Appendix S
Federal Register
Implementation of the Access to Baby Formula Act of 2022 and Related Provisions

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

A Rule by the Food and Nutrition Service on 12/14/2023

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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 (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 (http://www.regulations.gov).*

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Overview

On May 21, 2022, the President signed the Access to Baby Formula Act of 2022 (ABFA, Pub. L. 117-129 (https://www.govinfo.gov/link/plaw/117/public/129)) into law. ABFA amends Section 17 of the Child Nutrition Act of 1966 (CNA, 42 U.S.C. 1786 (https://www.govinfo.gov/link/uscode/42/1786)) 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 (https://www.ecfr.gov/current/title-7/part-246) to codify the provisions of ABFA and

rulemaking, FNS plans to provide WIC State agencies with technical assistance, which may include guidance documents, 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 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

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 (https://www.govinfo.gov/link/uscode/42/5121)), 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 (🗋 print page 86547) 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, 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 (https://www.govinfo.gov/link/plaw/116/public/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

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 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]

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C. WIC Disaster Planning

WIC State agencies are required to submit an annual plan for Program operations. Program regulations at 7 CFR 246.4 (https://www.ecfr.gov/current/title-7/section-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 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

Memorandum #2004-4: *Implementation of the Infant Formula Cost Containment Provisions of P.L. 108-265 (https://www.govinfo.gov/link/plaw/108/public/265)* to address Public Law 108-265 (https://www.govinfo.gov/link/plaw/108/public/265).[15]

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) (https://www.govinfo.gov/link/uscode/42/1786)) and WIC Program regulations at 7 CFR 246.16a (https://www.ecfr.gov/current/title-7/section-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

Emergency Assistance Act (42 U.S.C. 5121 (https://www.govinfo.gov/link/uscode/42/5121) *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 (https://www.govinfo.gov/link/uscode/42/247d)), 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 (https://www.govinfo.gov/link/uscode/42/1786)), 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) (https://www.ecfr.gov/current/title-21/section-7.3#p-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) (https://www.ecfr.gov/current/title-21/section-7.3#p-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) (https://www.ecfr.gov/current/title-21/section-7.3#p-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

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 (https://www.ecfr.gov/current/title-7/section-246.8) and 7 CFR parts 15 (https://www.ecfr.gov/current/title-7/part-15), 15a (https://www.ecfr.gov/current/title-7/part-15a) and 15b (https://www.ecfr.gov/current/title-7/part-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;
(🗋 print page 86550)

(4) Comply with 7 CFR 246.13(b) (https://www.ecfr.gov/current/title-7/section-246.13#p-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) (https://www.ecfr.gov/current/title-7/section-246.10#p-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

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;

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.

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 CFR 246.10(e)(1)(iv) (https://www.ecfr.gov/current/title-7/section-246.10#p-246.10(e)(1)(iv)) offers State agencies the flexibility to issue powder or concentrated liquid, 7 CFR 246.16a(c)(4) (https://www.ecfr.gov/current/title-7/section-246.16a#p-246.16a(c)(4)) requires infant formula manufacturers to bid on all three physical forms. Currently powder

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 (print page 86552) 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

(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.

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 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 (https://www.govinfo.gov/link/plaw/117/public/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

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. (print page 86554)

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.

On March 18, 2020, the Families First Coronavirus Response Act (FFCRA, Pub. L. 116-127 (https://www.govinfo.gov/link/plaw/116/public/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 (https://www.govinfo.gov/link/uscode/42/5121)) 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 U.S.C. 1786 (https://www.govinfo.gov/link/uscode/42/1786)) 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 (https://www.ecfr.gov/current/title-7/part-246) to codify the provisions of ABFA.

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 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

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 (https://www.ecfr.gov/current/title-7/section-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

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 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

(print page 86557)

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 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

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]

(🗋 print page 86558)

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

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 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 (https://www.govinfo.gov/link/uscode/5/601)) 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

Federalism Summary Impact Statement

Executive Order 13132 (/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 (/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 (/executive-order/12988), Civil Justice Reform

This final rule has been reviewed under Executive Order 12988 (/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

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 February 12, 2024.

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 (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. (🗋 print page 86560)

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.

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 × 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 × 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

Appendix I—WIC Burden Table

Regulatory section	Information collected	Estimated number of respondents	Annual responses per respondent	Total annual responses	Numb of burd hou per reque
Grand Subtotal: Reporting	90	1.82	164	85.38	14,0
RECORDKEEPING BURDEN ESTIMATES					
Affected Public: State and Local Agencies (including Indian Tribal Organization					
246.4(a)(30); 246.16a(j)	Emergency Period and Supply Chain Disruption Recordkeeping	15	1	15	
Subtotal: Recordkeeping		15	1.00	15	2.
Grand Total: Reporting and Recordkeeping		90	1.99	179	78.

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

- Penalties
- Reporting and recordkeeping requirements
- Women

Accordingly, the Department amends 7 CFR part 246 (https://www.ecfr.gov/current/title-7/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 (https://www.govinfo.gov/link/uscode/42/1786).

2. Amend § 246.2 by adding the definitions for "Emergency period," "Qualified administration requirement," "Recall" and, "Supply Chain (print page 86562) Disruption" in alphabetical order to read as follows:

§ 246.2 Definitions.

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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 (https://www.govinfo.gov/link/uscode/42/5121) *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 (https://www.govinfo.gov/link/uscode/42/5121) *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 (https://www.govinfo.gov/link/uscode/42/247d)).

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

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(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;

(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
(🗋 print page 86563)

(ii) Pay rebates on competitive, non-contract brand infant formula that meets the definition of infant formula at 7 CFR 246.2 (https://www.ecfr.gov/current/title-7/section-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

(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) (https://www.ecfr.gov/current/title-7/section-246.29#p-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,

Administrator, Food and Nutrition Service.

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 (https://www.fns.usda.gov/wic/policy-memorandum-2021-10).
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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 Public Law 117-129 (https://www.govinfo.gov/link/plaw/117/public/129)," June 6, 2022. Available online at: https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022 (https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022).
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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 (https://www.fns.usda.gov/resource/abbott-infant-formula-recall-waiver-expiration-memo)#.
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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 Public Law 117-129 (https://www.govinfo.gov/link/plaw/117/public/129), " June 6, 2022. Available online at: https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022 (https://www.fns.usda.gov/wic/implementation-access-baby-formula-act-2022).
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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 (https://www.fns.usda.gov/wic/policy-memorandum-2023-3-unwinding-infant-formula-flexibilities).
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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 (https://www.fns.usda.gov/wic/guide-coordinating-wic-service-during-disasters).
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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 (https://www.fns.usda.gov/pd/wic-program).
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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 (https://www.fns.usda.gov/disaster/pandemic/covid-19/wic-physical-presence-waiver).
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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/ (https://www.ers.usda.gov/amber-waves/2015/april/painting-a-more-complete-picture-of-wic-how-wic-impacts-nonparticipants/).

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