. 26:1A–7 and became effective prior to September 1, 1969. An adoption substantially amending pre-existing text became effective September 18, 1980 as R.1980 d.403. See: 12 N.J.R. 181(d), 12 N.J.R. 579(d). This subchapter expired September 18, 1985.

SUBCHAPTER 7. FROZEN DESSERTS

8:21–7.1 Definitions

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

"CFR" means the Code of Federal Regulations of the United States Government.

"Department" means the 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."

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; Roese–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 removal 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 liquers 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 ug 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, Roese–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.

(b) A separate license shall be obtained for each wholesale food and cosmetic establishment operated within the State.

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).
Provision for wholesale establishment added.

8:21–9.3 Exemptions

(a) The following establishments shall be exempt from the licensing provisions of P.L. 1971, c.158, but shall comply with all other provisions of Chapter 15, Title 24, N.J.S.A., and all pertinent rules and regulations enforced by the Department:

1. Retail food and cosmetic establishments;

2. Establishments subject to licensure under other provisions of Title 24, N.J.S.A.;

3. Establishments inspected and licensed by a local health department;

4. Growers of raw agricultural commodities delivering their produce to food processing establishments.

As amended, R.1974 d.184, eff. July 9, 1974.
See: 6 N.J.R. 232(a), 6 N.J.R. 310(a).

Case Notes

Health officer can inspect and license wholesale food and cosmetic establishments; health officer must be full time public employee; services cannot be outside contracted. State v. Board of Health of Morris Twp., 208 N.J.Super. 415, 506 A.2d 52 (App.Div.1986), appeal dismissed 107 N.J. 50, 526 A.2d 139 (1986).

See Eisler and Co. v. State, 124 N.J. Super. 357, 307 A.2d 113 (App. Div. 1973).

8:21–9.4 License requirement

(a) Every person owning or operating a wholesale food or cosmetic establishment within the State shall apply annually for a license to operate such establishment on forms provided by the department.

(b) The application shall have attached thereto an affidavit of the person or some member or officer of the association, partnership or corporation applying therefor, stating that the facts set forth therein are true and correct.

As amended, R.1978 d.167, eff. May 22, 1978.
See: 10 N.J.R. 147(a), 10 N.J.R. 249(b).
Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Provision for wholesale establishment added.

8:21–9.5 License fees

(a) The Department shall collect from each applicant for a license, under the provisions of these rules, an annual fee in the following amounts:

1. For each wholesale food or cosmetic establishment with a gross annual business not in excess of $100,000, $100.00;

2. For each wholesale food or cosmetic establishment with a gross annual business in excess of $100,000 but not in excess of $500,000, $300.00;

3. For each wholesale food or cosmetic establishment with a gross annual business in excess of $500,000, $500.00.

As amended, R.1983 d.456, effective October 17, 1983.
See: 15 N.J.R. 1317(a), 15 N.J.R. 1762(b).
License fees increased.
Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Fees restructured and lowered.

Case Notes

Fees not applicable to registrant for drug business. Eisler and Co. v. State, 124 N.J.Super. 357, 307 A.2d 113 (App.Div.1973).

8:21–9.6 Expiration of license; nontransferability of license

(a) Upon approval of the application for a license and of the sanitary condition of the food or cosmetic establishment and upon payment of the required license fee, the department shall issue to each applicant a license which shall expire one year from the last day of the month in which the original application is received and yearly thereafter.

(b) Such license shall not be transferable with respect to persons or locations.

As amended, R.1978 d.167, eff. May 27, 1978.
See: 10 N.J.R. 147(a), 10 N.J.R. 249(b).

8:21–9.7 Revocation of license

(a) Upon evidence duly ascertained by the Department or furnished to the Department by any local board of health, that the licensee licensed under the provisions of this Act is violating any of the rules, regulations or statutes as hereinbefore provided, the Department shall upon hearing and proof of allegation, revoke the license of such licensee. The hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(b) No such license shall be renewed or restored until the Department is satisfied that all the provisions of this Act and pertinent rules and regulations are complied with.

(c) The Department, when in its judgment the protection of public health warrants, may, before hearing suspend such license pending the hearing, in which event it shall be unlawful for the licensee whose license is thus suspended to engage in the business for which the license was granted during such period of suspension.

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

SUBCHAPTER 10. DESIGNATED FLUID MILK PRODUCTS

8:21–10.1 Definitions and product standards

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise. The following standards of identity conform to the Code of Federal Regulations for milk and cream (21 CFR 131).

"Acidified Sour Cream":

1. Description. Acidified sour cream results from the souring of pasteurized cream with safe and suitable acidifiers, with or without addition of lactic acid producing bacteria. Acidified sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Acidified sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

2. Optional ingredients.

i. Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

ii. Rennet.

iii. Safe and suitable nutritive sweeteners.

iv. Salt.

v. Flavoring ingredients, with or without safe and suitable coloring, as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Safe and suitable natural and artificial food flavoring.

3. Methods of analysis. Referenced methods in paragraph 3i and ii below are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Titratable acidity—"Acidity—Official Final Action."

4. Nomenclature. The name of the food is "Acidified sour cream." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in section 101.22 of Title 21 CFR. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened."

5. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of Title 21 CFR, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream."

"Acidified sour half-and-half":

1. Description. Acidified sour half-and-half results from the souring of pasteurized half-and-half with safe and suitable acidifiers, and with or without addition of lactic acid producing bacteria. Acidified sour half-and-half contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Acidified sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

2. Optional ingredients.

i. Safe and suitable ingredients to improve texture, prevent syneresis, or extend the shelf life of the product.

ii. Rennet.

iii. Safe and suitable nutritive sweeteners.

iv. Salt.

v. Flavoring ingredients, with or without safe and suitable coloring, as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Safe and suitable natural and artificial food flavoring.

3. Methods of analysis. Referenced methods in 3i and ii below are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Titratable acidity—"Acidity—Official Final Action."

4. Nomenclature. The name of the food is "Acidified sour half-and-half." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in section 101.22 of Title 21 CFR. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened."

5. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of Part 101 of Title 21 CFR, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream."

"And/or" where the term "and/or" is used, "and" shall apply where appropriate, otherwise "or" shall apply.

"Aseptically processed milk and milk products" means products which are hermetically sealed in a container and so thermally processed in conformance with 21 CFR 113 and the provisions of these regulations so as to render the product free of microorganisms capable of reproducing in the product under normal non-refrigeration conditions of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.

"Aseptic processing" means that the product has been subjected to sufficient heat processing, and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR 113 and these regulations and maintain the commercial sterility of the product under normal non-refrigerated conditions.

"Butter" means the food product known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 percent of milkfat, all tolerances having been allowed for.

"Buttermilk" means a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8–1/4 percent of milk solids-not-fat.

"Bulk milk pickup tanker" means a vehicle including the truck, tank and those appurtenances necessary for its use, used by a milk hauler to transport bulk raw milk for pasteurization from a dairy farm to a transfer station, receiving station or milk plant.

"Butter oil" means the clean, wholesome and unadulterated milkfat obtained from milk, cream, or butter, and which contains not less than 99 percent milkfat.

"Certified industry inspector" means an individual certified by the Department to conduct dairy farm inspections of producers shipping to New Jersey permit holders. Such certification shall be in accordance with the procedures established by the Department pursuant to the provisions of the Grade A Pasteurized Milk Ordinance (1989) (PHS–FDA Publication 229).

"CFR" means the Code of Federal Regulations of the United States Government.

"Cheese" shall mean and include those cheeses, processed cheeses, cheese foods, cheese spreads and related food for which definitions and standards of identity have been promulgated under the provisions of the Federal, Drug and Cosmetics Act and shall conform to such definitions and standards of identity as set forth therein.

"Commissioner" shall mean the Commissioner of the State Department of Health or his/her duly appointed agent.

"Concentrated milk and/or fluid milk products" means and includes the fluid milk products resulting from the removal of a considerable portion of the water from the milk and/or fluid milk products which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding product as defined.

"Cream" means the liquid milk product high in fat separated from milk, which may have been adjusted by adding thereto: Milk, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Cream contains not less than 18 percent milkfat.

"Cultured milk":

1. Description. Cultured milk is the food produced by culturing one or more of the optional dairy ingredients specified in 3 below, with characterizing microbial organisms. One or more of the other optional ingredients specified in 2 and 4 below, may also be added. When one or more of the ingredients specified in 4i below are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Cultured milk contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has a titratable acidity of not less than 0.5 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultrapasteurized prior to the addition to the microbial culture, and when applicable, the addition of flakes or granules of butterfat or milkfat.

2. Vitamin addition (optional).

i. If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food

contains not less than 2,000 International Units (400 ug of retinol equivalence) thereof, within limits of good manufacturing practice.

ii. If added, Vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units (10 ug) thereof, within limits of good manufacturing practice.

3. Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

4. Other optional ingredients.

i. Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, and the use of any other ingredients as approved by the FDA, to increase the nonfat solids content of the food.

ii. Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup; dried maltose sirup; malt extract; dried malt extract; malt sirup; dried malt sirup; honey; maple sugar; or any of the sweeteners listed in 21 CFR 168, except table sirup.

iii. Flavoring ingredients.

iv. Color additives that do not impart a color simulating that of milkfat or butterfat.

v. Stabilizers.

vi. Butterfat or milkfat, in the form of flakes or granules.

vii. Aroma and flavor-producing microbial culture.

viii. Salt.

ix. Citric acid, in a maximum amount of 0.15 percent by weight of the milk used, or an equivalent amount of sodium citrate, as a flavor precursor.

5. Methods of analysis. Referenced methods in 5i, ii and iii are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by "Total Solids, Method I—Official Final Action."

iii. Titratable acidity—"Acidity—Official Final Action."

6. Nomenclature. The name of the food is "cultured milk." The full name of the food shall appear on the principal display panel in type of uniform size, style and color. 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, and may be accompanied by a declaration such as a traditional name of the food or the generic name of the organisms used, thereby indicating the presence of the characterizing microbial organisms or ingredients, e.g., "kefir cultured milk," "acidophilus cultured milk," or when characterizing ingredients such as those in 4vi, vii, viii and ix above, and lactic acid-producing organisms are used the food may be named "cultured buttermilk."

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(1) The phrase "vitamin A" or "vitamin A added" or "vitamin D" "or vitamin D added," or "vitamin A and D added," as appropriate. The word "vitamin" may be abbreviated "vit."

(2) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavor.

ii. The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

7. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Dairy drink" means a product consisting of fluid skim milk or concentrated or dried skim milk recombined with water, with or without added milkfat, to which has been added a syrup or flavoring material, and which contains not less than 7–1/2 percent milk solids-non-fat.

"Department" means the State Department of Health.

"Drug" means:

1. Articles recognized in the official United States Pharmacopeia, official Hemeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them;

2. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

3. Articles (other than food) intended to affect the structure or any function of the body ***of man or other*** animals; and

4. Articles intended for use as a component of any articles specified in 1, 2 or 3 above, but does not include devices or their components, parts or accessories.

"Eggnog" means:

1. Description. Eggnog is the food containing one or more of the optional dairy ingredients specified in paragraph 2 below, one or more of the optional egg yolk-containing ingredients specified in paragraph 3 below and one or more of the optional nutritive carbohydrate sweeteners specified in paragraph 4 below or other sweetening agents approved by the U.S. Food and Drug Administration for use in milk or fluid milk products. One or more of the optional ingredients specified in paragraph 5 below may also be added. All ingredients used are safe and suitable. Eggnog contains not less than six percent milkfat and not less than 8.25 percent milk solids not fat. The egg yolk solids content is not less than one percent by weight of the finished food. The food shall be pasteurized or ultra-pasteurized and may be homogenized. Flavoring ingredients and color additives may be added after the food is pasteurized or ultra-pasteurized.

2. Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

3. Egg yolk-containing ingredients. Liquid egg yolk, frozen egg yolk, dried egg yolk, liquid whole eggs, frozen whole eggs, dried whole eggs, or any one or more of the foregoing ingredients with liquid egg white or frozen egg white.

4. Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup; dried maltose sirup; malt extract; dried malt extract; malt sirup; dried malt sirup; honey; maple sugar; or any of the sweeteners listed in 21 CFR 168, except table sirup.

5. Other optional ingredients.

i. Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food; provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

ii. Salt.

iii. Flavoring ingredients.

iv. Color additives that do not impart a color simulating that of egg yolk, milkfat, or butterfat.

v. Stabilizers.

6. Methods of analysis. Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat-Official Final Action."

ii. Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action."

