 3410-30-P

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

AGENCY: Food and Nutrition Service (FNS), U.S Department of Agriculture (USDA).

ACTION: Final rule with request for comment.

SUMMARY: This rulemaking serves to amend the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program regulations by incorporating provisions of the Access to Baby Formula Act of 2022 and making related amendments. ABFA establishes waiver authority for the Secretary of Agriculture to address certain emergencies, disasters, and supply chain disruptions impacting WIC, and adds requirements to State agency infant formula cost containment contracts to protect against disruptions to the Program in the event of a recall. The provisions focus on improving State agencies' ability to ensure continuity of Program operations during emergency periods (i.e., emergencies, disasters, and public health emergencies) and supply chain disruptions, while ensuring access to Program benefits among low-income pregnant and postpartum participants, infants, and children up to 5 years of age who are at nutritional risk.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to be assured of consideration. Online comments submitted through the Federal eRulemaking Portal on this rule must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comments on this final rule. USDA seeks comment on all aspects of this rule. Comments may be submitted in writing by one of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the online instructions for submitting comments.
- Regular U.S. Mail: WIC Administration, Benefits, and Certification Branch, Policy Division, Food and Nutrition Service, P.O. Box 2885, Fairfax, Virginia 22031-0885.
- Overnight, courier, or hand delivery: Allison Post, WIC Administration, Benefits, and Certification Branch, Policy Division, Food and Nutrition Service, 1320 Braddock Place, 3rd Floor, Alexandria, Virginia 22314.
- All written comments submitted in response to this final rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the written comments publicly available on the internet via http://www.regulations.gov.

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.

SUPPLEMENTARY INFORMATION:

I. Overview

On May 21, 2022, the President signed the Access to Baby Formula Act of 2022 (ABFA, Pub. L. 117-129) into law. ABFA amends Section 17 of the Child Nutrition Act of 1966 (CNA, 42 U.S.C. 1786) to (1) establish permanent waiver authority to the Secretary of Agriculture to address certain emergencies, disasters, and supply chain disruptions impacting WIC; and (2) require WIC State agency infant formula cost containment contracts to include specific remedies to protect against disruptions to the Program in the event of an infant formula recall. This rule amends 7 CFR Part 246 to codify the provisions of ABFA and implement related changes which will strengthen WIC's ability to address emergency periods and supply chain disruptions, particularly those impacting infant formula. For the purpose of this rule:

- emergency periods are defined as a public health emergency declared by the Secretary of Health and Human Services and any renewal of such a public health emergency; a presidentially declared major disaster; or a presidentially declared emergency, in alignment with the definition set forth in ABFA.[1,2]
- supply chain disruption is defined as a shortage of WIC supplemental foods, including infant formula, that limits WIC participants' ability to reasonably purchase WIC supplemental foods benefits within a State agency's jurisdiction, as determined, and declared by the Secretary, in alignment with the definition set forth in ABFA.[3]

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[1] Public Health Service Act, 42 U.S.C. 247d § 319 (2003). https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap6A-subchapII-partB-sec247d.pdf.

[2] Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. §102 (1988). https://www.fema.gov/sites/default/files/documents/fema_stafford_act_2021_vol1.pdf.

[3] FEMA, "*Disaster Declaration Process*," May 2011. Available online at: https://www.fema.gov/pdf/media/factsheets/dad_disaster_declaration.pdf.

Specifically, this rulemaking will:

1) Codify permanent, expanded waiver authority of the Secretary to help ensure continuity of WIC services during emergency periods and supply chain disruptions impacting WIC.
2) Codify requirements for WIC State agencies to include language in their WIC infant formula cost containment contracts that describes remedies in the event of an infant formula recall, including how an infant formula manufacturer would protect against disruption to supplemental food access by WIC participants.
3) Add a new provision that WIC State agencies must include as a part of the State Plan a "plan of alternate operating procedures" in the event of an emergency period, supplemental food recall, or other supply chain disruption.

In the development of this rule, the Department prioritized equity, access, and nutrition security for WIC applicants and participants.[4] The Department also recognizes that the rule may impact WIC State agencies, including Indian Tribal Organizations (ITOs), local agencies, clinics, and WIC-authorized vendors. Additionally, the Department recognizes that the rule may impact infant formula manufacturers. While WIC is not designed to be a disaster assistance program, this rule aims to improve the continuity of services and Program benefits and access to supplemental foods for participants during these unforeseen circumstances. Relatedly, customer service, participation, and retention, as well as program integrity, have also been considered in this rulemaking. To support WIC State agencies in equitable implementation of this rulemaking, FNS plans to provide WIC State agencies with technical assistance, which may include guidance documents,

[4] U.S. Department of Agriculture, Food and Nutrition Service, "*Food and Nutrition Security*." Available online at: https://www.usda.gov/nutrition-security#:~:text=Nutrition%20security%20means%20consistent%20access,Tribal%20communities%20and%20Insular%20areas.

memoranda, webinars, and/or presentations at conferences. In addition, FNS will explore ways to support WIC State agencies in providing alternative languages and formats and effective communication of program changes, including with auxiliary aids and services to participants and vendors.

Given the need for swift implementation of ABFA following recent disruptions to the supply chain and wide-ranging effects of the infant formula recall, this is a final rule with request for comments pursuant to the Administrative Procedure Act's exemption on matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.[5] It is imperative the provisions are implemented as soon as is feasible so that FNS and WIC State agencies have mechanisms in place to ensure continuity of operations and access to Program benefits for WIC participants. The Department has requested comments on specific topics in this rule that can inform future rulemaking, policy, and/or guidance related to infant formula and will consider comments on all aspects of the rule when developing guidance and policy. Given the prescriptive nature of ABFA and the need for swift implementation ultimately in the interest of WIC participants, the Department believes this approach best serves the public interest. The Department has collected, and will consider, input from stakeholders to ensure the implementation of this rule supports the WIC population and achieves the intended results. For example, FNS Regional Operations and Support has collected feedback on FNS' response to the infant formula recall and the Coronavirus Disease 2019 (COVID-19) public health emergency from FNS Regional Offices and WIC State agencies. FNS has considered this feedback in development of this rule and will continue to do so when developing guidance and policy to support the successful implementation of the rule. The

[5] Administrative Procedure Act, 5 U.S.C. 553 (1966). https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title5-section553&num=0&edition=prelim

Department recognizes the value of stakeholder feedback and will continue to seek and collect feedback to inform future technical assistance.

II. Background

A. Overview of WIC

WIC is currently administered by 89 WIC State agencies, including the 50 geographic states, the District of Columbia, 33 Indian Tribal Organizations (ITOs), and five U.S. Territories (the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands). By providing supplemental foods, nutrition education, including breastfeeding promotion and support, and referrals to health and other social services, WIC addresses the nutritional needs and safeguards the health of low-income pregnant and postpartum participants, infants, and children up to 5 years of age who are at nutritional risk.

According to their participant category and nutritional needs, WIC participants receive supplemental foods on a monthly basis from one of seven evidence-based food packages. The amounts and categories of foods provided are intended to supplement participants' diets and provide specific nutrients known to be lacking in the diets of WIC's target population.

WIC participants typically access supplemental foods, including infant formula, through a retail food delivery system. In such systems, a WIC shopper goes to a WIC-authorized vendor (i.e., a retail store authorized by the State agency), selects foods available in their benefit balance, and uses a food instrument, typically an Electronic Benefits Transfer (EBT) card, to purchase the items. Outside of a retail food delivery system, some WIC participants access their supplemental foods through a home food delivery or direct distribution system operated by the WIC State agency. Additionally, WIC participants with certain medical conditions who require exempt formulas or WIC-eligible nutritionals may receive these as part of, or in addition to, their WIC food package with appropriate documentation. These exempt formulas and WIC-eligible nutritionals are procured outside of the traditional WIC State agency cost-containment contracting process for standard milk and soy-based infant formula and may be purchased at the store like their other WIC items, or through other systems set up by the WIC State agency, depending on availability and need for the product(s).

B. WIC Program Waiver Authority

Historically, WIC has had limited authority to waive Program requirements. However, since the onset of the COVID-19 public health emergency, WIC has experienced a series of disruptions to Program operations necessitating the ability for USDA's Food and Nutrition Service (FNS) to have permanent waiver authority.

On February 17, 2022, a major infant formula manufacturer voluntarily recalled certain powder infant formula, including exempt infant formula. While recalls may be conducted because a mandatory order has been issued by the U.S. Food and Drug Administration (FDA) under statutory authority, they can also be conducted voluntarily by a manufacturer, as in this case. This recall exacerbated existing supply chain issues resulting from the ongoing COVID-19 public health emergency. During its early response to the shortage, FNS used waiver authority granted under Section 301 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, ("Stafford Act," 42 U.S.C 5121), to approve several waiver types for WIC State agencies to help WIC participants obtain infant formula. This was possible because of existing COVID-19 major disaster declarations covering the geographic areas of all WIC State agencies, including States, ITOs, and Territories.[6,7]

Section 301 of the Stafford Act provides any Federal agency charged with the administration of a federal assistance program with the authority to modify or waive administrative conditions for assistance that would otherwise prevent the giving of assistance if the inability to meet such conditions is a result of the major disaster. Activation of Section 301 of the Stafford Act requires a State Governor's request and the President's approval. When approved, these are referred to as Major Disaster Declarations. Section 301 of the Stafford Act cannot be activated by emergency declarations, public health emergencies, or supply chain disruptions. Prior to March 2020, Section 301 of the Stafford Act was the only waiver authority available to grant administrative flexibilities in WIC.

On March 13, 2020, the ongoing COVID-19 crisis was declared a public health emergency of sufficient severity and magnitude to warrant declaration of a nationwide public health emergency through the Secretary of Health and Human Services. Over the next several weeks, in response to the COVID-19 public health emergency, major disaster declarations were put into place covering all WIC State agencies, including States, Indian Tribal Organizations, and U.S. Territories, pursuant to Section 501(b) of the Stafford Act. While the major disaster declarations would eventually enable WIC State agencies to request regulatory waivers under the Stafford Act's authority,

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[6] FEMA, "COVID-19 Disaster Declarations," August 20, 2021. Available online at: https://www.fema.gov/covid-19.

[7] FEMA, "FEMA Assistance for Tribal Governments," March 17, 2021. Available online at: https://www.fema.gov/fact-sheet/fema-assistance-tribal-governments#:~:text=Tribes%20that%20are%20Recipients%20will%20have%20a%20direct,in%20the%20Tribal%20Declarations%20Pilot%20Guidance.%20More%20items.

immediate and additional flexibilities were necessary to support WIC State agencies.

