

§ 146.114

21 CFR Ch. I (4-1-06 Edition)

(1) *Definitions*—(i) *Lot*. A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) *Lot size*. The number of primary containers or units in the lot.

(iii) *Sample size*. The total number of sample units drawn for examination from a lot.

(iv) *Sample unit*. A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit.

(v) *Defective*. Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) *Acceptance number (c)*. The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) *Acceptable quality level (AQL)*. The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) *Sampling plans*:

Lot size (primary containers)	Size of container	
	<i>n</i> ¹	<i>c</i> ²
NET WEIGHT EQUAL TO OR LESS THAN 1 KG (2.2 LB)		
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
NET WEIGHT GREATER THAN 1 KG (2.2 LB) BUT NOT MORE THAN 4.5 KG (10 LB)		
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19
NET WEIGHT GREATER THAN 4.5 KG (10 LB)		
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13

Lot size (primary containers)	Size of container	
	<i>n</i> ¹	<i>c</i> ²
Over 42,000	200	19

¹ *n*=number of primary containers in sample.
² *c*=acceptance number.

Subpart B—Requirements for Specific Standardized Canned Fruit Juices and Beverages

§ 146.114 **Lemon juice.**

(a) *Identity*—(1) *Description*. Lemon juice is the unfermented juice, obtained by mechanical process, from sound, mature lemons (*Citrus limon* (L.) Burm. f.), from which seeds (except embryonic seeds and small fragments of seed which cannot be separated by good manufacturing practice) and excess pulp are removed. The juice may be adjusted by the addition of the optional concentrated lemon juice ingredient specified in paragraph (a)(2) of this section in such quantity so that the increase in acidity, calculated as anhydrous citric acid, does not exceed 15 percent of the acidity of the finished food. The lemon oil and lemon essence (derived from lemons) content may be adjusted in accordance with good manufacturing practice. The juice may have been concentrated and later reconstituted. When prepared from concentrated lemon juice, the finished food contains not less than 6 percent, by weight, of soluble solids taken as the refractometric sucrose value (of the filtrate), corrected to 20 °C, but uncorrected for acidity, in accordance with the “International Scale of Refractive Indices of Sucrose Solutions” in section 52.012 of “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference, and has a titratable acidity content of not less than 4.5 percent, by weight, calculated as anhydrous citrus acid. Copies of the incorporation by reference may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/

code_of_federal_regulations/ibr_locations.html. The food may contain one or any combination of the safe and suitable optional ingredients specified in paragraph (a)(2) of this section. Lemon juice, as defined in this paragraph, may be preserved by heat sterilization (canning), refrigeration, freezing, or by the addition of safe and suitable preservatives. When sealed in a container to be held at ambient temperatures, it is preserved by the addition of safe and suitable preservatives or so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Optional ingredients*. The optional safe and suitable ingredients referred to in paragraph (a)(1) of this section are:

(i) Concentrated lemon juice (lemon juice from which part of the water has been removed).

(ii) Water and/or lemon juice to reconstitute concentrated lemon juice in the manufacture of lemon juice from concentrate.

(iii) Preservatives.

(3) *Labeling*. (i) The name of the food is:

(a) "Lemon juice" (1) if the food is prepared from unconcentrated, undiluted liquid extracted from mature lemons; or (2) if the food is prepared from unconcentrated, undiluted liquid extracted from mature lemons to which concentrated lemon juice is added to adjust acidity as provided for in paragraph (a)(1) of this section.

(b) "Lemon juice from concentrate" or "reconstituted lemon juice" (1) if the food is prepared from concentrated lemon juice and water and/or lemon juice; or (2) if the food is prepared from lemon juice from concentrate and lemon juice. The words "from concentrate" or "reconstituted" shall be shown in letters not less than one-half the height of the letters in the word "lemon juice."

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container*. (1) The standard of fill of container for lemon juice, except when the food is frozen, is not less than 90 percent of the total capacity of

the container as determined by the general method for fill of container prescribed in §130.12(b) of this chapter, except (i) when the food is frozen or (ii) when the food is packaged in individual serving-size packages, containing ½ fluid ounce or less, for use as described in §1.24(a)(3) of this chapter.

(2) Compliance is determined as specified in §146.3(g)(2).

(3) If the lemon juice fails to meet the standard of fill as prescribed in paragraph (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill specified in §130.14(b) of this chapter, in the manner and form therein prescribed.

[45 FR 7786, Feb. 5, 1980, as amended at 47 FR 11830, Mar. 19, 1982; 49 FR 10100, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2881, Jan. 6, 1993; 63 FR 14035, Mar. 24, 1998]

§ 146.120 Frozen concentrate for lemonade.

(a) Frozen concentrate for lemonade is the frozen food prepared from one or both of the lemon juice ingredients specified in paragraph (b) of this section together with one or any mixture of safe and suitable nutritive carbohydrate sweeteners. The product contains not less than 48.0 percent by weight of soluble solids taken as the sucrose value determined by refractometer and corrected for acidity prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 22.025, "Frozen Concentrate for Lemonade (12)," under the heading "Soluble Solids by Refractometer—Official First Action," which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html When the product is diluted according to directions for making lemonade which shall appear on the label, the acidity of the lemonade, calculated as anhydrous citric acid, shall be not less than 0.70 gram