



Food and Nutrition Service

1320 Braddock Place
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SUBJECT: Questions and Answers Regarding the 2022 Infant Formula Shortage in the Child and Adult Care Food Program

TO: Regional Directors
Special Nutrition Programs
All Regions

State Directors
Child Nutrition Programs
All States

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Summary:	(1) This memo addresses questions related to infant formula use in the Child and Adult Care Food Program (CACFP) during the nationwide formula shortage in 2022. (2) This memorandum applies to State agencies administering, and local organizations operating, the Child and Adult Care Food Program. (3) This document relates to 7 CFR Part 226.

The ongoing infant formula shortage due to supply chain issues, which worsened due to a major formula recall in February 2022, has left many Child and Adult Care Food Program (CACFP) operators concerned about access to formula and their options for safely feeding infants in their care.

FNS has developed the following Questions and Answers to support CACFP operators and the families they serve during this unprecedented and evolving situation. FNS is also committed to continuing to monitor the situation, meeting with key stakeholders, and providing technical assistance to State agencies as issues arise. Additional questions not covered by this document should be directed toward the respective FNS Regional Office.

Sincerely,

Andrea Farmer
Acting Director
Policy and Program Development Division

Infant Formula in the Child and Adult Care Food Program: Questions and Answers

Infant Formula Availability

1. What counts as infant formula?

CACFP regulations at 7 CFR 226.2 define infant formula as any iron-fortified formula intended for dietary use solely as a food for normal, healthy infants; excluding those formulas specifically formulated for infants with inborn errors of metabolism or digestive or absorptive problems. Infant formula, as served, must be in liquid state at recommended dilution.

FNS policy memo [CACFP 06-2017 Feeding Infants and Meal Pattern Requirements in the Child and Adult Care Food Program; Questions and Answers](#), expands upon this definition as follows: The Food and Drug Administration (FDA) defines iron fortified infant formula as a product “which contains 1 milligram or more of iron in a quantity of product that supplies 100 kilocalories when prepared in accordance with label directions for infant consumption” (21 CFR 107.10(b)(4)(i)). Additionally, to be creditable for reimbursement, infant formula must meet the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and meet the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107. Infant formulas that are not regulated by FDA are not creditable in the CACFP.

FNS is aware that FDA is encouraging safe importation of infant formula from other countries and that the White House has commissioned importation of infant formula from outside of the United States. FNS will continue to monitor the situation and update guidance as necessary.

In summary, infant formula served in the CACFP must be:

- Iron-fortified (at least 1 mg of iron per 100 calories, as prepared)
- Mixed in the proportions recommended (not diluted)
- Regulated by the FDA

2. If my usual supplier is out of stock, where else can I buy infant formula for service in the CACFP?

Infant formula for the CACFP should only be purchased from reputable retailers such as local, regional or national grocers, pharmacies, or membership-based warehouses. Purchases may be made in-person or online from these retailers.

For the health and safety of infants in your care, avoid purchasing infant formula from individuals online or in-person, through social media groups, from foreign countries, or through other non-retail sources.

3. I always buy one certain brand of formula that I trust for the infants in my care, but I’m suddenly no longer able to find that brand. Is it safe to switch brands based on what is available at the time of purchase?

Yes, in most cases. If infants are consuming a general infant formula—that is, one that is not designed for a specialized medical need—Program operators may use different brands as available.

The American Academy of Pediatrics (AAP) recommends gradually introducing small amounts of the new formula with the usual formula if the infant does not like the taste or has difficulty tolerating a new formula. Note that it may take some time for an infant to adjust to a new formula; parents may wish to contact their child's pediatrician with questions about whether the infant is tolerating a particular formula.

Program Flexibilities

4. Are State agencies able to disregard the requirement to serve infant formula in CACFP in case of emergency?

Yes, but only after extensive efforts to obtain safe FDA-approved iron-fortified infant formula have failed, and only for infants aged six months and older who are receiving additional meal components beyond formula or breastmilk. FNS regulations at 7 CFR 226.20(e) state, "When emergency conditions prevent an institution or facility normally having a supply of milk from temporarily obtaining milk deliveries, the State agency may approve the service of breakfast, lunches, or suppers without milk during the emergency period." Further, FNS regulations at 7 CFR 226.2 define milk as "pasteurized fluid types of unflavored or flavored whole milk, lowfat milk, skim milk, or cultured buttermilk which meet State and local standards for such milk, except that, in the meal pattern for infants (0 to 1 year of age), milk means breast milk or iron-fortified infant formula." Therefore, milk, which includes breastmilk and infant formula in the infant meal pattern, may be omitted from certain reimbursable meals during a temporary emergency period if the State agency approves it. However, meals for infants younger than six months of age (where formula or breastmilk comprise the entirety of the meal) are not reimbursable if the program operator or parent or guardian does not offer the amounts of formula and/or breastmilk required in regulation at 7 CFR 226.20.