Therefore, on March 18, 2020, the Families First Coronavirus Response Act (FFCRA, Pub. L. 116-127) was signed into law to assist with the COVID-19 public health emergency. USDA received temporary authority to provide WIC State agencies with flexibilities necessary to continue operations and safely provide Program benefits to participants. Specifically, Section 2203 of FFCRA provided USDA with the statutory waiver authority necessary to waive the physical presence requirement for all applicants and participants seeking certification or recertification in WIC; and defer anthropometric (i.e., height/length and weight) and bloodwork requirements which are used to determine nutritional risk. As a result, FNS waived the statutory requirement for in-person WIC clinic visits, thereby encouraging social distancing, during the COVID-19 public health emergency. Under Section 2204 of FFCRA, WIC State agencies could also request USDA to waive or modify WIC regulations. Such requests could only be granted if the WIC State agency (1) could not meet regular Program requirements due to COVID-19, and (2) such waiver or modification was necessary to provide assistance to WIC participants. As prescribed in FFCRA, the Department had the authority to provide waivers through September 30, 2020, which was then extended through September 30, 2021, through the Continuing Appropriations Act, 2021 and Other Extensions Act (Pub. L. 116-159). Certain WIC waivers granted prior to September 30, 2021, were then extended through FNS' policy guidance until 90 days after the end of the nationally declared public health emergency under Section 319 of the Public Health Service Act,[8] which ended on May 11, 2023, per announcement from the U.S. Department of Health and Human Services (HHS). FFCRA provided USDA with the necessary authority to

[8] U.S. Department of Agriculture, Food and Nutrition Service, "*WIC Policy Memorandum #2021-10: Updated Expiration Schedule for Existing FNS-Approved WIC COVID-19 Waivers*," September 20, 2021. Available online at: https://www.fns.usda.gov/wic/policy-memorandum-2021-10.

provide WIC State agencies with the flexibility to pivot operations and continue serving Program participants during a public health emergency. However, USDA's authority was temporary and designed to specifically address COVID-19.

While the existing COVID-19 major disaster declarations and resulting Stafford Act authority provided a vehicle through which FNS could grant WIC State agencies waivers, under normal circumstances, such waiver authority would not typically be available for the Department to respond to an infant formula recall, nor could the Department issue nationwide waivers. As a result, in direct response to the infant formula recall, Congress recognized the need to provide USDA with permanent authority to waive or modify certain statutory and regulatory requirements when certain conditions are present.

ABFA amended Section 17 of the CNA (42 U.S.C. 1786) to (1) establish waiver authority for the Secretary of Agriculture to address certain emergencies, disasters, and supply chain disruptions impacting WIC; and (2) require WIC State agency infant formula cost containment contracts to include specific remedies to protect against disruptions to the Program in the event of a recall. Unlike the Stafford Act, ABFA provides USDA with the authority to issue waivers for one or more State agencies, including nationwide, and does not require that each State agency individually request specific waivers. As a result of ABFA, FNS issued an implementing policy memorandum describing the infant formula cost containment contract requirements and waiver authority.[9] In order to provide WIC State agencies with additional notice in anticipation of the expiration of the major disaster declarations in affected areas which formally ended May 11, 2023, FNS transferred waivers originally approved under the Stafford Act and

[9] U.S. Department of Agriculture, Food and Nutrition Service, "WIC Policy Memorandum #2022-6: *Implementation of the Access to Baby Formula Act of 2022 P.L. 117-129*," June 6, 2022. Available online at: https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022.

the existing COVID-19 major disaster declaration for the affected area to approval under the waiver authority granted by ABFA and the existing COVID-19 major disaster declaration for the affected area. Accordingly, to aid WIC participants in purchasing infant formula using WIC benefits, FNS extended waivers set to expire under the ABFA authority and established a new expiration date for most waivers granted in response to the infant formula recall through the earlier of either January 31, 2023, or 60 days after the expiration of the COVID-19 major disaster declaration in the affected area.[10] This revised expiration schedule applied to most waiver types, including those related to medical documentation, maximum monthly allowances of infant formula, imported formula authorization and issuance, and vendor substitutions.[11] This expiration date was again extended on December 19, 2022, in a letter sent to WIC State agencies and formally implemented through FNS Policy Memorandum #2023-3: *Unwinding Formula Flexibilities in WIC* on February 2, 2023. FNS communicated that revised expiration dates for the formula waivers included rolling extensions for various waivers through June 30, 2023, based on the continued need for flexibility by the WIC State agencies.[12]

C. WIC Disaster Planning

WIC State agencies are required to submit an annual plan for Program operations. Program regulations at 7 CFR 246.4 define State Plan requirements, but plans to address potential emergencies, disasters, or significant disruptions in operations are not currently one of the required elements. Nearly all State agencies already voluntarily maintain a

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[10] U.S. Department of Agriculture, Food and Nutrition Service, “WIC Policy Memorandum #2023-1: *Abbott Infant Formula Recall Waiver Expiration Schedules*,” November 8, 2022. Available online at: https://www.fns.usda.gov/resource/abbott-infant-formula-recall-waiver-expiration-memo#.
[11] U.S. Department of Agriculture, Food and Nutrition Service, “WIC Policy Memorandum #2022-6: *Implementation of the Access to Baby Formula Act of 2022 P.L. 117-129*,” June 6, 2022. Available online at: https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022.
[12] U.S. Department of Agriculture, Food and Nutrition Service, “WIC Policy Memorandum #2023-3: *Unwinding Infant Formula Flexibilities in WIC*,” February 1, 2023. Available online at: https://www.fns.usda.gov/wic/policy-memorandum-2023-3-unwinding-infant-formula-flexibilities.

disaster plan; however, these plans are typically part of a broader health department or other State agency disaster plan and do not address WIC-specific Program operations during emergencies nor do they typically address other operational disruptions beyond natural disasters.

FNS provides information to help WIC State agencies plan for meeting the needs of WIC participants and applicants prior to and during a disaster response; plan for continued WIC benefits during public health emergencies; and plan for other situations that disrupt regular WIC operations through the guidance document, *Guide to Coordinating Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Services When Regular Operations Are Disrupted*.[13] This guidance highlights operational flexibilities in WIC regulations that WIC State agencies may implement quickly. The COVID-19 public health emergency and the infant formula recall highlighted the need for all State agencies to have formal contingency plans in place to ensure the continuity of WIC operations during emergency periods (i.e., emergencies, disasters, and public health emergencies) and supply chain disruptions, while ensuring access to Program benefits among low-income pregnant and postpartum participants.

D. Infant Formula Cost Containment Historical Background

In the 1980s WIC State agencies became increasingly interested in cost containment initiatives due to rising food costs and their potential to limit Program participation due to insufficient funding. Infant formula represented a significant portion of WIC food costs so there was specific interest in infant formula cost containment contracts. Early

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[13] U.S. Department of Agriculture, Food and Nutrition Service, "*Guide to Coordinating Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Services When Regular Operations Are Disrupted*," January 18, 2022. Available online at: https://www.fns.usda.gov/wic/guide-coordinating-wic-service-during-disasters.

initiatives by some State agencies were so successful that in 1989, the Agriculture Appropriations Act of 1989 (Pub. L. 100-460) directed all WIC State agencies to explore the feasibility of cost-containment measures and implement such a measure if found to be viable. Although the provisions of the Agriculture Appropriations Act of 1989 expired on September 30, 1989, the Child Nutrition and WIC Reauthorization Act of 1989 (Pub. L. 101-147) extended these provisions and required the Secretary to prescribe regulations to carry out these provisions. The Child Nutrition and WIC Reauthorization Act of 1989 also outlined exceptions to these provisions, notably for ITOs that operate their own WIC Program and serve less than 1,000 participants.

The WIC Infant Formula Procurement Act of 1992 (Pub. L. 102-512) amended the CNA to enhance competition among infant formula manufacturers and reduce the per unit costs of infant formula purchased by WIC. In 1996, FNS issued WIC Policy Memorandum #96-6: *WIC Infant Formula Rebate Reviews*, which provides guidance to avoid rebate billing discrepancies and can serve as a WIC State agency reference during the procurement and contracting process.[14] Congress also amended the CNA through the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108-265) to include additional technical definitions that further clarified how cost containment systems must be structured. FNS established regulations to implement each of these laws and released WIC Policy Memorandum #2004-4: *Implementation of the Infant Formula Cost Containment Provisions of P.L. 108-265* to address Pub. L. 108-265.[15]

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[14] U.S. Department of Agriculture, Food and Nutrition Service, "WIC Policy Memorandum #96-6: *WIC Infant Formula Rebate Reviews*," March 12, 1996. Available online at: https://www.fns.usda.gov/wic/infant-formula-rebate-reviews.

[15] U.S. Department of Agriculture, Food and Nutrition Service, "WIC Policy Memorandum #2004-4: *Implementation of the Infant Formula Cost Containment Provisions of P.L. 108-265*," July 30, 2004. Available online at: https://www.fns.usda.gov/wic/implementation-infant-formula-cost-containment-provisions-pl-108-265#:~:text=This%20memorandum%20provides%20guidance%20on%20the%20implementation%20of,2004%2C%20%28Reauthorization%20Act%29%20enacted%20on%20June%2030%2C%202004.

During the onset of the nationwide infant formula shortage and prior to the passage of ABFA, there were no federal requirements for infant formula rebate contracts to include remedies in the event of a recall. FNS used its limited waiver authority under the Stafford Act to issue waivers to allow WIC State agencies to exceed the maximum monthly allowance for infant formula and exempt infant formula and issue non-contract brand formula without medical documentation (except in Food Package III). Each WIC State agency had to come to an agreement with the manufacturer holding their rebate contract on Program flexibilities allowed under these waivers to protect against disruption to Program participants. Additionally, the infant formula manufacturer whose product was the subject of the voluntary recall voluntarily paid rebates on competitive, non-contract brand infant formula in WIC State agencies where they held the contract.

E. Infant Formula Cost Containment Contracts

The Child Nutrition Act of 1966, (CNA, 42 U.S.C. 1786(h)(8)(A)(i)(I)) and WIC Program regulations at 7 CFR 246.16a require most WIC State agencies to continuously operate a cost containment system for infant formula. WIC State agencies have historically met this requirement through a competitive bidding process that requires sealed bids, for single-supplier rebate contracts. WIC State agencies solicit sealed bids and award a contract to the manufacturer offering the lowest price. Contracted manufacturers provide a rebate on each can of their infant formula purchased by Program participants through authorized WIC vendors. The WIC State agency invoices the manufacturer for payment directly to the WIC State agency, which does not impact the payments to retail stores who accept WIC transactions. The resulting rebate payments from manufacturers are used to offset WIC food costs, allowing WIC State agencies to serve more WIC participants. Each WIC State agency or alliance of State agencies that solicits for a rebate contract manages their own procurement and contracting process through execution and implementation. WIC State agencies may implement an alternative cost containment system; however, the system must provide a savings equal to or greater than a single-supplier competitive system through the process described in WIC regulations at 7 CFR 246.16a(d). To date, WIC State agencies have not implemented any alternative cost containment systems.

Once a contract is executed and implemented, the contract brand milk and soy-based formulas are added to the WIC State agency's Approved Product List (APL) and are made available for issuance and redemption throughout the State agency's WIC Program. A competent professional authority (CPA) in the WIC clinic setting is responsible for completing a nutrition assessment for WIC participants, and then prescribing and individually tailoring an appropriate food package. The primary contract brand milk- or soy-based infant formula is considered "first choice" and will be issued as the default in the food packages for infants who receive formula from WIC. Based on information from the participant, including cultural or dietary preferences, and/or nutrition assessment findings, an alternate formula, such as a soy-based option or another milk-based option, within the rebate contract (i.e., contract brand infant formula) may be deemed appropriate for issuance. Medical documentation is generally not required for milk- and soy-based contract brand infant formulas offered under the rebate contract.

Infant formula rebate funds offset a significant amount of food costs. In fiscal year 2022, infant formula rebate amounts totaled approximately $1.5 billion, the cost of providing benefits to an average of 1.32 million participants each month, or 21 percent of WIC participants monthly, as indicated by the WIC Financial Management and Participation Report (FNS-798).

