



Food and
Nutrition
Service

September 8, 2022

1320
Braddock
Place
Alexandria,
VA
22314

SUBJECT: Additional WIC Flexibilities in Response to the Impact of the Ongoing Coronavirus Disease 2019 (COVID-19) Pandemic on Nationwide Infant Formula Supply Chain Issues and 2022 Abbott Recall – Imported Infant Formula under FDA’s Infant Formula Enforcement Discretion

TO: All FNS Regional Offices
All WIC State agencies

This letter provides WIC State agencies flexibility related to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Federal requirements. The flexibilities are being provided due to the impact of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic and the resulting major disaster declarations, which exacerbated the 2022 Abbott recall of certain powder infant formula and exempt infant formula on the nationwide supply chain. USDA is collaborating across a number of government agencies to ensure that WIC participants are able to obtain safe formula.

To this end, USDA waives for all State agencies the requirements below, pursuant to the waiver authority granted under the Access to Baby Formula Act of 2022 (P.L. 117-129), providing USDA with waiver authority during a major disaster declaration. This approval applies to all State agencies that elect to use it, without further application. If the State agency elects to implement these flexibilities, it must notify its respective FNS Regional Office, which will acknowledge receipt. These waivers will remain in effect through November 30, 2022, or 60 days after the expiration of the major disaster declaration in the affected area, whichever is sooner.

These waivers allow WIC State agencies to authorize and issue certain infant formulas imported under the U.S. Food and Drug Administration’s (FDA) [Infant Formula Enforcement Discretion Policy](#). These waivers are necessary to provide assistance and do not substantially weaken the nutritional quality of supplemental foods provided by the WIC Program. In addition, they waive statutory and regulatory provisions that cannot be met under the conditions that prompted the major disaster declaration.

Under the FDA’s Infant Formula Enforcement Discretion policy, infant formula that is safe and nutritionally adequate may be introduced into interstate commerce, even if it does not comply with all of FDA’s statutory and regulatory requirements. Additionally, these infant formulas might not all meet federal WIC requirements. Therefore, the waivers listed below are necessary for WIC State agencies to authorize and issue these safe and nutritionally adequate products within the WIC Program.

The waivers/modifications being granted via this letter include:

- 42 USC 1786(f)(15)(A), 42 U.S.C. 1786 (h)(8)(ix)(II), 7 CFR 246.10(g), and 7 CFR

246.12(g)(10) which require that infant formula issued by WIC State agencies is only obtained from manufacturers registered with the FDA.

- 7 CFR 246.10(e)(12) minimum requirements and specifications for infant formula.

The waiver of this provision only applies to the minimum requirements and specifications for iron and caloric content, and may only be used to authorize and issue products that have an iron level of at least 0.6 mg/100 mL and an energy level of at least 19 kcal/oz.

These waivers only apply to infant formula being imported under FDA's enforcement discretion, as a result of the 2022 Abbott recall of certain powder infant formula and exempt infant formula during COVID-19 supply chain issues. Unless a State agency has additional active FNS waivers, all other federal WIC requirements must be met. WIC State agencies should work with their legal counsel, procurement offices, and infant formula rebate contractors, as appropriate.

USDA FNS appreciates WIC State agencies' commitment to quickly responding to the COVID-19 related nationwide supply chain issues that have been exacerbated by this recall.

Sincerely,

**DIANE
KRIVISKI**

Digitally signed by DIANE
KRIVISKI
Date: 2022.06.02
17:17:54 -04'00'

DIANE KRIVISKI
Associate Administrator
Supplemental Nutrition and Safety Programs

List of WIC State agencies that have elected the waivers for:
Additional WIC Flexibility in Response to the Impact of the Ongoing Coronavirus Disease 2019 (COVID-19) Pandemic on Nationwide Supply Chain Issues – Imported Infant Formula under FDA's Infant Formula Enforcement Discretion