

Appendix E

WIC Burden Narrative

This document explains the calculation of the burden hours and responses for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) under OMB #0584-0043, as revised to reflect program changes due to the final rule: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions in the WIC Food Packages. The resulting recalculations are highlighted below in bold and are reflected in the attached spreadsheet.

Note on the Number of Vendors

The Food and Nutrition Service (FNS) estimates that the requirement in the Revisions in the WIC Food Packages final rule for WIC-authorized retail vendors to stock three varieties of vegetables (previously, vendors were required to stock two varieties) may result in 150 fewer vendors submitting applications and/or fewer vendors signing agreements. This estimate assumes that among vendors with WIC redemptions in the bottom 10 percent nationwide, those such as small convenience stores that offer limited grocery items may have the greatest difficulty stocking an additional vegetable, and therefore will be most impacted by the small increase in the minimum stock requirement in the final rule. Therefore, this information collection request reflects an estimated decrease in the number of WIC-authorized retail vendors from 37,417 to 37,267.

REPORTING REQUIREMENTS

AFFECTED PUBLIC: STATE AND LOCAL AGENCIES (INCLUDING INDIAN TRIBAL ORGANIZATIONS AND US TERRITORIES)

1. Section 246.4 requires that by August 15 of each year, as a prerequisite for the receipt of funds from FNS, the State agency must submit all substantive changes to its State Plan (to include local agencies' annual nutrition education plan approval) to FNS for approval. State Plan reporting requirements include establishing the food delivery system as it operates at the State agency level; providing EBT project status reports; providing a description of any infant formula, vendor, or other cost containment systems; and describing the State agency's plan for alternate operating procedures during a disaster. FNS estimates that each State agency needs 170.62 burden hours annually to update their State Plan. Thus, 89 WIC State agencies x 170.62 hours per State Plan = 15,185.18 total annual burden hours for this provision. This has not changed since the last submission.
2. Section 246.4(a)(30) 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. 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. This may include but is not limited to addressing operation of specific program areas including access to program records, verification of certification issuance, food package adjustments, vendor requirements, benefit redemption, and food delivery systems; ensuring 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; establishing 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; designating emergency contacts; limiting disruption of infant formula benefits; reporting to FNS on alternate operating procedures implemented; and adjusting State agency specific minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized. Depending on the program disruption, a State agency may implement one or several alternate operating procedures.

Therefore, FNS estimates it takes State agencies 80 hours, or the equivalent of two work weeks, to implement operating procedures, accounting for variances. Thus, FNS estimates 1,200 annual burden hours for this provision (15 State agencies x 80 hours = 1,200). This has not changed since the previous submission.

3. Section 246.5(b) requires each organization interested in being authorized as a local agency to submit an application to the State agency. After receipt of the application the State agency is required to 1) provide written notification if an application is incomplete and identify the additional information needed, or 2) provide written notification of approval or disapproval. The average local agency agreement is for two years and there

are 1,810 local agencies. Therefore, FNS estimates that each year the State agency will process 905 ($1,810 / 2 = 905$) local agency applications. Each application requires two burden hours to complete.

Approximately 70 percent of all local agencies are State and local government entities, while the remaining 30 percent are non-profit businesses. Therefore, 70 percent of all applicant and participant certifications are reported under State and local agencies ($905 \times 0.70 = 633.5$). Thus, FNS estimates 1,267 annual burden hours for this provision (633.5 local agencies \times 2 burden hours per application = 1,267). This has not changed since the last submission.

4. Section 246.5(c)(2) requires that a State agency must provide a written justification to FNS for not funding a local agency to serve the highest priority area or special population. FNS estimates that 4 State agencies each year must provide a written justification for not funding one local agency which takes 10 minutes (0.167 burden hours) to complete. Thus, FNS estimates 0.67 annual burden hours for this provision (4 State agencies \times 1 local agency = 4 written justifications \times 0.167 hours = 0.67 burden hours). This has not changed since the last submission.
5. Section 246.5(e)(3)(ii) requires that a State agency provide a local agency with written notice not less than 60 days in advance of the pending action when disqualifying a local agency, which includes an explanation of the reasons for disqualification, the date of disqualification, and, except in cases of the expiration of a local agency's agreement, the local agency's right to appeal as set forth in § 246.18. FNS estimates that four State agencies will disqualify two percent of their local agencies each year ($1,810$ local agencies/ 89 State agencies = 20.34 local agencies per State agency \times 0.02 = 0.41 local agencies disqualified per State agency). Providing written notice to these local agencies will take 30 minutes (0.50 burden hours) to complete. Thus, FNS estimates 0.81 annual burden hours for this provision (4 State agencies \times 0.41 disqualified local agencies per State agency = 1.63 written notices \times 0.50 hours = 0.81 hours). This has not changed since the last submission.
6. Section 246.6 requires the State agency to enter into a signed agreement with each local agency, health and human service agency, and private physician that performs WIC functions. The average local agency agreement is for two years; therefore, FNS estimates each year that half of all local agencies (905) sign agreements with the State agency. Each agreement requires 1.5 burden hours to complete. Approximately 70 percent of all local agencies are State and local government entities, while the remaining 30 percent are non-profit businesses. Therefore, 70 percent of all local agency agreements are reported under the State and local agencies category ($905 \times 0.70 = 633.5$). Thus, FNS estimates 950.25 annual burden hours for this provision (633.5 local agencies \times 1.5 burden hours per agreement). This has not changed since the last submission.
7. Section 246.7(d) requires State agencies to provide local agencies with income guidelines, definitions, and procedures to be used in determining an applicant's income eligibility for the Program. Each year, FNS publishes WIC Income Eligibility Guidelines

which are available online through FNS' public site or PartnerWeb. FNS estimates that it takes State agencies 15 minutes (0.25 hours) to provide this information to 20.34 local agencies (1,810 local agencies / 89 State agencies = 20.34 local agencies per State agency). Thus, FNS estimates 452.5 annual burden hours for this provision (89 State agencies x 20.34 local agencies = 1,810 responses x 0.25 hours = 452.5 hours). This has not changed since the last submission.

8. Section 246.7(f)(2)(iii)(A) allows the State agency to extend the 10-day period of notification of eligibility for special nutritional risk applicants to 15 days when the local agency provides written justification of the need for such an extension. Currently, all State agencies have developed policies under which such an extension may be provided. FNS estimates that each year one-sixth of all local agencies make written requests for such extensions. Each request for an extension requires 15 minutes (0.25 hours) to complete. For the approximately 70 percent of all local agencies that are State or local government entities (1,810 local agencies x 0.70 = 1,267 local agencies), FNS estimates 52.79 annual burden hours for this provision (1,267/6 = 211.17 local agencies x 0.25 burden hours per request). This has not changed since the last submission.
9. Sections 246.7(b),(i),(n) and 246.11 require that pertinent certification data be collected and recorded by the local agency on a form (or forms) provided by the State agency (usually in the form of computer software) and that participants be notified of their rights and responsibilities, including notification of termination for failure to pick up food instruments, notification of disqualification, and notification of expiration of each certification period. Additionally, State and local agencies provide WIC Program applicants and participants or their designated proxies with information on other health-related and public assistance programs and, when appropriate, refer applicants and participants to such programs. When a State agency determines that screening is necessary to fulfill the referral requirements in this part, the State agency must require screening for the use of drugs and other harmful substances. Finally, WIC participants and applications receive their initial nutrition education including breastfeeding promotion and support, at the time of certification.

During the certification process participants are assigned a food package based on their nutrition risk assessment and categorical eligibility. **Due to the program (food package) changes in the final rule, it is estimated that it will take an additional three minutes per participant during the certification (the current estimate is 25 minutes per participant) for clinic staff to review procedures to ensure that they prescribe the food package correctly. Therefore, FNS estimates that the collection of certification data, the provision of appropriate notifications, and reviewing the food packages requires 28 minutes (0.4667 hours) per participant. Additionally, communicating the food package changes to current participants would require an estimated one-time five-minute (0.0833 hours) explanation per participant.**

FNS estimates 451,415.52 annual burden hours for the certification of women or adults (1,267 local agencies x [1,379,126 women or adult applicants x 0.70/1,267 = 761.95 certifications per local agency] = 965,388.20 responses x 0.4676 hours =

451,415.52 hours). This is an increase of 48,365.95 hours from the previous submission, due to a program change in the final rule.

FNS estimates 1,112,917.46 annual burden hours for the certification of children (1,267 local agencies x [3,400,090 children applicants x 0.70 / 1,267 = 1,878.50 child certifications per local agency] = 2,380,063 responses x 0.4676 hours = 1,112,917.46 hours). This is an increase of 119,241.16 hours from the previous submission due to a program change in the final rule.

FNS estimates 479,440.01 annual burden hours for the certification of infants (1,267 local agencies x [1,464,744 x 0.70 / 1,267 = 809.25 infant certifications per local agency] = 1,025,320.80 responses x 0.4676 hours = 479,440.01 hours). This is an increase of 51,368.57 hours from the previous submission due to a program change in the final rule.

FNS estimates 364,959.46 burden hours to explain the changes to the food package in this final rule once to all current WIC participants (6,243,960 participants / 1,808 = 3,449.70 explanations per local agency x 1,267 local agencies = 4,370,772 total explanations x five minutes (0.0835 hours) per explanation = 364,959.46 hours. This one-time increase to the local agency reporting burden is due to a program change in the final rule.

10. Section 246.7(j)(9) requires that when the State agency must suspend or terminate the program benefits of any participant during the participant's certification period due to shortages in program funds, the State agency must issue an advance notice to all affected participants. The State agency is also required to notify FNS prior to taking such action. FNS estimates that four State agencies may need to take such action per year. FNS further estimates that providing this notice to FNS would require five minutes (0.0835 hours). FNS estimates the total annual burden for this notice to FNS to be 0.33 burden hours (4 State agencies per year x 0.0835 hours per notice). This has not changed since the last submission.
11. Section 246.7(k) requires the State agency to ensure that Verification of Certification (VOC) cards are issued to participating migrants and to other participants who are likely to relocate during the certification period. Based on the number of participants with no priority reported, FNS estimates that three percent of participants receive VOC documentation. FNS further estimates that issuing VOCs requires five minutes (0.0835 burden hours). For the 70 percent of all local agencies that are government entities, FNS estimates the total annual burden for this provision to be 10,948.78 burden hours (1,267 local agencies x [6,243,960 participants x 0.03 x 0.70 / 1,267 = 103.49 VOC issuances per local agency] = 131,123.16 responses x 0.0835 hours = 10,948.78 hours). This has not changed since the last submission.
12. Section 246.8(c) requires State agencies to provide information in appropriate languages where a significant number or proportion of the population eligible to be served needs service or information in a language other than English. FNS estimates that 79 State

agencies provide information in languages other than English which takes 3 hours to complete. Thus, FNS estimates 237 burden hours for this provision (79 State agencies x 3 hours = 237 hours). This has not changed since the last submission.