III. Discussion of Regulatory Amendments

A. Add Waiver Authority Granted by the Access to Baby Formula Act

1. Add New Definitions (§ 246.2)

This rule adds definitions of *Emergency period, Qualified administrative requirement, Recall,* and *Supply chain disruption* consistent with ABFA statutory language.

a. This rule defines an *Emergency period* as a period during which there exists: 1) a presidentially declared major disaster as defined under Section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), 2) a presidentially declared emergency as defined under Section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), 3) a public health emergency declared by the Secretary of Health and Human Services under Section 319 of the Public Health Service Act (42 U.S.C. 247d), or 4) a renewal of such a public health emergency pursuant to Section 319. This aligns with the definition provided by AFBA and does not include State-declared emergencies, disasters, or public health emergencies.

b. This rule defines *Qualified administrative requirement* as 1) a statutory requirement under Section 17 of the CNA (42 U.S.C. 1786), or 2) a regulatory requirement issued pursuant to this section. This aligns with the definition provided by ABFA and encompasses the scope of Program requirements that may be waived or modified by the Secretary.

c. This rule defines *Recall* as it is defined in the U.S. Food and Drug Administration (FDA) regulations in 21 CFR 7.3(g) or any successor regulation. FDA defines recall as a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action (e.g., seizure). Recall does not include a market withdrawal, which is defined at 21 CFR 7.3(j) as a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation (e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.) or a stock recovery, which is defined at 21 CFR 7.3(k) as a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm (i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use). The Department is committed to continued alignment with FDA's definition of recall. Recalls may be conducted voluntarily by a manufacturer or may be required by FDA.

d. This rule defines *Supply chain disruption* as 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. This definition reflects ABFA statutory language and clarifies that supply chain disruption declarations as defined in this rulemaking are specifically for the purposes of WIC and do not impact or extend authority to other programs or entities. Supply chain disruptions can occur within any portion of a State agency's jurisdiction, throughout the State agency's jurisdiction, or within several State agencies' jurisdictions, including nationwide. In accordance with ABFA, supply chain disruptions include those caused by recalls of WIC supplemental foods. Other causes of supply chain disruptions under ABFA may include but are not limited to, labor shortages, temporary business disruptions, delays in the availability of products across a wide range of industries, production issues, a mismatch between supply and demand or other shortages impacting WIC supplemental foods. The Department recognizes that unforeseen circumstances beyond those described may also cause a shortage of WIC supplemental foods that limits participants' ability to purchase such foods using WIC benefits. However, not every potential cause described here, or potential unforeseen circumstance may impede the transaction and redemption of WIC benefits for supplemental foods. Therefore, the definition of supply chain disruption is not limited to any specific causes so that the Department maintains the flexibility to determine if a supply chain disruption has occurred and is able to respond to any future disruptions.

2. Specify Criteria for Establishing Waivers and Timeframes for Use (§ 246.29)

This rule creates a new provision at § 246.29 that specifies the criteria under which a waiver or modification may be established, information WIC State agencies must provide to FNS when requesting a waiver, and the timeframes during which waivers will remain available for use by WIC State agencies.

a. Requirements for Establishing a Waiver

This rule provides a non-exhaustive list of conditions that must be met for the Secretary to waive a qualified administrative requirement for one or multiple WIC State agencies during an emergency period or supply chain disruption. In accordance with ABFA statutory provisions, a waiver may be established when the following criteria are met 1) the qualified administrative requirement cannot be implemented during any part of the emergency period or supply chain disruption, 2) the waiver is necessary to serve participants, and 3) the waiver does not substantially weaken the nutritional quality of supplemental foods. If the criteria are met, the Secretary may issue either nationwide waivers available for WIC State agencies to opt into, or State agency-specific waivers.

The Department is including additional specifications in this rulemaking that the waiver or modification must:

1) Not materially impair any statutory or regulatory right of participants or potential participants as set forth at 7 CFR 246.8 and 7 CFR parts 15, 15a and 15b which includes all protected classes for federally assisted programs in USDA;
2) Not present an unreasonable barrier to participation;
3) Not create new or additional eligibility requirements for participation;
4) Comply with 7 CFR 246.13(b) to ensure State agencies maintain effective control over and accountability for all Program grants and funds;
5) Offer substitution options with similar nutritional quality, that most closely provide the maximum monthly allowance of supplemental foods, and that do not create new supplemental food categories as set forth in 7 CFR 246.10(e)(12) Table 4; and
6) Meet additional requirements for the request and approval as determined necessary by FNS.

Including these requirements is intended to provide WIC State agencies seeking waivers with basic parameters and to protect participants and applicants. While this rule will allow for more flexibilities in Program operations, the Department is committed to continued equity, access, and nutrition security for WIC applicants and participants and preventing unforeseen barriers to participation. Further, the Department is committed to clear and timely communication with State and local agency staff, WIC participants, and the public when an emergency period or supply chain disruption has been declared.

b. Information Required from WIC State Agencies Requesting a Waiver

ABFA laid out certain requirements that must be met for a waiver to be granted by FNS to a WIC State agency. A WIC State agency may request that a qualified administrative requirement be waived or modified through submission of a waiver request if the Secretary has not already issued an applicable nationwide waiver available for a WIC State agency to opt into. This rule establishes the minimum information a WIC State agency must provide to FNS when requesting a waiver to ensure that these criteria are met. Specifically, when submitting a request to FNS, WIC State agencies must provide:

(i) The qualified administrative requirement the State agency is requesting to waive or modify (including the statutory or regulatory citation) and an explanation for why it cannot be met;

(ii) Justification for why the waiver is necessary to continue WIC services;

(iii) An explanation that the waiver meets the conditions set forth in new section 7 CFR 246.29(a);

(iv) The emergency period or supply chain disruption under which the request is being made; and

(v) The period for which the flexibility is being requested.

The Department has deemed this the minimum information necessary to confirm the WIC State agency's request meets the conditions required to waive or modify a qualified administrative requirement during an emergency period or supply chain disruption. However, contingent on the specific situation, FNS maintains the right to require additional information from a WIC State agency to support its waiver request. For example, a WIC State agency seeking a waiver or waiver extension may be required to provide justification, including, but not limited to, data to support the request, how the waiver will be implemented, estimated impact on WIC food funds for the time period being requested, or an explanation of how the WIC State agency will track or monitor the continued necessity for the waiver. The Department recognizes that each emergency period and supply chain disruption is unique and therefore State agencies may be asked to provide different types of information relevant to the specific scenario. Additional information regarding the waiver submission and review process will be provided through subsequent policy guidance.

c. Duration of Waiver Availability

This rule codifies the timeframes during which waivers can be available for use by WIC State agencies, as provided by ABFA. Waivers may be established at any time during an emergency period or supply chain disruption.

A waiver established during an emergency period may be available for the duration of the emergency period and up to 60 days after the end of the emergency period. A waiver established during a declared supply chain disruption may be available for:

(i) a period of up to 45 days from a date determined by the Secretary and renewed with at least 15 days' notice provided by the Secretary, and

(ii) no more than 60 days after the supply chain disruption declaration ceases to exist.

In accordance with ABFA, if the Secretary determines that a supply chain disruption exists and issues a waiver, the Secretary will notify each State agency affected by the disruption. Likewise, the Secretary will notify each State agency affected by the disruption and granted a waiver as a result of the disruption at least 15 days prior to the end of the 45-day period if the supply chain disruption declaration has been renewed. FNS will communicate any supply chain disruption renewals as they occur and provide technical assistance on the process as needed.

B. Update Requirements for State Agency Infant Formula Cost Containment Contracts

1. Establish minimum required remedies for infant formula cost containment contracts (§ 246.16a)

This rule establishes that a State agency must include remedies in the event of a recall in their infant formula cost containment contract to protect against disruption in infant formula supply to participants. In accordance with applicable Program requirements and the infant formula cost containment contract, the State agency will determine when remedies take effect and remain in effect. At minimum, the State agency's infant formula cost containment contract must:

1) Allow infant formula to be issued in all unit sizes that may exceed the maximum monthly allowance. The State agency and contracted infant formula manufacturer must prioritize unit sizes that most closely provide the maximum monthly allowance;

2) Allow the issuance of non-contract brand formula without medical documentation (except in Food Package III);

3) When any contract brand infant formula of the contracted manufacturer is the subject of a recall, require the contracted manufacturer to:

(i) Provide the State agency with an action plan, within a timeframe established within the contract, which includes supply data, to meet infant formula demand and limit disruption to Program participants in the affected jurisdiction(s) and

(ii) Pay rebates on competitive, non-contract brand infant formula that meets the definition of infant formula at 7 CFR 246.2.

WIC State agencies may work with their legal counsel and procurement offices to include additional remedies beyond these regulatory minimum remedies in their infant formula contracts. WIC State agencies may also negotiate flexibilities that are within regulatory requirements and do not require Program waivers with their contracted infant formula manufacturers.

As previously described, in response to the sustained nationwide infant formula shortage—resulting from the February 17, 2022, voluntary recall of a major source of powder infant formula, including exempt infant formula—which exacerbated existing COVID-19 shortages, FNS used its limited waiver authority under the Stafford Act to issue waivers. This was possible because of existing COVID-19 major disaster declarations covering the geographic areas of all WIC State agencies, including States, ITOs, and Territories. These waivers allowed WIC State agencies to benefit from three specific remedies to: (1) exceed the maximum monthly allowance for infant formula to allow for the purchase of larger unit sizes; (2) issue non-contract brand formula without medical documentation (except in Food Package III); and (3) receive rebates for non-contract brand infant formula, when their contracted manufacturer's product was the subject of the recall. As a result, State agencies were able to allow for the purchase of available formula when the contract brand or size was unavailable during shortages. Because these three specific remedies assisted State agencies with meeting participants' needs during the sustained nationwide infant formula shortage, such remedies were included as suggestions in WIC Policy Memorandum #2022-6: *Implementation of the Access to Baby Formula Act of 2022 - PL 117-129* and are now being codified in this rulemaking.[16] Exceeding the maximum monthly allowance for infant formula to allow for the purchase of larger unit sizes and issuing non-contract brand formula without medical documentation (except in Food Package III) will continue to require an approved waiver before a State agency can operationalize these remedies, and must be operationalized within the active waivers' timeframe in order to remain in compliance with Program requirements.

[16] U.S. Department of Agriculture, Food and Nutrition Service, "WIC Policy Memorandum #2022-6: *Implementation of the Access to Baby Formula Act of 2022 P.L. 117-129*," June 6, 2022. Available online at: https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022.

During the sustained nationwide infant formula shortage, State agencies worked with their infant formula contracted manufacturer to collect supply data in order to respond to participant needs. This data proved valuable to State agencies' ability to respond to the shortages. Thus, the provision of an action plan, which includes supply data, to meet infant formula demand and limit disruption to Program participants in the affected jurisdiction(s) when any contract brand infant formula of the contracted manufacturer is the subject of a recall has been included as a minimum remedy in this rule. The State agency and contracted manufacturer must establish a timeframe by which the manufacturer must provide the State agency with an action plan following the recall of any contract brand infant formula of the contracted manufacturer. The Department recommends that these action plans be provided to State agencies within 48 hours following the recall of any contract brand infant formula of the contracted manufacturer.

