

Estimate of the Collection of Information Burden for the Special Supplemental Nutrition Program for Women, Infants and Children (OMB #0584-0043)

This document explains the calculation of the collection of information burden for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), as revised to include the reporting and recordkeeping requirements contained in the proposed rule "Discretionary WIC Vendor Provisions in the Child Nutrition and WIC Reauthorization Act of 2004, P.L. 108-265," which is currently in clearance. Some of the new provisions added to the WIC Regulations by this proposed rule would increase the reporting and recordkeeping burdens, as highlighted below in bold. The resulting changes in the information burden since the previous submission are discussed below, highlighted in bold. The resulting recalculations are also reflected in the attached spreadsheet.

Also, a number of adjustments are needed. Most of these adjustments are needed for the approved information burdens which have been calculated using the number of State agencies or vendors. Since the last submission, the Commonwealth of the Northern Mariana Islands has joined the WIC Program as a new State agency, effective October 1, 2005. This means that the WIC Program is now administered by 90 State agencies (50 Geographic States, 34 Indian Tribal organizations, the District of Columbia, and 5 Territories). Also, FNS estimates that the number of retail vendors has increased from 45,178 to about 50,000 since the last submission. The adjustments are addressed below in bold and in the spreadsheet.

REPORTING REQUIREMENTS

1. Section 246.4 requires that by August 15 of each year, as a prerequisite for the receipt of funds from the Food and Nutrition Service (FNS), the State agency must submit all substantive changes to its State Plan to FNS for approval. In the previous submission, the total annual burden estimated for this provision was 10,442 person hours (89 State agencies x 117.33 person hours per year). **Adjusted for the addition of 1 State agency, the total annual burden is now estimated at 10,560 person hours (90 State agencies x 117.33 person hours).** Additionally, this proposed rule would add the following State Plan requirements and resulting reporting burdens:

A. Section 246.4(a)(14)(iii), as amended by this proposed rule, would require WIC State agencies to set forth policies and procedures in their WIC State Plans for notifying a retail vendor in writing when an investigation reveals an initial violation for which a pattern of violations must be imposed in order to impose a sanction, unless the State agency determines that the notice would compromise an investigation. FNS estimates that this would require one person hour per State agency per year.

B. Section 246.4(a)(14)(xvii), as proposed to be added by this rule, would require WIC State agencies to set forth policies and procedures in their WIC State Plans for annually compiling and distributing to authorized WIC retail vendors a list of infant formula wholesalers, distributors, and retailers licensed under State law, and infant formula

**manufacturers registered with the Food and Drug Administration (FDA). FNS estimates that this would require one person hour per State agency per year.**

**Thus these two provisions would add 180 burden hours (90 State agencies x 2 provisions x 1 person hour per provision). Thus the new total annual reporting burden hours for § 246.4 for all State agencies is 10,740 (10,560 + 180), and the new total annual reporting burden hours for § 246.4 per State agency is 119.33 (10,740 ÷ 90).**

2. Section 246.5(b) requires each organization interested in being authorized as a local agency to submit an application to the State agency. The average local agency agreement is for two years; therefore, FNS estimates that each year half (0.5) of the 1,870 local agencies submit applications. FNS further estimates that each application requires 2 person hours to complete. Thus this provision results in 1,870 annual person hours (1,870 local agencies x 0.5 of all local agencies per year x 2 person hours per application).
3. 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 that each year half (0.5) of all local agencies sign agreements with the State agency. FNS further estimates that each agreement requires 1.5 person hours to complete. Thus this provision results in 1,247 person hours per year (1,870 local agencies x 0.5 local agencies per year x 1.5 person hours per agreement).
4. 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 (0.1667) make written requests for such extensions. FNS further estimates that each request for an extension requires 0.25 person hours to complete. Thus this provision results in 78 annual person hours (1,870 local agencies x 0.1667 of all local agencies per year x 0.25 person hours per request).
5. Sections 246.7(i) and 246.10(c)(1)(v) require that 1) in §246.7(i), pertinent certification data be collected and recorded on a form (or forms) provided by the State agency, 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; and, 2) in §246.10(c)(1)(v), medical documentation must be obtained in order to provide participants with infant formula not covered by the State agency's infant formula rebate contract.