7. Nomenclature. The name of the food is "eggnog." 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.

i. The following term shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

8. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Frozen yogurt mix" means the unfrozen fluid mixture from which frozen yogurt is made by freezing and shall contain not less than 3.25 percent milkfat and 8.25 percent milk solids not fat prior to the addition of bulky characterizing ingredients or sweeteners. In addition, the mix shall meet the requirements of N.J.A.C. 8:21–7.9 regarding culturing, titratable acidity and live yogurt culture organisms.

"Frozen lowfat yogurt mix" means the unfrozen fluid mixture from which frozen lowfat yogurt is made by freezing and shall contain not less than 0.5 percent milkfat nor more than 2.0 percent milkfat. In addition, the mix shall meet the requirements of N.J.A.C. 8:21–7.9 regarding culturing, titratable acidity and live yogurt culture organisms.

"Frozen nonfat yogurt mix" means the unfrozen fluid mixture from which frozen nonfat yogurt is made by freezing and shall contain not more than 0.5 percent milkfat. In addition, the mix shall meet the requirements of N.J.A.C. 8:21–7.9 regarding culturing, titratable acidity and live yogurt culture organisms.

"Goat milk" means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of these rules. The word "milk" shall be interpreted to include goat milk.

"Grade A dry milk products" means milk and whey products which have been produced for use in Grade A pasteurized fluid milk products and which have been manufactured under the provisions of the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey 1978 Recommended Sanitation Ordinance for Condensed and Dry Milk Products and Condensed and Dry Whey Used in Grade A Pasteurized Milk Products.

"Half–and–Half":

1. Description Half–and–Half is the food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

2. Optional ingredients. The following safe and suitable optional ingredients may be used.

i. Emulsifiers.

ii. Stabilizers.

iii. Nutritive sweeteners.

iv. Characterizing flavoring ingredients (with or without coloring) as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice.)

(2) Natural and artificial food flavoring.

3. Methods of analysis. The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition under "Fat—Official Final Action."

4. Nomenclature. The name of the food is "half-and-half." The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in 21 CFR 101.22.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The word "sweetened" if no characterizing flavor ingredients are used, but nutritive sweetener is added.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

5. Label declaration. When used in the food, each of the ingredients shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Health authority" means the duly authorized agent of the State Department of Health to act in the enforcement of the sanitary laws of the State.

"Heavy cream":

1. Description. Heavy cream is cream which contains not less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

2. Optional ingredients. The following safe and suitable optional ingredients may be used:

i. Emulsifiers.

ii. Stabilizers.

iii. Nutritive sweeteners.

iv. Characterizing flavoring ingredients (with or without coloring) as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice).

(2) Natural and artificial food flavoring.

3. Methods of analysis. The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition, under "Fat—Official Final Action."

4. Nomenclature.

i. The name of the food is "heavy cream" or alternatively "heavy whipping cream." The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in 21 CFR 101.22. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

5. Label declaration. When used in the food, each of the ingredients shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and thereby maintain the commercial sterility of its contents after processing.

"Homogenized milk" means milk which has been treated to insure breakup of the fat globules to such an extent that, after 48 hours of quiescent storage at 45 degrees Fahrenheit (7 degrees Celsius), no visible cream separation occurs on the milk, and the fat percentage of the top 100 milliliters of milk in a quart, or of proportionate volumes in containers of other sizes, does not differ by more than 10 percent from the fat percentage of the remaining milk as determined after thorough mixing.

"Ice cream mix" means the unfrozen fluid mixture from which ice cream is made by freezing and shall contain not less than ten percent by weight of milkfat except when fruit, nuts, cocoa, chocolate cakes or confections are added for the purpose of flavoring when it shall contain not less than ten percent by weight of milkfat except for such reduction of milkfat as is due to the addition of such flavoring, but in no case shall it contain less than eight percent by weight of milkfat. Chocolate and cocoa flavored ice cream mix shall in no event contain less than ten percent by weight of total fat.

"Ice milk mix" means the unfrozen fluid mixture from which ice milk is made by freezing and shall contain not less than three percent by weight of milkfat and not less than 14 percent by weight of total milk solids.

"Item" as listed in N.J.A.C. 8:21–10.6(d) and (e) means the Grade "A" Pasteurized Milk Ordinance (1989 Revision) (PHS/FDA Publication No. 229). The letter "r" refers to raw milk; the letter "p" refers to pasteurized milk.

"Lactose–Reduced Milk or Lactose–Reduced Lowfat Milk or Lactose–Reduced Skim Milk" means the product resulting from the treatment of milk, lowfat milk or skim milk by the addition of safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk, lowfat milk or skim milk.

"Light cream":

1. Description. Light cream is cream which contains not less than 18 percent but less than 30 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

2. Optional ingredients. The following safe and suitable ingredients may be used:

i. Stabilizers.

ii. Emulsifiers.

iii. Nutritive sweeteners.

iv. Characterizing flavoring ingredients (with or without coloring) as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice).

(2) Natural and artificial food flavoring.

3. Methods of analysis. The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition, under "Fat—Official Final Action."

4. Nomenclature. The name of the food is "Light cream," or alternatively "Coffee cream" or "Table cream." The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in 21 CFR 101.22.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

5. Label declaration. When used in the food, each of the ingredients shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Light Whipping Cream":

1. Description. Light whipping cream is cream which contains not less than 30 percent but less than 36 percent milkfat. It is pasteurized or ultra-pasteurized, and may be homogenized.

2. Optional ingredients. The following safe and suitable optional ingredients may be used:

i. Emulsifiers.

ii. Stabilizers.

iii. Nutritive sweeteners.

iv. Characterizing flavoring ingredients (with or without coloring) as follows:

(1) Fruit and fruit juices (including concentrated fruit and fruit juice).

(2) Natural and artificial food flavoring.

3. Methods of analysis. The milkfat content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition, under "Fat—Official Final Action."

4. Nomenclature. The name of the food is "Light whipping cream" or alternatively "Whipping cream." The name of the food shall be accompanied on the label

by a declaration indicating the presence of any characterizing flavoring, as specified in 21 CFR 101.22.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(2) The word "sweetened" if no characterizing flavoring ingredients are used, but nutritive sweetener is added.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

5. Label declaration. When used in the food, each of the ingredients shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Lowfat Milk":

1. Description. Lowfat milk is milk from which sufficient milkfat has been removed to produce a food having, within limits of good manufacturing practice one of the following milkfat contents: 1/2, 1, 1–1/2, or 2 percent. Lowfat milk is pasteurized or ultra-pasteurized, contains added vitamin A as prescribed by 2. below and contains not less than 8–1/4 percent milk solids not fat. Lowfat milk may be homogenized.

2. Vitamin addition:

i. Vitamin A shall be present in such quantity that each 946 milliliters (quart) of food contains not less than 2,000 International Units (400 ug of retinol equivalence), within limits of good manufacturing practice.

ii. Addition of vitamin D is optional. If added, Vitamin D shall be present in such quantity that each 946 milliliters (quart) of food contains 400 International Units (10 mug), within limits of good manufacturing practice.

3. Optional ingredients. The following safe and suitable ingredients may be used:

i. Carriers for Vitamins A and D.

ii. Concentrated skim milk, nonfat drymilk, or other milk derived ingredients to increase the nonfat solids content of the food: Provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

iii. When one or more of the optional milk derived ingredients in 3ii above are used, emulsifiers, stabilizers, or both, in an amount not more than two percent by weight of the solids in such ingredients.

iv. Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice).

(2) Natural and artificial food flavorings.

4. Methods of analysis. Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method. "Total Solids, Method I—Official Final Action."

iii. Vitamin D content—"Vitamin D—Official Final Action."

5. Nomenclature. The name of the food is "Lowfat milk." The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in 21 CFR 101.22.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(1) The phrase "...% milkfat," the blank to be filled in with the fraction 1/2, or multiple thereof, to indicate the actual fat content of the food.

(2) The phrase "vitamin A" or "vitamin A added," or, if vitamin D is added, the phrase "vitamin A and D added." The word "vitamin" may be abbreviated "vit."

(3) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(4) The phrase "with added milk solids not fat" if the food contains not less than 10 percent milk derived nonfat solids.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

6. Label declaration. When ingredients are used in the food as specified in 2ii, 3ii, 3iii and 3iv above, such ingredients shall be declared on the label as required by the applicable sections of 21 CFR 101 except that concentrated skim milk and nonfat dry milk may be declared as "nonfat milk solids."

"Lowfat yogurt" means:

1. Description. Lowfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph 3 below with a characterizing bacterial culture that contains the lactic acid-producing bacteria, Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraphs 2 and 4 below may also be added. When one or more of the ingredients specified in subparagraph 4i below are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Lowfat yogurt, before the addition of bulky flavors, contains not less than 0.5 percent nor more than two percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf-life of the food, lowfat yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

2. Vitamin addition (optional).

i. If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less then 2,000 International Units (400 mug of retinol equivalence) thereof, within limits of good manufacturing practice.

ii. If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units (10 mug) thereof, within limits of good manufacturing practice.

3. Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

4. Other optional ingredients.

i. Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food; provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

ii. Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup; dried maltose sirup; malt extract; dried malt extract; malt sirup; dried malt sirup; honey; maple sugar; or any of the sweeteners listed in 21 CFR 168, except table sirup.

iii. Flavoring ingredients.

iv. Color additives.

v. Stabilizers.

5. Methods of analysis. Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action".

ii. Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action."

iii. Titratable acidity—"Acidity—Official Final Action."

6. Nomenclature. The name of the food is "lowfat yogurt." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. 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.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(1) The phrase "...% milkfat," the blank to be filled in with the fraction ½ or multiple thereof closest to the actual content of the food.

(2) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(3) The parenthetical phrase "(heat treated after culturing)" shall follow the name of the food if the dairy ingredients have been heat treated after culturing.

(4) The phrase "vitamin A" or "vitamin A added," or "vitamin D" or "vitamin D added," or "vitamins A and D added," as appropriate. The word "vitamin" may be abbreviated "vit."

ii. The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

7. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Milk" means:

1. Description. Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in final package form for beverage use shall have been pasteurized or ultrapasteurized, and shall contain not less than 8¼ percent milk solids not fat and not less than 3¼ percent milkfat. Milk may have been adjusted by separating part of the milkfat therefrom, or by adding thereto cream, concentrated milk, dry whole milk, skim milk, concentrated skim milk, or nonfat dry milk. Milk may be homogenized.

2. Vitamin addition (Optional).

i. If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2000 International Units (400 mug of retinol equivalence) thereof within limits of good manufacturing practice.

ii. If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units (10 mug) thereof within limits of good manufacturing practice.

3. Optional ingredients. The following safe and suitable ingredients may be used:

i. Carriers for vitamins A and D.

ii. Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice).

(2) Natural and artificial food flavorings.

4. Methods of analysis. Referenced methods in 4i, ii and iii below are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action."

iii. Vitamin D content—"Vitamin D—Official Final Action."

5. Nomenclature. The name of the food is "milk." The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in section 21 CFR 101.22.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) If vitamins are added, the phrase "vitamin A" or "vitamin A added," or "vitamin D" or "vitamin D added," or "vitamin A and D" or "vitamins A and D added," as appropriate. The word "vitamin" may be abbreviated "vit."

(2) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

6. Label description. When used in the food, each of the ingredients specified in 2. and 3ii above, shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Milk hauler" means any person who collects or transports raw milk and/or raw milk products to or from a milk plant, receiving or transfer station.

"Milk shake mix or milk shake base" means a fluid milk product prepared from a combination of optional ingredients as prescribed in the definition for ice cream. It shall contain not less than 3–1/4 percent milkfat and not less than 14 percent total milk solids.

"Milk transport tank"—A milk transport tank is a vehicle including the truck and tank used by a milk hauler to transport bulk shipments of milk from a transfer station, receiving station or milk plant to another transfer station, receiving station or milk plant.

"Nonfat yogurt" means:

1. Description. Nonfat yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph 3 below with a characterizing bacterial culture that contains the lactic acid-producing bacteria, Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraphs 2 and 4 below may also be added. When one or more of the ingredients specified in subparagraph 4i below are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Nonfat yogurt, before the addition of bulky flavors, contains less than 0.5 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf-life of the food, nonfat yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

2. Vitamin addition (optional).

i. If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units (400 μg of retinol equivalence) thereof within limits of good manufacturing practice.

ii. If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units (10 μg) thereof within limits of good manufacturing practice.

3. Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

4. Other optional ingredients:

i. Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food; provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

ii. Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup; dried maltose sirup; malt extract; dried malt extract; malt sirup; dried malt sirup; honey; maple sugar; or any of the sweeteners listed in 21 CFR 168, except table sirup.

iii. Flavoring ingredients.

iv. Color additives.

v. Stabilizers.

