

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

#### 7 CFR Part 246

RIN 0584-AD36

#### Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Miscellaneous Vendor-Related Provisions

**AGENCY:** Food and Nutrition Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would amend the regulations governing the WIC Program to clarify issues that have arisen subsequent to the publication of the WIC Food Delivery Systems Final Rule on December 29, 2000, and to strengthen further the requirements for State vendor management and infant formula cost-containment systems. The rule contains provisions that would prohibit a State agency from requiring an infant formula manufacturer to provide free formula, services, or other items in its infant formula cost-containment bid solicitation and contract; require that a State agency provide an abbreviated administrative review when a vendor receives a WIC civil money penalty as a result of a Food Stamp Program (FSP) disqualification; and expand the types of vendor information that a State agency may release for general program purposes.

**DATES:** To be assured of consideration, written comments must be postmarked on or before November 25, 2005.

**ADDRESSES:** The Food and Nutrition Service invites interested persons to submit comments on this proposed rule. Comments may be submitted by any of the following methods:

- Mail: Send comments to Patricia Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302, (703) 305-2746.

- Web site: Go to <http://www.fns.usda.gov/wic>. Follow the online instructions for submitting comments through the link at the Supplemental Food Programs Division Web site.

- E-Mail: Send comments to [WICHQ-SFPD@fns.usda.gov](mailto:WICHQ-SFPD@fns.usda.gov). Include Docket ID Number 0584-AD36, Miscellaneous Vendor-Related Provisions Proposed Rule, in the subject line of the message.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identities of the individuals or entities submitting the comments will be subject to public disclosure. All written submissions will be available for public inspection at the address above during regular business hours (8:30 a.m. to 5 p.m.), Monday through Friday.

FNS also plans to make the comments publicly available by posting a copy of all comments on the FNS Web site at <http://www.fns.usda.gov/wic>.

**FOR FURTHER INFORMATION CONTACT:** Debra Whitford, Chief of the Policy and Program Development Branch, Supplemental Food Programs Division, at the address indicated above or at (703) 305-2746, during regular business hours (8:30 a.m.-5 p.m., Monday through Friday).

#### SUPPLEMENTARY INFORMATION:

##### Executive Order 12866

This rule has been determined to be not significant and was not reviewed by the Office of Management and Budget under Executive Order 12866.

##### Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). Roberto Salazar, Administrator, Food and Nutrition Service (FNS), has certified that this rule would not have a significant economic impact on a substantial number of small entities. This rule would modify language used in WIC infant formula rebate solicitations and contracts, as well as in vendor agreements. The effect of these changes would fall primarily on State agencies.

Vendors authorized by the WIC Program to provide supplemental foods, some of which are small entities, could also be affected. However, the impact on small entities is expected to be minimal.

##### Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the FNS generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local or tribal governments, in the aggregate, or the private sector, of \$100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires FNS to identify and consider a reasonable number of regulatory alternatives and adopt the most cost-effective or least burdensome alternative that achieves the objectives of the rule.

This proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and tribal governments or the private sector of \$100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

##### Executive Order 12372

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is listed in the Catalog of Federal Domestic Assistance under 10.557. For the reasons set forth in the final rule in 7 CFR 3015, Subpart V and related Notice (48 FR 29115), this program is included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

##### Federalism Summary Impact Statement

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

### Prior Consultation With State Officials

Prior to drafting this rule, we consulted with State agencies at various times. Because the WIC Program is a State-administered, federally funded program, our regional offices have formal and informal discussions with State agencies on an ongoing basis regarding program implementation and policy issues. This arrangement allows State agencies to raise questions and provide comments that form the basis for discretionary decisions in this and other WIC Program rules. We have also received oral and written requests for policy guidance on the implications of the Food Delivery Systems Final Rule from State agencies that deliver WIC services. These questions have helped us make the rule responsive to concerns of State agencies.

### *Nature of Concerns and the Need To Issue This Rule*

The rule addresses the need to assure the soundness of infant formula rebate solicitations and contracts. With limited exceptions, all State agencies must continuously operate a cost containment system for infant formula. Some have also established similar cost containment measures for other supplemental foods, such as infant juice and cereal. As a result of these systems, State agencies receive over \$1.5 billion annually in rebates on infant formula and other supplemental foods purchased by WIC participants. The rebates that State agencies receive allow them to maintain, and in some cases expand, program participation.

Infant formula manufacturers have questioned the inclusion of requirements to provide free formula, services, or other items in infant formula bid solicitations. Receipt of free formula reduces the amount of formula that the State agency potentially could purchase under rebate contracts and may lower the level of rebate bids received. A lower rebate could lead to a reduction in the number of eligible persons that the WIC Program is able to serve. This rule would modify the requirements for rebate solicitations and contracts to address this issue and thereby promote the viability of infant formula cost containment systems.