While this flexibility does exist in regulation, keep in mind that infant formula is a crucial source of nutrients for infants who are not fully breastfed, playing a significant role in this life stage marked by rapid growth and development. Thus, FNS strongly discourages CACFP operators from omitting formula and/or breastmilk from meals for infants of any age. The decision to omit infant formula from an infant meal in CACFP should be made jointly between the CACFP operator and the parent or guardian, and only under extreme circumstances where FDA-approved infant formula could not be procured through any legitimate retail channel and the parent or guardian was unable to supply formula for infant meals while in care. This decision should be reviewed on a daily basis, with rigorous ongoing efforts to procure adequate formula supplies for all infants (who are not fully breastfed) in care.

5. If an infant has a medical note calling for a specific substitute for infant formula, may the CACFP operator accommodate that request? Will the meal be reimbursable?

Yes, if specific conditions are met. While FNS regulations at 7 CFR 226.20(b)(2) require that breastmilk or iron-fortified infant formula, or portions of both, be fed to infants aged 0 through 11 months in CACFP, Program regulations at 7 CFR 226.20(g) also allow for meal component substitutions for reasons of disability, or medical or other special dietary needs. Requests for these substitutions must be in writing, signed by a recognized medical authority, and include the recommended alternative. In this case, the Program operator may serve the medically recommended substitution and still receive reimbursement for the meal.

- 6. If a physician or State recognized medical authority prescribes whole cow’s milk as a substitute for breastmilk or infant formula for an infant younger than 12 months of age, is the meal reimbursable?**

For children younger than 12 months of age, cow’s milk may be served as a substitute for breastmilk and/or infant formula, and be part of a reimbursable meal, if the substitution is supported by a medical statement signed by a licensed physician or a State recognized medical authority. A State recognized medical authority for this purpose is a State licensed health care professional who is authorized to write medical prescriptions under State law. The statement must explain the need for the substitution and must be kept on file by the center or day care home in order for the meal to be reimbursable.

- 7. If a parent supplies an infant formula that is not iron-fortified (“low-iron”), would service of this product require a medical statement to be creditable towards a reimbursable infant meal?**

Infant formulas that are not iron-fortified are generally not reimbursable in the CACFP. However, infant formulas that are not iron-fortified may be creditable towards a reimbursable meal if the substitution is supported by a medical statement. The medical statement must explain the need for the substitution, indicate the recommended infant formula, and be signed by a licensed physician or a State recognized medical authority. A State recognized medical authority for this purpose is a State licensed health care professional who is authorized to write medical prescriptions under State law. The statement must be submitted and kept on file by the center or day care home.

Feeding Infants in CACFP During a Formula Shortage

- 8. We are a small family-run day care provider; what should we do if we cannot provide formula to infants in our care?**

The questions and answers under “Program Flexibilities” in this document provide guidance on the flexibilities available to all types of CACFP institutions during the infant formula shortage; please review the options to see if one or more apply to your situation. In addition, maintain open communication with parents or guardians, making infant feeding decisions as a team. Consult with your sponsoring organization as appropriate for additional guidance.

- 9. May providers serve homemade infant formula in CACFP?**

No. Homemade infant formulas are not regulated by the FDA¹ and are not creditable under any circumstances in the CACFP. Additionally, both the FDA and the American Academy of Pediatrics strongly advises against homemade formula, stating that recipes are often not safe, do not meet infants’ nutritional needs, and in some cases, can be life-threatening².

¹ Food and Drug Administration. <https://www.fda.gov/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants>. Accessed May 19, 2022.

² American Academy of Pediatrics. <https://healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/Are-there-shortages-of-infant-formula-due-to-COVID-19.aspx>. Accessed May 16, 2022.