13. Section 246.9(c) requires that at the time of a claim against an individual for improperly issued benefits or at the time of participation denial or of disqualification from the Program, the State or local agency inform each individual in writing of the right to a fair hearing, of the method by which a hearing may be requested, and that any positions or arguments on behalf of the individual may be presented personally or by a representative such as a relative, friend, legal counsel or other spokesperson. Such notification is not required at the expiration of a certification period. FNS estimates that two percent of all participants may have a claim issued against them ($6,243,960 \times 0.02 = 124,879.20$ claims) and it will take the State agency five minutes (0.0835 hours) to provide written notification. Thus, FNS estimates 10,427.41 annual hours for this provision ($89 \text{ State agencies} \times [124,879.2 / 89 = 1,403.14 \text{ claims per State agency}] = 124,879.20 \text{ responses} \times 0.0835 \text{ hours} = 10,427.41 \text{ hours}$). This has not changed since the last submission.
14. Section 246.9(h) requires State and local agencies to process each request for a hearing under uniform rules of procedure and make these rules of procedure available for public inspection and copying. FNS estimates that approximately two percent of participants issued a claim will request a hearing ($124,879.20 \text{ claims} \times 0.02 = 2,497.58 \text{ hearings}$) and it will take the State agency three hours to process each hearing. Thus, FNS estimates 7,492.75 annual burden hours for this provision ($89 \text{ State agencies} \times [2,497.58 / 89 = 28.06 \text{ hearings per State agency}] = 2,497.58 \text{ responses} \times 3 \text{ hours} = 7,492.75 \text{ hours}$). This has not changed since the last submission.
15. Section 246.10(b)(1) requires each State agency to identify foods that are acceptable for use in the Program in their jurisdiction, in accordance with program regulations. This includes establishing criteria for and identifying foods, substitutions, brands and packaging the State agency will authorize for use in the Program. **The rule includes additional requirements and options for WIC-authorized foods that will impact State agencies' identification of foods, substitutions, brands, and packaging acceptable for use in the Program to include:**
 - **Requiring one other form of fruits and vegetables in addition to fresh.**
 - **Allowing greater flexibility to authorize additional package sizes (e.g., fresh fruits and vegetables, yogurt, bread).**
 - **Allowing plant-based yogurts and plant-based cheeses as substitution options for milk.**
 - **Requiring the authorization of lactose-free milk.**
 - **Allowing additional whole grain options as substitutes for bread.**
 - **Requiring the authorization of canned legumes in addition to dry legumes.**
 - **Allowing the authorization of nut and seed butters as an alternative to peanut butter.**

The Department estimates that on average it will take each State agency 43 hours annually to comply with this regulatory provision (to include the changes), which is

an increase of 3 hours (based on an estimated range of 2 to 4 hours) per State agency. This represents an average of a 5 to 10 percent increase in burden time. Therefore, the Department estimates 3,827 total annual burden hours for this provision (89 State agencies x 43 hours per State agency), which is an increase of 267 hours from the previous submission. This increase is due to a program change from the final rule.

16. Section 246.10(b)(2) requires each State agency to identify the brands of foods and package sizes acceptable for use in the Program in their States. Each State agency must also include a list of acceptable foods and their maximum monthly allowances. In accordance with the implementation of the Electronic Benefits Transfer (EBT)-Related Provisions of Public Law 111-296 Final Rule on March 1, 2016, a State agency must provide an updated Authorized Product List (APL) which includes each product's Universal Product Code (UPC). State agencies are required to provide the APL files quarterly. FNS estimates an annual reporting burden of 1.79 hours. The time estimated for a State agency to compile and submit an APL is 30 seconds (0.0083 hours). A State agency will submit an APL 4 times per year x 89 State agencies (average per year) = 216 x 0.0083 = 1.79 hours. This has not changed since the last submission.
17. Sections 246.10(b)(2)(i) requires each State agency to provide to local agencies a list of foods that are acceptable for use in the Program in their jurisdiction. As part of implementation, State agencies will be updating these lists to account for the final rule's changes to the WIC food packages, described at 246.10(e). **Within two years of the final rule's publication, State agencies must revise their food list and update food packages to comply with the rule. To implement these changes, which may include reviewing guidance from FNS, attending trainings from FNS, developing and providing trainings for local agencies, and providing status updates to FNS, FNS estimates a total of 8 annual burden hours for each State agency. Therefore, FNS estimates an implementation burden of 712 annual hours during the first two years following publication (89 x 8 = 712). This addition is due to a program change due to the final rule.**
18. Section 246.10(b)(2)(i) requires each State agency to provide to local agencies a list of foods that are acceptable for use in the Program in their jurisdiction. **Due to the changes in the WIC food packages the food lists will be revised. Local agencies will need to attend a State agency training on the revised food lists, which FNS estimates will require one hour. FNS estimates an additional one-time burden of 1,267 hours for local agencies to attend the State agency training (1,267 x 1.00 = 1,267). This increase is due to a program change due to the final rule.**
19. Section 246.10(d)(1) requires local agencies to obtain medical documentation in order to provide participants with infant formula not covered by the State agency's infant formula rebate contract. FNS estimates that one percent (0.01) of all infant certifications require an additional two minutes (0.0334 hours) for the documentation required to issue an infant formula that is not covered by the State agency's infant formula rebate contract. For the 70 percent of local agencies that are government entities, FNS estimates 342.46

total annual burden hours for this provision (1,267 local agencies x [1,464,744 infants x 0.01 x 0.70 / 1,267 = 8.09 medical documentations per local agency] = 10,253.21 responses x 0.0334 hours = 342.46 hours). This has not changed since the last submission.

20. Section 246.10(i) requires each State agency to submit to FNS a plan for substitution of food(s) acceptable for use in the Program to allow for different cultural eating patterns. The plan shall provide the State agency's justification, including a specific explanation of the cultural eating pattern and other information necessary for FNS to evaluate the plan. FNS estimates that approximately one State agency will submit a plan for substitutions every five years ($1 / 5 = 0.20$) which will take two hours to complete. Thus, FNS estimates 0.40 annual burden hours for this provision (0.20 State agencies x 2 hours = 0.40 hours). This has not changed since the last submission.
21. Sections 246.11(d)(1) and 246.7(b) require local agencies to make nutrition education, including breastfeeding promotion and support, available to all adult participants, and to parents or caretakers of infant and child participants, and whenever possible and appropriate, to child participants which takes 15 minutes (0.25 hours) to complete. Nutrition education may be provided through the use of individual or group sessions. Educational materials designed for Program participants may be utilized to provide education to pregnant, postpartum, and breastfeeding women and to parents or caretakers of infants and children participating in local agency services other than the program. For the 70 percent of local agencies that are government entities, FNS estimates 1,092,693 annual burden hours for this provision ($1,267$ local agencies x [6,243,960 participants x 0.70/1,267 = 3,449.70 nutrition education per local agency] = 4,370,772 responses x 0.25 hours = 1,092,693 hours). This has not changed since the last submission.
22. Section 246.11(d)(2) requires each local agency to develop and submit an annual nutrition education plan to the State agency. FNS estimates that 40 burden hours are needed for each local agency to comply with this provision. For the 70 percent of local agencies that are government entities, FNS estimates 50,680 total annual burden hours for this provision ($1,267$ local agencies x 40 hours per local agency = 50,680). This has not changed since the last submission.
23. Section 246.12(f)(3) requires State agencies to implement procedures to ensure that each food instrument and cash-value voucher submitted for redemption can be identified by the vendor or farmer that submitted the food instrument or cash-value voucher, which takes approximately three hours to complete. Thus, FNS estimates 267 annual burden hours for this provision (89 State agencies x 3 hours = 267 hours). This has not changed since the last submission.
24. Section 246.12(f)(4) requires State agencies to implement procedures that allow the participant, authorized representative, or proxy to pay the difference when a fruit and vegetable purchase exceeds the value of their cash-value vouchers, which takes approximately three hours to complete. Thus, FNS estimates 267 annual burden hours for

this provision (89 State agencies x 3 hours = 267 hours). This has not changed since the last submission.

25. Section 246.12(g)(4)(i) requires a State agency to annually collect information needed to determine whether currently authorized and new vendor applicants derive or may be expected to derive more than 50 percent of their annual food sales revenue from WIC food instruments. Based on the Vendor Cost Containment (VCC) Final Rule, FNS estimates that each State agency will need four burden hours to collect the information required to assess a vendor's status as an above-50-percent vendor.

FNS annually provides each State agency with a report comparing WIC redemptions to redemptions of the Supplemental Nutrition Assistance Program (SNAP) for each of its SNAP-authorized vendors; most WIC-authorized retail vendors are also SNAP-authorized. If a vendor's SNAP redemptions exceed its WIC redemptions, the vendor is considered to be a regular vendor, not an above-50-percent vendor. The latest "The Integrity Profile (TIP)" report shows that 840 WIC-authorized vendors have more WIC redemptions than SNAP redemptions. These are the only WIC-authorized vendors from which WIC State agencies need to obtain further documentation.

Regarding the 840 authorized vendors whose above-50-percent status must be assessed, there are about 9 such vendors per each State agency (840 authorized vendors / 89 State agencies = 9.44 vendors per State agency). FNS estimates 3,360 burden hours for State agencies (89 x 9.44 vendors = 940 responses x 4 hours = 3,360) for this provision. This has not changed since the last submission.

26. Section 246.12(g)(4)(ii)(B) requires State agencies to collect the shelf prices for WIC-approved foods from authorized retail vendors twice annually. Based on the VCC Final Rule, FNS estimates two hours per response for this provision. Approximately, 10 State agencies have been granted exemptions from collecting vendor shelf prices. **Therefore, 79 State agencies (89 State agencies – 10 State agencies = 79 State agencies) will each need to collect vendor shelf prices for approximately 472 vendors biannually (37,267 / 79 State agencies = 471.7 vendors x 2 = 943.47 responses per State agency). FNS estimates 149,068 annual burden hours for this provision (79 State agencies x 943.73 responses per State agency = 74,534 responses x 2 times per year). This is a decrease of 600 hours from the previous submission due to an estimated decrease in the number of vendors as a result of the rule. This decrease is due to a program change.**

As noted above, § 246.12(g)(4)(ii)(B) states that FNS may grant State agencies exemptions from the requirement to collect shelf prices. Approximately 10 State agencies currently have exemptions; FNS also estimates that 5 State agencies will request an exemption each year and that requesting an exemption under this provision will require 8 burden hours per response. FNS estimates 40 hours (5 State agencies x 8 annual burden hours) for the exemption requests. This has not changed since the previous submission.

