United States Department of Agriculture

Food and Nutrition Service

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SUBJECT: Infant Feeding in the CACFP- Revised

TO: Regional Directors
Special Nutrition Programs
All Regions

State Directors
Child Nutrition Programs
All States

The purpose of this memorandum is to consolidate, clarify, and provide additional guidance on infant formula and meal requirements in the Child and Adult Care Food Program (CACFP). This revision clarifies that infant formula must be regulated by the Food and Drug Administration (FDA) in order to be part of a reimbursable meal. Additionally, the memorandum extends the length of time refrigerated breastmilk may be stored at a center or day care home, updates guidance on creditable infant formulas, allows centers and day care homes to serve infant foods containing DHA, and addresses frequently asked questions. This memorandum consolidates and supersedes the following guidance:

- *Policy Regarding the Obligation of a Child Care Facility to Offer Infant Formula in the Child and Adult Care Food Program,* December 19, 1996;
- *Issues Related to Feeding Infants in the Child and Adult Care Food Program,* April 20, 2000;
- *Obligations of Child Care Centers and Day Care Homes to Offer Infant Meals in the Child and Adult Care Food Program,* May 17, 2002;
- *Baby Fruits or Vegetables with DHA,* December 19, 2002;
- *Reimbursement of Infant Meals in the Child Nutrition Programs,* April 28, 2003; and
- *Clarification on Acceptable Infant Formulas,* November 9, 2004.

Obligation to Offer and Reimbursement of Infant Meals

Centers and day care homes participating in CACFP must offer Program meals to all eligible children enrolled in their center or day care home. Program regulations define an enrolled child as "a child whose parent or guardian has submitted to an institution a signed document which indicated that the child is enrolled in child care" [7 CFR 226.2]. A center or day care home may not avoid this obligation by stating that the infant is not "enrolled" in the CACFP, or by citing logistical or cost barriers to offering infant meals. Decisions on offering Program meals must be based on whether the child is enrolled for care, not if the child is enrolled in the CACFP.

As long as an infant is in care during the meal service period, the center or day care home must offer the infant a meal that complies with Program requirements. An infant's parents or guardians may, at their discretion, decline the offered infant formula and supply expressed breastmilk or a creditable infant formula for the infant to consume. To receive reimbursement, the center or day care home's caregiver must serve and feed the infant a developmentally appropriate meal. Meals served to infants ages 0 through 3 months containing only breastmilk and/or iron-fortified infant formula that is provided by parents or guardians are reimbursable.

Breastmilk Storage

The Academy of Breastfeeding Medicine, a worldwide organization of physicians that establishes guidelines for healthy term infants, recommends a storage time of 72 hours for refrigerated breastmilk. Accordingly, in an effort to follow current scientific recommendations, the length of time a center or day care home may keep refrigerated bottles of fresh breastmilk is being extended to 72 hours from the time it was collected. The previously established standard included in the current *Feeding Infants: A Guide for Child Nutrition Programs* was 48 hours from the time it was collected. Bottles of fresh breastmilk must be stored in a refrigerator kept at 39° Fahrenheit or below. This change supports breastfeeding practices and increases flexibility for centers and day care homes. FNS will update the *Feeding Infants: A Guide for Child Nutrition Programs* (http://www.fns.usda.gov/tn/feeding-infants-guide-use-child-nutrition-programs) to reflect this change. Centers and day care homes should continue to follow all other breastmilk handling and storage guidelines listed in *Feeding Infants: A Guide for Child Nutrition Programs*.

Creditable Infant Formulas

CACFP regulations require that to be eligible for reimbursement infant formula served must be iron-fortified [7 CFR 226.20(b)(2)]. 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)]. The number of milligrams (mg) of iron per 100 kilocalories (calories) of formula can be found on the nutrition facts label of infant formulas.

