

1986, 100 Stat. 3207-116, 3207-120; Pub. L. 103-80, § 3(I), Aug. 13, 1993, 107 Stat. 777; Pub. L. 117-328, div. FF, title III, § 3401(c), (g)(1)-(4), (6), (l), Dec. 29, 2022, 136 Stat. 5838, 5840, 5841, 5845.)

### Editorial Notes

#### AMENDMENTS

2022—Subsec. (c)(1)(B). Pub. L. 117-328, § 3401(g)(6), substituted “subsection (d)(1)” for “subsection (c)(1)”.

Subsec. (d)(4). Pub. L. 117-328, § 3401(g)(3), added par. (4).

Subsec. (i)(1). Pub. L. 117-328, § 3401(g)(4), substituted “, which shall be reviewed by the Secretary every 4 years as appropriate. In reviewing such table, the Secretary shall consider any new scientific data or information related to infant formula nutrients, including international infant formula standards. The Secretary may revise the list of nutrients and the required level for any nutrient required by the table” for “or, if revised by the Secretary under paragraph (2), as so revised”.

Subsec. (j). Pub. L. 117-328, § 3401(c), added subsec. (j).

Subsec. (k). Pub. L. 117-328, § 3401(g)(1), added subsec. (k).

Subsec. (l). Pub. L. 117-328, § 3401(g)(2), added subsec. (l).

Subsec. (m). Pub. L. 117-328, § 3401(l), added subsec. (m).

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).

### Statutory Notes and Related Subsidiaries

#### 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].”

### § 350a-1. Protecting infants and improving formula supply

#### (a) Definitions

##### (1) In general

In this section, the term “infant formula” has the meaning given such term in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)).

##### (2) Omitted

#### (b) Office of Critical Foods

##### (1) In general

The Secretary shall establish within the Center for Food Safety and Applied Nutrition an office to be known as the Office of Critical Foods. The Secretary shall appoint a Director to lead such Office.

##### (2) Duties

The Office of Critical Foods shall be responsible for oversight, coordination, and facilitation of activities related to critical foods, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(ss)], as added by subsection (a)(2).

#### (c) Omitted

#### (d) Report

Not later than one year after December 29, 2022, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

(1) the number of premarket submissions for new infant formula the Secretary has received under section 412(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(d)) each year since 2012;

(2) how many of such submissions received requests from the Secretary for additional information;

(3) how long after receiving such submissions the Secretary sent such requests for additional information;

(4) what additional information the Secretary requested of the persons submitting such submissions; and

(5) the date each new infant formula described in subparagraph (A)<sup>1</sup> was first marketed, if available.

#### (e) Infant formula flexibilities

The Secretary shall publish a list on the website of the Department of Health and Human Services providing information on how to identify appropriate substitutes for infant formula products in shortage that are relied upon by infants and other individuals with inborn errors of metabolism or other serious health conditions.

#### (f) International harmonization of infant formula requirements

##### (1) In general

The Secretary—

(A) shall participate in meetings with representatives from other countries to discuss methods and approaches to harmonizing reg-

<sup>1</sup> So in original. There is no subparagraph (A).

ulatory requirements for infant formula, including with respect to inspections, labeling, and nutritional requirements; and

(B) may enter into arrangements or agreements regarding such requirements with other countries, as appropriate, including arrangements or agreements with a foreign government or agency of a foreign government to recognize the inspection of foreign establishments that manufacture infant formula for export to the United States.

**(2) Study on infant formula**

**(A) In general**

Not later than 60 days after December 29, 2022, the Secretary shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this paragraph as the “National Academies”) to examine and report on challenges in supply, market competition, and regulation of infant formula in the United States.

**(B) Contents of the report**

The report developed pursuant to the agreement under subparagraph (A) shall—

(i) assess and evaluate—

(I) infant formula marketed in the United States;

(II) any challenges in supply, or market competition with respect to such infant formula; and

(III) any differences between infant formula marketed in the United States and infant formula marketed in the European Union, including with respect to nutritional content and applicable labeling and other regulatory requirements; and

(ii) include recommendations, including for infant formula manufacturers, on measures to address supply and market competition in the United States.

