

FDA Evaluation of Infant Formula Response

September 2022



**U.S. FOOD & DRUG
ADMINISTRATION**

Foreword

By Steven M. Solomon D.V.M., M.P.H., Director, Center for Veterinary Medicine

On May 25, 2022, in the wake of an ongoing investigation of *Cronobacter* and revelations of a whistleblower complaint regarding Abbott Nutrition's infant formula manufacturing plant in Sturgis, Michigan, FDA Commissioner Robert M. Califf, M.D., requested that I undertake an internal agency review of the situation. My charge was to identify the challenges encountered in addressing the circumstances that eventually led to a shortage in supply of infant formulas that serve as the sole source of nutrition for many infants and for people with certain metabolic conditions that require specialty formulas. Dr. Califf also tasked me with framing out recommendations to address the findings from the internal review.

I am honored by Dr. Califf's request, although it may at first blush seem odd for a veterinarian to be asked to undertake a review of a product for human infants. But I am also a 32-year veteran of the agency, including 23 years in the agency's Office of Regulatory Affairs (ORA), which, among other functions, houses the FDA's inspectional programs. For the last six years, I have directed the Center for Veterinary Medicine, which regulates animal food and drugs. I have more than a nodding acquaintance with the challenges of managing a nationwide cadre of career staff, particularly during emergency response activities, as well as familiarity with the importance of ensuring the safety and wholesomeness of a product that serves as the sole source of nutrition. At the same time, I have been appropriately removed from the day-to-day activities of ORA, the Office of Food Policy and Response (OFPR), and the Center for Food Safety and Applied Nutrition (CFSAN) related to this specific response, allowing me to take a fresh view of the events that have unfolded over the past several months.

The findings and recommendations detailed in this report are the result of dozens of interviews with the FDA staff and leadership directly involved with the events that transpired. Their willingness to take part in the after-action assessment and to speak candidly about opportunities for improvements in the system speaks to their level of professionalism and commitment, both to the agency's mission and to continued improvement in ensuring the safety of our food supply.

The information that came out of these interviews allowed us to identify five major areas of need, with fifteen specific findings:

- Modern information technology that allows for the access and exchange of data in real time to all the people involved in response.
- Sufficient staffing, training, equipment, and regulatory authorities to fulfill the FDA's mission.
- Updated emergency response systems that are capable of handling multiple public health emergencies occurring simultaneously.
- Increased scientific understanding about *Cronobacter*, its prevalence and natural habitat, and how this translates into appropriate control measures and oversight.
- Assessment of the infant formula industry, its preventive controls, food safety culture and preparedness to respond to events.

A detailed discussion of the scope of this report, the specific findings that led to this incident, recommendations for improvement, and identification of necessary resources and authorities follow. There is no single action to explain the events that occurred, rather the report identifies a confluence of systemic vulnerabilities that demonstrate the need to focus on continued modernization and investment in the expertise and tools needed to better anticipate and address future public health challenges in this area.

This analysis also illustrates the importance for the agency to continuously reassess conditions and make necessary adjustments to keep pace with the constantly evolving public health challenges the agency tackles. The agency will require considerable resources to build the cohesive databases needed to replace several independent data collection systems that do not interact with each other, hire and train the requisite expertise to better assess the specific challenges presented by infant formula, and broaden the scientific understanding of *Cronobacter* in particular. It will be particularly important to continue to test the measures that are put into place, to ensure that they remain current and effective.

As public health servants, our commitment to protecting the nation's food supply should be never-ending. It requires continued testing and reassessment to fine-tune our approaches to meet new public health threats, evolving scientific developments and a changing marketplace. As we implement these changes, we must ensure that they address the issues that led to the shortage of a safe, wholesome food supply for our most vulnerable populations. This is one of our most important obligations.

In closing, I would particularly like to recognize the team who supported me with this evaluation, Melissa Safford and Lindsay Tobias, for their dedication to conducting the interviews, the resulting analysis, and helping develop this report. Without their commitment this report would not be possible.

Introduction

Between September 2021 and January 2022, the U.S. Food and Drug Administration received information about four cases of illness or death in infants who consumed powdered infant formula. After learning that each of these infants consumed powdered infant formula products manufactured by Abbott Nutrition in Sturgis, Michigan and initiating an investigation at the facility that revealed insanitary conditions, the FDA [warned](#) consumers not to use certain products manufactured at this facility. On Feb. 17, 2022, Abbott Nutrition issued a voluntary recall of certain infant formula products manufactured in Sturgis, Michigan, and temporarily ceased production. While necessary to safeguard public health, the recall and pause in production further stressed a supply chain already strained by the COVID-19 pandemic. A shortage of these products created hardships for parents and caregivers who rely on infant and specialty formulas to feed their babies, as well as loved ones with certain metabolic disorders.

