

deviation from the quality control procedures requirements of part 106 is necessary because of unusual or difficult technological problems in manufacturing the infant formula; and

(iii) A deviation from the labeling requirements of subpart B of this part is necessary because label information, including pictograms and symbols required by those regulations, could lead to inappropriate use of the product.

(e) *Notification requirements.* (1) Information required by paragraphs (b) and (c) of this section shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements, Infant Formula and Medical Foods Staff (HFS-850), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(2) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the Federal Food, Drug, and Cosmetic Act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the Food and Drug Administration Emergency Call Center at 866-300-4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate FDA dis-

trict office specified in part 5, subpart M of this chapter.

[50 FR 48187, Nov. 22, 1985, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17358, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 67 FR 9585, Mar. 4, 2002; 75 FR 32659, June 9, 2010; 79 FR 8074, Feb. 10, 2014]

Subpart D—Nutrient Requirements

§ 107.100 Nutrient specifications.

(a) An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	do	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300
	Percent calories	2.7
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	do	40	100
Vitamin E	do	0.7
Vitamin K	Micrograms	4
Thiamine (vitamin B ₁)	do	40
Riboflavin (vitamin B ₂)	do	60
Vitamin B ₆	do	35
Vitamin B ₁₂	do	0.15
Niacin ¹	do	250
Folic acid (folacin)	do	4
Pantothenic acid	do	300
Biotin ²	do	1.5
Vitamin C (ascorbic acid)	Milligrams	8
Choline ²	do	7
Inositol ²	do	4
Minerals			
Calcium	do	60
Phosphorus	do	30
Magnesium	do	6
Iron	do	0.15	3.0
Zinc	do	0.5
Manganese	Micrograms	5
Copper	Micrograms	60
Iodine	do	5	75
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150

¹The generic term "niacin" includes niacin (nicotinic acid) and niacinamide (nicotinamide).
²Required only for non-milk-based infant formulas.

In addition to the specifications established in the table in this paragraph for vitamins and minerals, the following also apply:

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(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.

(c) Any vitamin K added shall be in the form of phylloquinone.

(d) Vitamin B₆ shall be present at a level of at least 15 micrograms of vitamin B₆ for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.

[50 FR 45108, Oct. 30, 1985]

Subpart E—Infant Formula Recalls

SOURCE: 54 FR 4008, Jan. 27, 1989, unless otherwise noted.

§ 107.200 Food and Drug Administration-required recall.

When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.

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§ 107.210 Firm-initiated product removals.

(a) If a manufacturer has determined to recall voluntarily from the market an infant formula that is not subject to § 107.200 but that otherwise violates the laws and regulations administered by the Food and Drug Administration (FDA) and that would be subject to legal action, the manufacturer, upon prompt notification to FDA, shall administer such voluntary recall consistent with the requirements of this subpart.

(b) If a manufacturer has determined to withdraw voluntarily from the market an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to legal action, such removal from the market is deemed to be a market withdrawal, as defined in § 7.3(j) of this chapter. As required by § 107.240(a), the manufacturer shall promptly notify FDA of such violative formula and may, but is not required to, conduct such market withdrawal consistent with the requirements of this subpart pertaining to product recalls.

§ 107.220 Scope and effect of infant formula recalls.

(a) The requirements of this subpart apply:

(1) When the Food and Drug Administration has determined that it is necessary to remove from the market a distributed infant formula that is in violation of the laws and regulations administered by the Food and Drug Administration and that poses a risk to human health; or

(2) When a manufacturer has determined that it is necessary to remove from the market a distributed infant formula that:

(i) Is no longer subject to the manufacturer's control;

(ii) Is in violation of the laws and regulations administered by the Food and Drug Administration and against which the agency could initiate legal or regulatory action; and

(iii) Does not present a human risk.

(b) The Food and Drug Administration will monitor continually the recall action and will take appropriate