In establishing the remedies, the Department considered requiring manufacturers to maintain a stockpile of infant formula for use in the event of a recall. The Department considered potential logistics involved, such as: types and quantity of formula to stockpile, potential locations, the level of stockpile maintenance necessary to rotate stock, and development of a distribution plan related to stockpiling. Ultimately, the Department determined that the cost and administrative burden necessary to require manufacturers to maintain a stockpile in excess of manufacturers' usual inventory would likely be too extensive for practical implementation and would counteract any potential benefits for the Program.

Currently, the Program provides infant formula in all three physical forms available in the retail marketplace, which are powder, liquid concentrate, and ready-to-feed.[17] While 7

[17] Ready-to-feed formulas may be authorized only under certain circumstances, as specified at 7 CFR 246.10(e)(1)(iv).

CFR 246.10(e)(1)(iv) offers State agencies the flexibility to issue powder or concentrated liquid, 7 CFR 246.16a(c)(4) requires infant formula manufacturers to bid on all three physical forms. Currently powder is the predominant form in the marketplace and some manufacturers do not produce liquid concentrate. Requiring liquid concentrate in WIC could impact some manufacturers' ability to competitively bid and meet contractual requirements. Therefore, the Department is seeking public comment on the operational and financial impacts to the Program of modifying the requirement for infant formula manufacturers to bid on liquid concentrate. Through this rulemaking, the Department is not making any changes to the current bidding requirements at 7 CFR 246.16a(c)(4) or the physical forms of infant formula that may be issued in accordance with 7 CFR 246.10(e)(1)(iv).

2. Clarify terminology in infant formula cost containment contracts (§ 246.16a(c)(5))

This rule clarifies terminology at 7 CFR 246.16a(c)(5). Specifically, the current terms "responsive and responsible" used in the regulations to describe bidders are consolidated under this rulemaking to "responsive." Responsive is further defined for clarification, consistent with the intent stated in a previous rulemaking preamble, *Requirements for and Evaluation of WIC Program Bid Solicitations for Infant Formula Rebate Contracts (*65 FR 51213-51229)*,* and WIC Policy Memorandum #99-3: Evaluation Criteria for Infant Formula Rebate Contracts.[18,19]

[18] U.S. Department of Agriculture, Food and Nutrition Service, "Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Requirements for and Evaluation of WIC Program Bid Solicitations for Infant Formula Rebate Contracts," 65 FR 51213-51229. (August 23, 2000). Available online at: https://www.federalregister.gov/documents/2000/08/23/00-21423/special-supplemental-nutrition-program-for-women-infants-and-children-wic-requirements-for-and#:~:text=A%20key%20component%20to%20the%20success%20of%20infant,than%20savings%20generated%20by%20a%20competitive%20bidding%20system.

[19] U.S. Department of Agriculture, Food and Nutrition Service, "WIC Policy Memorandum #99-3: Evaluation Criteria for Infant Formula Rebate Contracts," October 14, 1998. Available online at: https://www.fns.usda.gov/wic/evaluation-criteria-infant-formula-rebate-contracts.

The inclusion of the terms responsive and responsible were initially intended to help ensure WIC State agencies select formula manufacturers that fully respond to the invitation to bid and meet eligibility requirements in statute and regulation. However, since these terms were not defined, they resulted in ambiguity in their application. This rule removes the responsibility requirement and defines the responsiveness requirement. Under the modified provision, a bidder must submit a bid that conforms to the solicitation and meets requirements at § 246.16a to be considered responsive. The rule adds language to clarify this meaning, which will provide consistent application of the term and ensure that all responsive bids will receive consideration.

C. Add Requirement for State Agency Plans of Alternate Operating Procedures (§ 246.4(a))

This rule adds a new provision requiring WIC State agencies to include a plan of alternate operating procedures, commonly referred to as a disaster plan, as part of their State Plan. This provision will ensure WIC State agencies have plans in place to support continuity of operations in the event of a disruption of WIC services, including but not limited to emergency periods, supplemental food recalls, and other supply chain disruptions.

State Plans are submitted annually by WIC State agencies as a prerequisite to receiving funds. State Plans must be updated as needed to reflect substantive changes to the State agencies' Program design and operation. Therefore, as a part of the State Plan, alternate operating procedures must also be updated as needed to reflect any substantive changes resulting from lessons learned as WIC State agencies respond to emergency periods and supply chain disruptions. Such updates will allow WIC State agencies to prepare and respond to these events more effectively in the future. Additionally, FNS encourages WIC State agencies to review their State Plans and ensure they continue to meet the needs of Program stakeholders. State Plans are a vehicle through which WIC State agencies can outline short- and long-term goals necessary to improve Program design and operation. For example, State agencies may include descriptions of goals and action plans to facilitate continued improvement in the delivery of Program benefits and service during Program disruptions as a part of their alternate operating procedures.

Both the COVID-19 public health emergency and the 2022 infant formula recall and sustained infant formula shortage required nearly all WIC State agencies to quickly develop and implement alternative plans for running their programs. While some WIC State agencies, such as those with experience in dealing with natural disasters, may have established alternative operations plans, these plans are typically part of a broader health department or other State agency disaster plan and do not address WIC-specific Program operations during disruptions nor do they typically address other operational disruptions beyond natural disasters. This resulted in ex post facto development of policies and procedures and ultimately varying levels of Program disruption during the COVID-19 public health emergency and the 2022 infant formula recall and sustained infant formula shortage. These two events highlight the need for all WIC State agencies to be prepared to continue operations when faced with a number of potential disruptions. The FNS-required alternate operating procedures set baseline minimum elements that must be included by all WIC State agencies, and in turn provide greater transparency to FNS on actions each State agency will take in the event of a disruption. The Department believes that proactive State agency development of robust alternate operating procedures will minimize the negative impact of such disruptions to WIC operations and services, position State agencies to be better prepared to adjust to unexpected situations, and ensure the availability of authorized supplemental foods, including infant formula.

The Department recognizes that a variety of situations, including a supplemental food recall, may prompt the Secretary to declare a supply chain disruption. However, WIC State agencies must be prepared to respond to supplemental food recalls whether or not an official supply chain disruption declaration has been made. As such, WIC State agencies' alternate operating procedures must specifically and directly address supplemental food recalls, with an emphasis on infant formula recalls, including specialty products, as part of the section addressing supply chain disruptions as a whole. The Department is committed to supporting WIC State agencies in prioritizing resources and developing a separate plan for the distribution of specialty formula.

The Department understands the same event may impact WIC State agencies differently dependent upon their geographic location, participant populations, and other factors. As such, the Department encourages each WIC State agency to consider potential events unique to their location and identify how the State agency will meet the needs of their participant populations when developing alternate operating procedures. To assist with anticipation of potential events, the Department expects WIC State agencies to establish relationships with relief agencies responsible for disaster and public health emergency planning applicable to the State agency's jurisdiction and participants and leverage these relationships as needed. Ultimately, the intent of such relationships is for the WIC State agency to make data-informed decisions in order to better meet the needs of their jurisdiction's populations. Nevertheless, WIC State agencies must also consider the unique and sudden nature of events that disrupt regular WIC operations when developing alternate operating procedures.

Alternate operating procedures must describe the process by which the WIC State agency will minimize the negative impact to WIC operations and services and ensure the availability of authorized supplemental foods, especially infant formula, to the extent feasible. At a minimum, alternate operating procedures must include:

(i) A plan to address operation of specific Program areas including:

a. Access to Program records;

b. Alternate certification and benefit issuance;

c. Verification of Certification (VOC) issuance;

d. Food package adjustments;

e. Vendor requirements;

f. Benefit redemption; and

g. Food delivery systems.

(ii) A plan to ensure continuity of WIC services and address the needs of participants with documented qualifying conditions receiving Food Package III, rural areas, tribal populations, and other priority populations in the affected area, as applicable;

(iii) A designated emergency contact within the State agency for emergency periods, supply chain disruptions, and supplemental food recalls;

(iv) A designated emergency contact within the State agency to address the needs of participants with documented qualifying conditions receiving Food Package III;

(v) A plan to establish a relationship 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 emergency periods, supplemental food recalls, and other supply chain disruptions;

(vi) A plan to limit the disruption of infant formula benefits in the event of an emergency period, supplemental food recall, and other supply chain disruption;

(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, or other supply chain disruption.

(viii) A plan to report to FNS on alternate operating procedures implemented during an emergency period, supplemental food recall, and other supply chain disruptions, which includes Program data and information on the impact of benefit use and delivery.

(ix) A plan to adjust State agency specific minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized.

Minimum requirements outlined in this provision reflect current guidance found in the *Guide to Coordinating WIC Service During Disasters*.[20] In developing and implementing the alternate procedures, State agencies must take into account existing requirements for technology projects in accordance with FNS Handbook 901.[21] For example, if a State agency decides to take steps to integrate changes to their management information system (MIS) to facilitate better service to participants during Program disruptions, State agencies should consult FNS Handbook 901 to secure approval and the requested

[20] U.S. Department of Agriculture, Food and Nutrition Service, "Guide to Coordinating WIC Service During Disasters," January 18, 2022. Available online at: https://www.fns.usda.gov/wic/guide-coordinating-wic-service-during-disasters.
[21] U.S. Department of Agriculture, Food and Nutrition Service, "FNS Handbook 901," January 8, 2020. Available online at: https://www.fns.usda.gov/sso/fns-handbook-901-v2-advance-planning-documents.

funding, if applicable. Subsequent to this rulemaking, FNS will issue updated guidance to WIC State agencies outlining required components of the plan and continue to ensure the existing guidance found in the *Guide to Coordinating WIC Service During Disasters* is up to date and available for reference.[22] This Guide will also provide additional detail regarding provisions for WIC State agency consideration in development of their disaster plans. For example, additional alternate operating procedures may include:

- designating alternate means and locations for certification and benefit issuance for circumstances in which the conventional means and locations are not possible or optimal;
- establishing a plan to support individuals seeking WIC services receiving a full nutrition assessment and appropriate referrals;
- establishing a plan with health care centers or other providers of exempt infant formula and WIC-eligible nutritionals for the distribution of these products to participants with documented qualifying conditions receiving Food Package III
- developing a WIC formula (infant formula, exempt infant formula, or WIC-eligible nutritional) distribution plan; and,
- if a WIC State agency already has a direct distribution or home delivery system in place, updating policy to specifically include provisions reasonable to institute during recalls and/or supplemental food shortages.

Ultimately, this provision is intended to minimize adverse impacts to WIC operations and the continuation of WIC benefits during an emergency period, supplemental food recall, and other supply chain disruptions impacting WIC's normal operations. Further, participants living in rural areas, on Tribal lands, following cultural or religious food

[22] U.S. Department of Agriculture, Food and Nutrition Service, "Guide to Coordinating WIC Service During Disasters," January 18, 2022. Available online at: https://www.fns.usda.gov/wic/guide-coordinating-wic-service-during-disasters.

practices, and/or having qualifying conditions and receiving Food Package III are potentially most impacted during an emergency period, supplemental food recall, and other supply chain disruptions. The Department expects this rule to ensure more consistent and safe access to the foods these most vulnerable participants need by anticipating and preparing how to meet those needs before any potential Program disruptions. This rule will allow for more flexibilities in Program operations and will require WIC State agencies to develop plans to address the needs of unique and vulnerable populations overall.