5. Methods of analysis. Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action".

ii. Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action."

iii. Titratable acidity—"Acidity—Official Final Action."

6. Nomenclature. The name of the food is "nonfat yogurt". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. 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.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(1) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The parenthetical phrase "(heat treated after culturing)" shall follow the name of the food if the dairy ingredients have been heat treated after culturing.

(3) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit."

ii. The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

7. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Official laboratory" means a biological, chemical, or physical laboratory which is under the direct supervision or approval of the State.

"Officially designated laboratory" means a commercial laboratory authorized to do official work by the supervising agency, or a milk industry laboratory officially designated by the supervising agency for the examination of producer samples of Grade A raw milk for pasteurization.

"Optional ingredients" shall mean and include 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 fluid milk products when approved by the Department under the Administrative Procedures Act.

"Pasteurization," "pasteurized", and similar terms shall mean the process of heating every particle of milk or milk product in properly designed and operated equipment, to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

	Temperature	Time	
+	145 degrees F (63 degrees C)	30	minutes
+	161 degrees F (72 degrees C)	15	seconds
	191 degrees F (89 degrees C)	1.0	second
	194 degrees F (90 degrees C)	0.5	second
	201 degrees F (94 degrees C)	0.1	second
	204 degrees F (96 degrees C)	0.05	second
	212 degrees F (100 degrees C)	0.01	second

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

Temperature	Time
155 degrees F (69 degrees C)	30 minutes
175 degrees F (80 degrees C)	25 seconds
180 degrees F (83 degrees C)	15 seconds

Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by the State Health Department.

"Reconstituted or recombined milk and/or fluid milk products" shall mean milk and fluid milk products as defined which result from the recombining of milk constituents with potable water.

"Sanitization" means the application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to the health authority.

"Skim milk":

1. Description. Skim milk is milk from which sufficient milkfat has been removed to reduce its milkfat content to less than 0.5 percent. Skim milk that is in final package form for beverage use shall have been pasteurized or ultra-pasteurized, shall contain added vitamin A as prescribed by paragraph 2 below and shall contain not less than 8¼ percent milk solids not fat. Skim milk may be homogenized.

2. Vitamin addition.

i. Vitamin A shall be present in such quantity that each 946 milliliters (quart) of food contains not less than 2,000 International Units (400 μg of retinol equivalence), within limits of good manufacturing practice.

ii. Addition of vitamin D is optional. If added, Vitamin D shall be present in such quantity that each 946 milliliters (quart) of food contains 400 International Units (10 μg), within limits of good manufacturing practice.

3. Optional ingredients.

The following safe and suitable optional ingredients may be used:

i. Carriers for vitamin A and D.

ii. Concentrated skim milk, nonfat dry milk, or other milk derived ingredients to increase the nonfat solids content of the food: Provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present, shall not be decreased as a result of adding such ingredients.

iii. When one or more of the optional milk derived ingredients in 3ii. are used, emulsifiers, stabilizers or a combination of both may be added in an amount not to exceed two percent by weight of the solids in such ingredients.

iv. Characterizing flavoring ingredients (with or without coloring, nutritive sweetener, emulsifiers, and stabilizers) as follows:

(1) Fruit and fruit juices (including concentrated fruit and fruit juice).

(2) Natural and artificial food flavorings.

4. Methods of Analysis. Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Milk solids not fat content (or total nonfat solids content)—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action."

iii. Vitamin D content—"Vitamin D—Official Final Action."

5. Nomenclature. The name of the food is "Skim milk" or alternatively "Nonfat milk." The name of the food shall appear on the label in type of uniform size, style, and color. The name of the food shall be accompanied on the label by a declaration indicating the presence of any characterizing flavoring, as specified in section 21 CFR 101.22.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name:

(1) The phrase "vitamin A" or "vitamin A added," or, if vitamin D is added, the phrase "vitamin A and D" or "vitamins A and D added." The word "vitamin" may be abbreviated "vit."

(2) The word "ultra-pasteurized" if the food has been ultra-pasteurized.

(3) The phrase "with added milk solids not fat" if the food contains not less than 10 percent milk derived nonfat solids.

ii. The following terms may appear on the label:

(1) The word "pasteurized" if the food has been pasteurized.

(2) The word "homogenized" if the food has been homogenized.

6. Label declaration. When used in the food, each of the ingredients specified in 2ii, 3ii, iii and iv above, shall be declared on the label as required by the applicable sections of 21 CFR 101.

"Sour Cream":

1. Description. Sour cream results from the souring, by lactic acid producing bacteria, of pasteurized cream. Sour cream contains not less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 14.4 percent milkfat. Sour cream has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

2. Optional ingredients.

i. Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

ii. Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

iii. Rennet.

iv. Safe and suitable nutritive sweeteners.

v. Salt.

vi. Flavoring ingredients, with or without safe and suitable coloring, as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice).

(2) Safe and suitable natural and artificial food flavoring.

3. Method of analysis. Referenced methods in 3i and ii below, are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Titratable acidity—"Acidity" [2]—Official Final Action."

4. Nomenclature. The name of the food is "Sour cream" or alternatively "Cultured sour cream." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in 21 CFR 101.22. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of characterizing flavoring, the name of the food shall be preceded by the word "sweetened."

5. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream."

"Sour half-and-half":

1. Description. Sour half-and-half results from the souring, by lactic acid producing bacteria, of pasteurized half-and-half. Sour half-and-half contains not less than 10.5 percent but less than 18 percent milkfat; except that when the food is characterized by the addition of nutritive sweeteners or bulky flavoring ingredients, the weight of milkfat is not less than 10.5 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the food; but in no case does the food contain less than 8.4 percent milkfat. Sour half-and-half has a titratable acidity of not less than 0.5 percent, calculated as lactic acid.

2. Optional ingredients.

i. Safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product.

ii. Sodium citrate in an amount not more than 0.1 percent may be added prior to culturing as a flavor precursor.

iii. Rennet.

iv. Safe and suitable nutritive sweeteners.

v. Salt.

vi. Flavoring ingredients, with or without safe and suitable coloring, as follows:

(1) Fruit and fruit juice (including concentrated fruit and fruit juice).

(2) Safe and suitable natural and artificial food flavoring.

3. Methods of analysis. Referenced methods in 3i and ii below are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action."

ii. Titratable acidity—"Acidity[2]—Official Final Action."

4. Nomenclature. The name of the food is "Sour half-and-half" or alternatively "Cultured sour half-and-half." The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. The name of the food shall be accompanied by a declaration indicating the presence of any flavoring that characterizes the product, as specified in 21 CFR 101.22. If nutritive sweetener in an amount sufficient to characterize the food is added without addition of

characterizing flavoring, the name of the food shall be preceded by the word "sweetened."

5. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101, except that bacterial cultures may be declared by the word "cultured" followed by the name of the substrate, e.g., "cultured cream."

"Sterilized" means the condition achieved by application of heat, chemical sterilant(s) or other appropriate treatment that renders the piping, equipment and containers used for milk and milk products free of viable microorganisms.

"Ultra-pasteurized"—The term "ultra-pasteurized," when used to describe a dairy product, means that such product shall have been thermally processed at or above 280°F (138°C) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

"Whipped cream" means the product defined in 21 CFR 131.150 or 131.157 into which air or gas has been incorporated. If nitrous oxide is used as the propellant in whipped cream, a permit is required from the State Department of Health pursuant to N.J.S.A. 24:6B.

"Yogurt" means:

1. Description. Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph 3 below with a characterizing bacterial culture that contains the lactic acid-producing bacteria, Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraphs 2 and 4 below may also be added. When one or more of the ingredients specified in subparagraph 4i below are used, they shall be included in the culturing process. All ingredients used are safe and suitable. Yogurt, before the addition of bulky flavors, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat, and has a titratable acidity of not less than 0.9 percent, expressed as lactic acid. The food may be homogenized and shall be pasteurized or ultra-pasteurized prior to the addition of the bacterial culture. Flavoring ingredients may be added after pasteurization or ultra-pasteurization. To extend the shelf-life of the food, yogurt may be heat treated after culturing is completed, to destroy viable microorganisms.

2. Vitamin addition (optional).

i. If added, vitamin A shall be present in such quantity that each 946 milliliters (quart) of the food contains not less than 2,000 International Units (400 μg of retinol equivalence) thereof within limits of good manufacturing practice.

ii. If added, vitamin D shall be present in such quantity that each 946 milliliters (quart) of the food contains 400 International Units (10 μg) thereof within limits of good manufacturing practice.

3. Optional dairy ingredients. Cream, milk, partially skimmed milk, or skim milk, used alone or in combination.

4. Other optional ingredients.

i. Concentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals, to increase the nonfat solids content of the food; provided, that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present shall not be decreased as a result of adding such ingredients.

ii. Nutritive carbohydrate sweeteners. Sugar (sucrose), beet or cane; invert sugar (in paste or sirup form); brown sugar; refiner's sirup; molasses (other than blackstrap); high fructose corn sirup; fructose; fructose sirup; maltose; maltose sirup; dried maltose sirup; malt extract; dried malt extract; malt sirup; dried malt sirup; honey; maple sugar; or any of the sweeteners listed in 21 CFR 168, except table sirup.

iii. Flavoring ingredients.

iv. Color additives.

v. Stabilizers.

5. Methods of analysis. Referenced methods are from "Official Methods of Analysis of the Association of Official Analytical Chemists," current edition.

i. Milkfat content—"Fat—Official Final Action".

ii. Milk solids not fat content—Calculated by subtracting the milkfat content from the total solids content as determined by the method "Total Solids, Method I—Official Final Action."

iii. Titratable acidity—"Acidity—Official Final Action."

6. Nomenclature. The name of the food is "yogurt". The full name of the food shall appear on the principal display panel of the label in type of uniform size, style, and color. 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.

i. The following terms shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(1) The word "sweetened" if nutritive carbohydrate sweetener is added without the addition of characterizing flavoring.

(2) The parenthetical phrase "(heat treated after culturing)" shall follow the name of the food if the dairy ingredients have been heat treated after culturing.

(3) The phrase "vitamin A" or "vitamin A added", or "vitamin D" or "vitamin D added", or "vitamins A and D added", as appropriate. The word "vitamin" may be abbreviated "vit."

ii. The term "homogenized" may appear on the label if the dairy ingredients used are homogenized.

7. Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of 21 CFR 101.

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 certified milk deleted; definitions added for eggnog, frozen yogurts, goat milk, nonfat yogurt, yogurt added.
Amended by R.1993 d.689, effective December 20, 1993.
See: 25 N.J.R. 4373(a), 25 N.J.R. 6013(a).

8:21–10.2 Labeling

(a) All bottles, containers and packages enclosing milk or milk products defined in N.J.A.C. 8:21–10.1 shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act, (21 USC 301), as amended, the Fair Packaging and Labeling Act, (15 USC 1451), the labeling provisions established under N.J.A.C. 8:21–10.1, and in addition, shall comply with the applicable requirements of this section as follows:

1. The words "Grade A" for milk and milk products handled, processed and packaged under the terms of the National Conference on Interstate Milk Shipments (IMS);

2. The identity of the plant where pasteurized;

3. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination;

4. The volume or proportion of water to be added for recombining in the case of concentrated milk or fluid milk products;

5. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products;

6. In the case of aseptically processed and packaged milk and milk products, "UHT;"

7. The words "ultra-pasteurized" if the milk or milk product has been ultra-pasteurized;

8. The word "Goat" shall precede the name of the milk or milk product when the product is or is made from goat milk.

(b) All vehicles and transport tanks containing milk or fluid milk products shall be legibly marked with the name and address of the milk plant or hauler in possession of the contents.

(c) Tanks transporting raw milk and fluid milk products to a milk plant are required to be marked with the name and address of the milk plant or hauler and shall be sealed. For each such shipment, a shipping statement shall be prepared containing at least the following information:

1. Shipper's name, address, and permit number;

2. Permit identification of hauler, if not employee of shipper;

3. Point of origin of shipment;

4. Tanker identity number;

5. Name of product;

6. Weight of product;

7. Grade of product;

8. Temperature of product;

9. Date of shipment;

10. Name of supervising health authority at the point of origin;

11. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk whether it has been heat-treated.

(d) The shipping statement required in (c) above shall be prepared in triplicate and shall be kept on file by the shipper, the consignee, and the carrier for a period of six months for the information of the health authority.

(e) The labeling information which is required on all bottles, containers or packages of milk or fluid milk products shall be in letters of an acceptable size, style, and color satisfactory to the Department and shall contain no marks or words which are misleading.

(f) The use of super grade designations such as "Grade AA Pasteurized," "Selected or Special Grade A Pasteurized," etc., shall not be permitted.

