



# Creditability of Infant Formulas Imported Through the Food and Drug Administration's 2022 Infant Enforcement Discretion Policy in the Child and Adult Care Food Program

## Purpose

This memorandum provides guidance to State agencies and local program operators on the use of infant formulas imported as part of the Food and Drug Administration's 2022 Infant Formula Enforcement Discretion Policy. This guidance applies to State agencies administering, and local organizations operating, the Child and Adult Care Food Program.

## Legal Authority

CACFP 01-2023

## Program Requirements

The ongoing novel coronavirus (COVID-19) pandemic, coupled with the [2022 Abbott recall](#) of certain infant formula, has had a substantial impact on the nationwide supply chain for infant formula. Child and Adult Care Food Program (CACFP) operators have experienced local infant formula shortages, threatening the nutritional quality of meals served to infants in their care. The Food and Drug Administration (FDA), under the Biden-Harris Administration, has taken steps to address the formula shortage, including temporarily exercising enforcement discretion with respect to certain statutory and regulatory requirements for infant formulas. As outlined in the [Infant Formula Enforcement Discretion Policy: Guidance for Industry \(issued May 2022\)](#), the FDA is permitting the import of certain infant formula products from abroad. As a result, a limited number of imported infant formulas are now available for immediate purchase in the U.S. domestic market.

CACFP regulations at 7 CFR 226.20(b)(2) require that breastmilk or iron-fortified infant formula, or portions of both, be served to infants ages 0-11 months. Meals must contain breastmilk or iron-fortified

infant formula supplied by the CACFP institution or facility, or by the parent or guardian, in order to be eligible for reimbursement. For further information on infant formula served in CACFP, regardless of its source, see FNS policy memo [CACFP 02-2018, Feeding Infants and Meal Pattern Requirements in the Child and Adult Care Food Program; Questions and Answers](#), and recently restated in [CACFP 10-2022, Questions and Answers Regarding the 2022 Infant Formula Shortage in the Child and Adult Care Food Program](#). Per program regulations, infant formula served in the CACFP must be iron-fortified. Our previously issued guidance documents describe infant formula as iron-fortified when it contains at least 1 mg of iron per 100 calories, as prepared; is mixed in the proportions recommended (not diluted); and is regulated by the FDA.

The intent of this memorandum is to clarify that the infant formulas imported into the U.S. as a result of the 2022 FDA Infant Formula Enforcement Discretion Policy may be served in the CACFP to meet the requirements of a reimbursable meal. These formulas have been determined to be nutritionally adequate and safe by the FDA<sup>[1]</sup>, and thus meet the intent of FDA regulation. Therefore, if an infant formula has been approved for enforcement discretion by the FDA, is iron-fortified, and is mixed in the proportions recommended, then it can be included as part of a reimbursable meal in CACFP. It is important to note that the mixing instructions on formulas imported from abroad may use the metric system; CACFP operators should be cognizant of this measurement difference and ensure formulas are appropriately and safely mixed. Visit [Tips for Preparing Imported Infant Formula](#) for help with common terminology used on imported formulas and common metric system conversions. *(Please see the attached Important Reminders on DECAL State Agency Rules on Infant Formula),*

As outlined in the [Infant Formula Transition Plan for Exercise of Enforcement Discretion: Guidance for Industry](#) (issued September 2022), the FDA is permitting the formulas approved for enforcement discretion to be imported to the U.S. until January 6, 2023, and FDA's continued exercise of enforcement after January 6, 2023 will be made on a case-by-case basis. Infant formulas for which the FDA has exercised enforcement discretion that are imported to the U.S. on or before this date, can remain on the market. Formulas approved for enforcement discretion by the FDA may be used to meet the requirements of a CACFP reimbursable meal, as stated herein, as long as they are available for sale in the U.S. retail market, and they are utilized prior to the formula expiration date. FNS acknowledges that the nationwide shortage of infant formulas is concerning for CACFP operators. FNS will continue to monitor the situation and provide technical assistance to State agencies as appropriate.

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<sup>[1]</sup> Under section 412(i) of the Federal Food Drug and Cosmetic Act and FDA regulations at 21 CFR 107.100, an infant formula must meet specific requirements for the levels of protein, fat, essential fatty acids, 15 vitamins, and 12 minerals. FDA regulations also establish labeling requirements, such as the specific presentation and formatting of nutrient information (21 CFR 107.10) and directions for use (107.20).

## Comments

**October 21, 2022 - Note:** As a reminder, DECAL's Child Care Services Division's (CCS) Rules and Regulations for [Child Care Learning Centers](#) and [Family Child Care Learning Homes](#) advise, as per

591-1-1-.15(3) and 290-2-3-.10(4), that if formula must be provided by a licensed child care center or family child care learning home, only commercially prepared, ready-to-feed formula shall be used.

Though Federal regulation does not limit CACFP facilities to serving only pre-mixed infant formulas, DECAL licensed child care centers and family child care learning homes that participate in the CACFP must serve only commercially prepared, ready-to-feed formula as required per CCS Rules and Regulations.

For questions concerning this memorandum, please contact Nutrition's Policy Administrator at (404) 651-8193.