27. Section 246.12(g)(4)(iii) requires each State agency to establish procedures to ensure that a vendor selected for participation in the program does not, subsequent to selection,

increase prices to levels that would make the vendor ineligible for authorization. It takes approximately three hours for the State agency to complete this requirement. Thus, FNS estimates 267 burden hours for this provision (89 State agencies x 3 hours = 267 hours). This has not changed since the last submission.

28. Section 246.12(g)(5) requires State agencies to conduct an on-site visit prior to or at the time of a vendor's initial authorization. FNS estimates that, on average, each State agency authorizes 17 new vendors each year. Each visit takes 40 minutes to confirm information included in the vendor's application, with an additional 20 minutes of round-trip travel time for a total of 1 hour. Thus, FNS estimates 1,513 burden hours for this provision (89 State agencies x 17 new vendors = 1,513 responses x 1 hour = 1,513 hours). This has not changed since the last submission.
29. Section 246.12(g)(8) allows State agencies to limit the periods during which applications for vendor authorization will be accepted and processed, except that applications must be accepted and processed at least once every three years. State agencies must develop procedures for processing vendor applications outside of its timeframes when it determines there will be inadequate participant access unless additional vendors are authorized. FNS estimates that it takes State agencies three hours to develop these procedures each year. Thus, FNS estimates 267 burden hours for this provision (89 State agencies x 3 hours = 267 hours). This has not changed since the last submission.
30. Section 246.12(h) requires State agencies to enter into written agreements with all authorized vendors. The agreements must be for a period not to exceed three years. The State agency must require vendors to reapply at the expiration of their agreements and must provide vendors with not less than 15 days advance written notice of the expiration of their agreements. FNS estimates that each State agency will review and enter into written agreements with a third of their vendors each year, each of which will take 40 minutes to complete (0.668 hours).

Each State agency will review approximately 138 vendor applications and agreements annually (37,267 x 0.33 / 89 State agencies = 138.18). Therefore, FNS estimates 8,215.14 burden hours for State agencies to review applications and sign the agreements (89 State agencies x 138.18 vendor applications and agreements per State agency = 12,298.11 vendor applications and agreements x 40 minutes (.668 hours) per application and agreement = 8,215.14 annual burden hours). With the estimated decrease in the number of vendors filing applications and agreements as a result of the final rule, FNS estimates a decrease of 33.07 burden hours (8,248.20 – 8,215.14) from the previous submission for this provision. This decrease is due to a program change from the final rule.

31. Section 246.12(i)(1) requires the State agency to conduct annual retail vendor training to assure that retail vendors have knowledge of program rules and procedures. FNS estimates that developing the content of retail vendor training materials requires eight hours per State agency. FNS estimates 712 hours for developing the training (89 State agencies x 8 burden hours = 712). This has not changed since the previous submission.

Additionally, FNS estimates that it will take two hours to provide training to each vendor (37,267 total vendors / 89 State agencies = 418.73 vendors per State agency), for an estimated 74,534 annual burden hours (89 State agencies x 418.73 vendors per State agency = 37,267 responses x 2 hours = 74,534). This is a decrease of 300 hours due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.

32. Section 246.12(j)(2),(8) requires State agencies to conduct routine monitoring visits on a minimum of five percent of the number of vendors authorized by the State agency as of October 1 of each fiscal year in order to survey the types and levels of abuse and errors among authorized vendors and to take corrective actions, as appropriate. The State agency must develop criteria to determine which vendors will receive routine monitoring visits. **FNS estimates that it takes each State agency one hour to identify and conduct onsite monitoring of five percent of vendors (37,267 total vendors x 0.05 / 89 State agencies = 20.94 vendors per State agency) with an additional 20 minutes (0.334 hours) for round trip travel time, for a total of 1.334 hours. Thus, FNS estimates 2,485.71 burden hours for this provision (89 State agencies x 20.94 vendors = 1,863.35 responses x 1.334 hours = 2,485.71 hours). This is a decrease of 10.01 hours from the previous submission due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.**
33. Section 246.12(j)(4),(6) requires that each year the State agency conduct compliance investigations of five percent or 1,863.35 retail vendors (37,267 total vendors x 0.05 = 1,863.35 / 89 = 20.94 vendors per State agency). State agencies use a variety of resources to conduct compliance investigations, including State agency staff, contractor staff, local agency staff, law enforcement and staff of other WIC State agencies. For each compliance investigation, the State agency is required to conduct either two compliance buys or one inventory audit per retail vendor. FNS estimates that it takes one burden hour to conduct a compliance buy and two burden hours to conduct an inventory audit, with an additional 20 minutes (0.334 hours) for roundtrip travel time, which results in a total of 2.334 burden hours per compliance investigation (either 2 compliance buys x 1 hour or 1 inventory audit x 2 hours plus 20 minutes). **FNS estimates 4,349.06 annual burden hours for this provision (89 State agencies x 20.94 vendors per State agency = 1,863.35 responses x 2.334 hours = 4,349.06 hours). This is a decrease of 17.51 hours from the previous submission due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.**
34. Section 246.12(k)(5) allows State agencies to pay vendors for food instruments and cash-value vouchers submitted for redemption after the specified period for redemption with justification and documentation. If the total value of such food instruments or cash-value vouchers submitted at one time exceeds \$500.00, the State agency must obtain the approval of the FNS Regional Office before payment. FNS estimates that two State agencies must obtain approval from the FNS Regional Office which will take three hours to complete. Thus, FNS estimates six burden hours for this provision (2 State agencies x 3 hours = 6 hours). This has not changed since the previous submission.

35. Section 246.12(l)(3) requires State agencies to notify a vendor in writing when an investigation reveals an initial incidence of a violation for which a pattern of incidences must be established in order to impose a sanction, before another such incidence is documented, unless the State agency determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation. FNS estimates that 1,048 vendors will be notified in writing of a violation ($1,048 / 89$ State agencies = 11.78 vendors per State agency) which will take 5 minutes to complete (0.0835 hours). Thus, FNS estimates 87.51 burden hours for this provision (89 State agencies \times 11.78 vendors = 1,048 responses \times 0.0835 hours = 87.51 hours). This has not changed since the previous submission.
36. Section 246.12(m) allows State agencies to use home food delivery systems in which authorized supplemental foods are delivered to the participant's home. Home food delivery systems must provide for procurement of supplemental foods in accordance with § 246.24, which may entail measures such as the purchase of food in bulk lots by the State agency and the use of discounts that are available to State agencies, and the accountable delivery of authorized supplemental foods to participants. FNS estimates that one State agency will use home delivery systems to deliver authorized supplemental foods to participants each month of the year (12 times) which will take 40 hours to complete. Thus, FNS estimates 480 burden hours for this provision (1 State agency \times 12 months of food delivery = 12 responses \times 40 hours = 480 hours). This has not changed since the previous submission.
37. Section 246.12(o) requires the State agency to develop and implement procedures to document the handling of complaints by participants and vendors. FNS estimates that 10,000 complaints are received a year from participants and vendors nationwide. FNS further estimates it takes one hour to process each complaint. The total annual burden estimated for this provision is 10,000 burden hours ($10,000$ complaints / 89 State agencies = 112.36 complaints per State agency. 89 State agencies \times 112.36 = 10,000 responses \times 1 hour per complaint = 10,000). This has not changed since the last submission.
38. Section 246.12(p) requires State agencies to establish standards for ensuring the security of food instruments and cash-value vouchers from the time the food instruments and cash-value vouchers are created to the time they are issued to participants, parents/caretakers, or proxies. For pre-printed food instruments or cash-value vouchers, these standards must include maintenance of perpetual inventory records throughout the State agency's jurisdiction; monthly physical inventory of food instruments or cash-value vouchers on hand throughout the State agency's jurisdiction; reconciliation of perpetual and physical inventories of food instruments and cash-value vouchers; and maintenance of all food instruments and cash-value vouchers under lock and key, except for supplies needed for immediate use. For EBT and print-on-demand food instruments and cash-value vouchers, the standards must provide for the accountability and security of the means to manufacture and issue such food instruments and cash-value vouchers. As most State agencies use EBT, FNS estimates that each State agency will take two hours to

develop and implement these standards. Thus, FNS estimates 178 burden hours for this provision (89 State agencies x 2 hours = 178 hours). This has not changed since the previous submission.

39. Section 246.12(q) requires the State agency to identify the disposition of all food instruments as either issued or voided and as either redeemed or unredeemed. Many State agencies currently track their food instrument inventories and disposition through their management information systems (MIS). FNS estimates it takes 40 hours to identify the disposition of all food instruments. The total annual burden estimated for this provision is 3,560 burden hours (89 State agencies x 40 burden hours). This has not changed since the last submission.
40. Section 246.12(u) requires State agencies to establish sanctions for participant violations. Participant sanctions may include disqualification from the Program for a period of up to one year. At the time the State agency notifies a participant of a disqualification, the State agency must advise the participant of the procedures to follow to obtain a fair hearing pursuant to § 246.9. FNS estimates that two percent of all WIC participants will be sanctioned each year (6,243,960 participants x 0.02 / 89 State agencies = 1,403.14 participant sanctions per State agency) which will take the State agency 5 minutes (0.0835 hours) to identify. Thus, FNS estimates 10,427.41 burden hours for this provision (89 State agencies x 1,403.14 participant sanctions per State agency = 124,879.80 responses x 0.0835 hours = 10,427.41 hours). This has not changed since the previous submission.
41. Section 246.12(v) allows State agencies to authorize farmers, farmers' markets, and/or roadside stands to accept cash-value vouchers for eligible fruits and vegetables. The State agency must enter into written agreements with all authorized farmers and/or farmers' markets. The agreement must be for a period not to exceed three years. The State agency must require farmers or farmers' markets to reapply at the expiration of their agreements and must provide farmers or farmers' markets with not less than 15 days advance written notice of the expiration of the agreement. FNS estimates that 1,085.37 farmers/markets will be authorized each year (3,289 total farmers/markets x 0.33 = 1,085.37/89 State agencies = 12.20 farmers/markets per State agency) which takes 40 minutes (0.668 hours) to complete. Thus, FNS estimates 725.03 burden hours for this provision (89 State agencies x 12.20 farmers per State agency = 1085.37 responses x 0.668 hours = 725.03 hours). This has not changed since the previous submission.
42. Section 246.12(v)(6) allow State agencies to disqualify a farmer or farmers' market for WIC Program abuse. The farmer or farmers' market has the right to appeal a denial of an application to participate, a disqualification, or a program sanction by the State agency. FNS estimates two percent of all farmers/markets will be disqualified (3,289 total farmers/markets x 0.02 = 65.78 farmers/markets / 89 State agencies = 0.74 farmers/markets per State agency), which will take five minutes (0.0835 hours) to complete. Thus, FNS estimates 5.49 burden hours for this provision (89 State agencies x 0.74 disqualifications per State agency = 65.78 responses x 0.0835 hours = 5.49 hours). This has not changed since the previous submission.

