
Fixing Our Regulatory Mayhem Upsetting Little Americans (FORMULA) Act

The already concerning shortage of baby formula has been exacerbated by the recent closure of Abbott's baby formula facility in Michigan. Numerous trade and regulatory barriers have led to the culmination of this crisis. Temporarily waiving these trade and regulatory barriers, while providing flexibilities to families in the WIC program, will enable families to access the infant formula they direly need.

In the United States, the market for infant formula is highly concentrated amongst three companies that control more than 90% of the produced formula.¹ There is a need for more suppliers of formula in the United States. Reports have surfaced that the out-of-stock rate for baby formula has risen from **11%** in November 2021 to **43%** in the first week of May this year.² As a result, retailers such as Walgreens and CVS have begun limiting formula purchases for families.³ Tragically, families have been forced to search long distances for formula to feed their babies, and children with metabolic diseases, who consume specialized formulas, are also finding it extremely difficult to find the formula they need, putting the health and safety of millions of American children at risk.⁴

Bill Specifics

6-Month Waiver on Infant Formula Tariffs

- Would eliminate tariffs on infant formulas from certain countries.^{5,6}

6-Month Waiver of FDA Regulations

- Would waive existing FDA Labeling and Nutrition requirements for infant formula with respect to commercial imports from certain countries with similar approval standards as the United States.^{7,8,9}
- Would waive statutes requiring commercial infant formula to derive only from FDA-approved facilities.
- Would prohibit the FDA from recalling infant formula solely for reasons pertaining to labeling.
- Would require manufacturers of the imported infant formula to notify the FDA concerning adulterated or misbranded formula.
- Would grant the FDA the authority to recall imported infant formula if it is unsafe for consumption.

6-Month Access to Alternative Formula's Under WIC

- Would allow WIC recipients to purchase alternative brand formulas that have been imported for 6-months.
- Would require the US Department of Agriculture to publicize the list of imported infant formulas that have been approved for use and marketing within their country of origin, along with the recommended measurements for mixing or otherwise preparing the formula.
 - Would require this list to made publicly available and located on the FDA and USDA websites.

¹ Rosenberg, Alyssa.

² Datasembly. [Datassembly Releases Latest Numbers on Baby Formula](#). (May 10, 2022).

³ Genovese, Daniella. [Target, CVS, Walgreens impose baby formula purchasing limits due to shortage](#). Fox Business. (May 10, 2022).

⁴ Evich, Helena Bottemiller. [‘I don’t know how my son will survive’: Inside the dangerous shortage of specialty formulas](#). Politico. (May 7, 2022).

⁵ 1901.10(cont.) of the [Harmonized Tariff Schedule](#)

⁶ Australia, Israel, Japan, New Zealand, Switzerland, South Africa, United Kingdom, Members of the European Union, and Member Countries of the European Economic Area.

⁷ [21 USC 350a](#)

⁸ [21 CFR Part 106](#), [21 CFR Part 107](#)

⁹ Countries listed above.