NUTRIENTS—Continued

Nutrient		Minimum[a]	Maximum[a]
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) of this section'' for ''(c)(1)(B) of this section,'' 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

Section 6 of Pub. L. 96–359 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].''

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 343, 374 of this title.

§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) "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.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 331 of this title.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or