Recently, monthly WIC participation has consisted of 5,940,588 women and children participants (1,949,149 women + 3,991,439 children) and 2,035,817 infants (7,976,404 total participants). Women and children participants are certified twice per year, and infants are certified once per year. Consequently, FNS estimates that the total number of certifications/notifications is 13,916,993 per year, (5,940,588 women and children

participants x 2 certifications/notifications per year) + (2,035,817 infants x 1 certification/notification per year).

FNS estimates that the collection of certification data and the provision of appropriate notifications require ten minutes (0.17 person hours) per participant, and further estimates that 1 percent (0.01) of all infant certifications require an additional two minutes (0.03 person hours) for the documentation required to issue an infant formula that is not covered by the State agency's infant formula rebate contract. Thus the total annual burden estimated for § 246.7(i) is 2,365,889 person hours, (13,916,993 total certifications/notifications per year x 0.17 person hours per certification/notification), and the total annual burden for § 246.10(c)(1)(v) is 611 (2,035,817 infant participants x 0.01 of all infant participants x 0.03 person hours per certification).

6. 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 4 State agencies may need to take such action per year. FNS further estimates that providing this notice to FNS would require 0.09 person hours. Thus FNS estimates the total annual burden for this notice to FNS to be 0.36 person hours (4 State agencies per year x 0.09 person hours per notice).
7. 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. The total annual burden is 15,004 person hours, based on 7,976,404 participants x 0.0209 = 166,707 participants provided VOC cards x .09 person hours per VOC card.
8. Section 246.10(b)(1) requires State agencies to identify foods that are acceptable for use in the Program in accordance with program regulations. This includes identifying which foods, substitutions, brands and packaging the State will authorize for use in the Program. State agencies conduct such food reviews and submit food lists as part of their annual State Plan. FNS estimates that 40 person hours are needed for each State agency to comply with this provision. Previously, FNS estimated 3,560 person hours for this provision, based on 89 State agencies. **Given the addition of 1 State agency, total annual burden hours are now estimated to be 3,600 (90 State agencies x 40 person hours per State agency).**
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 person hours are needed for each local agency to comply with this provision. Thus the total annual burden for this provision is 74,800 annual person hours (1,870 local agencies x 40 person hours per local agency).
10. Section 246.12(g)(4)(i) of the Vendor Cost Containment Interim Rule requires a State agency 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. A State agency that elects to

authorize vendors that meet the above-50-percent criterion must identify such vendors annually using a methodology approved by FNS. FNS estimates that each State agency will need 2 person hours to collect the information required to assess a vendor's status, and that each vendor will need 1 hour to provide the required information. Previously, FNS estimated 45,178 person hours for this provision, based on 89 State agencies and 45,000 vendors. **Given the addition of 1 State agency and 5,000 vendors, the total annual burden estimated for this provision is now 50,180 person hours ([90 State agencies x 2 person hours] + [50,000 vendors x 1 person hour]).**

