

by reference is given in the introductory text of paragraph (b)(5)(ii) of this section.

(c) *Label statements.* When the microbiological, physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(2) through (b)(5), of this section, the label shall bear the statement of substandard quality specified in §130.14(a) of this chapter except that, as appropriate, instead of or in addition to the statement specified in §130.14(a) the following statement(s) shall be used:

(1) “Contains Excessive Bacteria” if the bottled water fails to meet the requirements of paragraph (b)(2)(i)(A) of this section.

(2) “Excessively Turbid”, “Abnormal Color”, and/or “Abnormal Odor” if the bottled water fails to meet the requirements of paragraph (b)(3) (i), (ii), or (iii), respectively, of this section.

(3) “Contains Excessive _____,” with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., “Contains Excessive Arsenic,” “Contains Excessive Trihalomethanes”) except that “Contains Excessive Chemical Substances” may be used if the bottled water is not mineral water.

(4) “Excessively Radioactive” if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) *Adulteration.* Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act), or that consists in whole or in part of any filthy, putrid, or decomposed substance, or that is otherwise unfit for food under section 402(a)(3) of the act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) of this section. If *E. coli* is present in bottled water, then the

bottled water will be deemed adulterated under section 402(a)(3) of the act.

[60 FR 57124, Nov. 13, 1995; 60 FR 66495, Dec. 22, 1995, as amended at 61 FR 13264, Mar. 26, 1996; 61 FR 14480, Apr. 2, 1996; 63 FR 25769, May 11, 1998; 66 FR 16865, Mar. 28, 2001; 66 FR 17359, Mar. 30, 2001; 66 FR 35373, July 5, 2001; 66 FR 56035, Nov. 6, 2001; 58 FR 15355, Mar. 31, 2003; 68 FR 9881, Mar. 3, 2003; 70 FR 33700, June 9, 2005; 74 FR 25665, May 29, 2009; 76 FR 64813, Oct. 19, 2011]

PART 166—MARGARINE

Subpart A—General Provisions

Sec.

166.40 Labeling of margarine.

Subpart B—Requirements for Specific Standardized Margarine

166.110 Margarine.

AUTHORITY: 21 U.S.C. 321, 341, 343, 347, 348, 371, 379e.

Subpart A—General Provisions

§ 166.40 Labeling of margarine.

The Federal Food, Drug, and Cosmetic Act was amended by Pub. L. 459, 81st Congress (64 Stat. 20) on colored oleomargarine or margarine by adding thereto a new section numbered 407. Among other things, this section requires that there appear on the label of the package the word “oleomargarine” or “margarine” in type or lettering at least as large as any other type or lettering on the label, and a full and accurate statement of all the ingredients contained in such oleomargarine or margarine. It provides that these requirements “shall be in addition to and not in lieu of any of the other requirements of this Act”.

(a) Under section 403(g) of the Federal Food, Drug, and Cosmetic Act, any article that is represented as or purports to be oleomargarine or margarine must conform to the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act (Subpart B of this part), and its label must bear the name “oleomargarine” or “margarine”.

(b) The identity standard for oleomargarine or margarine applies to both the uncolored and the colored article.

(c) In considering the requirement that the word “oleomargarine” or “margarine” be in type or lettering at least as large as any other type or lettering on the label, it must be borne in mind that at least three factors are involved—the height of each letter, the area occupied by each letter as measured by a closely fitting rectangle drawn around it, and the boldness of letters or breadth of the lines forming the letters. The type or lettering used should meet the following tests:

(1) The height of each letter in the word “oleomargarine” or “margarine” should equal or exceed the height of any other letter elsewhere on the label.

(2) The area of the closely fitting rectangle with respect to any of the letters in the word “oleomargarine” or “margarine” should equal or exceed the area of such rectangle applied to the same or a corresponding letter elsewhere on the label.

(3) The letters in the word “oleomargarine” or “margarine” should be equal to or exceed in prominence and boldness, such as breadth of lines forming the letters, the same or corresponding letters elsewhere on the label.

(d) [Reserved]

(e) The word “oleomargarine” or “margarine” (and thus the other information called for by the statute) should appear on each panel of the package label that might reasonably be selected by the grocer for display purposes at the point of sale.

(f) The amendment covering colored oleomargarine or colored margarine states that, “for the purposes of * * * section 407 of the Federal Food, Drug, and Cosmetic Act, as amended, the term ‘oleomargarine’ or ‘margarine’ includes: (1) All substances, mixtures, and compounds known as oleomargarine or margarine; (2) all substances, mixtures, and compounds which have a consistency similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter”. Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine or margarine promulgated under section 401 of the act, it was the clear intent of Congress that any arti-

cle which is represented as or purports to be oleomargarine or margarine is misbranded if it fails to comply with the definition and standard of identity for oleomargarine or margarine even though it may meet the statutory definition.

(g) Section 407(a) states that “Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this act as if it had been introduced in interstate commerce”.

(h) Section 407(b)(4) requires that each part of the contents of the package be “contained in a wrapper which bears the word ‘oleomargarine’ or ‘margarine’ in type or lettering not smaller than 20-point type”. The Food and Drug Administration interprets this to mean that the height of the actual letters is no less than 20 points, or $20/72$ of 1 inch.

(i) The wrappers on the subdivisions of oleomargarine or margarine contained within the package sold at retail are labels within the meaning of section 201(k) and shall contain all of the label information required by sections 403 and 407 of the Federal Food, Drug, and Cosmetic Act, just as in the case of 1-pound cartons, except that wrappers on the subdivisions contained within the retail package shall be exempt from compliance with the requirements of section 403 (e)(1), (g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor and label declaration of ingredients when (1) the subdivisions are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; (2) the wrappers on the subdivisions are labeled with the statement “This Unit Not Labeled For Retail Sale” in type size not less than one-sixteenth inch in height. The word “Individual” may be used in lieu of or immediately preceding the word “Retail” in the statement.

[42 FR 14477, Mar. 15, 1977, as amended at 46 FR 31005, June 12, 1981; 47 FR 32421, July 27, 1982]