may exist and so notifies the manufacturer, withdrawal of a product's exempt status shall be effective on the date of receipt of notification from the Director of the Center for Food Safety and Applied Nutrition. Additional or modified requirements, or the withdrawal of an exemption, apply only to those formulas that are manufactured after the compliance date. A postponement of the compliance date may be granted for good cause.

(3) FDA may decide that withdrawal of an exemption is necessary when, on the basis of its review under paragraph (d)(1) of this section, it concludes that quality control procedures are not adequate to ensure that the formula contains all required nutrients, that deviations in nutrient levels are not supported by generally accepted scientific, nutritional, or medical rationale, or that deviations from subpart B of this part are not necessary to provide appropriate directions for preparation and use of the infant formula, or that additional labeling information is necessary.

(4) FDA will use the following criteria in determining whether deviations from the requirements of this subpart are necessary and will adequately protect the public health:

(i) A deviation from the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act is necessary to provide an infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition;

(ii) For exempt infant formulas subject to paragraph (b) of this section, a 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, 5001 Campus Dr., 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, 5001 Campus Dr., College Park, MD 20740, and to the appropriate FDA district 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	Do.	60	
Iodine	Do.	5	75
Selenium	Do.	2	7
Sodium	Milligrams	20	60
Potassium	Do.	80	200
Chloride	Do.	55	150

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

(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 B_6 shall be present at a level of at least 15 micrograms of vitamin B_6 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, as amended at 80 FR 35841, June 23, 2015]

Subpart E—Infant Formula Recalls

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