Finally, the Department recognizes WIC is not designed to be a disaster assistance program and is not considered a first response option for disaster survivors. As such, the Department continues to encourage WIC State agencies to work with State and local emergency services offices, as well as the Federal Emergency Management Agency (FEMA), to the maximum extent practicable, to provide participants with a coordinated disaster response during an emergency period.

IV. Implementation

Because the majority of the revisions described in this rulemaking are introducing opportunities for increased flexibility for WIC State agencies, this final rule will take effect 60 days after publication, except for § 246.4(a), which is the provision requiring WIC State agencies to include, as a part of the State Plan, a plan of alternate operating procedures, commonly referred to as a disaster plan, in accordance with FNS guidance.

For § 246.4(a), these changes are required to be implemented with State agency FY 2025 State Plan submissions, due to FNS no later than August 15, 2024. This timeline recognizes WIC State agencies will need the time to develop and refine their alternate operating procedures to meet the requirements of this provision.

Per WIC Policy Memorandum #2022-6: *Implementation of the Access to Baby Formula Act of 2022 - PL 117-129,* all contracts entered into or renewed on or after May 21, 2022, the date of enactment of ABFA, are expressly required by law to include language in their WIC infant formula rebate contracts that describes remedies in the event of an infant formula recall, including how an infant formula manufacturer would protect against disruption to Program participants in the State (i.e., ensure that WIC participants can purchase formula using WIC benefits). Section 246.16a as amended codifies these requirements and the provisions as described herein must be strictly applied to all infant formula contracts entered into or renewed once the final rule takes effect. FNS considers a new contract to be entered into upon award after a competitively bid process.

The Department seeks comments from WIC State agencies on the type and scope of administrative burden that may be associated with implementing the provisions in this rule in this manner.

Procedural Matters

Executive Order 12866, 13563 and 14094

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March

22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866, 13563 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled "Modernizing Regulatory Review" (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is "significant" and not "major" under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act).” Therefore, OMB has reviewed this final regulation, and the Department has provided the following assessment of their impact.

Regulatory Impact Analysis

As required for all rules designated as Significant by the Office of Management and Budget, an economic summary was developed for this final rule. The following summarizes the conclusions of the regulatory impact analysis:

Need for Action: As described in the preamble, this rulemaking serves to amend the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program regulations by incorporating provisions of the Access to Baby Formula Act of 2022 (ABFA) and making related amendments. ABFA establishes waiver authority for the Secretary of Agriculture to address certain emergencies, disasters, and supply chain disruptions impacting the WIC Program, and adds requirements to State agency infant formula cost containment contracts to protect against disruptions to the Program in the event of a recall. The amendments made via this rule are expected to improve State agencies’ ability to ensure continuity of Program operations during emergencies, disasters, and supply chain disruptions, while ensuring access to Program benefits among low-income infants, children, and pregnant, postpartum, and breastfeeding individuals.

Affected Parties: WIC participants and those involved in the provision of infant formula to WIC participants, including the USDA Food and Nutrition Service (FNS), State and local agencies, including Indian Tribal Organizations (ITOs), clinics, infant formula manufacturers, and retail vendors.

I. Statement of Need

On May 21, 2022, the Access to Baby Formula Act of 2022 (Pub. L. 117-129) was signed into law. ABFA amends Section 17 of the Child Nutrition Act of 1966 (CNA, 42 U.S.C. 1786) to (1) establish waiver authority to the Secretary of Agriculture to address certain emergencies, disasters, and supply chain disruptions impacting the WIC Program; and (2) require State agency infant formula cost containment contracts to include specific remedies to protect against disruptions to the Program in the event of a recall. This rule amends 7 CFR Part 246 to codify the provisions of ABFA, which strengthens WIC's ability to address emergencies, disasters, and supply chain disruptions, particularly those impacting infant formula.

II. Background

Established in 1974, the mission of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is to safeguard the health of low-income pregnant, postpartum, and breastfeeding individuals, infants, and children ages 1 through 4 years who are at nutritional risk by providing nutritious foods to supplement diets, nutrition education (to include breastfeeding promotion and support), and referrals to health and other social services. Participation in WIC is associated with improved pregnancy outcomes and lower infant mortality. WIC participation is also associated with improved diet quality.[23] In Federal fiscal year (FY) 2022, WIC served an average of 6.24 million infants, children, and pregnant, breastfeeding, and postpartum individuals per month.[24]

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[23] Caulfield, L., Bennett, W., Gross, S., Hurley, K., Ogunwole, S., Venkataramani, M., Lerman, J., Zhang, A., Sharma, R., Bass, E. (2022). Maternal and Child Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Comparative Effectiveness Review No. 253. Prepared by the Johns Hopkins University Evidence-based Practice Center under Contract No. 75Q80120D00003.) AHRQ Publication No. 22-EHC019. Rockville, MD: Agency for Healthcare Research and Quality. DOI: https://doi.org/10.23970/AHRQEPCCER253.

[24] U.S. Department of Agriculture Food and Nutrition Service. WIC Data Tables, 2021. Available online at: https://www.fns.usda.gov/pd/wic-program.

On March 13, 2020, the President declared the ongoing COVID-19 a public health emergency of sufficient severity and magnitude to warrant declaration of a nationwide emergency. The President later approved major disaster declarations for State agencies, including Indian Tribal Organizations and U.S. Territories pursuant to section 501(b) of the Stafford Act.

On March 18, 2020, the Families First Coronavirus Response Act (FFCRA, Pub. L. 116-127) was signed into law to assist with the COVID-19 public health emergency, which provided additional funding for WIC and offered additional flexibilities by providing USDA with authority to grant certain programmatic waivers to State agencies to enable WIC to continue serving WIC participants in the midst of a public health crisis (e.g., the physical presence requirement was waived to encourage social distancing and reduce in-person visits to WIC clinics).

On February 17, 2022, a major infant formula manufacturer voluntarily recalled certain powder infant formula, including exempt infant formula. This recall exacerbated existing supply chain issues resulting from the ongoing COVID-19 public health emergency. In response to this recall, USDA used its limited waiver authority granted under Section 301 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, "Stafford Act" (42 U.S.C 5121) to help WIC participants obtain infant formula. This was possible because of existing COVID-19 major disaster declarations in all WIC State agencies, including States, Indian Tribal Organizations, and U.S. Territories.

While the existing COVID-19 major disaster declaration and resulting Stafford Act authority provided a vehicle through which USDA could grant WIC State agencies waivers, under normal circumstances such waiver authority would not typically be available for the Department to respond to an infant formula recall, nor could the Department issue nationwide waivers. As a result, Congress recognized the need to provide long-term waiver flexibilities, and the President signed ABFA into law on May 21, 2022, in direct response to the infant formula recall. ABFA amended Section 17 of the Child Nutrition Act of 1966 (42 USC 1786) to (1) establish waiver authority to the Secretary of Agriculture to address certain emergencies, disasters, and supply chain disruptions impacting the WIC Program; and (2) require WIC State agency infant formula cost containment contracts to include specific remedies to protect against disruptions to the Program in the event of a recall.

This rule amends 7 CFR Part 246 to codify the provisions of ABFA.

III. List of Rule Provisions and Impacts:

Most of the provisions in this rule are required by ABFA; the provisions added by the Secretary that go beyond ABFA's requirements are noted below and include consolidating language in the regulations to describe bidders to "responsive" and requiring State agencies to create plans of alternate operating procedures. A list of the rule's provisions and a discussion of their likely impacts to the WIC Program, on Program cost, and on affected parties follows.

A. Add Waiver Authority Granted by the Access to Baby Formula Act

1. Add New Definitions

   i. Program Impact: This rule adds definitions of Emergency period, Qualified administrative requirement, Recall, and Supply chain disruption in order to incorporate ABFA statutory language.

   ii. Cost Impact: USDA estimates no change in cost associated with this provision. This change merely adds definitions required for operational clarity under ABFA.

iii. Impact on Affected Parties: USDA estimates no impact on affected parties. Impacts on affected parties that arise due to other provisions of this rule are discussed below.

2. Specify Criteria for Establishing Waivers or Modification and Timeframes for Use

   i. Program Impact: This rule creates a new provision at § 246.29 that specifies (1) criteria under which a waiver or modification may be established, (2) information State agencies must provide to FNS when requesting a waiver, and (3) the timeframes during which waivers will remain available for use by State agencies. One recent example of a category of waivers is physical presence waivers.[25] The Families First Coronavirus Response Act gave USDA authority to grant waivers to State agencies of the requirement that all individuals seeking to enroll or re-enroll in WIC do so in person (i.e., physical presence). This waiver also allowed State agencies to defer certain anthropometric (i.e., height/length and weight) and bloodwork requirements used to determine nutritional risk. The physical presence waiver allowed USDA to encourage social distancing and decrease the spread of COVID-19 while ensuring continuity of operations for State and local WIC agencies and for WIC participants.

   A second recent example of a category of waivers are the food package substitution waivers.[26] These waivers allowed State agencies to permit approved substitutes for the types and amounts of certain WIC-prescribed foods if their availability is limited. For example, as appropriate based on local food marketplace circumstances, State agencies were approved, upon request, to allow

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[25] Almost all State agencies (88 of 89 State agencies) used a physical presence waiver sometime during the COVID-19 pandemic. For more information on physical presence waivers by State agency, see https://www.fns.usda.gov/disaster/pandemic/covid-19/wic-physical-presence-waiver.

[26] A large majority of State agencies (70 of 89) issued food package substitution waivers for one or more food types. For more information on food package substation waivers by State agency, see https://www.fns.usda.gov/wic/food-package-substitution-waiver.

participants to substitute milk of any available fat content if prescribed varieties are not available; substitute authorized whole grains in package sizes up to 24 oz. when 16 oz. packages are not available; and/or substitute 18-count cartons of eggs when 12-count cartons are unavailable. These waivers enabled WIC participants to continue to receive appropriate supplemental foods during shortages of the specific products and/or package sizes that were previously authorized by the State agencies.

ii. Cost Impact: USDA was unable to reliably estimate the change in cost associated with this provision, beyond the very slight change in burden hours (38 hours across all State agencies annually) associated with this provision. Although USDA estimates a negligible increase in burden hours due to this provision, USDA also notes that formalizing the criteria for establishing waivers and timeframes for waiver use makes the waiver process more predictable for both State agencies and the Federal government and greatly decreases the likelihood of repeated waiver revisions and submissions in order to meet waiver requirements. USDA is unable to reliably quantify the costs of future waivers since the types and scope/scale of future waivers will be in response to unknown events. USDA notes that some waivers have the possibility to increase or decrease the cost of the Program, though USDA generally expects these possible cost impacts to be small. For example, it is possible that the physical presence waiver either increased or decreased administrative costs for some local WIC clinics, depending on whether the local clinics increased or decreased staffing or office space in response to moving to phone or online certification/recertification of participants. Ninety-nine percent of State agencies reported that the physical presence waivers were “very” or “extremely important” to ensuring quality services during the COVID-19 pandemic, and some State agencies reported that the physical presence waivers allowed them to serve more participants with fewer staff or in less time, which points to potential cost savings generated by the physical presence waivers.[27] Similarly, food package substitution waivers may increase or decrease food costs slightly, depending on whether the food package substitutions are for items slightly more or less expensive than those typically included in the food package. Approximately 90 percent of State agencies reported that the food substitution waivers were “very important” or “extremely important” to ensuring quality services during the COVID-19 pandemic, pointing to the waivers’ contribution to ensuring continued operations during the pandemic.[28] Neither the physical presence waiver nor the food package substitution waivers issued during the COVID-19 pandemic were found to result in significant increases or decreases in WIC spending at the Federal level.[29] In FY2019, FY2020, and FY2021, Federal spending on WIC was $5.3, $5.0, and $5.0 billion, respectively, while participation during the same Fiscal Years was 6.4, 6.2, and 6.2 million individuals. Therefore, the effect of waivers in the aggregate during the COVID-19 emergency does not appear to have had a significant effect on Federal WIC costs, though it is possible that individual waivers may have increased or decreased Federal WIC costs.