Amended by R.1993 d.689, effective December 20, 1993.
See: 25 N.J.R. 4373(a), 25 N.J.R. 6013(a).

8:21–10.3 Inspection of dairy farms and milk plants

(a) Each dairy farm, milk plant, receiving station, and transfer station whose milk and fluid milk products are intended for consumption within New Jersey or its police jurisdiction and each milk hauler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, transfer station or receiving station and his bulk milk pickup tanker and its appurtenances shall have an approved inspection prior to the issuance of a permit.

1. Following the issuance of a permit, each bulk milk pickup tanker and its appurtenances shall be inspected at least once every 12 months; each milk hauler who collects milk samples shall be evaluated at least once every 24

months; each milk plant and receiving station shall be inspected at least once every three months; and each dairy farm supplying milk and each transfer station shall be inspected at least once every six months.

2. Should the violation of any requirement set forth in N.J.A.C. 8:21–10.6, or in the case of a milk hauler also N.J.A.C. 8:21–10.4, be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before three days; this second inspection shall be used to determine compliance with the requirements of N.J.A.C. 8:21–10.6, or in the case of milk hauler also N.J.A.C. 8:21–10.4.

3. The health authority shall take immediate action to prevent further processing of milk or milk product when violations of critical processing element(s) have been identified. Should correction of such critical processing elements not be accomplished immediately, the health authority shall take prompt enforcement action. The following will be considered critical processing element violations:

i. Improper pasteurization, whereby every particle of milk or milk products may not have been heated to the proper temperature and held for the required time in properly designed and operating equipment;

ii. A cross connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or

iii. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

4. In the case of dairy plants producing aseptically processed milk and milk products, when an inspection of the dairy plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the health authority shall immediately take enforcement action to abate the hazard.

(b) One copy of the inspection report shall be handed to the operator, or other responsible person, or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the health authority upon request. An identical copy of the inspection report shall be filed with the records of the health authority.

(c) Every milk producer, hauler, distributor, or plant operator shall, upon request of the health authority, permit access of officially designated persons to all parts of his establishment or facilities to determine compliance with the provisions of these regulations. A distributor or plant operator shall furnish the health authority, upon request, for official use only, a true statement of the actual quantities of milk and fluid milk products of each grade purchased and sold, and a list of all sources of such milk and fluid milk products, records of inspections, tests, and pasteurization time and temperature records.

(d) It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of these regulations which is entitled to protection as a trade secret (including information as to quantity, quality, source or disposition of milk or fluid milk products, or results of inspections or tests thereof) to use such information to his own advantage or to reveal it to any unauthorized person.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Provisions for action on violation added at (a)3.

8:21–10.4 Examination of milk and fluid milk products

(a) It shall be the responsibility of the milk hauler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck, or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station, or other location approved by the health agency.

(b) During any consecutive six months, at least four samples of raw milk for pasteurization shall be collected in at least four separate months from each producer and at least four samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four separate months by the regulatory agency, from each milk plant after receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing. During any consecutive six months, at least four samples of heat-treated milk products, from plants offering such products for sale, shall be collected in at least four separate months. During any consecutive six months, at least four samples of pasteurized milk, flavored milk, flavored lowfat milk, flavored skim milk, each fat level of lowfat milk and at least four samples of defined fluid milk product except aseptically processed, shall be collected in at least four separate months from every milk plant. Samples of milk and fluid milk products shall be taken while in the possession of the producer or distributor at any time prior to delivery to the store or consumer. Samples of milk and fluid milk products from dairy retail stores, food service establishments, grocery stores, and other places where milk and fluid milk products are sold shall be examined periodically as determined by the health authority; and the results of such examination shall be used to determine compliance with standards, labeling and cooling requirements. Proprietors of such establishments shall furnish the health authority, upon request, with the names of all distributors from whom milk or fluid milk products are obtained.

(c) Required bacterial counts, somatic cell counts, and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, drug tests on each producer's milk shall be conducted at least four times during any consecutive six months. Required bacterial counts, drug tests, coliform determinations, phosphatase, and cooling temperature checks shall be performed on pasteurized milk and fluid milk products.

(d) Whenever two of the last four consecutive bacteria counts (except those for aseptically processed milk and milk products), somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for the milk and/or milk products, the health authority or a representative so designated shall send a written notice thereof to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of three days. Immediate suspension of permit and/or court action shall be instituted whenever the standard is violated by three of the last five bacteria counts, coliform determinations, cooling temperatures, or somatic cell counts. The Department shall offer to the person concerned a hearing pursuant to N.J.S.A. 24:10–57.8. The hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(e) Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or fluid milk product involved shall not be offered for sale.

(f) Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

(g) Whenever a drug residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected in accordance with Appendix N of the Grade "A" Pasteurized Milk Ordinance (1989 Revision) (PHS/FDA Publication No. 229) which is incorporated herein by reference. The Department shall offer to the producer concerned a hearing pursuant to N.J.S.A. 24:10–57.8. The hearing shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(h) Whenever a container or containers of aseptically processed milk or milk products is found to be unsterile due to underprocessing, the Department shall consider this to be an imminent hazard to public health and shall take immediate enforcement action to abate the hazard. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All products from the lot that was found to contain one or more unsterile units shall be recalled and disposed of as directed by the Department.

(i) Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the current edition of Standard Methods for the Examination of Dairy Products of the American Public Health Association, and the current Edition of Official Methods of Analysis of the Association of Official Analytical Chemists. Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the current edition of Evaluation of Milk Laboratories, Recommendations of the United States Public Health Service/Food and Drug Administration. Examinations and tests to detect adulterants, including pesticides, shall be conducted as the health authority requires. Assays of milk and fluid milk products to which vitamin(s) A and/or D have been added, shall be made at least annually in a laboratory acceptable to the health authority.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Sampling requirements added at (b); references to the Administrative Procedure Act added.
Amended by R.1993 d.689, effective December 20, 1993.
See: 25 N.J.R. 4373(a), 25 N.J.R. 6013(a).

8:21–10.5 Animal health

(a) All milk for pasteurization shall be from herds which are located in modified accredited tuberculosis areas as determined by the U.S. Department of Agriculture (U.S.D.A.), provided, that herds located in an area that fails to maintain such accredited status shall have been accredited by the U.S.D.A. as tuberculosis free, or shall have passed an annual tuberculosis test.

(b) All milk for pasteurization shall be from herds under a brucellosis eradication program which meets one of the following conditions:

1. Located in a certified brucellosis-free area as defined by the U.S.D.A. and enrolled in the testing program for such areas; or

2. Located in a modified certified brucellosis area as defined by the U.S.D.A. and enrolled in the testing program for such areas; or

3. Meet U.S.D.A. requirements for an individually certified herd; or

4. Participating in a milk ring testing program at least four times per year, at approximately 90–day intervals, with individual blood tests on all animals in herds showing suspicious reactions to the milk ring test; or

5. Having an individual blood agglutination test annually with an allowable maximum grace period not exceeding two months.

(c) For diseases other than brucellosis and tuberculosis, the health authority shall require such physical, chemical, or bacteriological tests as they deem necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency. Any diseased animal disclosed

by such test(s) shall be disposed of as the health authority directs.

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

8:21–10.6 Standards for milk and fluid milk products

(a) All raw milk for pasteurization, ultra pasteurization or aseptic processing, and all pasteurized, ultra-pasteurized or aseptically processed, milk and fluid milk products shall be produced, processed and pasteurized, ultra-pasteurized or aseptically processed to conform with the chemical, bacteriological, and temperature standards in (c) below and the sanitation requirements in (d) and (e) below.

(b) No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing methods integral therewith, and appropriate refrigeration shall be applied to milk and fluid milk products for the purpose of removing or deactivating microorganisms; provided, that in the bulk shipment of cream, skim milk, or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 125 degrees Fahrenheit (52 degrees Celsius) but less than 161 degrees Fahrenheit (72 degrees Celsius) for separation purposes is permitted when the resulting bulk shipments of cream, skim milk, and/or lowfat milk are labeled heat-treated.

(c) The chemical, bacteriological, and temperature standards for milk and fluid milk products are as follows:

1. Raw milk for pasteurization, ultra-pasteurization or aseptic processing.

i. Temperature—Cooled to 45 degrees Fahrenheit (seven degrees Celsius) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50 degrees Fahrenheit (10 degrees Celsius).

ii. Bacterial limits—Individual producer milk not to exceed 100,000 per ml. prior to commingling with other producer milk.

iii. Not exceeding 300,000 per ml. as commingled milk prior to pasteurization.

iv. Drugs:

(1) No zone equal to or greater than 16 mm with *Bacillus Stearothermophilus* disc assay method or

(2) No positive results on drug residue detection methods as referenced in Appendix N of the Grade "A" Pasteurized Milk Ordinance (1989 Revision) (PHS/FDA Publication No. 229) which is incorporated herein by reference.

v. Somatic Cell Count—Individual producer milk not to exceed 750,000 per ml. for cow's milk or 1,000,000 per ml. for goat's milk.

2. Pasteurized milk and fluid milk products.

i. Temperature—Cooled to 45 degrees Fahrenheit (seven degrees Celsius) or less and maintained thereat at the plant. A maximum of 45 degrees Fahrenheit (seven degrees Celsius) on delivery vehicles.

ii. Bacterial limits (not applicable to cultured products)—Milk and fluid milk products—20,000 per ml.—At processor level prior to delivery.

iii. Coliform limits—Not exceeding 10 per ml. prior to delivery; provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.

iv. Phosphatase (not applicable to bulk shipped, heat-treated milk products)—Less than 1 μg phenol per ml. by Scharer Rapid Method or less than 500 milliunits per L. by the Fluorometric Procedure (or equivalent by other means).

v. Drugs—No zone equal to or greater than 16 mm with *Bacillus Stearothermophilus* disc assay method or no positive results on drug residue detection methods acceptable to the Food and Drug Administration and the Department.

3. Aseptically processed milk and fluid milk products.

i. Temperature—None.

ii. Bacterial limits—No growth by test specified in N.J.A.C. 8:21–10.4.

iii. Drugs—No zone equal to or greater than 16 mm with *Bacillus Stearothermophilus* disc assay method or no positive results on drug residue detection methods acceptable to the Food and Drug Administration and the Department.

4. Pasteurized mixes for frozen desserts.

i. Temperature—Same as pasteurized milk and fluid milk products above.

ii. Bacterial limits (not applicable to cultured products)—50,000 bacteria per gm.

iii. Coliform limits—Not exceeding 10 per gm.

iv. Phosphatase—Less than 1 μg phenol per ml. by Scharer Rapid Method or less than 500 milliunits per L. by the Fluorometric Procedure (or equivalent by other means).

(d) Sanitation requirements for raw milk for pasteurization, ultra-pasteurization or aseptic processing are as follows:

1. Item 1r.—Abnormal Milk: Cows which show evidence of the secretion of abnormal milk in one or more quarters based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment, and the milk shall be discarded. Cows treated with, or cows which have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgement of the health authority, may be deleterious to human health, shall be milked last or with separate equipment, and the milk disposed of as the health authority may direct.

i. A strip cup shall be used to examine the first stream of milk from each teat of each milking animal at each milking for the purpose of detecting abnormalities and all such fore-milk shall be discarded. When any abnormal fore-milk is detected from any quarter of the udder, the producer shall immediately exclude all the milk from such animal from the supply and such milk shall not be sold, offered for sale or delivered for consumption as milk.

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

(1) California mastitis test—1 applicable to goat's milk only;

(2) Wisconsin mastitis test—18 mm. applicable to goat's milk only.

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

(1) A notice shall be given to the producer warning him of the excessive somatic cell count. The notice should also list the more likely causes of high somatic cell count.

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

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

2. Item 2r.—Milking Barn, Stable, or Parlor Construction: A milking barn, stable or parlor shall be provided on all dairy farms in which the cows being milked shall be housed during milking operations. The areas used for milking purposes shall:

i. Have floors constructed of concrete or equally impervious material; provided, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix B.V. of the Grade A Pasteurized Milk Ordinance (1989) (United States Public Health Service—FDA Publication 229);

ii. Have walls, and ceiling which are smooth, painted or finished in an approved manner, in good repair, ceilings dust tight;

iii. Have separate stalls or pens for horses, calves, and bulls;

iv. Be provided with natural and/or artificial light, well distributed for day and/or night milking;

v. Provide sufficient air space and air circulation to prevent condensation and excessive odors;

vi. Not be overcrowded; and,

vii. Have dust tight covered boxes or bins, or separate storage facilities for ground, chopped or concentrated feed.