The FDA's responsibility to respond to foodborne illness and contamination is a critical programmatic activity, and one the agency takes seriously. This incident involved unique circumstances, requiring the agency to address a relatively poorly understood pathogen, *Cronobacter sakazakii*, in a critical sole source of nutrition for vulnerable populations. While infant formulas, and particularly specialty and metabolic formulas, are regulated by the FDA as food, they are in many ways comparable to life-saving medications. Therefore, the FDA's foods program had to balance considerations of product safety and product availability in a way it has never had to before. This incident demonstrated the need for an integrated, multidisciplinary approach that included scientific, clinical, nutritional, analytical, and inspectional expertise; legal processes; supply chain and policy considerations; and resources to support this multidisciplinary work.

Given the unique circumstances and far-ranging consequences of the shortage, as well as the technology, process, policy, and resource challenges that became apparent during the management of the incident, the FDA initiated a comprehensive evaluation of the events leading up to, during, and after the recall initiation until June 4, 2022. The evaluation team, led by Dr. Steve Solomon, conducted 43 interviews with a total of 61 employees. Staff who participated offered perspectives from several levels of the agency, and represented many FDA centers and offices involved in the response to the incident.

Interviewees identified several actions their centers and offices had already initiated in response to challenges encountered during the incident. For example, improvements regarding how consumer complaints and whistleblower complaints are triaged and escalated have already been implemented in the Office of Operations, ORA, and CFSAN. CFSAN, in collaboration with ORA and OFPR, is also working to develop a Powdered Infant Formula Prevention Strategy to provide targeted root cause analysis guidance to industry.

Additionally, as of the date of this report's publication, work on multiple recommendations has already begun. The agency is collecting an inventory of every entry point for consumers, whistleblowers, other government agencies, clinicians, and other members of the public to facilitate notification to the FDA of their concerns about product safety and quality. This inventory will inform the actions and resources needed to streamline and connect the agency's systems so that concerns and complaints related to the safety of a facility and/or product can be electronically coordinated to produce the data set needed to rapidly assess emerging safety signals. Further, the agency has already initiated discussions to enhance its emergency operations capabilities and optimization, as well as considerations regarding the agency's role in the food supply chain, its current capabilities, and how additional resources and authorities could enhance future capabilities.

In all, interviews conducted during the evaluation clearly identified five common themes. This report outlines 15 findings supported by those interviews, as well as broad recommendations for the FDA to consider in addressing each finding from an enterprise level.

FDA Needs Modern Data Systems

- 1. Finding:** The FDA maintains multiple systems for the public and other stakeholders to submit product safety and quality complaints, adverse event reports, and product manufacturing concerns across regulated commodity areas. However, the technology that supports some of these systems is outdated, and the lack of coordination between systems makes it difficult for the agency to connect related submissions and rapidly identify emerging safety and quality issues.

Recommendation: The FDA should review its systems and processes for receiving information from external parties, including but not limited to industry, consumers, other federal agencies, and international regulators regarding product safety and quality, adverse events, and manufacturing. The FDA should consider the feasibility, resource requirements, and potential benefits of connecting existing systems or developing a single system to receive, track, and process such information and ensure timely notification of appropriate personnel of potential signals of significant public health threat.

- 2. Finding:** Inadequate processes and lack of clarity related to whistleblower complaints may have delayed the FDA's response to those complaints. A complaint sent via mail and other delivery systems by a confidential informant to agency leaders at FDA's White Oak campus was not delivered to the addressees.

Recommendation: The FDA should identify clear definitions for the terms "whistleblower," "confidential informant," and "informant," and develop policies and provide training to staff regarding how to identify, escalate, and appropriately manage confidentiality of such complaints. The agency should also consider connecting complaints from such individuals to information received from product safety complaints, and product manufacturing concerns systems to support more complete access to all safety information. The FDA is evaluating how best to integrate this data to gain a holistic view of all FDA-regulated products and/or manufacturing facilities. The FDA should also review and update its mail and package delivery procedures to ensure that all mail and packages are delivered and received by addressees in a timely manner.

- 3. Finding:** The FDA found that some samples taken from the Abbott Nutrition facility in Sturgis were delayed in transit by third party delivery companies. The evaluation also highlighted that the FDA's regulatory laboratories face challenges rapidly expanding testing capacity for *Cronobacter*.

Recommendation: The FDA should evaluate procedures for shipping and testing samples sent to regulatory laboratories and consider whether changes should be made to analytical capability and capacity, and ways to enable immediate notification and escalation of analytical results for significant public health threats. Data integration of laboratory findings with complaints and other reports has the potential to improve timely awareness of emerging public health threats.

