USDA
Food and Nutrition Service

OMB Docket #0584-NEW
WIC Food Packages

SUMMARY

This proposed rule revises the food packages under 7 CFR Part 246 to bring them in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics.

Currently, WIC Program burden hours are accounted for under docket #0584-0043, WIC Program Regulations. There are a number of regulatory actions affecting this package and to avoid any delay in implementation, we are processing this new burden under the WIC Program Regulations as a new collection. Once this rule is finalized and the burden approved, FNS will combine this burden with the #0584-0043 ICR under a change request.

SUPPORTING STATEMENT - SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN (WIC) REGULATIONS –WIC FOOD PACKAGES

Justification

1. Explain the circumstances that make the collection of information necessary.

The WIC Program is authorized by the Child Nutrition Act of 1966 (Attachment 1), as amended, and is administered by State and local agencies in accordance with WIC Program regulations at 7 CFR Part 246 (Attachment 2). Per §246.2 of the WIC regulations, "State agencies" are health departments or comparable agencies of the States, U.S. Territories, and Indian Tribal Organizations (ITO). Per §246.2 of the WIC regulations, "local agencies" include public or private non-profit health or human service agencies, Indian Health Service units, and health clinics of ITOs and intertribal councils or groups. The State agencies administer the WIC Program with funds provided by the USDA Food and Nutrition Service (FNS) pursuant to annual Federal-State agreements. The local agencies administer the WIC Program pursuant to annual or multi-year written agreements with State agencies. The local agencies certify participants and provide them with food instruments and nutrition education. The participants transact the food instruments for food at authorized retail vendors.

This is a new submission that would incorporate the information collection burden associated with requirements contained in the Proposed Rule, 7 CFR 246, "Revisions in the WIC Food Packages." (Attachment 3).

2. Indicate how, by whom, and for what purpose the information is to be used.

The proposed rule would revise the food packages to bring them in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics. The revisions would also: better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of foods, provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural preferences, and serve participants with certain qualifying conditions under one food package to facilitate efficient management of medically fragile participants.

There are only three provisions in the proposed rule that would result in a new information collection, they are:

- allowing medically fragile participants to receive supplemental foods in addition to infant formula, when appropriate medical documentation is provided;

- allowing children to receive soy-based beverages and tofu as a substitute for milk and women to receive additional quantities of tofu, when medical documentation is provided; and

- expanding the content requirements for the medical documentation.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques.

The Food and Nutrition Service makes every effort to comply with the Government Paperwork Elimination Act (GPEA). The proposed rule permits a State agency to obtain the medical documentation in either electronic or hard copy form.

4. Describe efforts to identify duplication.

The collection which would be added by this proposed rule would not duplicate any other collection.

5. Describe impacts on small businesses or other small entities (item 5 of OMB Form 83-1).

This proposed rule would not have any adverse information collection impact on any small businesses or other small entities. State agencies are not small businesses or small entities.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently.

Medically fragile participants would not be able to receive supplemental foods in addition to infant formula without the minimal information collection needed for this rule. In addition, the WIC State agency would not have information that would assist in working with the health care provider to manage the medical condition.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner that is inconsistent with 5 CFR 1320.6.

All of the reporting requirements related to the proposed rule conform to the parameters of 5 CFR 1320.6.

8. Provide a copy and identify the date and page number of publication in the *Federal Register* of the agency's notice, required by 5 CFR 1320.8(d).

(a) Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

This proposed rule has not yet been published. The proposed rule includes a 60-day notice for comments on the paperwork burden of the rule.

(b) Consultation with representatives of those from whom information is to be obtained.

As previously noted, WIC State agencies would be impacted by the information collection requirements associated with the provisions set forth in this proposed rule.

Over the years the Department has received numerous requests from WIC State and local agencies to modify the current food packages to permit greater substitution of foods or introduction of additional foods. These requests have come from formal and informal discussions and with State and local officials on an ongoing basis regarding program implementation and food package policy issues, and from written proposals and comments submitted to FNS by WIC State and local agencies to allow modifications and/or substitutions to the WIC food packages. Requests for revisions to the WIC food packages have also been received from Congress, participants, and organizations with interests in the welfare of WIC participants.

Examples of the different forums and methods FNS has used over the years to solicit WIC State and local agency staff input on the WIC food packages include the following.

Publishing an advanced notice of public rulemaking (ANPRM) in 2003 (68 FR 53903) to solicit comments to determine if the WIC food packages should be revised to better improve the nutritional intake, health and development of participants; and, if so, what specific changes should be made to the food packages. In response to the ANPRM, FNS received 195 total comments;

Commissioning the National Academies' Institute of Medicine (IOM) to independently review the WIC Food Packages. IOM solicited public comment on revisions to the WIC food packages, via 3 public hearings, letters and e-mail, throughout its 22-month study period. IOM considered these comments, as well as comments the Department received in response to the ANPRM, in developing

recommendations to revise the WIC food packages. IOM published its reports of these recommendations on April 27, 2005: "WIC Food Packages: Time for a Change." [3] This proposed rule incorporates IOM's recommendations;

Holding nine public outreach sessions across the nation as part of FNS' development of its 2004 reauthorization proposals. Interested parties, including WIC State and local staff, offered oral testimony and written statements on the WIC food packages as well as on a variety of other WIC issues;

Hosting annual meetings (1977-present) of the National Advisory Council on Maternal, Infant and Fetal Nutrition that includes WIC staff as members of the Council; the Council develops recommendations for FNS on how to improve operations of the WIC and Commodity Supplemental Food Programs, including aspects related to the authorized foods and food packages; and

Consulting and collaborating with the National WIC Association (NWA) on a wide variety of WIC issues, including those related to the WIC food packages (1983-present). NWA is a non-profit organization that was founded in 1983 by State and local agencies that administer the WIC Program. As of June 1, 2005, its paid membership included 73 of the 89 WIC State agencies, 675 local agencies, 4 State WIC Associations, and 18 sustaining members (i.e., for-profit and non-profit businesses or organizations). Functioning as a coalition of WIC agencies, NWA is dedicated to maximizing WIC resources through effective management practices. NWA also serves in a leadership role for WIC agencies by developing position papers on issues of concern to the WIC community.