3. Item 3r.—Milking Barn, Stable, or Parlor Cleanliness: The interior shall be kept clean. Floors, walls, windows, pipelines, and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking barn.

4. Item 4r.—Cow Yard: The cow yard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes: Provided, that in loafing or cattle-housing areas, cow droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the cow's udder and flanks. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cow yard.

5. Item 5r.—Milkhouse or Room—Construction and Facilities: A milkhouse or room of sufficient size shall be provided, in which the cooling, handling, and storing of milk containers and utensils shall be conducted, except as provided for in Item 12r. below.

i. The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

ii. The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner.

iii. The milkhouse shall have adequate natural and/or artificial light and be well ventilated.

iv. The milkhouse shall be used for no other purpose than milkhouse operations. There shall be no direct opening into any barn, stable, or into a room used for domestic purposes; Provided, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting self-closing solid door(s) hinged to be single or double acting is provided.

v. Water under pressure shall be piped into the milkhouse.

vi. The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

vii. When a transportation tank is used for the cooling and storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance.

6. Item 6r.—Milkhouse or Room–Cleanliness: The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils, and equipment, and other milkroom equipment shall be maintained in a clean condition. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals, and fowl.

7. Item 7r.—Toilet: Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the soil surface nor contaminate any water supply.

8. Item 8r.—Water Supply: Water for milkhouse and milking operations shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

9. Item 9r.—Utensils and Equipment Construction: All multiuse containers, equipment, and utensils used in the handling, storage or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. All milk pails used for hand milking and stripping shall be seamless and of the hooded type. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported, stored, and handled in a sanitary manner and shall comply with the applicable requirements of (e)13 item 11p below. Articles intended for single-service use shall not be reused.

i. Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with the applicable requirements of (e)13 items 10p and 11p below.

10. Item 10r.—Utensils and Equipment Cleaning: The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each usage.

11. Item 11r.—Utensils and Equipment Sanitization: The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be sanitized before each usage.

12. Item 12r.—Utensils and Equipment Storage: All containers, utensils, and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage, and shall be protected from contamination prior to use; provided, that milk pipelines and pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers and milk pumps and tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by the U.S. Food and Drug Administration, which meets these criteria may be stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product and solution contact surfaces from contamination at all times.

13. Item 13r.—Utensils and Equipment Handling: After sanitization, all containers, utensils, and equipment shall be handled in such manner as to prevent contamination of any product-contact surface.

14. Item 14r.—Milking, Flanks, Udders, and Teats: Milking shall be done in the milking barn, stable, or parlor. The flanks, udders, bellies, and tails of all milking cows shall be free from visible dirt and clipped as necessary. All brushing shall be completed prior to milking. The udders and teats of all milking cows shall be cleaned and treated with a sanitizing solution just prior to the time of milking, and shall be wiped dry before milking. Wet hand milking is prohibited.

15. Item 15r.—Milking: Surcingles, milk stools, and antikickers shall be kept clean and stored above the floor.

16. Item 16r.—Protection from Contamination: Milking and milkhouse operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers, and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.

17. Item 17r.—Personnel Handwashing Facilities: Adequate handwashing facilities shall be provided, including a lavatory fixture with running water, soap or detergent, and individual sanitary towels, convenient to the milkhouse, milking barn, stable, parlor, and flush toilet.

18. Item 18r.—Personnel Cleanliness: Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function, and immediately after the interruption of any of these activities. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

19. Item 19r.—Cooling: Raw milk for pasteurization shall be cooled to 45 degrees Fahrenheit (seven degrees Celsius) or less within two hours after milking: Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 50 degrees Fahrenheit (10 degrees Celsius).

20. Item 20r.—Vehicles: Vehicles used to transport milk from the dairy farm to the milk plant or receiving station shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out; and no substance capable of contaminating milk shall be transported with milk.

21. Item 21r.—Insect and Rodent Control: Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents, and by chemicals used to control such vermin. Milkrooms shall be free of insects and rodents. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

(e) Sanitation requirements for pasteurized, ultra-pasteurized and aseptically processed milk and fluid milk products.

1. A receiving station shall comply with Items 1p to 15p, inclusive, and 17p, 20p, and 22p below, except that the partitioning requirement of Item 5p shall not apply.

2. A transfer station shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p, and 22p below; and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p: Provided, that in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of bulk transport tanks shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p, and 22p below; and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p: Provided, that in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p, and 22p below; and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p: Provided, that in every case, overhead protection shall be provided.

3. Item 1p.—Floor Construction: The floors of all rooms in which milk or fluid milk products are processed, handled, or stored, or in which milk 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, that cold-storage rooms used for storing milk and fluid milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits; Provided further, that storage 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.

4. Item 2p.—Walls and Ceilings—Construction: Walls and ceilings of rooms in which milk or fluid milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed, shall have a smooth, washable, light-colored surface, in good repair.

5. Item 3p.—Doors and Windows: Effective means shall be provided to prevent the access of flies and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

6. Item 4p.—Lighting and Ventilation: All rooms in which milk and fluid milk products are handled, processed, or stored and/or in which milk containers, equipment, and utensils are washed shall be well lighted and well ventilated.

7. Item 5p.—Separate Rooms: There shall be separate rooms for:

i. Pasteurizing, processing, cooling and packaging of milk and fluid milk products;

ii. Cleaning of milk cans, bottles and cases; and

iii. Cleaning and sanitizing facilities for milk tank trucks;

iv. Provided that, in a receiving station cooling may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized;

v. Rooms in which milk or fluid milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes;

vi. Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged milk and milk products.

8. Item 6p.—Toilet/Sewage Disposal Facilities: Every milk plant shall be provided with toilet facilities which comply with the requirements of the health authority and the Uniform Construction Code, N.J.A.C. 5:23–1.1 et seq.

i. Toilet rooms shall not open directly into any room in which milk and/or fluid milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms, and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

9. Item 7p.—Water Supply: Water for milk plant purposes shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

10. Item 8p.—Handwashing Facilities: Convenient handwashing facilities shall be provided, including hot and cold and/or warm (90 degrees Fahrenheit to 105 degrees Fahrenheit) running water, soap, and individual sanitary towels or other approved hand-drying devices. Handwashing facilities shall be kept in a clean condition and in good repair.

11. Item 9p.—Milk Plant Cleanliness: All rooms in which milk and fluid milk products 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, packaging, and bulk milk storage rooms.

12. Item 10p.—Sanitary Piping: All sanitary piping, fittings, and connections which are exposed to milk and fluid milk products, or from which liquids may drip, drain, or be drawn into milk or fluid milk products, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be maintained in good repair and identified as to whether it is carrying raw or pasteurized milk or milk products. Identification of all piping shall be in a manner acceptable to the Department. Recommended colors are: red—raw milk, blue—pasteurized milk, green—clean-in-place system and yellow—non potable water system. Pasteurized milk and fluid milk products shall be conducted from one piece of equipment to another only through sanitary piping.

13. Item 11p.—Construction and Repair of Containers and Equipment: All multiuse containers and equipment with which milk or fluid milk products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which milk or fluid milk products come in contact shall be nontoxic, and shall have been manufactured, packaged, transported, and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

14. Item 12p.—Cleaning and Sanitizing of Containers and Equipment: The product-contact surfaces of all multiuse containers, utensils and equipment used in the transportation, processing, handling, and storage of milk and fluid milk products shall be effectively cleaned and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed milk or milk products beyond the final heat treatment process shall be sterilized before any aseptically processed milk or milk product is packaged and shall be resterilized whenever any unsterile product has contaminated it.

15. Item 13p.—Storage of Cleaned Containers and Equipment: After cleaning, all multiuse milk or fluid milk product containers, utensils, and equipment shall be transported and stored to assure complete drainage, and shall be protected from contamination before use.

16. Item 14p.—Storage of Single–Service Containers, Utensils, and Materials: Single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk and fluid milk products shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept therein a clean, dry place until used; and shall be handled in a sanitary manner.

17. Item 15p.—Protection from Contamination: Milk plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk or fluid milk products, ingredients, equipment, containers, and utensils. All milk or fluid milk products or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than milk and fluid milk products in the pasteurization plant shall be performed to preclude the contamination of such milk and fluid milk products. The storage, handling, and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and fluid milk products or ingredients of such milk and fluid milk products or the product-contact surfaces of all equipment, containers or utensils.

18. Item 16p.—Pasteurization and Aseptic Processing: Pasteurization shall be performed as required in N.J.A.C. 8:21–10.1. Aseptic processing shall be accomplished in accordance with the provisions of 21 CFR 113 and 108.

19. Item 17p.—Cooling of Milk: All raw milk and fluid milk products shall be maintained at 45 degrees Fahrenheit (seven degrees Celsius) or less until processed. All pasteurized milk and fluid milk products, except those to be cultured, shall be cooled to a temperature of 45 degrees Fahrenheit (seven degrees Celsius) or less immediately in approved equipment prior to filling and packaging. All pasteurized milk and fluid milk products shall be stored at a temperature of 45 degrees Fahrenheit (seven degrees Celsius) or less. On delivery vehicles, the temperature of milk and fluid milk products shall not exceed 45 degrees Fahrenheit (seven degrees Celsius). Every room or tank in which milk or fluid milk products are stored shall be equipped with an accurate thermometer. Provided, that aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

20. Item 18p.—Bottling and Packaging: Bottling and packaging of milk and fluid milk products shall be done at the place of pasteurization in approved mechanical equipment.

21. Item 19p.—Capping: Capping or closing of milk and fluid milk product container shall be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection.

22. Item 20p.—Personnel Cleanliness: Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his hands. All persons engaged in the processing, pasteurization, handling, storage, or transportation of milk and fluid milk products, containers, equipment and utensils shall wear clean outer garments. The use of tobacco by any person while engaged in the processing of milk or fluid milk products is prohibited. Adequate hair coverings shall be worn by persons engaged in the processing of milk and fluid milk products.

23. Item 21p.—Vehicles: All vehicles used for transportation of pasteurized milk and fluid milk products shall be constructed and operated so that the milk and fluid milk products can be maintained at 45 degrees Fahrenheit (seven degrees Celsius) or less, and are protected from sun, from freezing, and from contamination; provided, however, that the provisions of Item 17p above are adhered to.

24. Item 22p.—Surroundings: Milk plant surroundings shall be kept neat, clean, and free from conditions which might attract or harbor flies, other insects and rodents, or which otherwise constitute a health nuisance.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Temperature range of raw milk added at (b); exceptions for cultured and bulk-shipped, heat-treated products added; milk barn and returned milk requirements added.
Amended by R.1993 d.689, effective December 20, 1993.
See: 25 N.J.R. 4373(a), 25 N.J.R. 6013(a).

8:21–10.7 Transferring; delivery containers; cooling

(a) Except as permitted in these regulations, no milk producer, milk hauler or distributor shall transfer milk or fluid milk products from one container or milk tank truck to another on the street, in any vehicle, store, or in any place except a milk plant, receiving station, transfer station, or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

(b) It shall be unlawful to sell or serve any milk or fluid milk product except in the individual, original container received from the distributor, or from an approved bulk dispenser; Provided that, this requirement shall not apply to milk for mixed drinks requiring less than one-half pint of milk, or to cream, whipped cream or half-and-half which is consumed on the premises and which may be served from the original container of not more than one-half gallon capacity, or from a bulk dispenser approved for such service by the health authority.

(c) It shall be unlawful to sell or serve any pasteurized milk or fluid milk product which has not been maintained at a temperature of 45 degrees Fahrenheit (seven degrees Celsius) or less. If containers of pasteurized milk or fluid milk products are stored in ice, the storage container shall be properly drained.

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

8:21–10.8 Milk and milk products from points beyond the limits of routine inspections

Milk and fluid milk products from points beyond the limits of routine inspection of the Department may be sold in New Jersey; Provided that they are produced and pasteurized, ultra-pasteurized, or aseptically processed under regulations which are substantially equivalent to these regulations and have been awarded an acceptable milk sanitation compliance and enforcement rating made by a State Milk Sanitation Rating Officer certified by the U.S. Food and Drug Administration; Provided further, that said unit of government accepts New Jersey milk and fluid milk products certified by a certified New Jersey milk sanitation rating officer.

8:21–10.9 Personnel health

No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm or milk plant in any capacity which brings him into contact with the production, handling, storage, or transportation of milk, fluid milk products, containers, equipment

and utensils; and no dairy farm or milk plant operator shall employ in any such capacity any such person, or any person suspected of having any disease in a communicable form, or of being a carrier of such disease. Any producer or distributor of milk or fluid milk products, upon whose dairy farm, or in whose milk plant any communicable disease occurs, or who suspects that any employee has contracted any disease in a communicable form, or has become carrier of such disease, shall notify the health authority immediately.

