



## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### 7 CFR Part 246

[FNS-2023-0027]

RIN 0584-AE94

### **Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Implementation of the Access to Baby Formula Act of 2022 and Related Provisions; Correcting Amendments**

**AGENCY:** Food and Nutrition Service (FNS), USDA.

**ACTION:** Correcting amendments.

**SUMMARY:** On December 14, 2023, the U.S. Department of Agriculture's Food and Nutrition Service (FNS) published a final rule that went into effect on February 12, 2024. The rule amended the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) regulations to implement the provisions of the Access to Baby Formula Act of 2022 (ABFA) and make related amendments. In reviewing the resulting changes to the Code of Federal Regulations (CFR), FNS found that the final rule inadvertently omitted provisions from the CFR and contained several non-substantive errors. This document corrects those errors in the WIC regulations.

**DATES:** Effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Allison Post, Chief, WIC Administration, Benefits, and Certification Branch, Policy Division, Supplemental Nutrition and Safety Programs, Food and Nutrition Service, USDA, 1320 Braddock Place, Alexandria, Virginia, (703) 457-7708 or [Allison.Post@usda.gov](mailto:Allison.Post@usda.gov).

**SUPPLEMENTARY INFORMATION:** FNS published a final rule with request for comments in the Federal Register on December 14, 2023 (88 FR 86545), titled *Special Supplemental*

*Nutrition Program for Women, Infants, and Children (WIC): Implementation of the Access to Baby Formula Act of 2022 and Related Provisions.* The rule, which went into effect on February 12, 2024, revised the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) regulations at 7 CFR part 246 to incorporate Access to Baby Formula Act of 2022 (ABFA; Pub. L. 117-129) provisions and to make related amendments. The rule included changes to the introductory text of § 246.16a(c)(5) to clarify terminology describing bidders for infant formula cost containment contracts. In making this change, subparagraphs (i) through (iii) of § 246.16a(c)(5) were inadvertently removed, leaving only the introductory text of § 246.16a(c)(5). This action reintroduces the inadvertently omitted provisions. Additionally, the rule introduced several non-substantive errors into the WIC regulations. This action corrects those errors by:

- Editing definitions at § 246.2 to spell out the acronym “FDA” in the definition of “recall” and to clarify phrasing in the definition of “supply chain disruption.”
- Standardizing a repeated list of program disruptions used throughout § 246.4(a)(30) and adding missing semi-colons to § 246.4(a)(30)(i)(B) and (C).
- Adding the word “transaction” to § 246.4(a)(30)(i)(F) to correct terminology. The word “redemption” is currently used incorrectly to refer to both participant transactions and vendor redemptions.
- Correcting capitalization in § 246.16a(n)(2) and § 246.29(a).
- Replacing “USDA” with “the Secretary” in § 246.29 to align with phrasing used throughout WIC regulations.

This action incorporates all the corrections listed above into the final regulations. FNS does not expect these corrections to result in any policy or process changes.

#### **List of Subjects in 7 CFR Part 246**

Administrative practice and procedure, Civil rights, Food assistance programs, Grant programs—health, Grant programs—social programs, Indians, Infants and children, Maternal and child health, Nutrition, Penalties, Reporting and recordkeeping requirements, Women.

For the reasons discussed in the preamble, FNS corrects 7 CFR part 246 by making the following correcting amendments:

**PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN,  
INFANTS AND CHILDREN**

1. The authority citation for part 246 continues to read as follows:

Authority: 42 U.S.C. 1786.

2. In § 246.2, revise the definitions of “Recall” and “Supply chain disruption” to read as follows:

**§ 246.2 Definitions.**

\* \* \* \* \*

*Recall* means recall as defined in 21 CFR 7.3(g) or any successor regulation. Recalls may be conducted voluntarily by a manufacturer or may be required by the U.S. Food and Drug Administration (FDA).

\* \* \* \* \*

*Supply chain disruption* means a shortage of WIC supplemental foods that limits WIC participants’ ability to reasonably purchase supplemental foods using WIC benefits within a State agency’s jurisdiction, as determined, and declared by the Secretary for the purposes of WIC.