11. Section 246.12(g)(4)(ii)(B) of the Vendor Cost Containment Interim Rule requires State agencies to collect the shelf prices for WIC-approved foods from authorized retail vendors twice annually. In meeting this requirement, a State agency may limit data collection to prices that have changed since the vendor's previous submission. A State agency also may collect prices from a random sample of authorized vendors and/or for selected supplemental foods, rather than for all WIC-approved foods. FNS estimates that twice annually each State agency will need 1 person hour to collect vendors' shelf prices, and twice annually each vendor will need 1 per hour to report shelf prices. Previously, FNS estimated 90,178 person hours for this provision, based on 89 State agencies and 45,000 vendors. **Given the addition of 1 State agency and 5,000 vendors, the total annual burden estimated for this provision is now 100,180 ([90 State agencies x 2 collections x 1 person hour] + [50,000 vendors x 2 collections x 1 person hour]).**
12. Section 246.12(h) requires the State or local agency to enter into written agreements with retail vendors and provide them with not less than 15 days notice of the expiration of their agreements. The average retail vendor agreement is for two years; therefore, FNS estimates that each year half (0.5) of all retail vendors will submit applications. FNS further estimates that each application requires 1 person hour to complete. Previously, FNS estimated 22,500 State or local agency person hours for this provision, based on 45,000 vendors. **Given the addition of 5,000 vendors, the total annual burden estimated for this provision is now 25,000 person hours for State or local agency staff (50,000 retail vendors x 0.5 of all retail vendors per year x 1 person hour per application).**
13. Section 246.12(i)(1) requires the State or local 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 8 person hours per State agency. FNS further estimates that it takes 2 person hours to provide training to each vendor. Previously, FNS estimated 90,712 person hours for this provision, based on 89 State agencies and 45,000 vendors. **Given the addition of 1 State agency and 5,000 vendors, the total annual burden estimated for this provision is now 100,720 person hours, (90 State agencies x 8 person hours) + (50,000 vendors x 2 person hours).**
14. Section 246.12(j)(2) requires that each year the State agency conduct routine monitoring visits of five percent (0.05) of its retail vendors. These visits, conducted by State and/or local agency staff, are primarily used to detect administrative discrepancies such as inadequate stock. State agencies usually provide vendors with an opportunity to correct such discrepancies, although minor sanctions may be imposed,

such as small fines. Failure to correct some discrepancies, such as ongoing non-compliance with minimum stock requirements, may result in termination of the vendor agreement. FNS estimates that it takes one person hour to conduct a routine monitoring visit. Thus the total annual burden estimated for this provision is 2,500 person hours (50,000 retail vendors x 0.05 annual compliance investigation requirement x 1 person hour per compliance investigation).

15. Section 246.12(j)(4) requires that each year the State agency conduct compliance investigations of five percent (0.05) of its retail vendors. These investigations are used to detect serious violations, such as trafficking, which may result in sanctions such as disqualifications and civil money penalties. State agencies use a variety of resources to conduct compliance investigations, including State agency staff, contractor staff, local agency staff, law enforcement staff, and staff of other WIC State agencies. FNS estimates that it takes 1 person hour to conduct a compliance buy and 2 person hours to conduct an inventory audit, which results in a total of 2 person hours per compliance investigation (either 2 compliance buys x 1 person hour, or 1 inventory audit x 2 person hours). Previously, FNS estimated 4,500 person hours for this provision, based on 89 State agencies and 45,000 vendors. **Given the addition of 5,000 vendors, the total annual burden estimated for this provision is now 5,000 person hours (50,000 retail vendors x 0.05 annual compliance investigation requirement x 2 person hours per compliance investigation).**
16. 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 State and local agencies receive 10,000 complaints a year from participants and vendors. FNS further estimates it takes 1 person hour to process each complaint. The total annual burden estimated for this provision is 10,000 person hours (10,000 complaints x 1 person hour per complaint), which has not changed since the previous submission.
17. 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. FNS estimates that the State agency spends 40 person hours a year to account for the disposition of its food instruments. Previously, FNS estimated 3,560 person hours for this provision, based on 89 State agencies. **Given the addition of 1 State agency, the total annual burden estimated for this provision is now 3,600 person hours (90 State agencies x 40 person hours).**
18. Section 246.14(d)(1) requires the State agency to seek FNS approval of costs for automated data processing systems, 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 15 requests for such approvals and that each request requires 160 person hours for the State agency to document and submit. The total annual burden estimated for this provision is 2,400 person hours (15 requests per year x 160 person hours per request).