8:21–10.10 Procedure when infection is suspected

(a) When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk and/or fluid milk products, the health authority is authorized to require any or all of the following measures:

1. The immediate exclusion of that person from milk handling;

2. The immediate exclusion of milk supply concerned from distribution and use; and,

3. Adequate medical and bacteriological examination of the person, or his associates, and of his and their body discharges.

8:21–10.11 Future dairy farms and milk plants

(a) Properly prepared plans for all milk houses, milking barns, stables and parlors which are hereinafter constructed, reconstructed or extensively altered shall be submitted to the certified industry inspector or Department for review before work is begun.

(b) Properly prepared plans for all transfer stations, receiving stations and milk plants which are hereinafter constructed, reconstructed or extensively altered shall be submitted to the Department for review before work is begun.

(c) The certified industry inspector or Department shall review these plans and respond accordingly within 30 days of the date of submission. The certified industry inspector shall send a copy of the plans for any milk house, milking barn, stable or parlor to the Department after approval is granted.

(d) No milk house, milking barn, stable, parlor, transfer station, receiving station or milk plant shall be constructed, reconstructed or extensively altered except in accordance with plans previously submitted to the appropriate certified industry inspector, health and construction authorities.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Plans to be sent to Department of Health.

8:21–10.12 Dating of milk and fluid milk products

(a) Fluid milk products as defined in N.J.S.A. 24:10–57.1 and all types and varieties of cottage and soft cheeses designated by the Department, intended for direct sale to consumers, shall be legibly marked with a "shelf-life expiration date." This date shall be determined and applied on the final consumer package or container by the initial processor or manufacturer. Prior to determining this date, each processor or manufacturer shall notify the Department of the intended date selected by him for each fluid milk product. All data and material used by the processor or manufacturer in his determination of this date shall be made available to the Commissioner upon request. If the data and material submitted does not, in the opinion of the Commissioner, justify the "shelf-life expiration date," the Commissioner shall prohibit the sale of the product until such time as satisfactory data is supplied or until a new "shelf-life expiration date" consistent with the data is applied to the product.

(b) The packages or containers shall be marked with the legend "not to be sold after," or "sell by," or any other clearly understandable legend approved by the Department, followed by the "shelf-life expiration date." The designation of the month and date of the month after which the product shall not be sold may be numerical, such as "9–15" or "0915" for September 15 or with the use of an abbreviation for the month such as "Sep 15" or "Se 15."

(c) The "shelf-life expiration date" shall appear in a clear and legible manner and shall be placed on the part of the package or container most likely to be displayed, presented, or shown or examined under customary conditions of display for retail sale, and shall not interfere with the legibility of other mandatory labeling requirements of the product. However, cup containers that are labeled with the date on the bottom of the container shall have displayed on the cap or other conspicuous position information indicating the location of the date. The same provision applies for dates molded into plastic containers. Individual portion-pak containers not intended for direct resale to consumers shall be exempted, provided the bulk container in which they are distributed is properly dated. Containers and packages of frozen cream and frozen desserts mixes not intended for resale to consumers shall also be exempted from the provisions of this regulation.

(d) No milk product referred to in this regulation shall be sold or offered for sale after 11:59 P.M. of the date appearing on the package or container. Products delivered prior to the "shelf-life expiration date" may be consumed on the premises beyond the date appearing thereon.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Reference to certified milk deleted.
Amended by R.1993 d.689, effective December 20, 1993.
See: 25 N.J.R. 4373(a), 25 N.J.R. 6013(a).

8:21–10.13 Temporary marketing permit

Any person holding a current New Jersey milk plant license who wishes to manufacture a fluid milk 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, including, but not limited to: name, address, and telephone number of applicant; brand name of product; estimated amount of product to be produced; product description and specific difference(s) between the standardized fluid milk product and the product for which the temporary marketing permit is being requested. Such permit shall be for a period not to exceed one year; however it may be renewed pending action by the Department.

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

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

8:21–11.1 Scope

The following rules shall be met by all establishments used in the production, preparation, manufacture, packaging, storage, transportation or handling of food intended for sale or distribution at the wholesale or retail levels.

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 scope recodified from Forward; text on definitions recodified to 11.2.

8:21–11.2 Definitions

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

"Adulteration" means the term "adulteration" as defined in N.J.S.A. 24:5–8.

"Clean" means free of visible soil and thoroughly cleaned to sight and touch.

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

"Distressed foods" means foods which have been subject to "natural" or "local disaster" situations. The term also applies to food which has been involved in railroad and highway accidents, long-term bankruptcy proceedings, and foods which are otherwise suspected of being adulterated, misbranded or otherwise unsafe or unfit for human consumption.

"Embargo" means the term "embargo" as defined in N.J.S.A. 24:4–12.

"Flipper" means a container in which only one end is slack or slightly bulged. That end will remain flat if pressed in. Cans which bulge when sharply and squarely struck enddown on a flat surface are flippers, provided that the bulged end remains flat when pressed. Flippers result from a lack of vacuum.

"Food" means the following.

1. Articles used for food or drink for man or any other animal.
2. Chewing gum.
3. Articles used for components of any such article.
4. The term includes any raw, cooked or processed edible substance, beverage or ingredient used or intended for use or for sale in whole or in part for food.

"Food establishment" means any place used in the production, preparation, manufacture, packaging, storage, transportation, service or handling of food intended for sale or distribution at the wholesale or retail levels.

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

"Industrial mishandling" means damage to food containers through faulty manufacturing processes, faulty closure, denting of cans at the place of manufacture, mishandling during storage and transportation, damage caused at warehouse facilities and damage caused by mishandling at the retail level.

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

"Leaker" means a faulty hermetically sealed container which allows its contents to leak therefrom due to faulty seaming, rupture of the seal, industrial mishandling, severe denting, holes which develop in the container, and pressure which develops within the food container.

"Local disaster" means a fire, local flooding, disruption of electrical service, fuel shortage, leaking sprinkler system, faulty roofing, traffic accident, or similar conditions which may adversely affect the quality and safety of foods within a food establishment. "Local health authority" means the local board or local board of health of any municipality or the boards, body or officers in such municipality lawfully exercising any of the powers of the local board of health

under the laws governing such municipality, and includes any consolidated board of health or county local board of health created and established pursuant to law.

"Misbranding" means the term "misbranded" or "misbranding" as defined in N.J.S.A. 24:5–16, 17.

"Natural disaster" means a violent upheaval of nature in the form of heavy rainfall, tornado, hurricane, snow, hail, lightning, flood, wind, earthquake, or similar phenomena in which normal operations in a food establishment or foods during transit are disrupted.

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

"Reconditioning" means subjecting "distressed foods" to inspection, examination and treatment by washing, cleaning, buffing, sanitizing and any other process that will render the foods free from contamination and safe for use as food.

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

"Sanitize" means effective bactericidal treatment of clean surfaces by a process which has been approved by the department as being effective in destroying microorganisms, including pathogens.

"Springers" means containers in which one end of the can bulges. Manual pressure of the bulged end forces the opposite end out, or the same end will spring out when released of pressure. If both ends bulge but only one end remains flat when pressed, the can is a springer. Springers result from a moderate positive pressure within the can. Bulging or extensive denting of the side walls may produce a springer.

"Swells" means containers in which both ends of the can are bulged. Neither end will remain flat without pressure. Soft swells yield to manual pressure, but no impression can be made manually on hard swells. Swells result from positive pressure in the can usually because of spoilage of the contents. Some swells, especially in acidic products, may result from chemical reaction between the contents and the container.

"Wholesome" means in sound condition, clean, free from adulteration, and otherwise safe and suitable for use as food.

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 definitions recodified from 11.1; text on damaged cans unsuitable for sale recodified to 11.3.

8:21–11.3 Damaged cans unsuitable for sale

(a) No person shall offer for sale or hold with the intent to sell any can or jar with bulged ends, or containers which are swells, springers, or flippers; this requirement includes cans with bulged lids caused by severe dents; provided, however, that beer or carbonated beverage containers which appear to be slightly bulged due to naturally occurring gas would be exempt from this provision and further provided that foods subjected to industrial mishandling may be sold to a salvage or distressed food dealer for segregation and reconditioning purposes.

(b) No person shall offer for sale any hermetically sealed can, jar or containers with visible evidence of product leakage.

(c) No person shall offer for sale any pull top container which contains obvious fractures of the lip scorelines, or glass containers showing any evidence of loosening or opening of the closure or other condition which affects the integrity of the seal.

(d) No person shall offer for sale any badly rusted and/or severely pitted container which cannot be properly cleaned and reconditioned by a moderate buffing procedure.

(e) No person shall offer for sale any severely dented can in which the end seam is pulled out of position to such an extent that the malposition is readily noticeable and there is evidence that the end seam may have been placed under tension.

(f) No person shall offer for sale any severely dented can which contains a very deep, sharp, angular dent with very acute crimping of the body wall.

(g) No person shall offer for sale any severely dented can in which the end seam has been forced out of position to such an extent that the countersink has been buckled which materially affects or is likely to affect the safety and usability of the container.

(h) No person shall offer for sale any container in which there is an improper end seam closure whereby a portion of the cover or body flange has not been tucked properly into the end seam.

(i) No person shall offer for sale any food container which is not properly labeled or has lost its identity due to natural disaster and/or local disaster conditions and cannot be properly re-identified.

(j) No person shall offer for sale foods in paper, plastic, or similar food containers or wrappings which have been damaged by penetration to such an extent that the product contained therein has been contaminated or adulterated.

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

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 damaged cans unsuitable for sale recodified from 11.2; text on damaged food containers suitable for sale recodified to 11.4.

8:21–11.4 Damaged food containers suitable for sale

(a) Damaged food containers suitable for sale:

1. Any food container which contains a body dent which forces the end seams inward to such an extent that the countersink is involved, but no sharp edges are evident;

2. Any food container which contains moderately deep angular indentations with moderately acute crimping of the body wall;

3. Any food container which contains a moderately deep, sharp, angular indentation with moderately acute crimping of the body wall—the end seam malposition is so slight that it could be detected only by use of a straight edge or flat surface;

4. Any food container which contains deep, sharp vertical or side rim dents on the double seam, but not severe enough to cause the lid to bulge or buckle noticeably—provided, however, in instances where the dent is severe and the continuity of the seam is disrupted or a rise is noted in the end plate of the site of the rupture, the can would be unsuitable for sale for food purposes;

5. Any food container which contains slight rust, easily removable by cleaning or moderate buffing;

6. Any paper, plastic or similar food container or wrapping which contains only slight damage such as crushing and there is no evidence of penetration into the interior of the container or exposure of the foods contained therein.

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 damaged food containers suitable for sale recodified from 11.3; text on salvage of "food, drugs, devices or cosmetics ....." recodified to 11.5.

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

(a) General provisions are as follows:

1. All food, drugs and cosmetics and devices in establishments affected by polluted water, smoke, chemicals or other contaminating substance shall be promptly placed under written embargo until such time as their disposition can be supervised.

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

3. All adversely affected perishable foods should be ordered destroyed immediately by incineration or burial unless an approved salvage plan is available.

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

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

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

7. All affected food, drugs and cosmetics in containers other than hermetically sealed cans are to be destroyed either by incineration, denaturing and burial, or approved for industrial use. Containers sealed by rubber gaskets, crimping or other similar means which do not permit proper sanitization or decontamination should be destroyed.

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

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

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

ii. Sanitized by immersion in a solution of chlorine of at least 200 parts per million (ppm) strength for at least five minutes or by the use of equivalent solutions of quarternary ammonium compounds, iodine compounds or other chemicals that produce the same result;

iii. Rinsed in clean water, air dried or hand dried promptly and stored under embargo in a dry clean place for 15 days, provided, however, that foods subjected to intense heat such as in a fire shall be stored for 30 days;

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

(c) Rules concerning frozen and refrigerated foods and drugs are as follows.

1. Frozen or refrigerated food and drugs should be handled in accordance with instructions in subsections (a) and (b) of this section, except for those foods not subject to contamination but stored in places where power failures have occurred.

i. Potentially hazardous foods in cold storage rooms where temperatures have risen above 45 degrees Fahrenheit for an extended period of time should be destroyed. (Loss of power for less than 24 hours duration usually will not affect food and drugs if doors are not opened too frequently.)

ii. Frozen foods that have partially or wholly defrosted should be cooked immediately or destroyed and should not be refrozen unless cooked. (Loss of power for less than 48 hours duration usually will not affect the foods if doors are not opened too frequently.)

(d) Rules concerning malt, fermented or distilled alcoholic beverages are as follows.