43. Section 246.12(bb) requires State agencies to follow and demonstrate compliance with operating rules, standards and technical requirements as established by the Secretary; and other industry standards identified by the Secretary. State agencies must establish policy permitting the replacement of EBT cards and the transfer of participant benefit balances within no more than seven business days following notice by the participant or proxy to the State agency. Finally, State agencies must establish procedures to provide customer service during non-business hours that enable participants or proxies to report a lost, stolen, or damaged card, report other card or benefit issues, receive information on the EBT food balance and receive the current benefit end date. FNS estimates that it takes each State agency three hours to establish these policies and procedures. Thus, FNS estimates 267 burden hours for this provision (89 State agencies x 3 hours = 267 hours). This has not changed since the previous submission.
44. Section 246.14(d) requires the State agency to seek FNS approval of costs for automated data processing systems (ADP), capital expenditures over \$25,000 and management studies performed by outside agencies, departments and consultants. FNS estimates that each year it receives an average of 10 requests for such approvals and that each request requires 160 burden hours for the State agency to document and submit. In addition, FNS estimates that an additional 10 State agencies will seek approval each year during this reporting period for EBT implementation. The total annual burden estimated for this provision 3,200 annual burden hours (20 requests per year x 160 hours per request). This has not changed since the last submission.
45. Section 246.16(b)(3)(i)&(ii) allow State agencies to back spend into the prior fiscal year up to an amount equal to one percent of its current year food grant and one percent of its current year NSA grant. With prior FNS approval, the State agency may also back spend food funds up to an amount equal to three percent of its current year food grant in a fiscal year for food costs incurred in the prior fiscal year. FNS will approve such a request only if FNS determines there has been a significant reduction in infant formula cost containment savings that affected the State agency's ability to maintain its participation level. FNS estimates that 27 State agencies will seek FNS approval for back spend which will take 2 hours to complete. Thus, FNS estimates 54 burden hours for this provision (27 State agencies x 2 hours = 54 hours). This has not changed since the previous submission.
46. Section 246.16(d) requires the State agency to allocate WIC funds to local agencies based on claims submitted at least quarterly by the local agency. FNS estimates that State agencies distribute funds to 1,810 local agencies 4 times per year (1,810 local agencies x 4 = 7,240 distribution of funds/89 State agencies = 81.35 distribution of funds per State agency). Each distribution of funds requires two burden hours to complete. FNS estimates the total annual burden for this provision to be 14,480 annual burden hours (89 State agencies x 81.35 distribution of funds per State agency = 7,240 responses x 2 hours = 14,480 hours). This has not changed since the previous submission.
47. Section 246.16(e)(2)(i)&(ii) states that the amount allocated to any State agency for food benefits in the current fiscal year shall be reduced if such State agency's food

expenditures for the preceding fiscal year do not equal or exceed 97 percent of the amount allocated to the State agency for such costs. However, State agencies may request a waiver of the performance standard. Likewise, FNS will reduce the State agency's Nutrition Services and Administration (NSA) grant for the next fiscal year if the State agency's current fiscal year per participant NSA expenditure is more than 10 percent higher than its per participant NSA grant. To avoid a reduction to its NSA grant level, the State agency may submit a "good cause" justification explaining why it exceeded the applicable limit on excess NSA expenditures. This justification must be submitted at the same time as the close-out report for the applicable fiscal year. FNS estimates that 30 State agencies will request a waiver of the performance standard or submit a "good cause" justification to avoid a reduction in its grant level which will take 1.5 hours to complete. Thus, FNS estimates 45 burden hours for this provision (30 State agencies x 1.5 hours = 45 hours). This has not changed since the previous submission.

48. Section 246.16a requires all State agencies to continuously operate a cost containment system for infant formula, with some exceptions. All 79 State agencies operating a cost containment system currently utilize a single-supplier competitive system, in which the State agency solicits sealed bids from infant formula manufacturers to supply and provide a rebate for infant formulas. The State agency must conduct the procurement in a manner that maximizes full and open competition consistent with the requirements of this section. Regulations do not outline how frequently a State agency must renew their infant formula cost containment contracts. On average, State agency infant formula cost containment contracts are in effect for 5 years and take approximately 1,968 hours to complete solicitation or re-solicitation. Thus, FNS estimates 31,094 burden hours for this provision (79 State agencies / 5 years = 15.80 State agencies per year x 1,968 hours = 31,094 hours). This has not changed since the previous submission.
49. Section 246.16a(f) allows State agencies to request a postponement of the requirement to continuously operate a cost containment system when it has taken timely and responsible action to implement a cost containment system before its current system expires but has been unable to do so due to procurement delays, disputes with FNS concerning cost containment issues during the State Plan approval process or other circumstances beyond its control. The written postponement request must be submitted to FNS before the expiration of the current system. FNS estimates that two State agencies will request a postponement each year which will take eight hours to complete. Thus, FNS estimates 16 burden hours for this provision (2 State agencies x 8 hours = 16 hours). This has not changed since the previous submission.
50. Section 246.16a(g)(1)-(4) allows State agencies to implement cost containment systems for any WIC food other than infant formula. The State agency must provide notification to FNS by means of the State agency's State Plan; provide a minimum of 30 days between the publication of the solicitation and the date on which the bids are due, unless exempted by the Secretary; publicly open and read all bids aloud on the day the bids are due; and issue separate solicitations for authorized foods if any alliance served a monthly average of more than 100,000 infants during the preceding 12-month period. FNS estimates 2 State agencies will implement cost containment systems for WIC foods other

than infant formula which will take 480 hours to complete. Thus, FNS estimates 960 burden hours for this provision (2 State agencies x 480 hours = 960 hours). This has not changed since the previous submission.

51. Section 246.16a(j) 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. FNS estimates that incorporating minimum required remedies in infant formula cost containment contracts would require a one-time 40 hour burden per State agency, or the equivalent of a full work week. Therefore, FNS estimates that beginning in February 2024, implementing the *WIC: Implementation of the Access to Baby Formula Act of 2022 and Related Provisions* rule results in a one-time increase in 2,960 burden hours to State agencies' reporting burden (79 State agencies x 40 burden hours = 2,960 burden hours). This burden has not changed since the previous submission.

52. Section 246.17(c)(1) requires FNS to provide written notification of disqualification to all 89 State agencies that fail to comply with Program requirements. This provision also requires the State agency to provide written notification to local agencies that it determines have failed to comply with Program requirements.

FNS estimates that 10 local agencies will be disqualified per year. FNS further estimates that preparing and providing a written notice of disqualification requires eight burden hours per notice. FNS estimates the total annual burden for this provision to be 80 burden hours (10 local agency disqualifications per year / 89 State agencies = 0.11 responses per State agency; 89 State agencies x 0.11 = 10 responses x 8 hours per notice = 80). This burden has not changed since the previous submission.

53. Section 246.18 requires State agencies to provide full administrative reviews to vendors and farmers that appeal adverse actions. FNS estimates that 1,048 vendors and 2 percent of all farmers (3,289 x 0.02 = 65.78 farmers) will have adverse actions against them and of those vendors and farmers, 2 percent will appeal their adverse actions (0.02 x [1,048 vendors + 65.78] / 89 State agencies = 0.25 appeals per State agency), which will take 2 hours to complete. Thus, FNS estimates 44.55 burden hours for this provision (89 State agencies x 0.25 appeals per State agency = 22.28 responses x 2 hours = 44.55 hours). This has not changed since the previous submission.

54. Section 246.19(a)(2) requires the State agency to develop and submit a corrective action plan in response to an FNS management evaluation (ME) report. FNS also requests that State agencies respond to observations, also included in the ME report. FNS' goal is to conduct Target Area MEs on a three-year cycle with one-third (approximately 30) of State agencies being evaluated per year (0.33 x 89 = 29.37 State agencies per year). This

timeframe has changed from the previous submission. Previously, Targeted MEs were conducted on a four-year cycle; with this revision it is a three-year cycle. FNS estimates that each corrective action plan takes approximately 30 hours to develop and each observation response takes about 3 hours.

FNS estimates 881.1 annual burden hours for this provision ($0.33 \times 89 = 29.37$ State agencies \times 30 hours per corrective action plan = 881.1). This burden has not changed since the previous submission.

Additionally, FNS estimates 17 State agencies will respond to observations each year which will take 3 hours to complete. Thus, FNS estimates 51 burden hours for this provision (17 State agencies \times 3 hours = 51 hours). This has not changed since the previous submission.

55. Section 246.19(b)(3) requires State agencies to conduct monitoring reviews of each local agency at least once every two years (1,810 local agencies / 2 years = 905 local agencies reviewed each year / 89 State agencies = 10.17 local agencies per State agency) which will take two hours to complete. Such reviews shall include on-site reviews of a minimum of 20 percent of the clinics in each local agency or one clinic, whichever is greater. The State agency may conduct such additional on-site reviews as the State agency determines to be necessary in the interest of the efficiency and effectiveness of the program. Thus, FNS estimates 1,810 burden hours for this provision (89 State agencies \times 10.17 local agencies per State agency = 905 responses \times 2 hours = 1,810 hours). This has not changed since the previous submission.
50. Section 246.19(b)(5) requires the State agency to review target areas specified by FNS during local agency reviews. Section 246.19(b)(3) requires the State agency to conduct monitoring reviews of each local agency at least once every two years, which means that each year, half of all local agencies (1,810 local agencies / 2 years = 905 local agencies) will be reviewed. FNS estimates that the State agency will be required to address targeted areas during local agency reviews once every four years (905 local agencies / 4 years = 226.25 local agencies / 89 State agencies = 2.54 local agencies per State agency). FNS further estimates that it takes two hours for the State agency to address targeted areas during local agency reviews and report the results of the targeted reviews to FNS. FNS estimates 452.5 total annual burden hours for this provision (89 State agencies \times 2.54 local agencies per State agency = 226.25 responses \times 2 hours = 452.5 hours). This has not changed since the previous submission.
56. Section 246.20(a)(2) requires the State agency to develop and submit a corrective action plan to FNS addressing the findings of USDA Office of the Inspector General (OIG) State or local agency audits. FNS estimates that OIG performs one audit of WIC State and local agencies each year. FNS further estimates that each audit response requires 40 hours to complete. Thus, FNS estimates the total annual burden for this provision to be 40 burden hours (1 audit per year \times 40 hours per audit response). This has not changed since the last submission.