19. 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 1,870 local agencies 4 times per year. FNS also estimates that each distribution of funds requires 2 person hours to complete. The total annual burden estimated for this provision is 14,960 annual person hours (1,870 local agencies x 4 distributions per year x 2 person hours per local agency per distribution).
20. Section 246.17(c)(1) requires FNS to provide written notification of disqualification to 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. No State agency has ever been disqualified for noncompliance with program requirements, and fewer local agencies are terminated now that the Program has matured. When the Program first started, State agencies were interested in providing benefits to eligible applicants as quickly as possible. Consequently, State agencies authorized all local agencies that met the basic requirements. Since then, most local agencies have been in operation for over ten years, affording the State agency a reasonable period of time to evaluate its local agencies and terminate those considered substandard. As a result, substandard local agencies have been removed, and the number of local agencies disqualified annually from the Program has diminished. FNS estimates that 10 local agencies will be disqualified per year. FNS further estimates that preparing and providing a written notice of disqualification requires 8 person hours per notice. Thus the total annual burden estimated for this provision is 80 person hours (10 local agency disqualifications per year x 8 person hours per notice).
21. Section 246.19(a) requires the State agency to develop and submit a corrective action plan in response to an FNS management evaluation report. The FNS goal is to conduct management evaluations on all functional areas of the program for all State agencies within a four-year cycle. FNS estimates that each corrective action plan takes approximately 40 person hours to develop. Previously, FNS estimated 880 person hours for this provision, based on 89 State agencies. **Given the addition of 1 State agency, the total annual burden hours estimated for this provision is now 900 person hours (90 State agencies x 0.25 of all State agencies per year x 40 person hours per corrective action plan).**
22. Section 246.19(b)(5) requires the State agency to 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 (0.5) of all 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 (0.25). FNS further estimates that it takes 2 person hours for the State agency to address targeted areas during local agency reviews and report the results of the targeted reviews to FNS. The total annual burden estimated for this provision is 468 annual person hours (1,870 local agencies x 0.5 of all local agencies per year x 0.25 target reviews per year x 2 person hours per local agency per distribution).
23. 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 each year OIG performs 4 audits of WIC State and local agencies. FNS further estimates that each audit response requires 40 person hours to complete. In the previous submission, FNS estimated the total annual burden for this provision to be 160 person hours (4 audits per year x 40 person hours per audit response), which has not changed since the last submission.

#### RECORDKEEPING REQUIREMENTS

1. **Section 246.12(g)(10)** would require WIC State agencies to provide to authorized WIC retail vendors a list, on an annual basis, of infant formula wholesalers, distributors, and retailers licensed in the State in accordance with State law (including regulations), and infant formula manufacturers registered with FDA that provide infant formula. FNS has provided the State agencies with the list of the infant formula manufacturers registered with FDA. A State agency would contact the licensing agency in its State to obtain a list of the other suppliers. A State agency could satisfy this requirement by linking its web site to the list of licensed suppliers on the web site of the State's licensing agency. FNS estimates that this would require one burden hour per State agency per year. Thus this annual collection will require a total of 90 person hours.
2. **Section 246.12(h)(8)** would require WIC State agencies to establish a process for approval or disapproval of requests from above-50-percent vendors for permission to provide incentive items to WIC participants or other customers. FNS currently estimates that about 2,000 of the approximately 50,000 authorized vendors will be subject to incentive items restrictions. A State agency could decide not to allow any incentive items at all, in which case an approval process would not be necessary; FNS has received inquiries from several WIC State agencies indicating an interest in not allowing such incentive items at all.

Accordingly, we assume that half of the WIC State agencies will not allow any incentive items at all, and that half of the approximate 2,000 above-50-percent vendors nationwide reside in those States. We also assume that little time will be needed to approve/disapprove a request and record it, since this process only involves comparison of the vendor's price documentation with the less-than-\$2 limit established for such items in the rule. Indeed, the State agency may provide above-50-percent vendors with a list of allowable incentive items, valued above the less-than-\$2 nominal value limit per item; the vendor would indicate on the list which of these incentive items it wishes to use and return the list to the State agency. Thus FNS estimates that 45 State agencies will approve/disapprove incentive items for 1,000 above-50-percent vendors, and that each approval/disapproval will require 15 minutes, resulting in ~~250~~<sup>11,250</sup> total annual burden hours.

3. **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 2 person hours per year.