FDA Needs to Optimize its Emergency Response Capabilities

4. Finding: The emergency response to this food safety incident lacked clarity of roles between programmatic and incident command standard operating procedures. The FDA's Office of Emergency Management, agency leadership, communications staff, and subject matter experts must all work together to execute a timely and effective response. The agency lacks procedures for facilitating this complex coordination of staff on response activities that expand beyond the established foodborne outbreak response policies and procedures. This is particularly true for food safety product-related emergencies that require complex scientific and public health policy decision making. Further, in many cases, subject matter experts do not have incident command training and experience and the FDA does not have a mechanism for rapidly providing incident command training to these experts who are essential to the response effort.

Recommendation: The FDA should thoroughly evaluate its policies and procedures related to the formation, staffing, and operation of Incident Management Groups, Incident Management Teams, and Agency Executive Groups during complex food safety-related emergencies. This evaluation should include criteria for forming and demobilizing such entities, quickly identifying the leadership and expertise needed for the specific incident, and establishing appropriate roles, responsibilities, and decision-making processes. The FDA should also consider ways to rapidly increase the availability of trained staff to boost capacity and capabilities for incident response, especially during multiple simultaneous public health emergencies.

5. Finding: COVID-19 cases at the manufacturing facility delayed the FDA's in-person response to complaints raised regarding Abbott Nutrition's products manufactured in Sturgis, Michigan.

Recommendation: The FDA lacks authority for remote access to records or other information for many food related products. The agency should continue its evaluation of the additional authorities, tools and resources needed to remotely gather information from firms during public health emergencies when in-person inspections may not be feasible.

6. Finding: During the response effort to this food safety incident, the FDA needed effective mechanisms to rapidly engage with regulatory and public health partners to avoid confusion about roles and responsibilities.

Recommendation: The FDA should consider holding after action meetings with appropriate regulatory and public health partners, including but not limited to the Department of Justice, the Department of Agriculture, the Department of Health and Human Services, and the Centers for Disease Control and Prevention, to identify challenges encountered during this incident, including different agency interests related to public health and legal investigations, and develop solutions to improve future collaboration.

FDA Needs to Strengthen its Foods Workforce

7. Finding: While the training process for FDA investigators is robust, investigators conducting inspections of infant formula manufacturing facilities receive limited infant formula-specific training.

Recommendation: The FDA should determine the resources needed to develop a specialized training program for investigators and other personnel charged with inspection and oversight of infant formula and other medical foods manufacturing facilities, request those resources from Congress, and develop and implement a specialized training program.

8. Finding: The FDA's foods workforce maintains expertise across the 80% of the food supply regulated by the FDA. However, funding limitations have stalled the growth of the foods program, hindering the agency's ability to keep pace with the growing workload, increased complexity of supply chains, and scientific and technological changes in food manufacturing. The FDA's shortage of investigators, subject matter experts, and compliance personnel with infant formula expertise hinders the agency's ability to comprehensively inspect infant formula manufacturing facilities, review and evaluate new products, and respond to product concerns or complaints in a rapid manner.

Recommendation: The FDA should evaluate its workforce needs related to infant formula regulation and oversight and utilize the appropriations process to help secure the resources needed.

9. Finding: The critical nature of infant formula products as a sole source of nutrition posed unique challenges to public health complicating compliance actions compared to typical food compliance actions. This incident required an unusual level of agency leadership involvement to assess and weigh risks associated with potential product contamination against risks of essential products being unavailable due to a shortage. Typically, product safety is the primary driver during food safety incidents and product availability does not impact compliance actions.

Recommendation: The FDA should review its compliance procedures for critical food products and determine whether there is a need to clarify roles and responsibilities, consider the need for a decision matrix, and consider alternative activities to minimize product availability concerns when the product is a sole source of nutrition.

FDA Oversight Needs to Focus on Industry Accountability

10. Finding: The infant formula industry employs dated technology and record keeping practices that can cause delays in collecting critical information needed to perform and define the scope of recalls.

Recommendation: The FDA should articulate to the infant formula industry what the agency has determined are best practices for product sampling, hygienic design of facilities, environmental monitoring, traceability information, and recordkeeping based on current science and technology. The FDA should consider all options for how best to clearly communicate such practices to industry.

11. Finding: Conditions observed at the Abbott Nutrition facility were not consistent with a strong food safety culture.

Recommendation: A strong food safety culture is a prerequisite to effective food safety management. The FDA has initiated action with the New Era of Smarter Food Safety to foster, support, and strengthen food safety cultures in food facilities, and in homes. The FDA should evaluate this initiative for specific actions to target the infant formula industry.

12. Finding: The FDA and other federal agencies do not have the authority, expertise, or resources to manage supply chain issues and shortages of critical food products.

Recommendation: The FDA should conduct an analysis of its capabilities related to supply chain management for critical food products. The agency should work with the administration, Congress, and other federal agencies to establish industry and government roles and responsibilities for managing the supply chain of critical food products and identifying and securing authorities and resources to carry out those responsibilities where appropriate.

FDA Needs to Work with Engaged Stakeholders to Close Scientific Gaps and Build a More Robust Regulatory Program

13. Finding: *Cronobacter* is not a nationally reportable disease, and scientific gaps in understanding *Cronobacter* contamination and illness hindered the FDA's response throughout the incident.

Recommendation: The FDA should work with researchers in federal and state government, academia and industry to address gaps in scientific knowledge of *Cronobacter*. Based on an expanded scientific understanding, the FDA should update its policies, processes, and procedures to ensure the agency provides infant formula manufacturers appropriate preventive control measures for *Cronobacter*. In addition, the FDA should consider resuming, as well as reordering, unannounced surveillance inspections at domestic infant formula facilities each year and should evaluate factors such as including inspectional history, consumer complaints, and supply chain impacts.

14. Finding: The FDA's infant formula compliance program lacks specificity regarding *Cronobacter* and is limited by scientific gaps related to this pathogen.

Recommendation: The FDA should review and update its compliance program and associated Compliance Policy Guide for infant formula manufacturers to ensure it reflects current science on *Cronobacter*, provides consistent industry oversight, and provides better tools for investigators and compliance officers, enabling the agency to take a comprehensive approach to inspections of infant formula manufacturing facilities and compliance activities.

15. Finding: Consumer education regarding the safe handling and preparation of infant formula is limited.

Recommendation: The FDA should work with the CDC, USDA, and other stakeholders, especially including those in the pediatric field and other health care providers, to identify and develop additional tools and resources to educate parents and caretakers, so they understand the potential risks associated with powdered infant formula and how to reduce those risks through proper handling and preparation.

Additional Authorities & Resources

While this report clearly identifies recommendations for the agency to pursue to improve the safety of infant formula and certain medical foods, and better protect the supply chain, it's important to note that implementation of the recommendations will be contingent, in part, on the agency's ability to obtain the necessary resources and authorities to conduct this critical work. The specific resources and authorities required will be determined as the agency convenes working groups to focus on each of the recommendations. However, as this incident has evolved, individuals involved in the response have identified areas where resources and authorities related to food safety, supply chain, and program capacity have been inadequate.

Manufacturers are not required to make *Cronobacter* isolates available to the FDA for sequencing and uploading into the national database, which limits the data available to help identify clusters of illness and potential sources of contamination. There are also identified gaps in our authorities related to accessing and sharing information that could help promote regulatory compliance and facilitate future inspections, such as access to records in lieu of or in advance of inspections for medical foods and sharing confidential commercial information and trade secrets with regulatory partners. Without these authorities, it will be difficult for the FDA to identify early signals of potential safety issues and work with manufacturers to mitigate these hazards.

Further, the FDA does not have the authority to require manufacturers of infant formulas or certain medical foods to notify it when they become aware of a circumstance that could lead to a shortage of these products for U.S. consumers, or to require manufacturers to put in place risk management plans. Access to this information in a timely manner could help the FDA take steps to potentially ensure continued availability of these products for consumers who need them, and to help inform trusted regulatory partners.

Finally, disparate hiring authorities between the FDA's medical products programs and foods program makes it difficult to recruit, quickly onboard, and retain staff with scientific, technical, statistical, and other expertise in the food's workforce. Without the modern hiring authorities afforded under 21st Century Cures, the FDA's foods program will continue to be limited in its ability to hire and retain adequate numbers of talented investigatory and scientific staff with the agility and speed necessary to meet the programs' needs.

Together, with Congress, other government agencies, industry, and stakeholders, we look forward to addressing the challenges identified in this report.

Conclusion

Throughout the fall, the FDA will form working groups charged with implementing the recommendations. While the scope of this evaluation is limited to infant formula, some of the findings highlight systemic challenges that may require enterprise-level changes. These working groups will be charged with reporting progress to the Commissioner and the Agency Executive Committee. A year from this report's publication, the FDA's Office of Planning, Evaluation, and Risk Management will assess the agency's progress in implementing the recommendations outlined in this report and make the results of that assessment public. The FDA is also working with the Office of the Inspector General (OIG) on its audit related to the Abbott Nutrition's infant formula recall and looks forward to OIG's findings and recommendations.

The FDA is committed to working with Congress, state and federal partners, industry, and other stakeholders to ensure nutritious, safe infant formula and metabolic formulas are on store shelves for Americans who rely on these products as an essential source of nutrition.