57. Section 246.20(b) requires State agencies to obtain annual audits in accordance with 2 CFR part 200, subpart F, and appendix XI, Compliance Supplement, and USDA implementing regulations 2 CFR parts 400 and 415. In addition, State agencies must require local agencies under their jurisdiction to obtain audits in accordance with 2 CFR part 200, subpart F, and appendix XI, Compliance Supplement, and USDA implementing regulations 2 CFR parts 400 and 415. Each State agency shall make all State or local agency sponsored audit reports of Program operations under its jurisdiction available for the Department's review upon request. FNS estimates this takes eight hours to complete. Thus, FNS estimates 712 burden hours for this provision (89 State agencies x 8 hours = 712 hours). This has not changed since the previous submission.
58. Section 246.22(b)(2) allows State agencies to appeal a sanction against a State agency be afforded a hearing or review by an FNS Administrative Review Officer. The State agency must submit three sets of the following information to the FNS Administrative Review Officer: a clear, concise identification of the issue(s) in dispute; the State agency's position with respect to the issue(s) in dispute; the pertinent facts and reasons in support of the State agency's position with respect to the issue(s) in dispute and a copy of the specific sanction notice provided by FNS; all pertinent documents, correspondence and records which the State agency believes are relevant and helpful toward a more thorough understanding of the issue(s) in dispute; the relief sought by the State agency; the identity of the person(s) presenting the State agency's position when a hearing is involved; and a list of prospective State agency witnesses when a hearing is involved. FNS estimates that each year, one State agency will appeal a sanction which will take two hours to complete. Thus, FNS estimates two burden hours for this provision (1 State agency x 2 hours = 2 hours). This has not changed since the previous submission.
59. Section 246.23(a)(3) allows State agencies the opportunity to submit evidence, explanation or information concerning alleged instances of noncompliance or diversion before a final determination is made in such cases if issued a formal claim against the State agency. FNS estimates that each year, one State agency will appeal a claim which will take two hours to complete. Thus, FNS estimates two burden hours for this provision (1 State agency x 2 hours = 2 hours). This has not changed since the previous submission.
60. Section 246.26(h)(3) requires State or local agencies disclosing the information to enter into a written agreement with the other public organization or, in the case of a non-WIC use by a State or local WIC agency, the unit of the State or local agency that will be using the information. FNS estimates that a quarter of all State agencies (89 State agencies x 0.25 = 22.25) will enter into written agreements which will take 15 minutes (0.25 hours) to complete. Thus, FNS estimates 5.56 burden hours for this provision (22.25 State agencies x 0.25 hours = 5.56 hours). This has not changed since the previous submission.

AFFECTED PUBLIC: INDIVIDUALS & HOUSEHOLDS:
APPLICANTS FOR PROGRAM BENEFITS

1. Sections 246.7(i) and 246.11(e) require that certification data including income and nutritional risk be collected from all participants and recorded by the local agency on a form(s) provided by the State agency (usually in the management information system (MIS)). WIC Program regulations permit local agencies to accept an applicant's documented participation in certain other means-tested programs as evidence of income eligibility for the WIC Program. This provision helps to reduce the administrative burden on WIC local agency staff and eliminates duplication for program applicants. The income eligibility is established by applicants providing written documentation to the local agency either in the form of a benefit letter, identification card or in the form of an MIS check. Applicants or certain family members that receive Medicaid, SNAP, TANF or State-administered programs with income criteria at or below 185 percent of the federal poverty guidelines are not subject to the standard WIC income eligibility determination.

Nutritional risk is determined by a competent professional authority on the staff of the local agency through a nutritional assessment. This determination may be based on referral data submitted by a competent professional authority not on the staff of the local agency. At a minimum, height or length and weight measurements and a hematological test for anemia such as a hemoglobin or hematocrit shall be performed and/or documented in the applicant's file at the time of certification. In addition, medical/health history, dietary intake and environmental (e.g., homelessness and migrancy) information is collected to determine all relevant nutrition risk(s).

Though some information is collected for the entire household, some documentation (such as identification) is required for each WIC applicant. Additionally, infants less than six months of age may be certified through the month of their first birthday and children may be certified for one year.

Currently, FNS estimates that providing certification data to the local agency requires 25 minutes (0.4175 hours) on average per participant; ten minutes to provide their certification data and 15 minutes to receive their initial nutrition education. **Due to the program changes in the final rule, FNS estimates that the certification will take an additional three minutes for clinic staff to communicate the food package changes to each participant, for a total of 28 minutes (0.4667 hours) for certification per participant.**

Additionally, communicating the food package changes to current participants will require an estimated one-time five-minute explanation per participant.

Monthly WIC participation is 6,243,960 (1,379,126 women, 1,464,744 infants, and 3,400,090 children).

- **FNS estimates 644,879.32 hours for the certification of women (1,379,126 participants x 1 time per year = 1,379,126 x 0.4676 hours per response). This**

is an increase of 69,094.21 hours since the previous submission due to a program change due to the final rule.

- FNS estimates 1,589,882.08 hours for the certification of children (3,400,090 participants x 1 time per year = 3,400,090 x 0.4676 hours per response). This is an increase of 170,344.51 hours since the previous submission due to a program change due to the final rule.
 - FNS estimates 684,914.29 hours for the certification of infants (1,464,744 participants x 1 time per year = 1,464,744 x 0.4676 hours per response). This is an increase of 73,383.67 hours since the previous submission due to a program change due to the final rule.
 - FNS estimates 521,370.66 burden hours to explain the changes to the food package in this rule once to all WIC participants (6,243,960 participants x 1 explanation = 6,243,960 total explanations x 5 minutes (0.0835) hours per explanation = 521,370.66 total hours. This one-time increase is due to a program change due to the final rule.
2. Section 246.7(o) requires all applicants to be physically present at each WIC certification, with some exceptions. FNS estimates 20 minutes (0.334 hours) for round trip travel time, including time to park, if applicable. Thus, FNS estimates 2,085,482.64 burden hours for this provision (6,243,960 participants x 0.334 hours = 2,085,482.64 hours). This has not changed since the previous submission.

Because Section 246.7(o) requires all applicants to physically present at the time of certification, FNS estimates a total time at the clinic to be 38 minutes (0.5845 hours) plus an additional ten minutes to collect documentation ahead of each visit (0.167 hours), for a total of 48 minutes (0.75 hours). However, Section 246.7(i) already accounts for 28 minutes of an applicant's time for certification. Therefore, this provision estimates an additional 20 minutes (0.334 hours) to account for additional time not already captured during applicants' certifications, including time needed to read instructions, and answer questions. Thus, FNS estimates 2,085,482.64 burden hours for this provision. This has not changed since the previous submission.

3. Section 246.9 allows participants to appeal a State or local agency action that results in a claim against the individual for repayment of the cash value of improperly issued benefits or results in the individual's denial of participation or disqualification from the Program. FNS estimates that two percent (0.02) of all participants will be issued a claim, and two percent of those participants will appeal that claim (6,243,960 x 0.02 x 0.02 = 2,497.58 participant appeals) which will take two hours to complete. Thus, FNS estimates 4,995.17 burden hours for this provision (2,497.58 participants x 2 hours = 4,995.17 hours). This has not changed since the previous submission.
4. Section 246.10(d)(1) requires that medical documentation must be obtained from the parents or guardians of infant participants in order for the Program to provide these infants participants with infant formula not covered by the State agency's infant formula rebate contract. FNS estimates that one percent (1,464,744 total infants x 0.01 = 14,647.44 infants) of all infant certifications require an additional two minutes (0.0334

hours) for the documentation required to issue an infant formula that is not covered by the State agency's infant formula rebate contract. FNS estimates 489.22 hours for this provision (14,647.44 infants x 0.0334 hours = 489.22 hours). This has not changed since the previous submission.

This section also requires additional medical documentation for the issuance of the following supplemental foods: paragraph (ii) Any infant formula prescribed to a child or adult who receives Food Package III; paragraph (iii) Any exempt infant formula; paragraph (iv) Any WIC-eligible medical food; paragraph (v) Any authorized supplemental food issued to participants who receive Food Package III. FNS estimates that it takes an additional three minutes (0.0501 hours) for the documentation required for the issuance of these foods.

FNS estimates that approximately one percent of participants (6,243,960 participants x 0.01 = 62,439.60) will be issued supplemental foods under Food Package III; one percent of children (3,400,090 children x 0.01 = 34,000.90) will be authorized soy-based beverage or tofu under Food Package IV; and one percent of women (1,379,126 women x 0.01 = 13,791.26) will be authorized tofu and cheese in excess of the maximum substitution rate under Food Packages V and VII. FNS estimates 11,045.22 annual burden hours for this provision (62,439.60 participants + 34,000.90 children + 13,791.26 women = 110,231.76 participants x 0.0501 x 2 times per year). This has not changed since the previous submission.

5. Section 246.11(e) requires State agencies to provide nutrition education including breastfeeding promotion and support, to all participants. On average, participants receive nutrition education twice a year, the first of which occurs during the certification appointment and is included in the 246.7(i) burden estimate. Nutrition education takes 15 minutes (0.25 to complete). Thus, FNS estimates 1,560,990 burden hours for this provision (6,243,960 participants x 0.25 hours = 1,560,990 hours). This has not changed since the previous submission.
6. Section 246.12(r)(4) requires participants, parents and caretakers of infant and child participants, and proxies to pick up food instruments and cash-value vouchers in person when scheduled for nutrition education or for an appointment to determine whether participants are eligible for a second or subsequent certification period. However, in all other circumstances the State agency may provide for issuance through an alternative means such as EBT or mailing, unless FNS determines that such actions would jeopardize the integrity of program services or program accountability.

State agencies can issue up to a three-month supply of benefits to a participant at one time. On average, WIC households have two members that are WIC participants,¹ so only one trip would need to be made per household to pick up food instruments (6,243,960 total participants / 2 = 3,121,980 participants who have to pick up food instruments). FNS estimates that currently, participants in 17 State agencies with an offline EBT system are required to pick up benefits in person once every three months, and that one of these instances corresponds to an annual recertification appointment (3,121,980 participants

who have to pick up food instruments / 89 State agencies = 35,078.43 participants per State agency x 17 offline State agencies = 596,333.25 participants in offline State agencies). Additionally, FNS estimates that in 72 State agencies with an online EBT system, only new participants are required to pick up their EBT card in person, and that this would occur outside of the certification appointment (3,121,980 participants who have to pick up food instruments / 89 State agencies = 35,078.43 participants per State agency x 72 offline State agencies = 2,525,646.74 participants in online State agencies). On average, participants spend 20 minutes in round trip travel to the clinic. FNS estimates picking up food instruments in person requires 30 minutes (0.5 hours) per trip: 20 minutes of round-trip travel time and 10 minutes to obtain the food instruments, which includes any wait times.