In the previous submission, FNS estimated that the total annual burden for this provision was 178 person hours, based on 89 State agencies. **Given the addition of 1 State agency, FNS now estimates that the total annual burden for this provision is 180 person hours (90 State agencies x 2 person hours per year).**

4. 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. FNS estimates that each routine monitoring visit takes 1 person hour to document. In the previous submission, FNS estimated that the total annual burden for this provision was 2,250 person hours, based on 45,000 vendors. **The total annual burden now estimated for this provision is 2,500 person hours (50,000 vendors x 0.05 annual routine monitoring requirement x 1 person hour per visit).**
5. Section 246.12(j)(6) requires the State agency to document 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. 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 1 person hour to document a compliance buy and 2 person hours to document an inventory audit, which results in 2 person hours per compliance investigation (either 2 compliance buys x 1 person hour, or 1 inventory audit x 2 person hours). In the previous submission, the total annual burden estimated for this provision was 4,500 person hours, based on 45,000 vendors. **The total annual burden now estimated for this provision is ~~5,000~~ 45,000 person hours (50,000 vendors x 0.05 annual compliance investigations requirement x 2 person hours per investigation).**
6. Section 246.12(l)(3) would require 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 such violation is documented, unless the State agency determines, in its discretion, on a case-by-case basis, that notifying the vendor would compromise an investigation. Prior to imposing a sanction for a pattern of violations, the State agency would either provide such notice to the vendor, or document in the vendor file the reason(s) for determining that such notice would compromise an investigation. Approximately 2,300 vendors investigated annually commit violations involving a pattern. We assume that little time will be needed to issue the notice, which presumably will entail a standardized format with space for the vendor's name and address and for listing the violations. We also assume that little time will be needed to document in the vendor file the reason(s) such notice would compromise an investigation and thus would not be sent. Thus FNS estimates that the State agencies will either issue such notices or make such entries in vendor files 2,300 times, and that issuing each notice or making such entries will require 15 minutes, resulting in ~~575~~ 51750 total annual burden hours.
7. 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 5 person hours per year. Previously, FNS estimated that the total annual burden for this provision to be 445 person hours, based on 89 State agencies. **FNS now estimates that the total annual burden for this provision is 450 person hours (90 State agencies x 5 person hours per year).**

8. Section 246.25(a) requires both the State and local agency to maintain full and complete records regarding financial operations and food delivery systems. FNS estimates that this recordkeeping requirement takes the State or local agency 2 person hours per month. Previously, FNS estimated the total annual burden for this provision at 47,016 person hours, based on 1,870 local agencies and 89 State agencies. **Given the addition of 1 State agency, FNS now estimates the total annual burden to be 47,040 person hours (90 State agencies + 1,870 local agencies = 1,960 x 2 person hours per month x 12 months per year).**
9. Section 246.25(a) requires the State and local agency to maintain full and complete records regarding nutrition education. FNS currently estimates annual participation of women and children is 5,940,588 (1,949,149 women + 3,991,439 children) and participation of infants is 2,035,817 (7,976,404 total participants). Women and children receive nutrition education twice per year, and infants receive nutrition education once per year. Consequently, FNS currently estimates that the total number of nutrition education contacts is 13,916,993 per year, (5,940,588 women and children participants x 2 contacts per year) + (2,035,817 infants x 1 contact per year). FNS further estimates that documenting nutrition education contacts takes 1 minute (0.017 person hours) per participant. Thus the total annual burden currently estimated for this provision is 236,589 person hours (13,916,993 contacts per year x 0.017 person hours per contact).
10. Section 246.25(a) requires the State and local agency to maintain full and complete records regarding fair hearing procedures. FNS estimates that documentation of the fair hearing procedures takes 0.25 hours per State or local agency. Previously, FNS estimated the total annual burden for this provision based on 1,870 local agencies and 89 State agencies. **One new State agency has now been added, resulting in 490 annual person hours (1,870 local agencies + 90 State agencies = 1,960 x 0.25 person hours per State or local agency). This does not result in a new total annual person hours for this provision, because previously 1,959 x 0.25 = 489.75 had been rounded up to 490.**