10. Will providers be reimbursed for serving a mixture of whole cow's milk and infant formula when formula stock is low?

Such mixtures might be reimbursable, but only under specific conditions. Mixing whole milk and infant formula is an allowable practice for children 1 year of age (i.e., 12-23 months). However, cow's (or other animal) milk is not creditable in CACFP infant meals for children younger than 12 months unless a written medical note signed by a State recognized medical authority and specifying the necessity of this substitution is on file. Infants may have trouble digesting animal milks before the age of 1 year; thus, feeding cow's milk to an infant is not recommended as a standard practice and is not broadly reimbursable in CACFP.

11. Are parents or guardians allowed to supply infant formula for use in CACFP?

Yes, if this practice complies with State and local health codes. FNS regulations at 7 CFR 226.20(b)(2) clarify that infant formula may be supplied by an institution or facility, or by a parent or guardian. In both cases, meals containing creditable infant formula that are served to the infant by the child care provider are eligible for reimbursement, including meals when an infant is only consuming infant formula. In situations where an infant or child does not have a diet-restricting disability, parents or guardians may provide one component of the CACFP meal as long as the Program operator provides all remaining components.

Note that CACFP operators should make every attempt to procure adequate amounts of iron-fortified infant formula for all infants in care and should not ask parents or guardians to supply formula as a cost-savings or convenience practice. Previous FNS guidance³ has stated that State agencies and sponsoring organizations must ensure that the parent or guardian is truly choosing to provide the component. However, in this temporary infant formula shortage, Program operators may consider collaborating with parents or guardians to develop a plan that could include them supplying formula on a limited and strictly as-needed basis.

12. May a parent donate extra formula or food received through the Special Supplemental Nutrition Program for Women, Infants, and Children's (WIC) to his or her infant's center or day care home?

A parent may provide one meal component for their own infant or infants, such as infant formula received through WIC. However, parents or guardians cannot donate formula or food they receive through WIC to the center or day care home for general use. Parents or guardians with formula or food received through WIC that their infant has not consumed should be referred to their WIC program for guidance. Please visit <https://www.fns.usda.gov/wic/toll-free-numbers-wic-state-agencies> to find WIC State agency contact numbers.

13. If a CACFP institution is offered a donation of infant formula, are they allowed to accept it?

³ United States Department of Agriculture, Food and Nutrition Service. *CACFP 06-2017: Feeding Infants and Meal Pattern Requirements in the Child and Adult Care Food Program; Questions and Answers* (<https://fns.usda.gov/sites/default/files/cacfp/CACFP06-2017os.pdf>.) Published January 17, 2017.

Yes, if the process complies with State and local health codes. CACFP institutions may receive donations of food items to meet any component of a reimbursable meal. However, the health and safety of program participants is paramount; institutions should be mindful of expiration dates, evidence of potential tampering, and other potential food safety issues when using donated foods in CACFP meals.

14. Should Program operators purchase formula manufactured outside of the United States if local supplies have dwindled?

FDA has recently made a concerted effort to help increase the supply of infant formula in the United States. The FDA is working closely with other federal entities, including USDA and the White House, on this rapidly evolving situation. One of the initiatives that FDA is engaging in is the possible import of infant formula that is considered safe and nutritionally adequate from other countries. More information regarding this imported formula and its ability to credit towards CACFP will be provided as information becomes available. Infant formulas that are not regulated by FDA are not creditable in the CACFP.

15. Do CACFP infant formulas have to be approved by the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)?

No. CACFP infant formulas do not have to be approved by WIC. WIC's infant formula requirements vary slightly from CACFP's, including a higher iron requirement (1.5 mg of iron per 100 calories). Therefore, some infant formulas that may be creditable in CACFP, such as infant formulas with 1 mg of iron per 100 calories, may not be eligible in WIC.

16. Where can I find more information on feeding infants during the formula shortage?

The American Academy of Pediatrics is a well-respected resource for evidence-based information on infant nutrition and infant health; the Academy has published a webpage dedicated to helping parents and other caregivers during the infant formula shortage at <https://healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/Are-there-shortages-of-infant-formula-due-to-COVID-19.aspx>.

Additionally, FNS maintains a webpage on infant formula safety at: <https://www.fns.usda.gov/ofs/infant-formula-safety>. While the content highlights regulatory flexibilities for WIC State agencies, most of the information, including advice for consumers and infant formula safety tips, is applicable to infants more broadly and may be useful to CACFP operators.

17. What should parents do if they are unable to find formula for their infants?

If parents come to CACFP institutions for help or advice on feeding infants at home, please refer them to their pediatrician or local pediatric clinic to discuss safe and appropriate feeding alternatives for their individual child(ren).