The rule also would address two issues affecting WIC vendors. First, State agencies have questioned the need to offer a full administrative review to vendors who receive a WIC civil money penalty as a result of FSP disqualification. State agencies are required to impose a civil money penalty when they determine that an authorized vendor that has been

disqualified from the FSP is needed to ensure participant access to supplemental foods. In responding to this issue, the rule seeks to assure a vendor's right to due process while encouraging the most cost-effective use of State agency resources.

In addition, while implementing the WIC Food Delivery Systems Final Rule, State agencies have sought approval to release basic vendor information that the rule designates as confidential. This proposed rule seeks to accommodate State agency requests to release such information, while preserving the overall confidentiality of vendor information.

### *Extent to Which We Will Meet Those Concerns*

The rule would substantially resolve the vendor management problems State agencies have identified. It increases a State agency's flexibility in conducting appeals of a civil money penalty imposed in lieu of reciprocal disqualification from the WIC Program, and in disclosing vendor information as part of sound program management. It also supports the integrity of State agency infant formula rebate systems by eliminating gratis provisions in infant formula cost-containment contracts.

### Executive Order 12988

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

### Civil Rights Impact Analysis

FNS has reviewed this proposed rule in accordance with Departmental Regulation 4300-4, "Civil Rights Impact Analysis," to identify and address any major civil rights impacts this rule might have on minorities, women, and persons with disabilities. All data available to FNS indicate that protected individuals have the same opportunity to participate in the WIC Program as non-protected individuals. FNS specifically prohibits State and local government agencies that administer the WIC Program from engaging in actions that discriminate based on race, color, national origin, sex, age or disability.

Regulations at 7 CFR 246.8 specifically state that Department of Agriculture regulations on non-discrimination (7 CFR parts 15, 15a and 15b) and FNS instructions ensure that no person shall on the grounds of race, color, national origin, age, sex, or disability be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination under the Program.

Discrimination in any aspect of program administration is prohibited by these regulations, Department of Agriculture regulations on non-discrimination (7 CFR parts 15, 15a, and 15b), the Age Discrimination Act of 1975 (Pub. L. 94-135), the Rehabilitation Act of 1973 (Pub. L. 93-112, section 504), and title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d). Enforcement action may be brought under any applicable Federal law. Title VI complaints shall be processed in accordance with 7 CFR part 15. Where State agencies have options, and they choose to implement a particular provision, they must implement it in such a way that it complies with the regulations at 7 CFR 246.8.

### Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This proposed rule contains no new information collection requirements that are subject to OMB approval. The existing recordkeeping and reporting requirements, which were approved under OMB control number 0584-0043, will not change as a result of this rule.

### Government Paperwork Elimination Act

FNS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

### *Background on Vendor-Related Provisions*

On December 29, 2000, the WIC Food Delivery Systems Final Rule as published at 65 FR 83248, made major amendments to the WIC Program regulations in response to an increasing concern on the part of FNS, States, the

Office of the Inspector General, and Congressional reviewers that the WIC Program was vulnerable to abuse by vendors and participants. It was also believed that WIC could serve additional participants at no additional cost by eliminating the abuse. The WIC Food Delivery Systems Final Rule responded to this concern by providing detailed standards for effective vendor management systems, including mandatory selection criteria, training requirements, high-risk vendor identification criteria, and vendor monitoring requirements. As WIC State agencies consistently apply these standards, program accountability and efficiency in food delivery should increase.

FNS postponed the implementation date of the rule from February 27, 2002, to October 1, 2002, to give State agencies additional time to modify policies, procedures, and management information systems and to notify vendors and others affected by impending changes. Since that time, FNS has provided technical assistance and clarifications to State agencies regarding the rule's intent and requirements.

This proposed regulation responds to vendor management issues that have arisen subsequent to the publication of the WIC Food Delivery Systems Final Rule. The limited provisions of this proposed rule are consistent with the objectives of the WIC Food Delivery Systems Final Rule. They promote sound vendor management practices and seek to maximize the funds available to State agencies for providing supplemental foods.

#### *Background on Infant Formula Cost Containment*

In response to rising food costs in the 1980's and the desire to use their food grants more efficiently, several WIC State agencies initiated infant formula rebate systems. At the time, infant formula expenditures represented almost 40 percent of all WIC food costs, making infant formula rebates an important cost-containment strategy. Rebate savings amounted to just over \$30 million in fiscal year 1988 and grew to about \$1.5 billion in fiscal year 2003. These rebate savings are a critical component of the WIC Program, allowing an additional two million participants (nearly one out of every four participants) to be served. Without these savings, millions of low-income women, infants and children would not have the advantage of nutritious supplemental foods, nutrition education, and health care referrals provided by the WIC Program.

