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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

RIN 0584–AD73

[FNS–2007–0009]

Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Implementation of Nondiscretionary WIC Certification and General Administrative Provisions

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim final rule.

SUMMARY: This interim final rule amends the regulations for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) by implementing most of the nondiscretionary provisions of the Child Nutrition and WIC Reauthorization Act of 2004 that address participant certification and general program administration in the WIC Program. It also implements the exclusions from income eligibility determinations set forth in the National Defense Authorization Act for Fiscal Year (FY) 2006 and in the National Flood Insurance Act of 1968, as amended, and clarifies an inconsistency related to fair hearings and notices of adverse actions that was inadvertently omitted in the publication of the Final WIC Miscellaneous Rule. Finally, this rulemaking includes technical amendments to correct the address and telephone numbers to which complaints alleging discrimination in the WIC Program should be directed, and to correct the address of the Western Regional Office of the Food and Nutrition Service (FNS).

The provisions set forth in this rulemaking are nondiscretionary, i.e., the Department has not exercised any authority to interpret the statutory provisions beyond the language that is specifically provided in the legislation. However, the Department believes that at least one of the provisions in this rulemaking may generate additional questions or comments concerning its implementation. Therefore, the rule is being issued as an interim final rule, to afford the public the opportunity to comment on the possible implications of the provisions contained herein.

DATES: *Effective Date:* This rule will become effective on May 2, 2008.

Implementation Date: State agencies must implement the provisions of this rule no later than April 2, 2008.

Comment Date: To be considered, comments on this interim rule must be postmarked on or before June 2, 2008.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Under the ''Comment or Submission'' tab, enter Docket ID # FNS–2007–0009 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Mail:* Send comments to Patricia N. Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302, (703) 305–2746.

Comments submitted in response to this interim 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. FNS will make the comments publicly available on the Internet via *http://www.regulations.gov*. Information regarding the interim rule will be available on the FNS Web site at *http://www.fns.usda.gov/wic*.

FOR FURTHER INFORMATION CONTACT: Debra R. Whitford, Chief, Policy and Program Development Branch, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, VA 22302, (703) 305–2746, or *Debbie.Whitford@fns.usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be significant and was reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Impact Analysis

As required for all rules that have been designated as Significant by the Office of Management and Budget, a Regulatory Impact Analysis was developed for this rule. A complete copy of the Impact Analysis is available by contacting FNS as indicated in the **ADDRESSES** section of this Preamble.

The following summarizes the conclusions of the regulatory impact analysis:

Need for Action

This action is needed to implement the nondiscretionary provisions of the Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265, as well as several additional nondiscretionary legislative provisions affecting the WIC Program. The rule contains several nondiscretionary provisions related to certification, operation, and general administration in the WIC Program, including expanded definitions of ''nutrition education'' and ''supplemental foods''; new exclusions from WIC income eligibility determinations; a new assurance of nondiscrimination; new requirements affecting infant formula rebate contracts; additional exceptions to the physical presence requirement for certification; new requirements and stipulations regarding food delivery systems; and expanded allowances in the areas of funding and financial management.

Benefits

FNS has already issued policy and guidance to State agencies on implementation of the legislative requirements addressed in this rulemaking, since all of the provisions of the Child Nutrition and WIC Reauthorization Act of 2004 were effective by law on either June 30, 2004; July 1, 2004; or October 1, 2004. Consequently, FNS believes that the current rule will accomplish the goals of the Act concerning participant certification and general program

administration. Additionally, the rule has provisions that improve participant access and that give State agencies added flexibility.

Costs

Overall, most of the provisions will result in little or no change in program costs.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–602). Although not required by the Act, Nancy Montanez Johner, Under Secretary, Food, Nutrition, and Consumer Services, hereby certifies that this rule will not have a significant impact upon a substantial number of small entities. The provisions implemented through this rulemaking apply to all State agencies administering the WIC Program, regardless of size. Further, several of the provisions contained in this rule represent options now available to WIC State agencies, rather than new requirements for the operation and administration of the Program.

Public Law 104–4, Unfunded Mandate Reform Act of 1995 (UMRA)

Title II of the UMRA 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, FNS must generally prepare a written statement, including a cost-benefit analysis, for proposed and interim final/final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments in the aggregate, or to 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 least costly, more cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector of $100 million or more in any one year. This rule is therefore 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 No. 10.557. For the reasons set forth in the final rule in 7 CFR part 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.