The use of waivers in the past has generally focused on ensuring continued operation of the WIC Program as normally as possible under temporary and extraordinary circumstances. Waiver authority as authorized by ABFA must

[27] Unpublished data collected by USDA as a part of State agency reporting on FFCRA waiver use. These data will be released in an upcoming USDA report.
[28] Ibid.
[29] WIC program data for the periods before and during the COVID-19 pandemic (available online at https://www.fns.usda.gov/pd/wic-program) do not show any substantial increase or decrease in WIC spending, in spite of the hundreds of waivers in place during the COVID-19 pandemic.

continue to be used primarily for this purpose; therefore, USDA does not predict that the future use of waivers will lead to either substantial costs or savings.

iii. Impact on Affected Parties: USDA estimates an increase in burden on State agencies as a result of this provision, but this provision will also clarify and standardize the steps that a State agency must undertake in order to submit a waiver request, which could save some State agencies effort in the long run by preventing State agencies from having to resubmit waiver requests multiple times because their initial requests do not meet the waiver requirements or do not provide enough information for FNS to understand why the waiver is necessary in order to continue Program operations.. USDA also notes that waiver authority has generally been granted to FNS programs when it was needed in the past, and this provision does not make the process for requesting a waiver more burdensome than it already was when FNS implemented waivers during the COVID-19 public health emergency. More generally, waiver authority allows USDA and State and local WIC agencies to continue to operate the WIC Program as intended during extraordinary times, without compromising the quality of WIC services or supplemental nutrition and without increasing the burden on WIC participants. Clear requirements and a simplified waiver process will allow State agencies and USDA to put waivers in place more quickly, enabling State agencies and USDA to rapidly respond to emergency situations and meet waiver applicant and participant needs.

B. Update Requirements for State Agency Infant Formula Cost Containment Contracts

1. Establish minimum required remedies for infant formula cost containment contracts.

i. Program Impact: While ABFA generally requires that infant formula cost containment contracts include remedies to protect against disruption to Program participants in the event of an infant formula recall, this rulemaking codifies into regulations specific minimum remedies that assisted State agencies with meeting participants' needs during a major infant formula recall. The minimum remedies must include (1) that infant formula issuance may exceed the maximum monthly allowance to allow for the purchase of all unit sizes; (2) non-contract brand formula can be issued without medical documentation (except in Food Package III); and (3) when the contracted brand infant formula is the subject of the recall, require the contracted infant formula manufacturer to provide the State agency with an action plan, which includes supply data, to meet infant formula demand and limit disruption to Program participants in the affected jurisdiction(s) within 10 calendar days of the recall, and pay rebates on competitive, non-contract brand infant formula that meets the definition of infant formula at 7 CFR 246.2. WIC State agencies may work with their legal counsel and procurement offices to include additional remedies beyond these regulatory minimum remedies in their infant formula contracts. WIC State agencies may also negotiate flexibilities that are within regulatory requirements and do not require Program waivers with their contracted infant formula manufacturers.

ii. Cost Impact: USDA was unable to reliably estimate the change in costs associated with this provision, beyond the small change in burden hours (148 hours across all State agencies annually) associated with this provision. Although USDA acknowledges that there will be cost impacts associated with this provision in the event of future recalls, at this time, USDA is unable to reliably quantify the costs of future remedies, since the types and scope/scale of future remedies will be in response to unknown events, and therefore, USDA does not include a formal estimate of the 5-year cost of this provision. Instead, the following section provides a historic look at the frequency, scale, and cost of previous infant formula recalls for illustrative purposes as well as an estimate of the cost impact that could result from even modest changes to infant formula contract rebate rates.

The first two parts of the provision grant administrative flexibilities to ensure continued formula supply to WIC participants (1) by enabling State agencies to issue all unit sizes and, in some cases, exceed the maximum monthly allowance for formula during issuance if some package sizes are not available in the local marketplace (2) by enabling State agencies to issue non-contract brand formula without medical documentation (except in Food Package III) in the event that the contract brand formula is unavailable.

The third part of the provision – that the contracted infant formula manufacturer will pay rebates on competitive non-contract brand infant formula when the contracted infant formula manufacturer's product is the subject of the recall – has the potential to impose costs on infant formula manufacturers. As described above, during the most recent major infant formula recall, the infant formula manufacturer whose product was the subject of the voluntary recall temporarily continued paying rebates on competitive non-contract brand infant formula in the WIC State agencies where they held the contract. Adding this remedy to future infant formula cost containment contracts requires all infant formula manufacturers to pay these rebates in the future when their product is the subject of a recall, which in turn could pose an added cost to the manufacturer subject to the recall while their product is off the market.

In the event that a supply chain disruption necessitates issuing a waiver to a State agency allowing the issuance of non-contract infant formula without medical documentation, but where the contracted infant formula manufacturer in that State agency is not the subject of a recall and thus not obligated to pay rebates on non-contract products as described above, then USDA expects to see a decrease in rebate income relative to the amount of non-contract brand formula issued in that State agency. Any decrease in rebate income relative to the amount of non-contract brand formula issued would increase WIC food expenditures on infant formula for USDA, as was the case in State agencies without contracts with a specific major infant formula manufacturer during the 2022 major infant formula recall. While the Department is not able to estimate the scale of future recalls, a look back at typical infant formula rebate amounts, prior to the 2022 voluntary recall by a major infant formula manufacturer of certain powder infant formula, including exempt infant formula, provides a helpful estimate of possible costs. USDA received approximately $1.6 billion in WIC infant formula rebates in FY 2021, while the monthly average number of fully formula-fed infant participants was approximately 962,000, and the monthly average number of partially breastfed infant participants was approximately 329,000, resulting in an average monthly rebate of $103.38 per infant receiving a WIC food package with infant formula. As an example of scale, it would therefore cost USDA around $10.3 million to cover the lost rebate amounts for 100,000 average infants receiving formula per month, based on FY 2021 costs.[30]

Our analysis suggests that most infant formula recall events in the past 20 years have been recalls of small amounts of products – usually single batches or lot numbers, and almost all covering fewer than around 100,000 cans of infant formula per recall – and would not require the kind of large-scale intervention that the major infant formula recall in 2022 required. One available list of infant

[30] Analysis of FNS administrative data, available at https://www.fns.usda.gov/pd/wic-program.

formula recalls from 1982-2005 showed no large nationwide recalls (except for one in 2001 that was a result of mislabeling, not product contamination).[31] Similarly, a search of FDA's Enforcement Database showed only small recalls of infant formula (fewer than 100,000 cans per recall that likely did not disrupt the supply chain) from June 2012 through 2022, until the large major infant formula recall.[32]

Finally, USDA notes that these provisions may impact rebate amounts offered on infant formula contracts moving forward. If this rule changes the incentive for infant formula manufacturers to increase or decrease rebate bids on infant formula contracts through the competitive bidding process, it could increase or decrease the rebate amounts offered by infant formula manufacturers to State Agencies. This would consequently decrease or increase Federal WIC food costs. However, when examining the limited number of infant formula contracts awarded either (1) since the start of the major infant formula recall, or (2) since the passage of ABFA, which included contracts that require the three remedies outlined in this rule, USDA was not able to discern a pattern of either increased or decreased formula rebate bids; some offered rebate amounts increased slightly and others decreased slightly, similar to how formula contracts have changed over time in the past. Therefore, USDA is not able to estimate that these provisions will have an impact on the rebates offered in future infant formula contracts. However, to provide a sense of scale, USDA notes that WIC received $1.6 billion in rebates from infant formula and food manufacturers in FY2021; a nationwide 5 percent increase or decrease in average infant formula rebate amounts offered to State

[31] See http://flca.info/HTMLobj-154/Recalls.pdf. Accessed December 7, 2022.
[32] Search available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports. Accessed December 7, 2022.

agencies would decrease or increase Federal WIC food spending by $80 million per year.

iii. Impact on Affected Parties: The extent to which other impacts of these provisions will be realized largely depends on how often and at what scale they are needed in responding to future recalls. In the event that an infant formula manufacturer is never subject to a recall, then the impact of these remedies on infant formula manufacturers will be minimal.

In the event of a recall, these provisions grant substantial benefits to WIC State and local agencies, WIC vendors, and WIC participants. The minimum remedies described above benefit WIC State agencies by providing a substantially streamlined administrative process to approve and issue new infant formula benefits in the event of a recall. WIC vendors benefit from the certainty that WIC participants will continue to be issued and be able to purchase infant formula. Finally, these remedies are intended to protect WIC participants from disruptions in access to infant formula during product recalls.

For infant formula manufacturers, if their product is subject to a recall these provisions will require them to pay rebates on non-contract infant formula in their contracted State agencies. However, these provisions also provide certainty as to how all stakeholders in the WIC infant formula supply chain – the Federal Government, State and local WIC agencies, WIC vendors, WIC clinics, and infant formula manufacturers – will respond and what responsibilities they bear in the event of a formula recall.

2. Clarify terminology in infant formula cost containment contracts.

i. Program Impact: This rule will clarify terminology at 7 CFR 246.16a(c)(5). Specifically, the current terms "responsive and responsible" used in the regulations to describe bidders are consolidated to "responsive." Responsive is further defined for clarification; to be responsive, a bidder must submit a bid that conforms to the solicitation and must meet requirements at 246.16a. The rule adds language to clarify this meaning, which will enhance consistent application of the term and ensure that all responsive bids will receive consideration. This provision is not required by ABFA.

ii. Cost Impact: USDA is not able to estimate a change in cost associated with this provision. Improved clarity may slightly lower administrative costs to State agencies or infant formula manufacturers.

iii. Impact on Affected Parties: This change improves the clarity of the bidding process for infant formula contracts between State agencies and infant formula manufacturers.

C. Add Requirement for State Agency Plans of Alternate Operating Procedures

i. Program Impact: This rule will add a new provision that State agencies must include as a part of the State Plan a plan of alternate operating procedures, commonly referred to as disaster plans, in the event of a disruption of WIC services. Requiring States to have these plans in place prior to a disaster will help mitigate potential impacts as States would have uniform baseline measures in place to address potential barriers to Program operations and allow State agencies to respond more quickly during these unforeseen events. This provision is not required by ABFA.

ii. Cost Impact: USDA was unable to estimate the change in cost associated with this provision, beyond the change in burden hours (1,869 hours across all State agencies annually) associated with this provision. Some State agencies may already include components of a plan of alternate operating procedures in their State Plan; for these State agencies, this provision poses a minimal additional burden to update their procedures in accordance with regulations. Although there may be a small increase in burden as State agencies write alternative operating procedures to include in future State Plans, USDA anticipates that having these plans in place may decrease burden on State agencies and improve State agencies' responsiveness during a disaster, although USDA is not able to quantify these potential benefits.

iii. Impact on Affected Parties: USDA anticipates a small increase in burden on some State agencies. However, USDA expects that having these plans in place will leave State agencies more prepared in the event of a disaster and will help mitigate the disruptions WIC participants might face in the event of a disaster.

