

S. 4436 Protect Infant Formula from Contamination Act

Section 1. Short title.

This section designates the short title of the bill as the “Protect Infant Formula from Contamination Act”.

Section 2. Mandating Testing of Infant Formula.

This section requires infant formula manufacturers to report, within 24 hours, any confirmed positive test result of Cronobacter or Salmonella of finished infant formula product to the Food and Drug Administration (FDA). Infant formula manufacturers are also required to submit the isolate of confirmed positive test results to the agency. The FDA is required to confirm receipt of the confirmed positive test result to the manufacturer within 72 hours. Not later than 90 days after receipt of a confirmed positive test results, FDA shall confirm that the infant formula manufacturer has performed, or is performing, an appropriate investigation and corrective action, if applicable.

Section 3. Reporting to Improve the Safety and Supply of Infant Formula.

This section requires FDA to produce a progress report on the implementation of recommendations to improve the safety and supply of infant formula. This section also requires FDA to issue quarterly reports for a 5-year period on infant formula supply chain resiliency, and an annual report on the adequacy of supply for a 5-year period.