1. Hermetically sealed cans of beer and soda may be salvaged in accordance with subsection (b) of this section.

2. Whiskeys and liquors shall only be salvaged for redistillation to commercial grade alcohol. (See N.J.A.C. 8:21–11.5(a)1, 4, 5 and 6.)

3. Contaminated containers of alcoholic beverages shall be retained under embargo whenever possible in order to provide an opportunity for the owner to seek possible tax reimbursement.

(e) Rules concerning paper, plastic or similar type food containers, wrappings or utensils are as follows.

1. Paper, plastic or similar food containers, wrappings or utensils which have been exposed to natural or local disasters or industrial mishandling, and have been contaminated by flood or other contaminated water or chemicals during a fire shall be condemned for food purposes and caused to be destroyed; provided, however, that the paper, plastic or similar food containers with multiple layers which have been slightly dampened with water and the inner layers remain dry, and the foods contained therein not adversely affected, may be salvaged by stripping the outer layers and properly repackaging and labeling.

2. Single service food containers, utensils and wrapping materials which have been exposed to natural or local disasters or industrial mishandling shall be destroyed for use on or with foods.

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

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

(g) All mud, debris and other soil shall be removed from floors, sidewalls and ceilings of a food, drug or cosmetic establishment, be flushed with clean water, treated with a hypochloride solution, be thoroughly ventilated, and then allowed to dry.

(h) Every food establishment shall provide a single designated area (morgue) identified by a sign in which damaged or distressed food containers shall be placed pending proper disposition.

(i) All food, drug, and cosmetic establishments utilizing a private water supply system shall contact the Department of Environmental Protection or the local health authority relative to a sanitary survey of the entire water supply system and for directions for disinfecting the water supply and water supply system.

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 salvage of "food, drugs, devices or cosmetics . . ." recodified from 11.4; text on disposal of distressed foods recodified to 11.6.

8:21–11.6 Disposal of distressed foods

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

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

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

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

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

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

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

7. Small lots of condemned foods may be denatured or decharacterized and disposed of by a method in which there is no possible way the foods can be recovered and re-enter food channels.

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

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

10. In no instance shall any poisonous, toxic or other dangerous food which may have an adverse environmental impact be disposed of without prior permission from the Department of Environmental Protection.

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 disposal of distressed foods recodified from 11.5.

SUBCHAPTER 12. (RESERVED)

Subchapter Historical Note

Subchapter 12, Manufacturing, Storage, Distribution and Handling of Nonalcoholic Beverages and Bottled Water, 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 12 was repealed by R.1990 d.563, effective November 19, 1990. See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).

SUBCHAPTER 13. RULES GOVERNING WHOLESALE FOOD ESTABLISHMENTS

8:21–13.1 Scope

The following rules shall apply to all wholesale food establishments, including establishments bottling nonalcoholic beverages. For the purpose of these rules, the term "food" used throughout these rules shall also include "nonalcoholic drink" as defined under N.J.S.A. 24:12–1.

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 separability recodified to 13.2; new rule on scope added.

8:21–13.2 Separability

If any provision or application of any provision of this regulation is held invalid, that invalidity shall not affect other provisions or applications of this regulation.

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 separability recodified from 13.1; definitions recodified to 13.3.

8:21–13.3 Definitions

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

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practices.

"Adulteration" means the term "adulteration" as defined in N.J.S.A. 24:5–8.

"Approved" shall mean acceptable to the Department, Local Health Authority, or other appropriate Administrative Agency based on its determination as to the conformance with applicable standards and good public health practices.

"Color additive" means a material which is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and when added or applied to a food, drug, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that the term does not include any material which the Commissioner, by regulation, determines is used (or is intended to be used) solely for a purpose or purposes other than coloring and nothing herein contained shall be construed to apply to any pesticide chemical, soil, or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest. The term "color" includes black, white, and intermediate grays.

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

"Federal Act" means the Federal Food, Drug and Cosmetic Act (Title 21, U.S.C. 301 et seq.: 52 Stat. 1040 et seq.).

"Food" means:

1. Articles used for food or drink for man or other animals;

2. Chewing gum; and

3. Articles used for components of any such article.

The term also includes any raw, cooked or processed edible substance, beverage or ingredient used or intended for use or for sale in whole or in part of food.

"Food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that the term does not include:

1. A pesticide chemical in or on a raw agricultural commodity; or

2. A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

3. A color additive; or

4. Any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71).

"Food contact surfaces" are those surfaces that contact food and those surfaces from which drainage onto foods or onto surfaces that contact food ordinarily occurs during the normal course of operations.

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

"Lot" means a collection of primary containers or units of the same size, type, and style containing a finished product produced under conditions as nearly uniform as possible and designated by a common container, code or marking; and, in any event, "lot" means no more than a day's production or 24 hours.

"Misbranding" means the "misbranded" or "misbranding" as defined in N.J.S.A. 24:5–16 and 17.

"Multiservice containers" means containers intended for use more than one time.

"Nonalcoholic drink" means beverages as defined under N.J.S.A. 24:12–1.

"Nontoxic materials" means materials for food contact surfaces utilized in the transporting, processing, storing, or packaging of food which are free of substances which may render the food injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the food.

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

"Pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is a "pesticide" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

"Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, storage, processing, packaging, labeling, or handling of food and nonalcoholic drinks which is not sold or distributed directly to the ultimate consumer (retail).

"Potentially hazardous food" means any food which consists in whole or in part of milk or milk products, eggs, meat, poultry, fish, shellfish, edible crustacea, or other ingredients, including synthetic ingredients, in a form capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. The term does not include clean, whole, uncracked, odor-free shell eggs, or foods which have a pH level of 4.6 or below or a water activity (a_w) value of 0.85 or less.

"Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

"Rework" means clean unadulterated product, removed after or during processing, that is suitable for reprocessing and for use as food.

"Safe temperatures", as applied to potentially hazardous food, means temperatures of 45 degrees Fahrenheit or below, and 140 degrees Fahrenheit or above unless otherwise specified, and 0 degrees Fahrenheit or below for frozen foods.

"Sanitize" means adequate treatment of surfaces by a process that is effective in destroying the vegetative cell of microorganisms of public health significance and in substantially reducing numbers of other microorganisms. Such treatment shall not adversely affect the product and shall be safe for the consumer.

"Single service container" means a container intended for one-time usage only.

Amended by R.1990 d.563, effective November 19, 1990.
See: 22 N.J.R. 2465(a), 22 N.J.R. 3559(a).
Definitions recodified from 13.2; nonalcoholic drink added; text on facilities for storage, distribution, etc. recodified to 13.4.

8:21–13.4 Facilities and procedures for the storage, distribution, handling and processing of food and nonalcoholic drinks

(a) Grounds: The grounds surrounding a plant under the control of the operator shall be kept in a condition that will not cause the food to be contaminated and/or adulterated. The methods for adequate maintenance as a minimum shall be:

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

2. Maintaining roads, yards, and other parking lots so that they do not constitute a source of contamination to the food.

3. Adequately draining areas that may contribute contamination to food by seepage, by foot-borne filth, or by providing a breeding place for rodents, insects or other pests.

(b) Plant layout and design: Buildings used for and in conjunction with the handling of food shall be suitable in size, construction and design to facilitate maintenance and sanitary operations for processing purposes. The plant layout and design shall be in such a manner that the purity, quality, and wholesomeness of the food therein manufactured, produced, packaged, prepared, stored, sold or distributed shall not be impaired. No loading or unloading of trucks or other vehicles shall take place within an establishment unless acceptable segregation or isolation of the mixing, processing or filling operations is provided. The plant and facilities shall:

1. Be kept in good repair and shall be maintained in a sanitary condition at all times.

2. Provide sufficient space for such placement of equipment and storage of materials as is necessary for sanitary operations.

3. Take proper precautions to reduce the potential for contamination of end products, raw materials, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination shall be reduced by any effective means including the separation by location, partition, air flow, enclosed systems or other effective means, of the following operations:

i. Receiving;

ii. Raw material storage;

iii. Food preparation and processing operations;

iv. Weighing, wrapping, packaging, and packing;

v. Finished product storage and shipping;

vi. Portable equipment and utensil cleaning and sanitizing; and

vii. Equipment and vehicle maintenance.

4. Provide floors, walls and ceilings that are of such construction as to be easily cleanable and shall be kept clean and in good repair. Fixtures, ducts, and pipes shall be installed in such a manner that drip or condensation does not contaminate the food, raw materials or food contact surfaces. Aisles or walking spaces between equipment and walls shall be unobstructed and of sufficient width to permit employees to perform their duties without contamination of the food or food contact surfaces.

5. Permanently fixed artificial light sources shall be installed to provide:

i. At least 20 foot candles of light in utensils and equipment storage areas and in laboratory and toilet areas.

ii. At least 10 foot candles of light in walk-in refrigerating units, dry food storage areas, and in all other areas. This shall also include dining areas during cleaning operations.

iii. Permanently fixed artificial light sources shall be installed to provide at least 30 foot candles of light on all food preparation surfaces and at equipment or utensil-washing work levels.

iv. Light fixtures which are located in processing, preparation, equipment/utensil washing areas or other areas where food may be exposed shall be of the safety/shatter-proof type, or otherwise protected to prevent food contamination and/or adulteration in cases of breakage.

6. Ventilation:

i. All rooms shall have sufficient ventilation to keep them free of excessive heat, steam, grease, condensa-

tion, vapors, obnoxious odors, smoke, product dust and fumes;

ii. Exhaust hoods and ventilating devices shall be maintained clean and operated in areas where needed to expel excessive heat, steam, vapor, smoke, grease, fumes, product dust and obnoxious odors and to prevent the dissipation of these objectionable odors throughout the room.

iii. On all new installations or in extensively remodeled establishments, ventilating systems, including hood ventilators, shall be designed, maintained and operated in accordance with N.J.A.C. 5:23–1 and shall be designed to prevent grease or condensate from dripping into food or onto food preparation surfaces.

iv. All ducts in ventilating hoods shall be provided with filters which are readily removable for cleaning and replacement excepting those systems which are effectively self-cleaning.

v. Ventilation systems shall comply with applicable State and local fire prevention requirements and shall, when vented to the outside air, discharge in such a manner as not to create a nuisance.

vi. Where intake or exhaust air ducts are used, they shall be designed and maintained so as to prevent the entrance of dust, dirt, insects, rodents or other contaminating materials.

vii. In new or extensively remodeled establishments, all rooms from which obnoxious odors, vapors or fumes originate shall be mechanically vented to the outside.

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 facilities for storage, distribution, etc. recodified from 13.3; text on sanitary facilities recodified to 13.5.

8:21–13.5 Sanitary facilities and controls

(a) The establishment shall be provided with adequate sanitary facilities and control measures to protect the purity, quality, and wholesomeness of the food. Facilities and controls shall include, but not be limited to the requirements of this section.

(b) Water supply: The water supply shall be sufficient for the operations intended and shall be derived from an adequate and approved source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where the processing of food, the cleaning of equipment, utensils, or containers, or employee sanitary facilities require.

1. The water supply shall be from a public or private 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. 7:10–1) 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.

(c) Sewage: 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 N.J.A.C. 7:9–2, Standards for the Construction of Individual Subsurface Sewage Disposal Systems, the New Jersey Water Pollution Control Act regulations, N.J.A.C. 7:14 and local laws, ordinances, and regulations.

(d) Plumbing: Plumbing shall be so sized, installed and maintained in accordance with applicable State and local standards as to carry sufficient quantities of water to required locations throughout the establishment; prevent contamination of the water supply; properly convey sewage and liquid waste from the establishment to the sewer or sewage disposal system; and does not constitute a source of contamination of food, equipment, or utensils or create an insanitary condition or nuisance.

(e) Drains: Provide adequate floor drainage in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

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

1. Toilet facilities shall be installed in accordance with N.J.A.C. 5:23–1. When a common toilet is used for employees and patrons, access shall not be through food preparation, food storage and utensil and equipment washing areas.

2. A supply of toilet tissue shall be provided at each toilet at all times. Handwashing signs, for example, "Wash Hands Before Resuming Work", shall be posted conspicuously in all toilet rooms and at each separate lavatory facility in a food plant. Easily cleanable receptacles shall be provided for waste materials and such receptacles in toilet rooms for women shall be covered. Such receptacles shall be emptied at least once a day, and more frequently when necessary, to prevent excessive accumulation of waste material.