Building on the success of voluntary State infant formula rebate systems, Public Law 100-460, the Department's fiscal year 1989 appropriations act, required all WIC State agencies (except Indian State agencies with participation levels under 1,000) to explore the feasibility of cost-containment measures for infant formula and implement such measures where feasible. As a result of this mandatory legislative requirement, WIC State agencies with participation levels over 1,000 implemented infant formula cost-containment measures, primarily infant formula rebate systems.

The passage of the Child Nutrition and WIC Reauthorization Act of 1989 (section 123(a)(6) of Pub. L. 101-147) made this cost-containment requirement a permanent program feature. As a result, section 17(h)(8)(A) of the Child Nutrition Act of 1966 (CNA), as amended (42 U.S.C. 1786(h)(8)(A)), requires WIC State agencies to implement a competitive bidding system for the procurement of infant formula, or an alternate infant formula cost-containment measure that yields savings equal to or greater than savings generated by a competitive bidding system.

Over time, infant formula cost-containment systems have changed considerably. Current rebate regulations were last updated through an interim rule published on August 23, 2000, at 65 FR 51213, which addressed a number of contracting issues and bid evaluation requirements. This proposed rule further strengthens the bid solicitation and contracting process for infant formula cost-containment systems.

#### *Gratis Provisions in Infant Formula Rebate Solicitations and Contracts (7 CFR 246.16a(j)(4))*

Over the past several years the Department has noticed an increase in the quantity of sample infant formula required in infant formula rebate solicitations and contracts. The Department is concerned not only with the increased quantity of sample infant formula required in rebate contracts, but also with contract requirements for other gratis items, such as educational materials, conference support, and supplies. Gratis provisions could have the effect of reducing rebate savings not only to individual State agencies, but also to the WIC Program nationally.

Historically the Department has discouraged the inclusion of gratis provisions in infant formula rebate contracts, including requirements for free units of infant formula. We believe that such stipulations generate lower rebate bids, primarily because such extras are not "free". Therefore, the

proposed regulations at 7 CFR 246.16a(j)(4) would prohibit State agencies from issuing rebate bid solicitations or entering into rebate contracts that contain provisions requiring bidders to provide gratis products and services, such as sample infant formula.

State agencies that provide sample infant formula to infants in limited situations, such as when trying to determine the specific infant formula to use to address a particular medical condition, may purchase reasonable quantities of sample formula for this purpose with WIC food funds.

#### *Abbreviated Administrative Reviews (7 CFR 246.18(a)(1)(ii))*

The Department proposes to require a State agency to offer an abbreviated administrative review when a vendor appeals a WIC civil money penalty (CMP) imposed in lieu of a disqualification that stems from a FSP disqualification. Section 17(n) of the CNA and regulations at 7 CFR 246.12(l)(1)(vii) require a WIC State agency to disqualify a vendor who has been disqualified from the FSP, unless participant access would be jeopardized. The disqualification is not subject to administrative or judicial review under the WIC Program. If the State agency determines that the vendor is needed to ensure participant access to supplemental foods, the State agency must impose a CMP in lieu of a disqualification as provided in WIC regulations at 7 CFR 246.12(l)(1)(ix). Under regulations at 7 CFR 246.18(a)(1)(i), the imposition of a CMP in lieu of disqualification is subject to a full administrative review.

The Department believes that a CMP imposed in lieu of a reciprocal disqualification does not warrant a full administrative review. Rather, such action should be subject to an abbreviated administrative review because at issue are two factual questions only, namely, whether the vendor has been disqualified from the FSP and whether the State agency correctly calculated the amount of the CMP. Answers to these questions can easily be established within the context of an abbreviated review; thus, the expenditure of time and resources required to conduct a full administrative review is unwarranted. Offering an abbreviated review would be the more cost-effective means of honoring the vendor's due process protections.

In addition to its cost-effectiveness, an abbreviated administrative review for a CMP based on a reciprocal WIC disqualification is consistent with the adverse actions for which WIC

regulations currently allow abbreviated reviews. Regulations at 7 CFR 246.18(a)(1)(ii) identify adverse actions that are subject to abbreviated administrative reviews. This section specifies that the State agency must provide abbreviated administrative reviews to vendors who appeal a WIC disqualification that is based on a FSP CMP for hardship, as well as a WIC disqualification or CMP based on a mandatory sanction imposed by another WIC State agency. Imposition of a CMP in lieu of a reciprocal disqualification is similar to these adverse actions for which a State agency must provide an abbreviated review. Under the proposed revision, a State agency would retain the option to provide a full administrative review as stated in regulations at 7 CFR 246.18(a)(1)(ii).