**(C) Final report**

The agreement under subparagraph (A) shall specify that the National Academies shall, not later than 1 year after December 29, 2022, complete such study and submit a report on the results of such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

**(g) Transparency and accountability to support infant formula innovation**

**(1) to (4) Omitted**

**(5) Guidance**

Not later than 1 year after December 29, 2022, the Secretary shall issue guidance regarding information sponsors may consider including in submissions required under section 412(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(d)), including considerations for meeting each of the requirements of paragraphs (1), (2), and (3) of subsection (d).

**(6) Omitted**

**(h) Response to recall**

**(1) Manufacturer submission**

**(A) In general**

Promptly after the initiation of a recall of infant formula, the manufacturer of the recalled infant formula shall submit information to the Secretary regarding such recall.

**(B) Contents**

A submission under subparagraph (A) shall include the following:

(i) A plan (including an estimated timeline, as applicable) of actions the manufacturer will take, suited to the individual circumstances of the particular recall, including—

(I) to identify and address any cause of, and contributing factor in, known or suspected adulteration or known or suspected misbranding; and

(II) if appropriate, to restore operation of the impacted facilities.

(ii) In the case that a recall of the manufacturer’s infant formula products, and subsequent actions to respond to such recall, impacts over 10 percent of the production of the infant formula intended for sale in the United States, a plan to backfill the supply of the manufacturer’s infant formula supply if the current domestic supply of such infant formula has fallen, or is expected to fall, below the expected demand for the formula.

**(2) Report to Congress**

**(A) In general**

Promptly after a submission under paragraph (1) is received, the Secretary shall provide such submission, together with the information specified in subparagraph (B), in a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

**(B) Contents**

A report under subparagraph (A) shall include the following:

(i) Information concerning the current domestic supply of infant formula, including—

(I) a breakdown of the specific types of formula involved; and

(II) an estimate of how long current supplies will last.

(ii) If a submission or submissions under paragraph (1) show that the recall and subsequent actions to respond to the recall impact over 10 percent of the domestic production of infant formula intended for sale in the United States—

(I) actions to work with the impacted manufacturer or other manufacturers to increase production; and

(II) specification of—

(aa) any additional authorities needed regarding production or importation to fill a supply gap; and

(bb) any supplemental funding necessary to address the shortage.

**(3) Sunset**

This subsection shall cease to have force or effect on September 30, 2026.

**(i) Coordination with manufacturer**

**(1) In general**

**(A) Communication following inspection**

Upon completing an inspection of an infant formula manufacturing facility impacted by a recall, the Secretary, acting through the Commissioner of Food and Drugs, shall provide the manufacturer involved a list of any actions necessary to—

- (i) address deficiencies contributing to the potential adulteration or misbranding of product at the facility; and
- (ii) safely restart production at the facility.

**(B) Response to manufacturer**

Not later than 7 days after receiving a written communication from a manufacturer of infant formula containing corrective actions to address manufacturing deficiencies identified during an inspection of a facility engaged in the manufacturing of an infant formula impacted by a recall, the Secretary, acting through the Commissioner of Food and Drugs, shall provide a substantive response to such communication concerning the sufficiency of the proposed corrective actions.

**(2) Inspections**

The Secretary shall ensure timely communication with a manufacturer of infant formula following an inspection of a facility engaged in the manufacturing of infant formula for consumption in the United States. If a reinspection of a manufacturer of an infant formula is required to ensure that such manufacturer completed any remediation actions or addressed any deficiencies, the Secretary shall reinspect such facility in a timely manner. The Secretary shall prioritize and expedite an inspection or reinspection of an establishment that could help mitigate or prevent a shortage of an infant formula.

**(3) Annual inspections**

Not later than 6 months after December 29, 2022, and not less than once per calendar year thereafter, the Secretary shall conduct inspections, including unannounced inspections, of the facilities (including foreign facilities) of each manufacturer of an infant formula required to be registered under section 412(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(c)(1)(A)), in accordance with a risk-based approach and ensure timely and effective internal coordination and alignment among the Office of Regulatory Affairs and the Center for Food Safety and Applied Nutrition. In meeting the inspection requirements under this subsection, the Secretary may rely on inspections conducted by foreign regulatory authorities, under arrangements or agreements, and conducted by State agencies under contract, memoranda of understanding, or any other obligation.

