(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c). An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions prescribed under this paragraph.

(i) Nutrient requirements

(1) An infant formula shall contain nutrients in accordance with the table set out in this subsection or, if revised by the Secretary under paragraph (2), as so revised.

(2) The Secretary may by regulation—

(A) revise the list of nutrients in the table in this subsection, and

(B) revise the required level for any nutrient required by the table.

NUTRIENTS

Nutrient		Minimum[a]	Maximum[a]
Protein (gm)	1.8[b]		4.5.
Fat:			
gm	3.3		6.0.
percent cal	30.0		54.0.
Essential fatty acids (linoleate):			
percent cal	2.7		
mg	300.0		
Vitamins:			
A (IU)	250.0	(75 μg)[c]	750.0 (225 μg).[c]
D (IU)	40.0		100.0.
K (μg)	4.0		
E (IU)	0.7	(with 0.7 IU/gm linoleic acid).	
C (ascorbic acid) (mg).	8.0		
B_1 (thiamine) (μg)	40.0		
B_2 (riboflavin) (μg)	60.0		
B_6 (pyridoxine) (μg)	35.0	(with 15 μg/gm of protein in formula).	
B_{12} (μg)	0.15		
Niacin (μg)	250.0		
Folic acid (μg)	4.0		
Pantothenic acid (μg).	300.0		
Biotin (μg)	1.5[d]		
Choline (mg)	7.0[d]		
Inositol (mg)	4.0[d]		
Minerals:			
Calcium (mg)	50.0[e]		
Phosphorus (mg)	25.0[e]		
Magnesium (mg)	6.0		
Iron (mg)	0.15		
Iodine (μg)	5.0		
Zinc (mg)	0.5		
Copper (μg)	60.0		
Manganese (μg)	5.0		
Sodium (mg)	20.0		60.0.
Potassium (mg)	80.0		200.0.
Chloride (mg)	55.0		150.0.

[a] Stated per 100 kilocalories.
[b] The source of protein shall be at least nutritionally equivalent to casein.
[c] Retinol equivalents.
[d] Required to be included in this amount only in formulas which are not milk-based.
[e] Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.

(June 25, 1938, ch. 675, § 412, as added Pub. L. 96–359, § 2, Sept. 26, 1980, 94 Stat. 1190; amended Pub. L. 99–570, title IV, § 4014(a), (b)(1), Oct. 27, 1986, 100 Stat. 3207–116, 3207–120; Pub. L. 103–80, § 3(*l*), Aug. 13, 1993, 107 Stat. 777.)

AMENDMENTS

1993—Subsec. (h)(1). Pub. L. 103–80 substituted ''(e)(1)(B)'' for ''(c)(1)(B),'' in concluding provisions.

1986—Subsecs. (a) to (d). Pub. L. 99–570, § 4014(a)(7), added subsecs. (a) to (d) and struck out former subsecs. (a) relating to adulteration and regulatory oversight, (b) relating to notice to the Secretary by a manufacturer and requirements and scope of that notice, (c) relating to additional notice requirements for the manufacturer, and (d) relating to procedures applicable to recalls by a manufacturer.

Subsecs. (e), (f). Pub. L. 99–570, § 4014(a)(1), (7), added subsecs. (e) and (f) and redesignated former subsecs. (e) and (f) as (g) and (h), respectively.

Subsec. (g). Pub. L. 99–570, § 4014(a)(1), (2), redesignated subsec. (e) as (g) and substituted ''Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula'' for ''No manufacturer shall be required under this subsection to retain any record respecting the distribution of an infant formula for a period of longer than 2 years from the date the record was made''. Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 99–570, § 4014(a)(1), redesignated subsec. (f) as (h).

Subsec. (h)(1). Pub. L. 99–570, § 4014(a)(3), (4), substituted ''(a), (b), and (c)'' for ''(a) and (b)'' and ''(e)(1)'' for ''(c)(1)''.

Pub. L. 99–570, § 4014(a)(5), which directed that ''(d)(1)(B)'' be substituted for ''(e)(1)(B)'' in second sentence could not be executed because ''(e)(1)(B)'' did not appear. See 1993 Amendment note above.

Subsec. (h)(2). Pub. L. 99–570, § 4014(a)(6), substituted ''(a), (b), and (c)'' for ''(a) and (b)''.

Subsec. (i). Pub. L. 99–570, § 4014(a)(1), (b)(1), redesignated subsec. (g) as (i), designated existing provisions as par. (1), substituted ''paragraph (2)'' for ''subsection (a)(2) of this section'', substituted a period for the colon after ''as so revised'', and added par. (2).

EFFECTIVE DATE OF 1980 AMENDMENT

Pub. L. 96–359, § 6, Sept. 26, 1980, 94 Stat. 1193, provided that: ''Section 412 of the Federal Food, Drug, and Cosmetic Act (added by section 2) [this section] shall apply with respect to infant formulas manufactured on or after the 90th day after the date of the enactment of this Act [Sept. 26, 1980].''

§ 350b. New dietary ingredients

(a) In general

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 342(f) of this title unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the

manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) Petition

Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, the decision of the Secretary shall be considered final agency action.

(c) Notification

(1) In general

If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administration of such determination. Such notification by the Secretary shall include, at a minimum, the name of the dietary supplement or article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

(2) Definitions

For purposes of this subsection—

(A) the term ''anabolic steroid'' has the meaning given such term in section 802(41) of this title; and

(B) the term ''analogue of an anabolic steroid'' means a substance whose chemical structure is substantially similar to the chemical structure of an anabolic steroid.

(d) "New dietary ingredient" defined

For purposes of this section, the term ''new dietary ingredient'' means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

(June 25, 1938, ch. 675, § 413, as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331; amended Pub. L. 111–353, title I, § 113(a), Jan. 4, 2011, 124 Stat. 3920.)

AMENDMENTS

2011—Subsecs. (c), (d). Pub. L. 111–353 added subsec. (c) and redesignated former subsec. (c) as (d).

GUIDANCE

Pub. L. 111–353, title I, § 113(b), Jan. 4, 2011, 124 Stat. 3921, provided that: ''Not later than 180 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350b(a)(2)], the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identify [sic] of a new dietary ingredient.''

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 350c. Maintenance and inspection of records

(a) Records inspection

(1) Adulterated food

If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article, and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

(2) Use of or exposure to food of concern

If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining