

To: CAHAN San Diego Participants

Date: May 20, 2022

From: Medical Care Services

Health Advisory: Nationwide shortage of infant formulas may increase risk for inadequate nutrition in infants

Key Messages

- Parents may be struggling to obtain sufficient formula to feed their infant and may resort to unsafe practices, such as diluting formula or using homemade formulas.
- The Department of Health and Human Services (HHS) has launched a website (hhs.gov/formula) with resources for families struggling to find baby formula.
- The American Academy of Pediatrics (AAP) and the California Department of Public Health (CDPH)'s Women, Infants & Children (WIC) program have also released guidance for healthcare professionals and families during this time. Refer to these resources and others at the end of this advisory.
- Providers are requested to report any adverse clinical outcomes that may be a result of inadequate infant nutrition secondary to the formula shortage by emailing <u>HealthCareSupport.HHSA@sdcounty.ca.gov</u>.

Situation

A February 24, 2022, <u>CAHAN</u> notified participants of a Centers for Disease Control and Prevention (CDC) investigation of cases of *Cronobacter sakazakii* infection in multiple states potentially linked to powdered infant formula. Many Abbott Nutrition products were voluntarily recalled, and production was paused on formulas manufactured in their Sturgis, Michigan plant. This event, in combination with supply chain delays, has resulted in a nationwide shortage of infant formula.

Background

Previously, the United States Food and Drug Administration (FDA), on February 24, 2021, issued a health advisory against using recipes to make homemade infant formula. Using homemade infant formula may lead to significant health problems for infants. The American Academy of Pediatrics (AAP) strongly advises against homemade formulas for the same reasons. Babies need very specific amounts of vitamins and minerals. Homemade formulas may contain too little or too much of certain components and/or may have an increased risk of contamination.

Over the last week, numerous resources have been released by the AAP, the Department of Health and Human Services (HHS), and the California Department of Public Health (CDPH)/Women, Infants, and Children (WIC) program to assist families and providers during the formula shortage. These and other resources can be found at the bottom of this health advisory.

The Federal government is taking action to address the infant formula shortage by invoking the Defense Production Act to increase baby formula supplies and launching <u>Operation Fly Formula</u> to accelerate the importation of infant formula. FDA has been working with Abbott and other manufacturers to increase formula production and availability, including reaching an agreement to allow the Sturgis facility to reopen within the next couple of weeks.

CDPH/WIC is also working closely with federal partners at the United States Department of Agriculture (USDA) to monitor participant access to WIC-provided formulas. The USDA has provided state WIC agencies regulatory flexibilities in response to the recall. However, CDPH/WIC has a contractual agreement with Mead Johnson for Enfamil products. As such, at this time, WIC families must purchase the formula available on their WIC card. Other brands of formula cannot be purchased. If a WIC family's healthcare provider has written a prescription for a special formula, and it is not available at any stores, they should contact their local WIC office. Their doctor may write a prescription for another special formula or multiple special formulas that will work for their baby.

Providers should take the current formula shortage into account when counseling families to make important feeding decisions for their babies. The resources provided below can be utilized to provide families with accurate information about the risks and benefits of formula feeding so they can make a true, informed choice. Parents who are breastfeeding or are considering breastfeeding should be provided with appropriate anticipatory guidance and support. Academy of Breastfeeding Medicine's (ABM) evidence-based <u>clinical protocols</u> can be helpful for breastfeeding, human milk, and lactation best practices and are available in a variety of languages.

Provider Actions Requested

- 1. Share information about safe feeding practices with parents of infants.
- 2. Inquire about feeding practices at each visit, especially with children less than one year of age.
- 3. **Report any suspect and confirmed** adverse clinical outcomes related to infant formula and feeding practices during business hours Monday through Friday by email to HealthCareSupport.HHSA@sdcounty.ca.gov.
- 4. Review and consider printing the resources below for education with your staff and the families of your patients.

Resources

- AAP: Healthychildren.org article <u>With the baby formula shortage, what should I do if I can't find any?</u> (available in <u>Spanish</u>)
- AAP: 2011 <u>Pediatrics in Review article</u> with a formula comparison chart
- AAP-CA3: Baby Formula Shortage and What Parents Should Do graphic
- Abbott: Healthcare professionals can order a product and have it shipped to a patient or hospital by downloading
 the form at https://abbottnutrition.com/metabolics and faxing the completed form with a physician order to 877293-9145.
- ABM: Statement on Shortage of Breastmilk Substitutes
- CDPH: Infant Formula website (www.cdph.ca.gov/formula; available in multiple languages)
- CDPH: <u>5/13/2022 Health Advisory</u>: CDPH Advises Parents and Caregivers Against Making or Feeding Homemade Infant Formula to Infants
- CDPH: Infant Formula Communications Toolkit (available in multiple languages)
- HHS: <u>Fact Sheet: Helping Families Find Formula During the Infant Formula Shortage</u> (hhs.gov/formula; available in <u>Spanish</u>)

Thank you for your participation.

CAHAN San Diego

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Secure Website: http://cahan.ca.gov _ Public Website: http://www.cahansandiego.com



State of California—Health and Human Services Agency California Department of Public Health



Health Advisory: CDPH Advises Parents and Caregivers Against Making or Feeding Homemade Infant Formula to Infants

May 13, 2022

Situation Summary

The impacts of the ongoing pandemic and the recent 2022 Abbott recall of certain powdered infant formula has led to periodic location- and product-based shortages of major brands of infant formula. The infant formula supply chain disruptions have affected all infant formula consumers in the state of California; parents and caregivers may be seeking to increase dilution of existing formula or use homemade infant formula recipes to feed infants.

The United States Food and Drug Administration (FDA) on February 21, 2021 issued a health advisory against using recipes to make homemade infant formula. Using homemade infant formula can lead to significant health problems for infants. An infant's nutritional needs are very specific, especially in the first year of life. Homemade infant formula may contain too little or too much of certain components, such as vitamins and minerals (like iron). Homemade infant formula may also have an increased risk of contamination, which could lead to infants becoming ill or developing an infection.

Background

In the advisory released last year, the FDA stated the following reasons why parents and caregivers should not to make and feed their infants homemade formula:

Infant formula as the sole source of nutrition for infants and is strictly regulated by the FDA. The FDA has requirements for certain nutrients in infant formula, and if the formula does not contain these nutrients at or above the minimum level or within the specified range, the infant formula is adulterated. Homemade infant formula recipes have not been evaluated by the FDA and may lack nutrients vital to an infant's growth.

The FDA generally regulates commercially available infant formula, which are marketed in liquid and powder forms, but typically does not regulate recipes for homemade formula. The FDA does not recommend that parents and caregivers make infant formula at home because of serious health and safety concerns. The potential problems with homemade formulas include contamination and absence of or inadequate amounts of critical nutrients.





These problems are very serious, and the consequences range from severe nutritional imbalances to foodborne illnesses, both of which can be life-threatening. Because of these severe health concerns, the FDA strongly advises parents and caregivers not to make and feed their infants homemade infant formula.

Recommendations

Practice Safe Infant Formula Preparation

Infants need a specific balance of nutrients. To protect infant health,use products that meet federal standards that ensure formula is not only as close as possible to human milk as possible but safe and free of harmful bacteria. Infant formula should be prepared according to the package directions.

In order to prevent illness in infants, parents and caregivers are advised to **avoid to the extent possible** the following actions listed below.

- Watering down formulas by adding more water when mixing powdered formula or adding extra water to ready-to-serve, non-concentrated liquid formula.
- Making a homemade formula from ingredients at the store, such as powdered cow milk or raw milk and sugar.
- Feeding infants under one-year-old cow milk or other milk <u>substitutes</u> from the dairy section of the grocery store, such as almond or soy beverages (sometimes labeled as milk).
- Using imported formulas from other countries that are not reviewed by the FDA.

Parents or caregivers of infants who have consumed a homemade infant formula should contact their healthcare provider to receive further care and guidance; and providers should report any illnesses or symptoms possibly related to the formula dilution or substituion to their local Health Department so that further public health assistance can be provided.

How to Find Infant Formula in Stores

CDPH recommends the following to parents and caregivers seeking to purchase infant formulas in stores:

- Call the store directly and ask if the formula you need is available or when they will get some.
- Parents and caregivers using benefits from the California WIC program should use their
 formula benefits early. More trips to the store may be required. The store may limit how
 many cans of formula purchased at one time. WIC can also support eligible partially
 breastfeeding parents and caregivers increase their breastmilk supply and with use of breast
 pumps. Additional WIC updates are available online or on MyFamily.WIC.ca.gov.
- Ask a health care provider for guidance on alternative formulas you could use.

Parents and caregivers can also consult the resources contained in the United States Department of Health and Human Services <u>Fact Sheet: Helping Families Find Formula During the Infant Formula Shortage</u> for assistance in finding infant formula.

<u>The FDA provides regular updates</u> on the investigation at the Abbott Sturgis, MI production facility. The last update was March 31, 2022. Subscribe to updates from the FDA to receive reliable and timely information. The FDA also provides a <u>consumer-friendly webpage</u> about the recall and formula safety.

For infants under three months, born prematurely, or who have a weakened immune system, both the FDA and Centers for Disease Control and Prevention (CDC) are currently recommending additional precautions.

For More Information

California Department of Public Health/Women, Infants and Children Program

 https://www.cdph.ca.gov/Programs/CFH/DWICSN/Pages/Information-for-WIC-Families-on-Infant-Formula-Availability.aspx.

United States Food and Drug Administration

- FDA: FDA Advises Parents and Caregivers to Not Make or Feed Homemade Infant Formula to Infants
- FDA: Infant Formula: Safety Do's and Don'ts
- FDA: Questions & Answers for Consumers Concerning Infant Formula

Centers for Disease Control and Prevention

CDC: Powdered Infant Formula Preparation and Storage

United States Department of Agriculture

- USDA: Infant Formula Safety
- AAP: Recommendations for Finding Infant Formula during the Shortages
- AAP: Is Homemade Baby Formula Safe?