

Appendix J
WIC Policy Memorandum #2023-3
Unwinding Infant Formula Flexibilities in
WIC



Food and
Nutrition
Service

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Date: February 1, 2023

SUBJECT: WIC Policy Memorandum #2023-3
Unwinding Infant Formula Flexibilities in WIC

TO: Regional Directors
Special Nutrition Programs
All Regional Offices

Background

On February 17, 2022, the United States Food and Drug Administration (FDA) announced a recall of certain powdered Abbott infant formulas, which exacerbated existing supply chain issues resulting from the ongoing Coronavirus Disease 2019 (COVID-19) pandemic. In response, the United States Department of Agriculture (USDA) Food and Nutrition Service (FNS) approved select State agency requests for statutory and regulatory flexibility in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to assist participants in using their WIC infant formula benefits.

On November 8, 2022, FNS published [WIC Policy Memorandum #2023-1 Abbott Infant Formula Waiver Expiration Schedule](#) which extended active waivers to January 31, 2023, or 60 days after the end of the Presidentially-declared COVID-19 major disaster declaration in the affected area, whichever is sooner. However, FNS recognizes that WIC State agencies may need additional flexibility to ensure uninterrupted access to infant formula for WIC families even as WIC State agencies transition back to normal operations. The intent of this policy memorandum is to formally describe the timeline for this transition, as previously described in the [December 19, 2022 letter to State agencies](#).

Phased Approach to Waiver Expiration

FNS is extending the expiration date for certain waivers as described below as a result of the prolonged supply chain issues associated with the COVID-19 public health emergency, exacerbated by the Abbott infant formula recall, and the expressed need of State agencies for advanced notice of waiver expiration.

Barring a significant change in the availability of infant formula, USDA expects this to be the final extension. State agencies should start to plan for the transition back to normal program operations. In order to assist State agencies in the planning and execution of the infant formula waiver unwinding, FNS has included a chart outlining the expiration schedule described below by waiver type as Attachment A to this memorandum. For all waivers listed below, the

expiration is the date specified or 60 days after the end of the Presidentially-declared COVID-19 major disaster **declaration** in the affected area, whichever is earlier. Infant formula waivers are extended as follows:

Waivers for Food Package I & II: Medical Documentation and Non-Contract Formulas

- **Medical Documentation for Food Packages I & II - Infant**
Allows healthy infants receiving Food Package I or II to receive a different brand of formula without medical documentation through **February 28, 2023**.
- **Imported Infant Formula under FDA's Infant Formula Enforcement Discretion for Non-Contract Standard Formulas**
Allows healthy infants receiving Food Package I or II to receive imported formula outside of their contracted brand through **February 28, 2023**. Non-contract brand formulas that do not meet the minimum specifications for infant formula (iron and kcal) or do not meet registration requirements with the FDA for issuance in WIC should be removed from the Authorized Products List before March 1, 2023.

Waivers for Food Package I & II: Package Size and Contract Formulas

- **Maximum Monthly Allowance (MMA) for Food Packages I & II – Infant Formula**
Allows healthy infants receiving Food Package I or II to receive alternate container sizes that are manufactured by the State's infant formula rebate contractor per contract agreement through **April 30, 2023**.
- **Imported Infant Formula under FDA's Infant Formula Enforcement Discretion for Formulas Produced by the Respective State Agency's Contract Manufacturer**
Allows healthy infants receiving Food Package I or II to receive certain imported formulas within the State agency's contracted brand through **April 30, 2023**. Contract brand formulas that do not meet the minimum specifications for infant formula (iron and kcal) or do not meet registration requirements with the FDA for issuance in WIC should be removed from the Authorized Products List before May 1, 2023.

Waivers for Food Package III: Specialty Formulas for Infants with Special Medical Needs

- **Maximum Monthly Allowance (MMA) for Food Package III – Infant Formula**
Allows medically-fragile infants receiving Food Package III to receive alternate container sizes, including those that are larger than usually allowed through **June 30, 2023**.

- **Imported Infant Formula under FDA’s Infant Formula Enforcement Discretion for Issuance of Certain Imported Specialty Formulas Only**

Allows medically-fragile infants receiving Food Package III to receive certain imported formulas through **June 30, 2023**. Specialty formulas issued under Food Package III that do not meet registration requirements with the FDA for issuance in WIC should be removed from the Authorized Products List before July 1, 2023.

These extensions apply to all WIC State agencies with a waiver in place. A WIC State agency may discontinue the use of a waiver at any time by notifying their FNS Regional Office when the waiver is no longer needed.

Vendor Communication

This transition will involve all Program stakeholders including the State agency’s WIC authorized vendors. As part of this transition, WIC State agencies should continue to communicate proactively with their vendor population about this phased return to normal operations and work collaboratively with their vendors and contract manufacturer so ordering and stocking procedures shift to align with the State agency’s return to the primary use of contract-brand formula. State agencies have flexibility regarding minimum stocking requirements (MSRs) for infant formula. During this phased transition to normal Program operations, State agencies should continue to work collaboratively with vendors on MSRs for infant formula.

USDA FNS will continue to monitor this dynamic situation and support WIC State agencies in their efforts to ensure WIC participant access to infant formula as they work with formula manufacturers, authorized WIC vendors, and Program stakeholders to transition back to normal operations.

To support this ongoing response, WIC State agencies are encouraged to report issues with the available supply of infant formula to their respective [FNS Regional Office](#).



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Attachment: Expiration schedule by waiver type

Waiver Type	Purpose	Revised Expiration Date*
Vendor Exchanges- Infant Formula	Allows stores to exchange recalled formula purchased with WIC benefits.	<i>Expired September 30, 2022</i>
WIC Vendor Formula Substitutions during a transaction	Allows stores to substitute formula manually when online benefit technology is not available (i.e., offline EBT states)	<i>January 31, 2023</i>
Medical Documentation for Food Packages I & II - Infant Formula	Allows healthy infants receiving Food Package I or II to receive a different brand of formula without medical documentation.	<i>February 28, 2023</i>
Imported Infant Formula under FDA’s Infant Formula Enforcement Discretion	Allows healthy infants receiving Food Package I or II to receive imported formula outside of their contracted brand . Minimum specifications for infant formula (iron and kcal) and registration with the FDA for issuance in WIC are waived under this provision.	<i>February 28, 2023</i>
Maximum Monthly Allowance (MMA) for Food Packages I & II - Infant Formula	Allows healthy infants receiving Food Package I or II to receive alternate container sizes that are manufactured by the State’s infant formula rebate contractor per contract agreement. This may include larger container sizes than are usually allowed.	<i>April 30, 2023</i>
Imported Infant Formula under FDA’s Infant Formula Enforcement Discretion w/in Contract Brand	Allows healthy infants receiving Food Package I or II to receive certain imported formulas. Minimum specifications for infant formula (iron and kcal) and registration with the FDA for issuance in WIC are waived under this provision.	<i>April 30, 2023</i>
Maximum Monthly Allowance (MMA) for Food Package III – Infant Formula	Allows medically-fragile infants receiving Food Package III to receive alternate container sizes, including those that are larger than usually allowed.	<i>June 30, 2023</i>
Imported Specialty Infant Formula under FDA’s Infant Formula Enforcement Discretion	Allows medically-fragile infants receiving Food Package III to receive certain imported formulas. Registration with the FDA for issuance in WIC is waived under this provision.	<i>June 30, 2023</i>

*Or 60 days after the end of the Presidentially-declared COVID-19 major disaster declaration in the affected area, whichever is earlier.