

## S 4256

### Protecting Infants from Formula Shortages Act of 2022

**Congress:** 117 (2021–2023, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** May 18, 2022

**Current Status:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (May 18, 2022)

**Official Text:** <https://www.congress.gov/bill/117th-congress/senate-bill/4256>

### Sponsor

**Name:** Sen. Casey, Robert P., Jr. [D-PA]

**Party:** Democratic • **State:** PA • **Chamber:** Senate

### Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Brown, Sherrod [D-OH]	D · OH		May 18, 2022
Sen. Duckworth, Tammy [D-IL]	D · IL		May 18, 2022
Sen. Gillibrand, Kirsten E. [D-NY]	D · NY		May 18, 2022
Sen. Warren, Elizabeth [D-MA]	D · MA		May 18, 2022
Sen. Klobuchar, Amy [D-MN]	D · MN		May 19, 2022
Sen. Smith, Tina [D-MN]	D · MN		May 19, 2022
Sen. Hickenlooper, John W. [D-CO]	D · CO		May 26, 2022

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 18, 2022

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
117 HR 7989	Identical bill	<b>Jun 8, 2022:</b> Referred to the House Committee on Energy and Commerce.

## **Protecting Infants from Formula Shortages Act of 2022**

This bill imposes requirements on manufacturers of infant formula and medical foods for individuals with inborn errors of metabolism.

A manufacturer of such a food must notify the Food and Drug Administration (FDA) of any circumstance that is likely to lead to a meaningful disruption of the U.S. supply of the food, including a discontinuance or interruption of manufacturing. The manufacturer must submit the notification at least six months prior to the cause of the disruption or, if that is not possible, as soon as practicable. The FDA must provide the Department of Agriculture and appropriate organizations information about the cause of the disruption.

The FDA must inform a person (an individual or entity) of their failure to comply with these notification requirements. If the failure continues for a certain time period, the person shall be subject to fines, imprisonment, or both.

During a public health emergency, the FDA may impose additional conditions for such notifications and designate additional categories of food that are subject to the notification requirements.

The bill also requires each manufacturer of such a food to develop and maintain a redundancy risk management plan that identifies and evaluates risks for each manufacturing establishment for the food.

### **Actions Timeline**

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- **May 18, 2022:** Introduced in Senate
- **May 18, 2022:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.