Therefore, FNS estimates that currently participants in offline State agencies spend 894,499.89 hours each year picking up food instruments in person (596,333.25 participants in offline State agencies x 3 pick-ups per year = 1,788,999.78 responses x 0.50 hours = 894,499.89 hours), and participants in online State agencies spend 1,262,823.37 hours each year picking up food instruments (2,525,646.74 x 1 pick up per year = 2,525,646.74 responses x 0.50 hours = 1,262,823.37). This has not changed since the previous submission.

AFFECTED PUBLIC: BUSINESS: RETAIL VENDORS
(WIC-AUTHORIZED RETAIL VENDORS AND NONPROFIT BUSINESSES)

1. Section 246.5(b) requires each organization interested in being authorized as a local agency to submit an application to the State agency. After receipt of the application the State agency is required to 1) provide written notification if an application is complete and identify the additional information needed, or 2) provide written notification of approval or disapproval. The average local agency agreement is for two years. Approximately 30 percent of all local agencies are nonprofit businesses (1,810 local agencies x 0.30 = 543 local agencies / 2 years = 271.5). Each application requires two burden hours to complete. Thus, FNS estimates 543 burden hours for this provision (271.5 local agencies x 2 hours = 543 hours). This has not changed since the previous submission.
2. Section 246.6 requires the State agency to enter into a signed agreement with each local agency, health and human service agency, and private physician that performs WIC functions. The average local agency agreement is for two years; therefore, FNS estimates each year that half of all local agencies (905) sign agreements with the State agency. Each agreement requires 1.5 burden hours to complete. Approximately 30 percent of all local agencies are nonprofit businesses (905 x 0.30 = 271.5). Thus, FNS estimates 407.25 annual burden hours for this provision (271.5 local agencies x 1.5 burden hours per agreement). This has not changed since the previous submission.
3. Section 246.7(f)(2)(iii)(A) allows the State agency to extend the 10-day period of notification of eligibility for special nutritional risk applicants to 15 days when the local agency provides written justification of the need for such an extension. Currently, all State agencies have developed policies under which such an extension may be provided. FNS estimates that each year one-sixth of all local agencies make written requests for such extensions. Each request for an extension requires 15 minutes (0.25 hours) to complete. For the 30 percent of local agencies that are non-profit businesses (1,810 x 0.30 = 543), FNS estimates 22.63 annual burden hours for this provision (543 / 6 = 90.5 local agencies x 0.25 burden hours per request). This has not changed since the previous submission.
4. Sections 246.7(b),(i),(n) and 246.11 require that pertinent certification data be collected and recorded by the local agency on a form (or forms) provided by the State agency (usually in the form of computer software) and that participants be notified of their rights and responsibilities, including notification of termination for failure to pick up food instruments, notification of disqualification and notification of expiration of each certification period. Additionally, State and local agencies provide WIC Program applicants and participants or their designated proxies with information on other health-related and public assistance programs, and when appropriate, refer applicants and participants to such programs. When a State agency determines that screening is necessary to fulfill the referral requirements in this part, the State agency must require screening for the use of drugs and other harmful substances. Finally, WIC participants and applications receive their initial nutrition education including breastfeeding

promotion and support, at the time of certification.

During the certification process participants are assigned a food package based on their nutrition risk assessment and categorical eligibility. Due to the program (food package) changes in the final rule, FNS estimates that it will take an additional three minutes per participant during the certification (the current estimate is 25 minutes per participant) for clinic staff to review procedures to ensure that they prescribe the food package correctly with the changes. Therefore, in total, FNS estimates that the collection of certification data, the provision of appropriate notifications, and reviewing the food packages require 28 minutes (0.4676 hours) per participant.

Additionally, communicating the food package changes to current participants would require an estimated one-time five-minute explanation per participant.

For the 30 percent of all local agencies that are nonprofit businesses (1,810 x 0.30 = 543 local agencies):

- **FNS estimates 193,463.80 annual burden hours for the certification of women or adults (543 local agencies x [1,379,126 women or adult applicants x 0.30 / 543 = 761.95 certifications per local agency] = 413,737.8 responses x 0.4676 hours = 193,463.80 hours). This is an increase of 20,728.26 hours since the previous submission due to a program change due to the final rule.**
 - **FNS estimates 476,964.63 annual burden hours for the certification of children (543 local agencies x [3,400,090 children applicants x 0.30 / 543 = 1,878.50 child certifications per local agency] = 1,020,027 responses x 0.4676 hours = 476,964.63 hours). This is an increase of 51,103.35 hours since the previous submission due to a program change due to the final rule.**
 - **FNS estimates 205,474.29 annual burden hours for the certification of infants (543 local agencies x [1,464,744 x 0.30 / 543 = 809.25 infant certifications per local agency] = 439,423.20 responses x 0.4676 hours = 205,474.29 hours). This is an increase of 22,015.10 hours since the previous submission due to a program change due to the final rule.**
 - **FNS estimates 156,411.20 burden hours to explain the changes to the food package in this rule once to all current WIC participants (6,243,960 participants / 1,810 = 3,449.70 per local agency x 543 non-profit local agencies = 1,873,188 total explanations x five minutes (0.0835 hours) per explanation = 156,411.20 hours. This one-time increase to the non-profit WIC local agency reporting burden is due to a program change due to the final rule.**
5. Section 246.7(k) requires the State agency to ensure that Verification of Certification (VOC) cards are issued to participating migrants and to other participants who are likely to relocate during the certification period. Based on the number of participants with no

priority reported, FNS estimates that three percent of participants receive VOC documentation. FNS further estimates that issuing VOCs requires five minutes (0.0835 burden hours). For the 30 percent of all local agencies that are nonprofit businesses ($1,810 \times 0.30 = 543$), FNS estimates the total annual burden for this provision to be 4,692.34 burden hours ($543 \text{ local agencies} \times [6,243,960 \text{ participants} \times 0.03 \times 0.30 / 543 = 103.49 \text{ VOC issuances per local agency}] = 56,195,64 \text{ responses} \times 0.0835 \text{ hours} = 4,692.34 \text{ hours}$). This has not changed since the last submission.

6. Section 246.10(b)(2)(i) requires each State agency to provide to local agencies a list of foods that are acceptable for use in the Program in their jurisdiction. **Due to the changes in the WIC food packages in the final rule, the food lists will be revised. Local agencies will need to attend a State agency training on the revised food lists, which FNS estimates will require one hour. FNS estimates an increase of 543 burden hours for non-profit WIC local agencies to attend the State agency training ($543 \text{ local agencies} \times 1.00 \text{ hour} = 543 \text{ hours}$). This one-time increase is due to a program change due to the final rule.**
7. Section 246.10(d)(1) requires local agencies to obtain medical documentation in order to provide participants with infant formula not covered by the State agency's infant formula rebate contract. FNS estimates that one percent (0.01) of all infant certifications require an additional two minutes (0.0334 hours) for the documentation required to issue an infant formula that is not covered by the State agency's infant formula rebate contract. For the 30 percent of all local agencies that are nonprofit businesses ($1,810 \times 0.30 = 543$), FNS estimates 146.77 total annual burden hours for this provision ($543 \text{ local agencies} \times [1,464,744 \text{ infants} \times 0.01 \times 0.30 / 543 = 8.09 \text{ medical documentations per local agency}] = 4,349.23 \text{ responses} \times 0.0334 \text{ hours} = 146.77 \text{ hours}$). This has not changed since the last submission.
8. Sections 246.11(d)(1) and 246.7(b) require local agencies to make nutrition education, including breastfeeding promotion and support, available to all adult participants, and to parents or caretakers of infant and child participants, and whenever possible and appropriate, to child participants, which takes 15 minutes (0.25 hours) to complete. Nutrition education may be provided through the use of individual or group sessions. Educational materials designed for Program participants may be utilized to provide education to pregnant, postpartum, and breastfeeding women and to parents or caretakers of infants and children participating in local agency services other than the program. For the 30 percent of all local agencies that are nonprofit businesses ($1,810 \times 0.30 = 543$), FNS estimates 468,297 annual burden hours for this provision ($543 \text{ local agencies} \times [6,243,960 \text{ participants} \times 0.30 / 543 = 3,449.70 \text{ nutrition education per local agency}] = 1,873,188 \text{ responses} \times 0.25 \text{ hours} = 468,297 \text{ hours}$). This has not changed since the last submission.
9. Section 246.11(d)(2) requires each local agency to develop and submit an annual nutrition education plan to the State agency. FNS estimates that 40 burden hours are needed for each local agency to comply with this provision. For the 30 percent of all local agencies that are nonprofit businesses ($1,810 \times 0.30 = 543$), FNS estimates 21,720 total

annual burden hours for this provision (543 local agencies x 40 hours per local agency = 21,720). This has not changed since the last submission.

10. Section 246.12(g)(4)(i) requires State agencies to collect information needed to determine whether currently authorized vendors and new vendor applicants derive or may be expected to derive more than 50 percent of their annual food sales revenue from WIC food instruments. FNS estimates two vendor hours per response for this requirement.

FNS annually provides each State agency with a report comparing the WIC redemptions to the redemptions of the Supplemental Nutrition Assistance Program (SNAP) for each of its vendors which is authorized by SNAP. If a vendor's SNAP redemptions exceed its WIC redemptions, that vendor is considered to be a regular vendor, not an above-50-percent vendor. The most recent report shows that only 840 WIC authorized vendors have more WIC redemptions than SNAP redemptions. These are the only WIC authorized vendors from which WIC State agencies need to obtain further documentation.

FNS estimates 1,680 burden hours for vendors for this provision (840 vendors x 2 hours). This has not changed since the last submission.

