CHAPTER 21

FOOD AND DRUGS

Authority

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

Source and Effective Date

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

Executive Order No. 66(1978) Expiration Date

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

Chapter Historical Note

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

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

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

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

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

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

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

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

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

1979 Revisions: Revisions became effective April 12, 1979 as R.1979 d.143. See: 11 N.J.R. 236(a). Further amendments became effective August 6, 1979 as R.1979 d.299. See: 11 N.J.R. 327(b), 11 N.J.R. 440(c). Further amendments became effective August 16, 1979 as R.1979 d.322. See: 11 N.J.R. 277(b), 11 N.J.R. 441(d). Further amendments became effective November 13, 1979 as R.1979 d.454. See: 11 N.J.R. 504(b), 11 N.J.R. 622(d).

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

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

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

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

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

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

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

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

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

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

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

CHAPTER TABLE OF CONTENTS

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

8:21–1.1 Definitions

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 through 8:21–2.12 (Reserved)

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 through 8:21–2.34 (Reserved)

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)

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 through 8:21–3.7 (Reserved)

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 1/20 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 through 8:21–3.18 (Reserved)

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)

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

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.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 STANDARDS FOR BOTTLED WATER

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.

(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 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, 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 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 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.

(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 sur-

faces 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.