Previously, FNS provided a list of *Iron-Fortified Infant Formulas That Do Not Require a Medical Statement.* FNS has not updated or provided this list for some time and will no longer maintain such a list due to the continuous development of new or re-formulated infant formula products making an accurate all-inclusive list impractical. The following criteria may be used to determine whether or not a formula is eligible for reimbursement without a medical statement:

1. Ensure that the formula is not an FDA Exempt Infant Formula. An exempt infant formula is an infant formula labeled for use by infants who have inborn errors of metabolism or low birth weight, or who otherwise have unusual medical or dietary problems, as defined in 21 CFR 107.3.

2. Look for "Infant Formula with Iron" or a similar statement on the front of the formula package. All iron-fortified infant formulas must have this type of statement on the package.

3. Use the nutrition facts label as a guide to ensure that the formula is iron-fortified. The nutritive values of each formula are listed on the product's nutrition facts label. To be considered iron-fortified, an infant formula must have 1 mg of iron or more per 100 calories of formula when prepared in accordance with label directions.

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)) (http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapII-sec321.pdf) and meet the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) (http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapIV-sec350a.pdf) and the regulations at 21 CFR parts 106 and 107 (http://www.ecfr.gov/cgi-bin/text-idx?gp=&SID=39344f21c8c795a9fc3f485db0aefeb9&mc=true&tpl=/ecfrbrowse/Title21/21CIsubchapB.tpl). Requiring an infant formula be compliant with the FDA regulatory standards on infant formula is consistent with the Special Supplemental Nutrition Program for Women, Infants, and Children's (WIC) infant formula requirements and ensures that all infant formulas served in the CACFP meet nutrient specifications and safety requirements. If a formula is purchased outside of the United States, it is likely that the formula is not regulated by the FDA, and therefore, it may not be creditable under the CACFP.

Formulas classified as Exempt Infant Formulas by FDA may be served as a part of a reimbursable meal if the substitution is supported with 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 be submitted and kept on file by the center or day care home. FNS recently expanded the list of acceptable medical professionals that may sign a medical statement for meal accommodations for children whose disability restricts their diets. For more information see SP 32-2015, SFSP 15-2015, CACFP 13-2015, *Statements Supporting Accommodations for Children with Disabilities in the Child Nutrition Programs*, available at http://www.fns.usda.gov/statements-supporting-accommodations-children-disabilities-cnp. Information on FDA Exempt Infant Formula is available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm106456.htm.

State agencies should contact the FNS Regional Office in situations where the creditability of an infant formula is uncertain.

DHA Enriched Infant Foods

Docosahexaenoic acid, known as DHA, is an omega-3 fatty acid that may be added to infant formulas and infant foods. While the science is mixed on the benefits of DHA and ARA (arachidonic acid, another omega-3 fatty acid), some studies suggest they may have positive effects on visual function and neural development. For these reasons, manufacturers and consumers are interested in adding DHA and ARA to infant formula and food products.

Previously, the service of any infant foods containing DHA was prohibited due to the concern that the source of DHA in infant foods, such as egg yolk, and other ingredients, additives, or extenders in those foods may result in a food sensitivity or a food allergy (*Baby Foods and Vegetables with DHA*, December 19, 2002). However, DHA itself cannot cause allergic reactions and, according to the American Academy of Pediatrics, there is no current convincing evidence to delay the introduction of foods considered to be major food allergens, including eggs. Based on this, FNS is now allowing single-ingredient infant foods containing DHA to be creditable in the CACFP infant meal pattern. Child care centers and day care home providers now may serve infant foods containing DHA, as long as they meet all other crediting requirements.

State agencies are reminded to distribute this information to Program operators immediately. Program operators should direct any questions regarding this memorandum to the appropriate State agency. State agency contact information is available at http://www.fns.usda.gov/cnd/Contacts/StateDirectory.htm. State agencies should direct questions to the appropriate FNS Regional Office.

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Attachment A

Questions and Answers
New questions are preceded by three asterisks (***)

1. ***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.

2. ***What is an "iron-fortified" infant formula?**

   There are currently two types of infant formula available in the United States, either "iron-fortified" or "low-iron." The Food and Drug Administration considers an infant formula to be "iron-fortified" if it has 1 milligram of iron or more per 100 kilocalories. A "low-iron" infant formula has less than 1 milligram of iron per 100 kilocalories. The American Academy of Pediatrics recommends formula-fed infants receive iron-fortified infant formula to prevent iron-deficiency anemia.