11. Section 246.12(g)(4)(ii)(B) requires State agencies to collect the shelf prices for WIC-approved foods from authorized retail vendors twice annually unless they have received an exemption from this provision from FNS. FNS estimates that 79 WIC State agencies must collect shelf prices from vendors. FNS estimates that each vendor would need two hours to report shelf prices (one hour x 2 times per year). **FNS estimates 132,318.79 annual burden hours for this provision (37,267 vendors x (79/89) State agencies = 33,079.70 x 2 times per year = 66,159.39 x 2 burden hours per response). This is a decrease of 532.58 hours since the previous submission due to an estimated decrease in the number of vendors. This decrease is due to a program change.**

12. Section 246.12(g)(5) requires State agencies to conduct an on-site visit prior to or at the time of a vendor's initial authorization. FNS estimates that, on average, each State agency authorizes 17 new vendors each year (89 State agencies x 17 new vendors per State agency = 1,513 total new vendors). Each visit takes 40 minutes (0.668 hours) to confirm information included in the vendor's application. Thus, FNS estimates 1,010.68 burden hours for this provision (1,513 vendors x 0.668 hours = 1,010.68 hours). This has not changed since the last submission.

13. Section 246.12(h) requires the State agency to enter into written agreements with retail vendors. State agencies require the vendor to submit a signed vendor agreement with the completed application form. Retail vendor agreements can be for up to three years; therefore, FNS estimates that each year one-third of all retail vendors will submit application/agreement forms. FNS further estimates that each application/agreement form requires one hour for the vendor to complete.

Retail vendor agreements can be for up to three years; therefore, FNS estimates that each year one-third of all retail vendors will submit application/agreement forms

(37,267 total vendors x 0.33 = 12,298.11 vendors). FNS further estimates that each application/agreement form requires one hour for the vendor to complete. Therefore, FNS estimates 12,298.11 burden hours for this provision (12,298.11 vendors x 1 hour = 12,298.11 hours). This results in a decrease of 49.50 hours since the previous submission, from 12,347.61 to 12,298.11 hours, due to the estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.

14. Section 246.12(h)(3)(xiii) requires vendors to inform and train cashiers and other staff on program requirements. FNS estimates that each vendor will train staff annually, which takes one hour to complete. **Thus, FNS estimates 37,267 annual burden hours for this provision (37,267 vendors x 1 hour = 37,267 hours). This is a decrease of 150 hours since the previous submission due to an estimated decrease in the number of vendors due to the final rule. This decrease is due to a program change.**
15. Section 246.12(h)(8)(i) requires above-50-percent vendors to request approval from their WIC State agencies for incentive items which these vendors may provide to WIC participants or other customers. There are currently 973 above-50-percent vendors authorized by 10 WIC State agencies. Of these 10 State agencies, 4 allow above-50-percent vendors to give incentive items and will collect this information. FNS estimates that this reporting burden will involve one hour per response. FNS estimates an annual reporting burden of 340 hours for vendors as a result of this provision (850 vendors x (4 above-50-percent vendors / 10 State agencies) x 1 hour per response = 340 annual burden hours). This has not changed since the previous submission.
16. Section 246.12(i) requires at least one representative of each vendor to receive annual training. Prior to or at the time of a vendor's initial authorization, and at least once every three years thereafter, the training must be in an interactive format that includes a contemporaneous opportunity for questions and answers. Examples of acceptable vendor training include on-site cashier training, off-site classroom-style train-the-trainer or manager training, a training video, and a training newsletter. All vendor training must be designed to prevent program errors and noncompliance and improve program service. FNS estimates that annual vendor training takes two hours to complete. **Thus, FNS estimates 74,534 annual burden hours for this provision (37,267 vendors x 2 hours = 74,534 hours). This is a decrease of 300 hours since the previous submission due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.**
17. Section 246.12(v) requires farmers and farmers' markets to enter into written agreements with State agencies in order to become authorized to accept cash-value vouchers or benefits which takes one hour to complete. The agreement must be for a period not to exceed three years, with a third of farmers/markets authorized each year (3,289 farmers/markets x 0.33 = 1,085.37 farmers authorized annually). The State agency must require farmers or farmers' markets to reapply at the expiration of their agreements and must provide farmers or farmers' markets with not less than 15 days advance written notice of the expiration of the agreement. FNS estimates 1,085.37 annual burden hours

for this provision ($1,085.37 \times 1 \text{ hour} = 1,085.37 \text{ hours}$). This has not changed since the previous submission.

18. Section 246.12(v)(1)(v) requires farmers and farmers' markets to accept training on cash-value voucher procedures and provide training to any employees with cash-value voucher responsibilities on such procedures, which takes two hours to complete. Thus, FNS estimates 6,578 annual burden hours for this provision ($3,289 \text{ farmers/markets} \times 2 \text{ hours} = 6,578 \text{ hours}$). This has not changed since the previous submission.
19. Section 246.16a requires that State agencies must continuously operate a cost containment system for infant formula, with some exceptions. All State agencies that must operate a cost containment system for infant formula use a single-supplier competitive system. There are currently three suppliers that supply and provide a rebate for infant formulas. Rebates are issued to State agencies each month which takes suppliers approximately four hours to complete. Thus, FNS estimates 144 annual burden hours for this provision ($3 \text{ suppliers} \times 12 \text{ months} = 36 \text{ responses} \times 4 \text{ hours} = 144 \text{ hours}$). This has not changed since the previous submission.
20. Section 246.16a(j) 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 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 4 burden hours for this provision ($1 \text{ infant formula manufacturer} \times 4 \text{ burden hours} = 4 \text{ burden hours}$). This has not changed since the previous submission.
21. Section 246.18(a)(1) allows vendors to appeal adverse actions. FNS estimates that 1,048 vendors receive adverse actions annually and that 2 percent of those vendors will appeal those adverse actions ($1,048 \times 0.02 = 20.96 \text{ vendors}$), which takes 2 hours to complete. Thus, FNS estimates 41.92 annual burden hours for this provision ($20.96 \text{ vendors} \times 2 \text{ hours} = 41.92 \text{ hours}$). This has not changed since the previous submission.
22. Section 246.18(a)(4) allows farmers and farmers' markets to appeal an action of the State agency denying its application to participate, imposing a sanction, or disqualifying it from participation in the program. FNS estimates that two percent of all farmers/markets will receive an adverse action, and that two percent of those farmers/markets will appeal their adverse action ($3,289 \times 0.02 \times 0.02 = 1.32 \text{ farmers/markets}$), which will take two hours to complete. Thus, FNS estimates 2.63 annual burden hours for this provision ($1.32 \times 2 \text{ hours} = 2.63 \text{ hours}$). This has not changed since the previous submission.

RECORDKEEPING REQUIREMENTS

AFFECTED PUBLIC: STATE AND LOCAL AGENCIES (INCLUDING INDIAN TRIBAL ORGANIZATIONS AND US TERRITORIES)

1. Section 246.4(d) requires State agencies to keep on file for public inspection a copy of the approved State Plan or the WIC portion of the State agency's composite plan of operations. FNS estimates that it will take each State agency ten minutes (0.167 hours) to complete this filing. Thus, FNS estimates 14.86 annual burden hours for this provision (89 State agencies x 0.167 hours = 14.86 hours). This has not changed since the last submission.
2. Sections 246.4(a)(30) and 246.16a(j) require State agencies to 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 infant formula manufacturers are required 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 takes 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 30 burden hours for this provision (15 State agencies x 2 burden hours = 30 burden hours). This has not changed since the previous submission.
3. Section 246.10(d)(1) requires medical documentation for the issuance of the following supplemental foods: paragraph (ii) Any infant formula prescribed to a child or adult who receives Food Package III; paragraph (iii) Any exempt infant formula; paragraph (iv) Any WIC-eligible medical food; (v) Any authorized supplemental food issued to participants who receive Food Package III. FNS estimates that it will take one minute (0.0167 per record) for each clinic (10,000 clinics) to file the medical documentation provided by participants. Approximately 70 percent of all local agencies are government entities (1,810 x 0.7 = 1,267). Each local agency will record medical documentation from clinics twice a year (10,000 clinics / 1,267 local agencies x 0.70 x 2 = 11.05 records per local agency). Thus, FNS estimates 233.8 annual burden hours (1,267 local agencies x 11.05 records per local agency = 14,000 responses x 0.0167 hours = 233.8 hours). This has not changed since the last submission.
4. Section 246.12(g)(10) requires WIC State agencies to annually provide authorized WIC retail vendors a list of State-licensed infant formula wholesalers, distributors and retailers, and FDA-registered infant formula manufacturers. FNS has provided the list of FDA-registered manufacturers to State agencies. A State agency would contact the licensing agency for its jurisdiction to obtain a list of the other suppliers. A State agency

could satisfy this requirement by linking its website to the list of licensed suppliers on the website of its jurisdiction's licensing agency. The total annual burden hours for the list requirement are estimated at 4,450 (89 State agencies x 50 burden hours per response = 4,450 total annual burden hours). This has not changed since the previous submission.

5. Section 246.12(h)(1)(i) requires the State agency to enter into written agreements with retail vendors. State agencies require the vendor to submit a signed vendor agreement with the completed application form. Retail vendor agreements can be for up to three years; therefore, FNS estimates that one-third of all retail vendors will submit applications each year. FNS further estimates that each application requires one hour to collect and record in the State agency's recordkeeping system; most State agencies use an electronic MIS for this purpose.

FNS estimates 12,298.11 annual burden hours for this provision for State agencies [89 State agencies x (37,267 vendors x 0.33 = 12,298.11 / 89 State agencies = 138.18 vendors per State agency) = 12,298.11 responses x 1 hour = 12,298.11 hours]. This results in a decrease of 49.50 hours since the previous submission, from 12,347.61 to 12,298.11 hours due to the estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.