\* \* \* \* \*

3. In § 246.4:

a. Revise paragraphs (a)(30)(i)(B), (C), and (F), and paragraphs (a)(30)(iii), (v), and (vii) to read as follows:

**§ 246.4 State plan.**

(a) \* \* \*

(30) \* \* \*

(i) \* \* \*

(B) Alternate certification and benefit issuance;

(C) Verification of Certification (VOC) issuance;

\* \* \* \* \*

(F) Benefit transaction and redemption; and

\* \* \* \* \*

(iii) A designated emergency contact within the State agency for an emergency period, supplemental food recall, and other supply chain disruptions;

\* \* \* \* \*

(v) A plan to establish relationships with relief agencies responsible for disaster and public health emergency planning applicable to the State agency's jurisdiction and participants to support data-informed approaches when responding to an emergency period, supplemental food recall, and other supply chain disruptions;

\* \* \* \* \*

(vii) A communications plan to keep FNS, State and local agency staff, authorized WIC vendors, WIC participants, and the public informed during an emergency period, supplemental food recall, and other supply chain disruptions;

\* \* \* \* \*

4. In § 246.16a:

a. Add paragraphs (c)(5)(i) through (iii); and

b. Revise paragraph (n)(2).

The addition and revision read as follows:

**§ 246.16a Infant formula and authorized foods cost containment.**

\* \* \* \* \*

(c) \* \* \*

(5) \* \* \*

(i) *Calculating the standardized number of units of infant formula.* The State agency must specify a standardized number of units (e.g., cans) of infant formula by physical form (e.g., concentrated liquid, powdered, and ready-to-feed) to be bid upon. The standardized number of units must contain the equivalent of the total number of ounces by physical form needed to give the maximum allowance to the average monthly number of infants using each form. The number of infants does not include infant participants who are exclusively breastfed and those who are issued exempt infant formula. The average monthly number of infants using each physical form must be based on at least 6 months of the most recent participation and issuance data. In order to calculate the standardized number of units of infant formula by form to be bid upon, the average monthly number of infants using each physical form is multiplied by the maximum monthly allowable number of ounces for each form (as allowed under table 1 to § 246.10(e)(9)), and divided by the corresponding unit size (i.e., number of ounces per unit being bid). In order to compare bids, total cost is calculated by multiplying this standardized number of units by the net price for each physical form. Alternative calculations that arrive at a mathematically equivalent result are acceptable.

(ii) *Determining the lowest total monthly net price or highest rebate.* To determine the lowest total monthly net price a State agency must multiply the net price per unit by the established standardized amount of infant formula to be bid upon as calculated in paragraph (c)(4)(i) of this section. If the bid evaluation is based on highest rebate offered, the State agency must multiply the rebate offered by the established amount of infant formula to be bid upon as calculated in paragraph (c)(4)(i) of this section.

(iii) *Highest rebate limitation.* Before issuing the bid solicitation, a State agency that elects to evaluate bids by highest rebate must demonstrate to FNS's satisfaction that the weighted average retail prices for different brands of infant formula in the State vary by 5 percent or less.

The weighted average retail price must take into account the prices charged for each type and physical form of infant formula by authorized vendors or, if a State agency elects, it may include stores that do not participate in the WIC program in the State. The State agency must also base calculations on the proportion of each type and physical form of infant formula the State agency issues based on the data provided to bidders pursuant to paragraph (c)(5) of this section.

\* \* \* \* \*

(n) \* \* \*

(2) Allow the issuance of non-contract brand infant formulas without medical documentation, with the exception of participants receiving Food Package III as defined in § 246.10(e)(3); and

\* \* \* \* \*

5. In § 246.29:

- a. Revise the last sentence of the introductory text of paragraph (a); and
- b. Revise the introductory text of paragraph (c).

The revisions read as follows:

**§ 246.29 Waivers of program requirements.**

(a) \* \* \* To be considered, a waiver or modification issued under this section must meet the following requirements:

\* \* \* \* \*

(c) *State agency waiver requests.* State agencies shall submit requests for a modification or waiver for the Secretary's approval. Requests shall include but not necessarily be limited to:

\* \* \* \* \*

**Patrick A. Penn,**

*Deputy Under Secretary,*

*Food, Nutrition and Consumer Services.*

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