Also, FNS will inform the State agencies of the publication of the proposed rule to ensure adequate time for providing comments on the proposed rule's reporting requirements. FNS will analyze all comments received in response to the Notice and make any necessary changes in finalizing this rule.

9. Explain any decision to provide any payment or gift to respondents.

There are no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents.

No confidential information is involved with the proposed rule.

11. Provide additional justification for any questions of a sensitive nature.

This submission does not add any questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information.

(a) Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

Sections 246.10(d) would require medical documentation for the issuance of any supplemental foods issued to participants who receive Food Package III; any authorized soy-based beverage or tofu issued to children who receive Food Package IV; and, any additional authorized tofu and cheese issued to women who receive Food Packages V and VII that exceeds the maximum substitution rate.

In addition, the content of the medical documentation would be expanded to include: 1) contact information for the participant's healthcare provider making the medical determination; 2) date of medical determination; 3) the specific supplemental foods to be prescribed; 4) amount prescribed per day; 5) the medical determination of the qualifying condition(s) which warrants the supplemental foods; and 6) the length of time the supplemental foods is medically required.

FNS estimates that approximately 1 percent of participants (86,375) will be issued supplemental foods under food package III; 1 percent of children (42,408) will be authorized soy-based beverage or tofu under Food Package IV; and, 1 percent of women (14,000) will be authorized tofu and cheese in excess of the maximum substitution rate under Food Packages V and VII.

REPORTING REQUIREMENT

FNS estimates that it will take three minutes (0.05 person hours) for the documentation required to issue the authorized foods, thus resulting in an estimated burden of 14,278 (142,783 total participants x 0.05 person hours x 2 certification periods per year).

RECORDKEEPING REQUIREMENT

FNS estimates that it will take one minute (0.016 per record) for each clinic (10,000 clinics) to file the medical documentation provided by participants, for an estimated burden of 320 (10,000 clinics x 0.016 hours per record x 2 times per year).

RECORDKEEPING AND REPORTING

The total annual reporting and recordkeeping burden estimated for the revisions in this proposed rule is 14,598 (14,278 plus 320).

(b) Provide separate hour burden estimates for each form and aggregate the hour burden in Item 13 of OMB Form 83-1.

A summary of burden is attached.

(c) Provide estimates of the annualized cost to respondents for the hour-burdens for collections of information.

Respondent Costs

Current burden hours per #: :	0
Estimated burden hours this collection:	14,598
Total respondent burden hours requested:	14,598

TOTAL RESPONDENT COSTS: $324,368*

* At $22.22 per burden hour, including overhead costs, office supplies, etc. This rate was obtained from the U.S. Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupational Wages in the United States.

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information.

(a) Include a total capital and start-up component (annualized over its expected useful life), and a total operation and maintenance and purchase of services component.

(b) Present ranges of cost burdens and explain the reasons for the variance.
There are no startup or annual maintenance costs. All costs associated with the hour burden are shown in the responses to Items 12 and 14 of this document.

14. Provide estimates of annualized cost to the Federal government.

(a) Federal cost of rulemaking (promulgation, preparation of guidance, and implementation):

(1) FNS National Office Staff:	1.00 staff years	
FNS Regional Staff:	1.75 staff years	
	2.75 staff years	
Subtotal:		$192,500*
(2) Overhead cost, travel, office supplies, etc.:		$ 10,000
Mailing and telephone:		200
Publication costs:		1,000
Distribution costs:		500

Subtotal: $ 11,700

Federal Program Maintenance Costs: $204,200*

(b) Federal cost of program maintenance (reporting and recordkeeping, monitoring, assistance, review and analysis):

(1) FNS National Office Staff: 1.0 staff years
FNS Regional Staff: 3.5 staff years
4.5 staff years

Subtotal: $3,150,000*

* At $70,000 per staff year

(2) Overhead cost, travel, office supplies, etc.: $10,000
Mailing and telephone: $ 500
Subtotal: $10,500

Federal Program Maintenance Costs: $3,160,000

TOTAL FEDERAL COSTS: $3,364,000 ($204,200 + $3,160,000)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This is a new requirement under Proposed Rule 7 CFR Part 246, "Revisions in the WIC Food Packages," and will increase the FNS burden by 14,598 hours. These hours are attributed to a Program Change.

16. For collection of information whose result will be published, outline plans for tabulation and publication.

There are no plans to publish the results of this information collection for statistical use.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

We are not seeking OMB approval to not display the expiration date.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-1.

There are no exceptions to the certification statement.

ATTACHMENTS

Attachments

Attachment 1:	WIC Legislation (Child Nutrition Act of 1966, as amended, October 4, 2005)
Attachment 2:	WIC Regulations (7 CFR Part 246, January 1, 2006)
Attachment 3:	FNS Proposed Rule, “Revisions in the WIC Food Packages” (in clearance)
Attachment 4:	Summary of Burden

FNS:SFPD:DebbieWhitford
FC: REG-1-1
DOC:I:PPDB:WIC Food Pkg ICB Justification