6. Section 246.12(h)(8)(i) requires WIC State agencies to establish a process for approving incentive items that above-50-percent vendors may provide to WIC participants or other customers. There are currently 973 above-50-percent vendors authorized by 10 WIC State agencies. Of these 10 State agencies, only 4 allow above-50-percent vendors to give incentive items and would need to collect this information and in turn would need to maintain the records. FNS estimates that this recordkeeping burden will involve one hour per response. FNS estimates an annual burden of 389.2 hours as a result of this provision (973 vendors x (4 above-50-percent vendors / 10 State agencies) x 1 hour per response = 389.2 annual burden hours). This has not changed since the previous submission.
7. Section 246.12(i)(4) requires the State agency to document the content of its vendor training and the participation of its vendors in the training. FNS estimates that documenting the content of and participation in vendor training takes the State agency two hours per year. FNS estimates 178 annual burden hours for this provision (89 State agencies x 2 hours per year). This has not changed since the previous submission.
8. Section 246.12(j)(6) requires the State agency to document the routine monitoring visits it conducts on its vendors. **Section 246.12(j)(2) requires the State agency to conduct routine monitoring visits of five percent (0.05) of its vendors each year (37,267 vendors x 0.05 = 1,863.35 vendors / 89 State agencies = 20.94 vendors per State agency). FNS estimates that each routine monitoring visit takes 30 minutes (0.5 hours) to document. FNS estimates 931.68 annual burden hours for this provision (89 State agencies x 20.94 vendors per State agency = 1,863.35 responses x 0.50 hours = 931.68 hours). This is a decrease of 3.75 hours since the previous submission due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.**

9. Section 246.12(j)(6)(ii) requires the State agency to keep a record of the compliance investigations it conducts on its vendors. Section 246.12(j)(4) requires the State agency to conduct compliance investigations of five percent (0.05) of its vendors each year (37,267 vendors x 0.05 = 1,863.35 vendors / 89 State agencies = 20.94 vendors per State agency). For each compliance investigation, the State agency is required to conduct either two compliance buys or one inventory audit per vendor. FNS estimates that it takes one hour to document a compliance buy and two hours to document an inventory audit, which results in two hours per compliance investigation to maintain the associated records (either 2 compliance buys x 1 hour, or 1 inventory audit x 2 hours). **FNS estimates 3,726.70 annual burden hours for this provision (89 State agencies x 20.94 vendors per State agency = 1,863.35 responses x 2 hours = 3,726.70 hours). This is a decrease of 15 hours since the previous submission due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.**
10. Section 246.12(l)(3) requires the State agency to notify a vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be established in order to impose a sanction before another violation is documented, unless the State agency determines notifying the vendor would compromise an investigation. Prior to imposing a sanction for a pattern of violations, a State agency would either provide a notice to the vendor or document in the vendor file the reason(s) that such notice would compromise an investigation. Approximately 1,048 vendors investigated annually commit violations involving a pattern (1,048 vendors / 89 State agencies = 11.78 vendors per State agency). FNS estimates one hour per response for this activity, for an annual total of 1,048 burden hours (89 State agencies x 11.78 vendors per State agency = 1,810 responses x 1 hour = 1,048 hours). This has not changed since the previous submission.
11. Section 246.12(m)(2)(iii) requires State agencies to retain records of delivery of supplemental foods and bills sent or payments received for such supplemental food for home food delivery systems for at least three years. FNS estimates that one State agency will use a home food delivery system and that it will take them 12 minutes (0.2004 hours) to retain records annually. Thus, FNS estimates 0.2004 annual burden hours for this provision (1 State agency x 0.2004 hours = 0.2004 hours). This has not changed since the previous submission.
12. Section 246.19(b) requires State agencies to conduct monitoring reviews of each local agency at least once every two years (1,810 local agencies / 2 years = 905 local agencies / 89 State agencies = 20.34 local agencies per State agency). FNS estimates that it will take State agencies 30 minutes (0.50 hours) to record reports from monitoring reviews. Thus, FNS estimates 905 annual burden hours for this provision. This has not changed since the previous submission.
13. Section 246.20(b) requires that State agencies must obtain annual audits in accordance with 2 CFR part 200, subpart F, and appendix XI, Compliance Supplement, and USDA

implanting regulations 2 CFR parts 400 and 415. Each State agency shall make all State or local agency sponsored audit reports of Program operations under its jurisdiction available for the Department's review upon request. FNS estimates it will take State agencies 10 minutes (0.167 hours) to record audit reports. Thus, FNS estimates 14.86 annual burden hours for this provision (89 State agencies x 0.167 hour = 14.86 hours). This has not changed since the previous submission.

14. Section 246.23(c)(1) requires the State agency to maintain documentation on file regarding the disposition of cases involving improperly obtained or improperly disposed of benefits that result from participant violations. FNS estimates that this recordkeeping requirement takes the State agency five hours per year. FNS estimates 445 annual burden hours for this provision (89 State agencies x 5 hours per year). This has not changed since the previous submission.
15. Section 246.25(a) requires both State and local agencies to maintain full and complete records regarding financial operations and food delivery systems. However, such recordkeeping actually occurs at the State agency level because State agencies use a centralized MIS. FNS estimates that this recordkeeping requirement takes the State or local agency two burden hours per month. For the 70 percent of all local agencies that are government entities (1,810 x 0.7 = 1,267), FNS estimates 32,544 total annual burden hours for this provision (89 State agencies + 1,267 local agencies = 1,356 x 2 hours per month x 12 months per year = 32,544 hours). This has not changed since the previous submission.
16. Section 246.25(a) requires the State and local agency to maintain full and complete records regarding nutrition education. The local agency enters the data into a system hosted at the State agency level. For the 70 percent of all local agencies that are government entities (1,810 x 0.7 = 1,267), FNS currently estimates annual participation of women, infants, and children is 6,243,960 (6,243,960 participants / 1,267 local agencies x 0.70 = 3,449.70 participants per local agency). FNS further estimates that it takes the State or local agency one minute (0.0167 hours) per participant to document the nutrition education contacts. Participants should receive nutrition education twice per year. FNS estimates 145,983.78 annual burden hours for this provision (1,267 local agencies x 3,449.70 participants per local agency x 2 times per year = 8,741,544 responses x 0.0167 hours = 145,983.78 hours). This has not changed since the previous submission.
17. Section 246.25(a) requires State and local agencies to maintain full and complete records regarding fair hearing procedures. Such recordkeeping actually occurs at the State agency level because most fair hearings are conducted at the State agency level. For State agencies and the 70 percent of all local agencies that are government entities (1,810 x 0.7 = 1,267), FNS estimates that documentation of the fair hearing procedures takes 15 minutes (0.25 hours) per State or local agency. FNS estimates 339 annual burden hours for this provision (1,267 local agencies + 89 State agencies = 1,356 x 0.25 hours per State or local agency). This has not changed since the previous submission.

18. Section 246.26(h)(3) requires that State agencies disclosing confidential applicant and participant information for non-WIC purposes must enter into a written agreement with the other public organization or, in the case of a non-WIC use by a State or local WIC agency, the unit of the State or local agency that will be using the information. FNS estimates that 76 State agencies enter into a written agreement with other organizations, and it takes State agencies ten minutes (0.167 hours) to record those agreements. Thus, FNS estimates 12.69 annual burden hours for this provision (76 State agencies x 0.167 hours = 12.69 hours). This has not changed since the previous submission.

AFFECTED PUBLIC: BUSINESS: RETAIL VENDORS
(WIC-AUTHORIZED RETAIL VENDORS AND NONPROFIT BUSINESSES)

1. Section 246.10(d)(1) requires medical documentation for the issuance of the following supplemental foods: paragraph (ii) Any infant formula prescribed to a child or adult who receives Food Package III; paragraph (iii) Any exempt infant formula; paragraph (iv) Any WIC-eligible medical food; paragraph (v) Any authorized supplemental food issued to participants who receive Food Package III. FNS estimates that it will take one minute (0.0167 hours per record) for each clinic (10,000 clinics) to file the medical documentation provided by participants.

Approximately 30 percent of all local agencies are nonprofit businesses ($1,810 \times 0.30 = 543$). Therefore, 30 percent of all medical documentation is reported under the businesses category. Each local agency will record medical documentation from clinics twice a year (10,000 clinics / 543 local agencies $\times 0.30 \times 2 = 11.05$ records per local agency). Thus, FNS estimates 100.2 annual burden hours (543 local agencies $\times 11.05$ records per local agency = 6,000 responses $\times 0.0167$ hours = 100.2 hours). This has not changed since the previous submission.

2. Section 246.12(h)(3)(xvi) requires that vendors maintain inventory records used for Federal tax reporting purposes and other records the State agency may require for the period of time specified by the State agency in the vendor agreement. FNS estimates that it takes vendors approximately ten minutes to complete (0.167 hours). **Thus, FNS estimates 6,223.59 annual burden hours for this provision (37,267 vendors $\times 0.167$ hours = 6,223.59 hours). This is a decrease of 25.05 hours since the previous submission due to an estimated decrease in the number of vendors as a result of the final rule. This decrease is due to a program change.**
3. Section 246.25(a) requires both State and local agencies to maintain full and complete records regarding financial operations and food delivery systems. However, such recordkeeping actually occurs at the State agency level because State agencies use a centralized MIS. FNS estimates that this recordkeeping requirement takes the State or local agency two burden hours per month. For the 30 percent of all local agencies that are nonprofit businesses ($1,810 \times 0.30 = 543$), FNS estimates 13,032 total annual burden hours for this provision (543 local agencies $\times 2$ hours per month $\times 12$ months per year = 13,032 hours). This has not changed since the previous submission.
4. Section 246.25(a) requires State and local agencies to maintain full and complete records regarding nutrition education. The local agency enters the data into a system hosted at the State agency level. FNS currently estimates annual participation of women, infants, and children is 6,243,960 (6,243,960 participants / 543 local agencies $\times 0.30 = 3,449.70$ participants per local agency). FNS further estimates that it takes the State or local agency one minute (0.0167 hours) per participant to document the nutrition education contacts. Participants should receive nutrition education twice per year. For the 30 percent of all local agencies that are non-profit businesses ($1,810 \times 0.30 = 543$), FNS estimates 62,564.48 annual burden hours for this provision (543 local agencies $\times 3,449.70$

participants per local agency x 2 times per year = 3,746,376 responses x 0.0167 hours =62,564.48 hours). This has not changed since the previous submission.

5. Section 246.25(a) requires State and local agencies to maintain full and complete records regarding fair hearing procedures. Such recordkeeping actually occurs at the State agency level because most fair hearings are conducted at the State agency level. For the 30 percent of all local agencies that are non-profit businesses (1,810 x 0.30 = 543), FNS estimates that documentation of the fair hearing procedures takes 15 minutes (0.25 hours) per State or local agency. FNS estimates 135.75 annual burden hours for this provision (543 local agencies x 0.25 hours per State or local agency). This has not changed since the previous submission.

PUBLIC DISCLOSURE REQUIREMENTS

AFFECTED PUBLIC: STATE AND LOCAL AGENCIES (INCLUDING INDIAN TRIBAL ORGANIZATIONS AND US TERRITORIES)

1. Section 246.5(d)(2) requires State agencies, when seeking new local agencies, to publish a notice in the local media (unless it has received an application from a local public or nonprofit private health agency that can provide adequate services). The notice will include a brief explanation of the Program, a description of the local agency priority system, and a request that potential local agencies notify the State agency of their interest. FNS estimates that a third of all State agencies ($89 \text{ State agencies} \times 0.33 = 29.37 \text{ State agencies}$) will seek new local agencies each year through a public notice which will take 30 minutes to complete (0.50 hours). Thus, FNS estimates 14.69 annual burden hours for this provision ($29.37 \text{ State agencies} \times 0.50 \text{ hours} = 14.69 \text{ hours}$). This has not changed since the previous submission.