IV. Summary of Impacts

A. Cost Impact

The costs of the rule that were able to be estimated are the result of an increase in reporting and recordkeeping burden associated with the provisions of the rule (an increase of 2,055 reporting and recordkeeping hours annually across all State agencies), most of which are due to the provision requiring alternative operating procedures in State Plans. USDA estimates these costs to be $0.6 million to the State agencies over the five years from FY 2024 to FY 2028.[33]

[33] Costs associated with State agency burden hours are calculated using the hourly total compensation for all State and Local workers from the Bureau of Labor and Statistics (BLS) for FY 2021 and inflated according to the CPI-W increase in OMB's economic assumptions for the FY2023 President's Budget for years FY2024-FY2028 (https://data.bls.gov/timeseries/CMU3010000000000D).

Table 1: Estimated State Agency Costs Due to Change in Administrative[34] Burden, FY 2024 - 2028

	Fiscal Year (millions)					
	2024	**2025**	**2026**	**2027**	**2028**	**Total**
Increase in State Agency Reporting and Recordkeeping Burden	$ 0.1	$ 0.1	$ 0.1	$ 0.1	$ 0.1	**$ 0.6**

B. Benefit Impact

As discussed in detail above, the provisions of this rule strengthen USDA and WIC State agencies' ability to address emergencies, disasters and supply chain disruptions, particularly those impacting infant formula by (1) codifying permanent, expanded waiver authority of the Secretary to help ensure continuity of WIC services during certain emergencies, disasters, and supply chain disruptions impacting the WIC Program; (2) codifying requirements for State agencies to include language in their WIC infant formula cost containment contracts that describes remedies in the event of an infant formula recall, including how an infant formula manufacturer would protect against disruption to benefit access by WIC participants, and (3) requiring that State agencies include as a part of their State Plans a "plan of alternate operating procedures" in the event of an emergency period, supply chain disruption, or supplemental food recall.

Although USDA is not able to quantify the benefits generated by this rule, USDA expects for the provisions of this rule to improve the Federal Government's and State agencies'

[34] Amounts may not sum to the total shown due to rounding.

readiness to respond to emergencies, disasters, or supply chain disruptions. Improved readiness should decrease uncertainty to State and local WIC agencies, WIC clinics, infant formula manufacturers, WIC-authorized vendors, and WIC participants and should improve the continued provision of WIC services and benefits to WIC participants in the event of a emergencies, disasters, or supply chain disruption.

C. Participation and Distributional Impacts

As noted in the above analysis, the Department does not project a participation impact attributable to this rule; the changes made by this rule are largely administrative in nature and strive to ensure continued, smooth operation of WIC during extraordinary events. The changes are unlikely to be visible to WIC-eligible individuals and WIC participants in a way that affects their decision to participate or continue to participate in the WIC Program.

Previous analyses have studied the effects that WIC has on individuals who do not participate in WIC.[35] The Department is unable to reliably estimate an effect of this rule on non-WIC participants, as the provisions of this rule that are non-administrative and not costed (i.e., the non-administrative consequences of the waiver provisions and the infant formula contract provisions) do not come into force except in response to future, unpredictable events. Furthermore, the limited datapoints the Department does have do

[35] See, for example, Oliveira, V. and Frazão, E. (2015), “Painting a More Complete Picture of WIC: How WIC Impacts Nonparticipants,” available online at https://www.ers.usda.gov/amber-waves/2015/april/painting-a-more-complete-picture-of-wic-how-wic-impacts-nonparticipants/.

not indicate that this rule is likely to affect infant formula rebates in a meaningful way and, therefore, is unlikely to affect the wider infant formula market. To the extent that the provisions of this rule helps ensure continued infant formula supply in the event of a supply chain disruption, this rule could have positive spillover effects on non-WIC participants, as the infant formula available for purchase to WIC participants will also be available for purchase by non-WIC participants.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Pursuant to that review, it has been certified this rule would not have a significant impact on a substantial number of small entities.

This final rule would not have a significant economic impact on a substantial number of small entities. This final rule would not have an adverse impact of small entities in the WIC; the impact is not significant as it allows for greater options and flexibilities to support the continuation of WIC services during emergency periods and supply chain disruptions. State agencies are already required to continuously operate a cost containment system for infant formula, with some exceptions. Notably, ITOs with 1,000 or fewer participants are exempt from this provision. Further, the Department has encouraged WIC State agencies to develop disaster plans in the event of disruptions to Program operations. Of the 89 WIC State agencies, 82 State agencies have disaster plans in place.

Factual Basis:

The provisions of this final rule apply to small local agencies operating the Special Supplemental Nutrition Program for Women, Infants and Children, and to State agency staff who must monitor local agencies in remote locations. These entities meet the definitions of "small governmental jurisdiction" and "small entity" in the Regulatory Flexibility Act. These entities will not be negatively impacted by the changes and options in this rule.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as not a 'major rule' as defined by 5 U.S.C. 804(2).

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments, and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local or tribal governments, in the aggregate, or the private sector, of $177 million or more in 2023 (when adjusted for inflation; GDP deflator source: Table 1.1.9 at http://www.bea.gov/iTable) in any one year. When such a statement is needed for a rule, Section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This final rule does not contain Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments, or the private sector of $146146177146146 million or more in any one year. Thus, the rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

Executive Order 12372

The Special Supplemental Nutrition Program for Women, Infants, and children (WIC) is listed in the Catalog of Federal Domestic Assistance under Number 10.557 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under Section (6)(b)(2)(B) of Executive Order 13132.

The Department has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, under Section 6(b) of the Executive Order, a federalism summary is not required.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This rule is not intended to have retroactive effect unless so specified in the Effective Dates section of the final rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed the final rule, in accordance with the Department Regulation 4300-004 "Civil Rights Impact Analysis," to identify and address any major civil rights impacts the proposed rule might have on participants on the basis of race, sex, national origin, disability, and age. The requirements outlined in the final rule aim to remove barriers to WIC food access. The changes would impact WIC State agencies, including ITOs, WIC local agencies and clinics, participants and WIC vendors in ways that are expected to increase equity and access for WIC participants during times of disaster.

To mitigate potential impacts on Program access for LEP populations and persons with disabilities, FNS will provide WIC State agencies with technical assistance aimed at ensuring that communications about program changes are available in appropriate languages and in alternative formats for persons with disabilities. After reviewing the potential impacts, FNS does not believe the rule would result in civil rights impacts on protected groups of WIC participants and applicants. However, the FNS CRD will propose further outreach and mitigation strategies to alleviate any unforeseen impacts, if deemed necessary.

Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Tribal consultation regarding this rule was conducted on November 8, 2022. FNS provided an opportunity for consultation on the rule and Tribal leaders were generally supportive. If a Tribe requests consultation on this rulemaking in the future, FNS will work with USDA's Office of Tribal Relations to ensure meaningful consultation is provided.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; 5 CFR part 1320) requires the Office of Management and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This final rule impacts existing information collection requirements that are contained in OMB Control Number 0584-0043 Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program Regulations – Reporting and Recordkeeping (expiration date December 31, 2023) which are subject to review and approval by OMB in accordance with the Paperwork Reduction Act of 1995. Additionally, the waiver elements of this rule are already in effect but codified in this rule and have been previously approved by OMB under OMB #0584-0687. Any further public comment on the waiver information collection solicited in response to this rule will be used to inform the next revision of the information collection. Therefore, FNS is submitting for public comment in this rule the changes in the information collection burdens in OMB Control Numbers 0584-0043 that would result from adoption of this rule. The information collection and recordkeeping requirements included in this final rule have been submitted by the Agency to OMB for approval which is currently pending. FNS will not collect any information associated with this rule until the information collections are approved by OMB.

Comments on the information collection for this final rule must be received by [Insert date 60 days from publication in the Federal Register].

Comments may be sent to: Allison Post, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 3rd Floor, Alexandria, VA 22314. Comments will also be accepted through the Federal eRulemaking Portal. Go to http://www.regulations.gov and follow the online instructions for submitting comments electronically.

Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information shall have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

a. Revisions to OMB Control Number 0584-0043

Title: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) Program Regulations – Reporting and Recordkeeping Burden.

OMB Number: 0584-0043

Expiration Date: 12/31/2023

Type of Request: Revision of a currently approved collection.

Abstract: This is a revision of existing information collection requirements in the information collection under OMB Control Number 0584-0043 that are affected by this rulemaking. Under this rule, the Department amends 7 CFR Part 246 to codify the provisions of ABFA and implement related changes which will strengthen WIC's ability to address emergency periods and supply chain disruptions, particularly those impacting infant formula. This final rule impacts the burden associated with reporting and recordkeeping requirements for State agencies. This final rule may also result in additional financial costs to State agencies.

(i) Burden Revisions related to State Plan Requirements

This rule requires WIC State agencies to include, as a part of the State Plan, a plan of alternate operating procedures, commonly referred to as a disaster plan in accordance with FNS guidance. Although current WIC regulations do not require WIC State agencies to develop and implement disaster plans, the Department has always encouraged WIC State agencies to develop them. While many WIC State agencies have a disaster plan, they are typically part of a broader health department or other State agency disaster plan and do not address WIC-specific Program operations during emergency periods and supply chain disruptions.

FNS estimates that 82 WIC State agencies have a disaster plan, and that it will take these State agencies an additional 16 hours to update their existing disaster plans to conform with the added specific requirements for these plans included in this rulemaking. Of the remaining 7 WIC State agencies who do not have existing disaster plans, FNS estimates that it will take these State agencies 80 hours to develop disaster plans in accordance with this rulemaking. Therefore, FNS estimates that this rule would result in an increase of 21 burden hours to each State agency's reporting burden ((82 State agencies x 16 hours) + (7 State agencies x 80 hours)/89 State agencies = 21 burden hours). This would increase the burden hours to submit an annual State Plan from 134.62 to 155.62 which would increase the associated reporting burden by 1,869 burden hours.

(ii) Burden Revision Related to Infant Formula Cost Containment Contracts Remedies

This rule requires State agencies to include minimum required remedies in infant formula cost containment contracts to ensure that, in the event of an infant formula recall, any State agency for whom the Secretary has issued a waiver(s) under the conditions described in § 246.29 will be able to enact remedies to protect against disruption to Program participants. All State agencies must continuously operate a cost containment system for infant formula, with some exceptions. Notably, ITOs with 1,000 or fewer participants are exempt from this provision. As such, 79 State agencies out of 89 WIC State agencies have infant formula cost containment contracts. Contracts that State agencies entered into after ABFA was enacted on May 21, 2022 may already include some of the requirements specified in this rule, as WIC Policy Memorandum #2022-6 suggested remedies that are being codified in this rule. However, regardless of whether State agencies have included some of the remedies into their contracts, this rule includes greater specificity on the requirements outlined in WIC Policy Memorandum #2022-6 and an additional requirement. Therefore, incorporating the rule's minimum required remedies in infant formula cost containment contracts would require an estimated one-time two-hour burden per State agency. Therefore, FNS estimates that this rule would result in a one-time increase in 148 burden hours to State agencies' reporting burden (79 State agencies x 2 burden hours = 148 burden hours).