*Confidentiality of Vendor Information (7 CFR 246.26(e))*

Regulations at 7 CFR 246.26(e) restrict the use or disclosure of information that individually identifies a vendor, except for the vendor's name, address and authorization status, to persons directly connected with the administration or enforcement of WIC or FSP; persons directly connected with the administration or enforcement of any Federal or State law; or vendors who are subject to an adverse action.

This rule proposes to amend the regulations at 7 CFR 246.26(e) to expand the types of vendor information allowed for general release that would not be subject to confidentiality restrictions. This additional information would include a vendor's telephone number, Web site and e-mail address, WIC identification number, and store type (e.g., retail, commissary, pharmacy, etc.). Allowing WIC State agencies to provide participants with vendors' telephone numbers and Web site and/or email addresses would assist participants with locating authorized vendors in their neighborhood or local service area. Knowing a vendor's store type also would enable participants to determine where to transact their food instruments.

The proposed rule would also allow WIC State agencies to issue public notices of vendor disqualifications (including the length of disqualification and the reason for the disqualification) and to provide the information to authorized vendors and program participants. The FSP, which has such authority and periodically issues public notices on retailer disqualifications, has found that disclosing this information serves as a strong deterrent to retailer fraud and abuse. The Department believes that issuing public notices of

WIC vendor disqualifications would deter vendor fraud and abuse in the WIC Program as well. Publicizing this information also would alert program participants when the WIC Program no longer authorizes a particular vendor.

The Department considers this amendment to regulations at 7 CFR 246.26(e) to be in the best interests of the Program. Notwithstanding this change, the Department continues to believe that limiting the use and disclosure of confidential vendor information encourages vendors to provide the information that State agencies need in order to authorize and monitor vendors and to maintain effective investigative techniques.

**List of Subjects in 7 CFR Part 246**

Food assistance programs, Food donations, Grant programs—Social programs, Infants and children, Maternal and child health, Nutrition education, Public assistance programs, WIC, Women.

Accordingly, 7 CFR part 246 is proposed to be amended as follows:

**PART 246—SPECIAL SUPPLEMENTAL NUTRITION PROGRAM FOR WOMEN, INFANTS AND CHILDREN**

1. The authority citation for Part 246 continues to read as follows:

**Authority:** 42 U.S.C. 1786.

2. In § 246.16a:

a. Amend paragraph (j)(2) by removing the word “or” at the end of the paragraph;

b. Amend paragraph (j)(3) by removing the period at the end of the paragraph and adding in its place a semicolon followed by the word “or”; and

c. Add paragraph (j)(4).

The addition reads as follows:

**§ 246.16a Infant formula cost containment.**

\* \* \* \* \*

(j) \* \* \*

(4) Require infant formula manufacturers to provide gratis infant formula, services, or other items.

\* \* \* \* \*

3. In § 246.18, add a new paragraph (a)(1)(ii)(I) to read as follows:

**§ 246.18 Administrative review of State agency actions.**

(a) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(I) A civil money penalty imposed in lieu of disqualification based on a Food Stamp Program disqualification (§ 246.12(l)(i)(vii)).

\* \* \* \* \*

**§ 246.26 [Amended]**

4. In § 246.26, amend the first sentence of the introductory text of paragraph (e) by removing the words “and authorization status” and by adding, in their place, the words “, telephone number, website/email address, authorization status, WIC identification number, and disqualification information (including the length of the disqualification and the reason for the disqualification).”

Dated: July 20, 2005.

**Roberto Salazar,**

*Administrator, Food and Nutrition Service.*

[FR Doc. 05–14873 Filed 7–26–05; 8:45 am]

**BILLING CODE 3410–30–P**

**DEPARTMENT OF AGRICULTURE**

**Agricultural Marketing Service**

**7 CFR Part 1033**

[Docket No. AO–166–A72; DA–05–01–A]

**Milk in the Mideast Marketing Area; Tentative Partial Decision on Proposed Amendments and Opportunity To File Written Exceptions to Tentative Marketing Agreement and Order**

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** This tentative partial decision adopts on an interim final and emergency basis proposals that would amend certain features of the pooling standards of the Mideast milk marketing order. Specifically, this decision will: (1) Prohibit the ability to simultaneously pool the same milk on the Mideast Federal milk order and on a marketwide equalization pool administered by another government entity; (2) lower the diversion limit standards; and (3) increase the performance standards for supply plants. A separate decision will be issued that will address proposals to deter the de-pooling of milk, adopt transportation credits and clarify the *Producer* definition of the order. This decision requires determining if producers approve the issuance of the amended order on an interim basis.

**DATES:** Comments should be submitted on or before September 26, 2005.

**ADDRESSES:** Comments (6 copies) should be filed with the Hearing Clerk, STOP 9200—Room 1031, United States Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC 20250–9200. You may send your comments by the electronic process available at the Federal e-Rulemaking portal: <http://>