3. Hot and cold water under suitable pressure shall be provided in toilet facilities. (90°F–105°F)

(g) Hand-washing facilities: Adequate and convenient facilities for handwashing and, where appropriate, hand sanitizing shall be provided at each location in the plant where good sanitary practices require employees to wash or sanitize and dry their hands. Such facilities shall be furnished with running water at 90 degrees Fahrenheit to 105 degrees Fahrenheit for handwashing, effective hand-cleaning and sanitizing preparations, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

1. Handwashing facilities shall be installed in accordance with N.J.A.C. 5:23–1 and used only for the washing of hands and arms.

2. Each handwashing facility shall be designed to provide hot and cold or temperated water. Tempering may be accomplished by means of a mixing valve or combination faucet. Any self-closing, slow-closing, or metering faucet used shall be designed to provide a flow of water for at least 15 seconds without the need to reactivate the faucet. Steam-mixing valves are prohibited.

(h) Rubbish and offal disposal: Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, prevent waste from becoming an attractant and harborage or breeding place for vermin, and prevent contamination of food, food-contact surfaces, ground surfaces, and water supplies. Rubbish and offal disposal shall also be in conformance with N.J.A.C. 8:24–6.10.

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 sanitary facilities recodified from 13.4; text on sanitary operations recodified to 13.6.

8:21–13.6 Sanitary operations

(a) General maintenance: Buildings, fixtures, and other physical facilities of the plant shall be kept in good repair and shall be maintained in a sanitary condition. Cleaning operations shall be conducted in such a manner as to minimize the danger of contamination of food and food-contact surfaces. Detergents, sanitizers, and other supplies employed in cleaning and sanitizing procedures shall be free of significant microbiological contamination and shall be safe and effective for their intended uses. Only such toxic materials as are required to maintain sanitary conditions, for use in laboratory testing procedures, for plant and equipment maintenance and operation, or in manufacturing or processing operations shall be used or stored in the plant. These materials shall be identified and used only in such manner and under conditions as will be safe for their intended uses and stored in such a manner as to preclude the contamination to the product.

(b) Animal and vermin control: No animals or birds, other than those essential as raw material, shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing and storage areas and to protect against the contamination of foods in or on the premises by animals, birds, and vermin (including, but not limited to, rodents and insects). The use of insecticides or rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging materials with illegal residues.

1. No person shall apply insecticides or rodenticides in or around any food establishment unless they do so in full compliance with New Jersey Department of Environmental Protection regulations N.J.A.C. 7:30.

(c) Sanitation of equipment and utensils: All utensils and food-contact surfaces of equipment shall be cleaned as frequently as necessary to prevent contamination of food and food products. Nonfood-contact surfaces of equipment used in the operation of food plants shall be cleaned as frequently as necessary to minimize accumulation of dust, dirt, food particles, and other debris. Single-service articles (such as utensils intended for one-time use, paper cups, paper towels, etc.) shall be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that prevents contamination of food and food-contact surfaces.

1. Where necessary to prevent the introduction of undesirable microbiological organisms into food products, all utensils and food-contact surfaces of equipment used in the plant shall be cleaned and sanitized prior to such use and following any interruption during which such utensils and contact surface may have become contaminated.

2. Where such equipment and utensils are used in a continuous production operation, the contact surfaces of such equipment and utensils shall be cleaned and sanitized on a predetermined schedule using adequate methods for cleaning and sanitizing. Sanitizing agents shall be effective and safe under conditions of use.

3. Any facility, procedure, machine, or device may be acceptable for cleaning and sanitizing equipment and utensils if it is established that such facility, procedure, machine, or device will routinely render equipment and utensils clean and provide adequate sanitizing treatment.

4. Equipment and utensil cleanliness and sanitizing procedures shall also be in conformance with the procedures as outlined in N.J.A.C. 8:24–5.3 through 5.6.

(d) Storage and handling of cleaned portable equipment and utensils: Cleaned and sanitized portable equipment and utensils with food-contact surfaces shall be stored in such a location and manner that food-contact surfaces are protected from splash, dust, and other contamination.

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 sanitary operations recodified from 13.5; text on equipment and procedures recodified to 13.7.

8:21–13.7 Equipment and procedures

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

1. Food-contact surfaces shall be corrosion free when in contact with food. They shall be made of nontoxic material that will withstand the environment of its intended use and action of food ingredients, cleaning compounds, and sanitizing agents. All food-contact surfaces shall be maintained to prevent product contamination.

2. Seams in food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles or to prevent microbiological contamination in places where dirt or organic material might accumulate.

3. Equipment that is in the processing or food handling area and that does not come into contact with product shall be so constructed that it can be kept in a clean condition.

4. Ingredient and product holding, conveying, and processing systems that include, but are not limited to, gravimetric, pneumatic, closed, and automated systems shall be of a design and construction that enables them to be cleaned and sanitized.

5. Regulating and recording controls, thermometers, other temperature measuring devices and temperature recording devices on equipment used to sterilize, pasteurize, or otherwise control or prevent growth of microorganisms in raw materials or products shall be accurate, effective, and adequate in number for their designated uses.

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

7. Instruments used for measuring or regulating pH, acidity, water activity, or other conditions that control or prevent undesirable microbial growth in foods shall be precise and properly maintained.

8. All compressed air or other gases, mechanically introduced into foods or used to clean food-contact surfaces or equipment, shall be adequately filtered or washed and shall be free of oil and other extraneous material that might contaminate the foods.

9. All equipment ports, hatches and other openings shall be provided with tight fitting covers and shall be kept in place and used to prevent airborne contamination and/or adulteration.

10. The design, construction, installation, and materials for food equipment, shall be in compliance with N.J.A.C. 8:24–5.1 and 5.2.

11. Equipment used to bottle, cap, and sanitize multiuse containers in a nonalcoholic drink bottling plant shall conform to the requirements set forth under N.J.A.C. 8:21–5.7(f) and (g), and N.J.A.C. 8:21–5.11.

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 equipment and procedures recodified from 13.6; text on personnel recodified to 13.8; nonalcoholic drink bottling requirements added at (a)11.

8:21–13.8 Personnel

(a) No person, while affected by a disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other sources of microbiological contamination, shall work in a plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by that person, or of disease being transmitted by that person to other individuals.

(b) All persons, while working in direct contact with food preparation, food ingredients, or food contact surfaces shall conform to good hygienic practices to the extent necessary to prevent contamination of food products. The methods for maintaining cleanliness shall include, but are not limited to:

1. Wearing clean outer garments in a manner that prevents the contamination of food;

2. Maintaining a high degree of personal cleanliness;

3. Washing hands thoroughly (and sanitizing if necessary to prevent contamination by undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from work station, and at any other time when the hands may have become soiled or contaminated;

4. Removing all insecure jewelry and during periods in which food and beverages are manipulated by hand, removing from hands any jewelry;

5. If gloves are used in food handling, maintaining them in an intact, clean, and sanitary condition. Gloves shall be made of non-absorbent material, and can be easily cleaned and sanitized if they are designed for reuse;

6. Wearing hair nets, headbands, caps, beard covers, or other effective hair restraints in an effective manner; and

7. Refrain from smoking in food preparation areas.

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 personnel recodified from 13.7; text on production and process controls recodified to 13.9.

8:21–13.9 Production and process controls

(a) All operations in the receiving, inspecting, transporting, packaging, segregating, preparing, processing, and storing of food shall be conducted in accord with adequate sanitation principles. Overall sanitation of the plant shall be under the supervision of an individual assigned responsibility for this function. All reasonable precautions, including the following, shall be taken to assure that production procedures do not contribute contamination such as filth, harmful chemicals, undesirable microorganisms, or any other objectionable material to the processed product.

(b) Raw materials and ingredients shall be inspected and segregated as necessary to assure that they are clean, wholesome, and fit for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as required to remove soil or other contamination. Water used for washing, rinsing, or conveying of food products shall be of approved quality, and water shall not be reused for washing, rinsing, or conveying products in a manner that may result in contamination of food products.

(c) Containers and carriers of raw ingredients shall be inspected on receipt to assure that their condition has not contributed to the contamination or deterioration of the products.

(d) When ice is used in contact with food products, it shall be made from potable water and shall be used only if it has been manufactured in accordance with accepted standards and stored, transported, and handled in a sanitary manner.

(e) Food processing areas and equipment used for processing human food shall not be used to process nonhuman food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.

(f) Processing equipment shall be maintained in a sanitary condition through frequent cleaning including sanitization where indicated. Insofar, as necessary, equipment shall be taken apart for thorough cleaning.

(g) All food processing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for undesirable bacterial or other microbiological growth, toxin formation, or deterioration or contamination of the processed product or ingredients. This may require careful monitoring of such physical factors as time, temperature, humidity, pressure, flow-rate and such processing operations as freezing, dehydration, heat processing, and refrigeration to assure that mechanical breakdowns, time delays, temperature fluctuation, and other factors do not contribute to the decomposition or contamination of the processed products.

(h) Chemical microbiological, or extraneous-material testing procedures shall be utilized where necessary to identify sanitation failures or food contamination, and all foods and ingredients that have become contaminated shall be rejected or treated or processed to eliminate the contamination where this may be effectively accomplished.

(i) Packaging processes and materials shall not transmit contaminants or objectionable substances to the products and shall provide adequate protection from contamination.

(j) Meaningful coding of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity shall be utilized to enable positive lot identification to facilitate, where necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use. Records shall be retained for a period of time that exceeds the shelf life of the product, except that they need not be retained more than two years.

(k) Storage and transportation of finished products shall be under such conditions as will prevent contamination, including development of pathogenic or toxigenic microorganisms, and will protect against undesirable deterioration of the product and the container. All potentially hazardous food shall be kept at the 45 degrees Fahrenheit or below or 140 degrees Fahrenheit or above, and frozen foods at or below 0 degrees Fahrenheit during transportation, provided that, cold food may be allowed to reach 55 degrees Fahrenheit and hot food may be allowed to reach 130 degrees Fahrenheit if they are to be consumed within one-half hour of plating. During transportation all food shall be in covered containers or completely wrapped or packaged so as to be protected from contamination and maintain safe temperatures except for hanging meats and raw agricultural products, which will be prepared for consumption in such a manner to remove the danger of possible contaminants. All food transportation vehicles, including carts, trucks, vans, and trailers shall be kept clean, free of vermin and in good repair.

(*l*) Perishable and potentially hazardous food shall be stored at safe temperature and in accordance with the standards set forth in N.J.A.C. 8:24–3.2.

(m) Containers of food shall be stored above the floor, on clean racks, dollies or other clean surfaces in such a manner as to be protected from splash and other contamination. Additionally, foods in bulk storage must be elevated four to six inches above the floor on racks or dollies and aisles must be provided between articles in storage and walls, and masses of foods must be broken down into manageable cells with aisles to allow for cleaning and inspection and to prevent insect and rodent harborage.

1. Foods in bulk storage shall be stored at least 12 inches from each wall and there shall be a white inspection strip on the floor along each wall where food is stored.

2. Foods packaged in cans, glass or other vermin-proof containers sealed in shipping cartons and stored on clean surfaces in rooms, the floors of which are not frequently washed or otherwise subjected to water, need not be elevated and aisles need not be provided if containers are in temporary storage for five days or less or stored on dollies, skids, racks or open-ended pallets, provided such equipment is easily removable either by hand or with the use of pallet moving equipment that is on the premises and used, and the areas are clean, and rodent, insect or other vermin harborages are not provided.

(n) The following Federal standards as now enforced and hereafter amended, shall apply in determining whether the food, facilities, methods, practices and controls used in the conformance with or operated or administered in conformity with good manufacturing practices to assure that food for consumption is safe: Code of Federal Regulations, Title 21, Subchapter B Food for Human Consumption, sections 100, 101, 102, 104, 105, 109.15, 110.40, 113, 114, 118, 122, 123, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, 169, 170, 172, 173, 174, 175, 176, 177, 178, 179, 181, 182, 184, 186, 189 and 193.

(*o*) Foods shall be considered unsafe if any of the following occurs:

1. If it bears or contains any added or adulterous substance which is unsafe; or

2. If it is, or it bears or contains any food additive which is unsafe; provided that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under the Federal Act and the raw agricultural commodity has been subjected to processing such canning, freezing, dehydration, or milling, the residue of such pesticide chemical remaining in or on the processed food shall not be deemed unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or

3. If it is, or it bears or contains a color additive which is unsafe under the Federal Act.

4. If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect under the Federal Act.

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 production and process controls recodified from 13.9; text on emergency occurrences recodified to 13.10.

8:21–13.10 Emergency occurrences

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

(b) Only those salvaged foods which comply with N.J.A.C. 8:21–11.1 entitled "Dented Cans: Salvaged or Distressed Foods, Alcohol and Nonalcoholic Beverages and Industrial Mishandling" may be used or offered for sale.

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 emergency occurrences recodified from 13.9.