**(j) National strategy on infant formula**

**(1) In general**

The Secretary, in consultation with the Secretary of Agriculture and other heads of relevant departments and agencies, shall develop and issue, not later than 90 days after December 29, 2022, a national strategy on infant formula to increase the resiliency of the infant formula supply chain, protect against future contamination and other potential causes of supply disruptions and shortages, and ensure parents and caregivers have access to infant formula and information they need.

**(2) Immediate national strategy**

The national strategy under paragraph (1) shall include efforts—

(A) to increase the resiliency of the infant formula supply chain in the short-term by—

(i) assessing causes of any supply disruption or shortage of infant formula in existence as of December 29, 2022, and potential causes of future supply disruptions and shortages;

(ii) assessing and addressing immediate infant formula needs associated with the shortage; and

(iii) developing a plan to increase infant formula supply, including through increased competition; and

(B) to ensure the development and updating of education and communication materials for parents and caregivers that cover—

(i) where and how to find infant formula;

(ii) comparable infant formulas on the market;

(iii) what to do if a specialty infant formula is unavailable;

(iv) safe practices for handling infant formula; and

(v) other topics, as appropriate.

**(3) Long-term strategy**

Not later than 90 days after the submission of the report described in subsection (f)(2), the Secretary shall update the national strategy under paragraph (1) to include efforts to improve preparedness against infant formula shortages in the long-term by—

(A) outlining methods to improve information-sharing between the Federal Government and State and local governments, and other entities as appropriate, regarding shortages;

(B) recommending measures for protecting the integrity of the infant formula supply and preventing contamination;

(C) outlining methods to incentivize new infant formula manufacturers to increase supply and mitigate future shortages; and

(D) recommending other necessary authorities to gain insight into the supply chain and risk for shortages, and to incentivize new infant formula manufacturers.

**(k), (l) Omitted**

**(m) Importation for personal use**

**(1) In general**

Notwithstanding any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

301 et seq.), during the 90-day period beginning on December 29, 2022, an individual may, without prior notice to the Food and Drug Administration, import up to a 3-month supply of infant formula for personal use from—

- (A) Canada;
- (B) any country in the European Union; or
- (C) any other country that is determined by the Secretary to be implementing and enforcing requirements for infant formula that provide a similar assurance of safety and nutritional adequacy as the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

**(2) Limitations**

Infant formula may be imported pursuant to paragraph (1) only if the infant formula—

- (A) is exclusively for personal use and will not be commercialized or promoted; and
- (B) does not present an unreasonable risk to human health.

**(3) Reporting of adverse events**

If a health care provider becomes aware of any adverse event which the health care provider reasonably suspects to be associated with infant formula imported pursuant to paragraph (1), the health care provider shall report such adverse event to the Commissioner of Food and Drugs.

**(4) Public notice**

The Secretary, acting through the Commissioner of Food and Drugs, shall post on the public website of the Food and Drug Administration notice that—

- (A) infant formula imported pursuant to paragraph (1) may not have been manufactured in a facility that has been inspected by the Food and Drug Administration;
- (B) the labeling of such infant formula may not meet the standards and other requirements applicable with respect to infant formula under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and
- (C) the nutritional content of infant formula imported pursuant to paragraph (1) may vary from that of infant formula meeting such standards and other requirements.

**(5) Sense of Congress**

It is the sense of Congress that persons considering the personal importation of infant formula should consult with their pediatrician about such importation.

(Pub. L. 117-328, div. FF, title III, §3401, Dec. 29, 2022, 136 Stat. 5838.)

**Editorial Notes**

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (m)(1), (4)(B), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Food and Drug Omnibus Reform Act of 2022, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Section is comprised of section 3401 of div. FF of Pub. L. 117-328. Subsec. (a)(2) of section 3401 of div. FF of Pub. L. 117-328 amended section 321 of this title. Subsecs. (c), (g)(1)-(4), (6), and (l) of such section 3401 amended section 350a of this title. Subsec. (k) of such section 3401 enacted section 350m of this title.

**Statutory Notes and Related Subsidiaries**

DEFINITION OF “SECRETARY”

Pub. L. 117-328, div. FF, title III, §3002, Dec. 29, 2022, 136 Stat. 5807, provided that: “In this title [see Short Title of 2022 Amendment note set out under section 301 of this title], except as otherwise specified, the term ‘Secretary’ means the Secretary of Health and Human Services.”

**§ 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