

# *It Took Sick Babies to Get Here*

The Case for the Infant Formula Safety  
Modernization Act of 2026

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# Never Let a Crisis Go to Waste

- “Never let a serious crisis go to waste” — Rahm Emanuel’s line, usually said with a wink. I am going to say it without one.
- 1993, Jack in the Box: that E. coli outbreak pushed USDA’s Food Safety and Inspection Service to declare E. coli O157:H7 an adulterant in ground beef in 1994.
- One decision that made hamburger dramatically safer — a crisis put to use, not wasted.
- We have a window open like that right now.

# We Knew About Cronobacter for Twenty Years

- 2001: a Cronobacter outbreak in a Tennessee NICU kills a newborn, traced to powdered formula.
- April 2002: FDA warns hospitals that powdered formula is not sterile.
- 2022: Abbott's Sturgis plant — about 40% of the U.S. supply — shuts down after Cronobacter, triggering a national shortage.
- The danger was named two decades before Sturgis. We knew.



Abbott · Sturgis, 2022

# Then Botulism — Twice

- ByHeart, Nov. 2025: the first U.S. botulism outbreak ever tied to infant formula — every infant hospitalized.
- Traced to an ingredient — organic whole milk powder. A Blendhouse facility had already been flagged “Official Action Indicated.”
- Nara Organics, June 2026: more infants hospitalized. Formula sold at Target, manufactured in Europe.
- A second outbreak in the same year was not a freak event. It was foreseeable.

**48**

infants · 17 states  
ByHeart · Nov 2025

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**3**

infants · 3 states  
Nara · June 2026

# Not New — and Not Only Ours

- Europe, 2025–26: a multi-country recall over cereulide (*Bacillus cereus*) in a Chinese-supplied oil; “silent” withdrawals.
- New Zealand, 2013: Fonterra’s botulism scare in whey protein concentrate triggers a global formula recall.
- France, 2017: Salmonella at Lactalis’ Craon plant — the same strain that hit the same plant in 2005.
- China, 2008: melamine sickens an estimated 300,000 infants and kills at least six.

# A Pattern, Not Bad Luck



*Not bad luck — a system that tests for too little, too late, and tells too few people when something goes wrong.*

# What the Bill Does (1 of 2)

- **Expand pathogen testing:** a real required list, with *C. botulinum* on it. Today the law covers only *Cronobacter* and *Salmonella*.
- **Mandate environmental testing:** standardized monitoring of Zones 2 and 3, to catch contamination before it ships.
- **Set consistent standards:** FDA sets the testing frequency, so “we tested” means the same thing everywhere.

# What the Bill Does (2 of 2)

- **Early FDA notification:** report a positive within one business day, even before product leaves the plant.
- **Foreign manufacturers:** the same standards whether formula is made in Iowa or imported.
- **Strengthen oversight:** notify Congress of positives and “Official Action Indicated” findings.
- **A 90-day clock:** FDA must finalize the rules. We have waited long enough.

# Why It Should Pass

- **Bipartisan:** a Democrat and a Republican on the same bill. Not a left-or-right question.
- We turned Jack in the Box into a rule that made hamburger safer. We can do the same for the formula we feed newborns.
- Pass it, then make it so the next infant-formula case is one nobody can find.
- The goal, as always: to put myself out of business by making food safe.



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# Questions