Additionally, this rule requires infant formula manufacturers to provide State agencies with an action plan to meet formula demand and limit disruption to Program participants in the affected jurisdiction(s) in the event of an infant formula recall. This plan must include current supply data to assist the State agency in their recall response. Based on the rarity of large-scale infant formula recalls, FNS estimates that one State agency and one infant formula manufacturer will be impacted by an infant formula recall each year, and that it will take the infant formula manufacturer 4 hours to provide the State agency with an action plan with current supply data. Therefore, FNS estimates that this rule would result in an additional 4 burden hours to businesses' reporting burden (1 infant formula manufacturer x 4 burden hours = 4 burden hours).

(iii) Burden revisions related to emergency period and supply chain disruption recordkeeping.

This rule requires State agencies establish a plan to report to FNS on alternate operating procedures implemented during an emergency period, supplemental food recall, and other supply chain disruptions, which includes Program data and information on the impact of benefit use and delivery. Additionally, this rule requires infant formula manufacturers to provide State agencies with an action plan to meet formula demand and limit disruption to program participants in the affected jurisdiction(s) in the event of an infant formula recall. This plan must include current supply data to assist the State agency in their recall response. FNS estimates that 15 State agencies will implement alternate operating procedures in the event of an emergency period or supply chain disruption, including an infant formula recall, each year. FNS estimates that it will take State agencies 2 hours to record data related to alternate operating procedures implemented during an emergency period or supply chain disruption, and supply data from infant formula manufacturers in the event of an infant formula recall. Therefore, FNS estimates that this rule would result in an additional 30 burden hours to State agencies' recordkeeping burden (15 State agencies x 2 burden hours = 30 burden hours).

Respondents: State agencies, including Indian Tribal Organizations and U.S. Territories (note that burden estimates for local agencies are not affected by this rule).

Estimated Number of Respondents: 90

Estimated Number of Responses per Respondent: 1.99

Estimated Total Annual Burden on Respondents: 14,032

APPENDIX I: WIC Burden Table								
Regulatory Section	**Information Collected**	**Estimated Number of Respondents**	**Annual Responses per Respondent**	**Total Annual Responses**	**Number of Burden Hours per Request**	**Estimated Total Burden Hours**	*Previous Submission: Total Hours per Person*	Difference Due to Program Changes
REPORTING BURDEN ESTIMATES								
Affected Public: State and Local Agencies (including Indian Tribal Organizations and U.S. Territories)								
246.4	State Plan	89	1	89	155.62	13,850.18	*11,981.18*	1,869.00
246.16a(j)	Infant formula cost containment contracts remedies	74	1	74	2	148	*0*	148*
Subtotal *Reporting: State and Local Agencies*		**89**	**2**	**163**	**85.88**	**13,998**	**11,981**	**2,017.00**
Affected Public: Business: Retail Vendors (WIC-Authorized Food Stores)								
246.16a(j)	Infant formula contractor action plan	1	1	1	4	4	*0*	4
Subtotal Reporting: Retail Vendors *		**1**	**1.00**	**1**	**4.00**	**4**	**0**	**4**
GRAND SUBTOTAL: REPORTING		**90**	**1.82**	**164**	**85.38**	**14,002**	***11,981***	**2,021**
RECORDKEEPING BURDEN ESTIMATES								
Affected Public: State and Local Agencies (including Indian Tribal Organizations and U.S. Territories)								
246.4(a)(30); 246.16a(j)	Emergency Period and Supply Chain Disruption Recordkeeping	15	1	15	2	30	0	30
SUBTOTAL: RECORDKEEPING		**15**	**1.00**	**15**	**2.00**	**30**	**0**	**30**
GRAND TOTAL: REPORTING AND RECORDKEEPING		**90**	**1.99**	**179**	**78.39**	**14,032**	***11,981***	**2,051**

* There is a one-time information collection burden associated with this provision.

Summary of Requested Burden Revisions:

Table 4: Summary of Requested Burden Revisions to # 0584-0043			
	Responses	**Respondents**	**Time Burden**
Current Inventory: * Total Burden	**48,798,800**	**6,913,189**	**4,547,099**
Current Inventory: * Reporting	21,254,756	6,913,189	4,017,132
Current Inventory: * Recordkeeping	27,544,044	11,897	529,967
Total Burden Revision Requested	**48,798,890**	**6,913,190**	**4,549,150**
Burden Revision Requested: Reporting	21,254,831	6,913,190	4,019,153
Burden Revision Requested: Recordkeeping	11,897	27,544,059	529,997
Difference in Total Burden from Rulemaking	**90**	**1**	**2,051**

E-Government Act Compliance

The Department is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

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.

Accordingly, the Department amends 7 CFR part 246 as follows:

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. Amend § 246.2 by adding the definitions for “Emergency period,” “Qualified administration requirement,” “Recall” and, “Supply Chain Disruption” in alphabetical order to read as follows:

§ 246.2 Definitions.

* * * * *

Emergency period means a period during which there exists:

(1) A presidentially declared major disaster as defined under section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.).

(2) A presidentially declared emergency as defined under section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.).

(3) A public health emergency declared by the Secretary of HHS under section 319 of the Public Health Service Act (42 U.S.C. 247d).

(4) A renewal of such a public health emergency pursuant to section 319.

* * * * *

Qualified administrative requirement means a statutory requirement under Section 17 of the Child Nutrition Act of 1966 (CNA; 42 U.S.C. 1786) or a regulatory requirement issued pursuant to this section.

* * * * *

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 FDA.

* * * * *

Supply chain disruption means a shortage of WIC supplemental foods that limits WIC participants' ability reasonably to 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. Amend § 246.4 by adding paragraph (a)(30) to read as follows:

§ 246.4 State plan.

(a) * * *

(30) Plans of alternate operating procedures, commonly referred to as disaster plans, to support the continuation of WIC services during an emergency period as defined at §246.2, supply chain disruption as defined at §246.2, and supplemental food recall. State agencies must consider the unique and sudden nature of an emergency period, supplemental food recall, and other supply chain disruptions when developing alternate operating procedures. Alternate procedures must describe the process by which the State agency will minimize the negative impact to WIC operations and services and ensure the availability of authorized supplemental foods, especially infant formula, to the extent feasible. At a minimum, alternate operating procedures must include-

(i) A plan to address operation of specific Program areas including-

(A) Access to Program records;

(B) Alternate certification and benefit issuance

(C) Verification of Certification (VOC) issuance

(D) Food package adjustments;

(E) Vendor requirements;

(F) Benefit redemption; and

(G) Food delivery systems.

(ii) A plan to ensure continuity of WIC services and address the needs of participants with documented qualifying conditions receiving Food Package III, rural areas, Indian tribal organizations, and other priority populations in the affected area as applicable;

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

(iv) A designated emergency contact within the State agency to address the needs of participants with documented qualifying conditions receiving Food Package III;

(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 emergency periods, supplemental food recalls, and other supply chain disruptions;

(vi) A plan to limit the disruption of infant formula benefits in the event of 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;

(viii) A plan to report to FNS on alternate operating procedures implemented during an emergency period, supplemental food recall, and other supply chain disruptions which includes Program data and information on the impact of benefit use and delivery; and

(ix) A plan to adjust State agency specific minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized.

* * * * *

4. In § 246.16a:

a. Revise paragraph (c)(5); and

b. Add a new paragraph (n).

The revision and addition read as follows:

§ 246.16a Infant formula and authorized foods cost containment.

* * * * *

(c) * * *

(5) A State agency must award the contract(s) to the responsive bidder(s) offering the lowest total monthly net price for infant formula or the highest monthly rebate (subject to paragraph(c)(4)(ii) of this section) for a standardized number of units of infant formula. To be responsive, a bidder must submit a bid by the deadline set by the State agency that conforms to the solicitation and must meet requirements at 246.16a and set forth in the bid solicitation. The State agency must calculate the lowest net price using the lowest national wholesale cost per unit for a full truckload of the infant formula on the date of the bid opening.

* * * * *

(n) *What minimum recall-related provisions must be included in infant formula cost containment contracts?* A State agency must include remedies in the event of a recall in their infant formula cost containment contract to protect against disruption in infant formula supply to participants. The State agency will determine when remedies take effect and remain in effect, in accordance with applicable Program requirements and the infant formula cost containment contract. At minimum, recall remedies in the State agency's infant formula cost containment contract must:

(1) Allow infant formula to be issued in all unit sizes that may exceed the maximum monthly allowance. The State agency and contracted infant formula manufacturer must prioritize unit sizes that most closely provide the maximum monthly allowance;

(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 section 246.10(e)(3) of this Part; and

(3) When any contract brand infant formula of the contracted manufacturer is the subject of a recall, require the contracted infant formula manufacturer to:

(i) Provide the State agency with an action plan, within a timeline established within the contract, which includes supply data, to meet infant formula demand and limit disruption to Program participants in the affected jurisdiction(s); and

(ii) Pay rebates on competitive, non-contract brand infant formula that meets the definition of infant formula at 7 CFR 246.2.

5. Add § 246.29 to read as follows:

§ 246.29. Waivers of program requirements.

(a) *Required conditions.* The Secretary may waive or modify any qualified administrative requirement for one or more State agencies during an emergency period or supply chain disruption. Waivers or modifications may be issued following a State agency request or at the discretion of the Secretary. To be considered, a waiver or modification issued under this Section must meet the following requirements:

(1) The qualified administrative requirement cannot be implemented during any part of the emergency period or supply chain disruption.

(2) The waiver or modification is necessary to serve participants and does not substantially weaken the nutritional quality of supplemental foods.

(3) The waiver or modification would not result in material impairment of any statutory or regulatory rights of participants or potential participants as set forth at 7 CFR 246.8 or 7 CFR parts 15, 15a and 15b.

(4) The waiver or modification would not create a barrier to participation.

(5) The waiver or modification would not create additional eligibility requirements for participation.

(6) The waiver or modification would comply with 7 CFR 246.13(b).

(7) The waiver or modification must offer substitution options with similar nutritional quality, that most closely provide the maximum monthly allowance of supplemental foods, and that do not create new supplemental food categories as set forth in 7 CFR 246.10(e)(12) Table 4.

(8) A State agency that requests a waiver or modification meets additional requirements for the request and approval as determined necessary by FNS.

(b) *Timeframes for waiver request and use.* (1) Waiver starts. A waiver or modification may be granted any time during an emergency period or supply chain disruption.

(2) Waiver duration.

(i) A waiver or modification established during an emergency period may be available for the emergency period and up to 60 days after the end of the emergency period.

(ii) A waiver or modification established during a supply chain disruption may be available for:

(A) a period of up to 45 days from the date of waiver issuance and renewed with at least 15 days' notice provided by the Secretary; and

(B) no more than 60 days after the supply chain disruption declaration ceases to exist.

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

(1) The qualified administrative requirement the State agency is requesting to modify or waive (including the statutory or regulatory citation) and an explanation for why it cannot be met;

(2) Justification for why the waiver is necessary to continue WIC services;

(3) An explanation that the waiver meets the conditions set forth in 7 CFR 246.29(a);

(4) The emergency period or supply chain disruption under which the request is being made;

(5) The period for which the flexibility is being requested.

Cynthia Long,
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