3. **When an infant receives both breastmilk and formula, is the meal eligible for reimbursement?**

   Yes. Meals served to infants younger than 12 months of age may contain iron-fortified infant formula, breastmilk, or a combination of both, as long as the total number of ounces offered to the infant meets or exceeds the minimum amount required in the CACFP infant meal pattern.

4. **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.

   FNS recognizes that infants have unique dietary needs and that decisions concerning diet during the first year of life are for the infant's health care provider and parents or guardians to make together.

5. **Are meals served to children 12 months and older reimbursable if they contain infant formula?**

   Yes, for a period of one month, when children are 12 to 13 months of age, meals that contain infant formula may be reimbursed to facilitate the weaning from infant formula to cow's milk. While weaning, infants should be presented with both types of foods at the same meal service to gradually encourage acceptance of new food. Breastmilk continues to be considered an acceptable milk alternative for children over 12 months of age.

   Meals containing infant formula that are served to children 13 months and older are reimbursable when it 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.

6. **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?**

   Generally, infant formulas that are not iron-fortified are not reimbursable in the CACFP. However, infant formulas that are not iron-fortified may be served and 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.

7. **Is a meal reimbursable if the parent or guardian provides the majority of the meal components for infants older than three months?**

   Yes. FNS recognizes that infants have unique dietary needs and parents or guardians are often most in touch with their infant's dietary preferences. Therefore, parents or guardians may choose to provide one or more of the meal components in the CACFP infant meal patterns for infants older than three months, as long as this is in compliance with local health codes. In order for a meal with parent or guardian provided components to be reimbursable the center or provider must provide at least one of the meal components in at least the minimum required serving size. Centers and sponsoring organizations must ensure that the parent or guardian is truly choosing to provide the preferred component(s) and that the center or provider has not requested or required the parent or guardian to provide the components in order to complete the meal and reduce cost to the center or provider.

8. ***Is yogurt creditable in the infant meal pattern?**

Yogurt is not and has never been a creditable food component in the CACFP infant meal pattern. The American Academy of Pediatrics recommends delaying the introduction of cow's milk until 1 year of age and the Institute of Medicine recommends delaying the introduction of both cow's milk and cow's milk-based products, including yogurt, until 1 year of age. FNS will update the *Feeding Infants: A Guide for Child Nutrition Programs* (http://www.fns.usda.gov/tn/feeding-infants-guide-use-child-nutrition-programs) to reflect this policy because it currently lists yogurt as a meat/meat alternate that may be introduced starting at 8 months of age.

9. ***Are foods that are considered to be a major food allergen or foods that contain these major food allergens allowed for infant meals?**

Foods that contain one or more of the eight major food allergens identified by the FDA (milk, egg, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) and are appropriate for infants are allowed and can be part of a reimbursable meal. The American Academy of Pediatrics states there is no current convincing evidence that delaying the introduction of foods that are considered to be major food allergens has a significant positive effect on the development of food allergies. Even though most food allergies cause relatively mild and minor symptoms, some food allergies can cause severe reactions, possibly life-threatening. With this in mind, it is good practice to check with parents or guardians of all infants to learn about any concerns of possible allergies and their preference on how solid foods are introduced. Additionally, please note that the CACFP meal patterns only allow egg yolks to be served as a meat/meat alternate for infants.

10. ***Are commercially prepared mixed or combination infant foods (e.g., infant dinners with vegetables and chicken) reimbursable in the infant meal pattern?**

Commercially prepared mixed or combination foods are not reimbursable in the infant meal pattern. It is extremely difficult to identify the required food components and prove that the amount of the food components in mixed infant foods meet the meal pattern requirements. Additionally, many commercially prepared infant mixed food products contain more ingredients that could possibly cause an allergic reaction in those children with allergies and may have added sugar that may promote the development of tooth decay as well as provide few nutrients.