Prior to enactment of the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265), the Department held listening sessions at selected locations throughout the country at which representatives of the WIC community had the opportunity to identify areas of interest and concern that they wanted the Reauthorization Act to address. Staff from FNS' headquarters and regional offices also had both formal and informal discussions with State and local officials on an ongoing basis regarding program operation and administration. All of these discussions allowed State and local WIC agencies, as well as other interested parties, to provide feedback that formed the basis for the nondiscretionary legislative provisions contained in Pub. L. 108–265 and implemented through this rulemaking.

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 three categories called for under Section 6(b)(2)(B) of Executive Order 13132. FNS has considered the impact of this rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, under Section 6(b) of the Executive Order, a federalism summary impact statement is not required.

Executive Order 12988

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

In the Special Supplemental Food Program for Women, Infants and Children (WIC), the administrative procedures that must be exhausted are as follows:

- State agency hearing procedures pursuant to 7 CFR 246.9 must be exhausted for participants concerning denial of participation, disqualification, and claims;
- State agency hearing procedures pursuant to 7 CFR 246.18(a)(1) must be exhausted for vendors concerning denial of authorization, termination of agreement, disqualification, civil money penalty or fine;
- The State agency process for providing the vendor an opportunity to justify or correct the food instrument pursuant to 7 CFR 246.12(k)(3) must be exhausted for vendors concerning delaying payment for a food instrument or a claim;
- State agency hearing procedures pursuant to 7 CFR 246.18(a)(3) must be exhausted for local agencies concerning denial of application, disqualification, or any other adverse action affecting participation;
- FNS hearing procedures pursuant to 7 CFR 246.22 must be exhausted for State agencies concerning sanctions imposed by FNS; and
- Administrative appeal to the extent required by 7 CFR 3016.36 must be exhausted for vendors and local agencies concerning procurement decisions of State agencies.

Civil Rights Impact Analysis

FNS has reviewed this rule in accordance with the Department Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. FNS has determined that the rule's intent and provisions will not adversely affect access to WIC services by eligible persons. 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 governments that administer the WIC Program from engaging in actions that discriminate based on race, color, national origin, age, sex, 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 basis 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 of this rulemaking, 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 such collection(s) may be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This interim 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.

E-Government Act Compliance

FNS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and other services, and for other purposes. State Plan amendments regarding the implementation of the provisions contained in this rule, as is the case with the entire State Plan, may be transmitted electronically by the State agency to FNS. Also, State agencies may provide vendor and infant formula rebate data, as well as their financial reports, to FNS electronically.

Public Participation

This action is being finalized without prior notice or public comment under authority of 5 U.S.C. 553(b)(3)(A) and (B). The Child Nutrition and WIC Reauthorization Act of 2004, Public Law 108–265, contained provisions that must be implemented exactly as set forth in the legislation, with no discretion exercised by the Department regarding such implementation. Further, State agencies have already been informed that these nondiscretionary provisions must be implemented prior to the issuance of amendments to the program regulations. Therefore, Under Secretary Nancy Montanez Johner has determined, in accordance with 5 U.S.C. 553(b), that a Notice of Proposed Rulemaking and Opportunity for Public Comments is unnecessary and contrary to the public interest and, in accordance with 5 U.S.C. 553(d), finds that good cause exists for making this rule effective without prior public comment.

Background

The Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265, also known as the Reauthorization Act), enacted on June 30, 2004, contained a number of nondiscretionary provisions related to certification, operation, and general administration. These provisions include:

- Expanded definitions of ''nutrition education'' and ''supplemental foods'';
- New requirements affecting infant formula rebate contracts;
- Additional exceptions to the physical presence requirement for certification;
- New requirements and stipulations regarding food delivery systems; and
- Expanded allowances in the areas of funding and financial management.

FNS issued policy and guidance to State agencies on implementation of these nondiscretionary legislative requirements. All of the provisions of the Child Nutrition and WIC Reauthorization Act of 2004 implemented by this rulemaking were effective by law as noted below. Effective dates for the provisions of the National Defense Authorization Act for Fiscal Year 2006, and amendments to the National Flood Insurance Act of 1968 which are being incorporated into the regulations are also indicated below. All subsequent references to Program regulatory provisions in this preamble are to title 7, Code of Federal Regulations, unless otherwise indicated.

June 30, 2004 (date of enactment): § 246.12(g)(4); § 246.14(e), § 246.14(e)(1), § 246.14(e)(3)(iii), § 246.14(e)(4), and § 246.14(e)(5); and § 246.16(b)(3)(ii)(A).

July 1, 2004: § 246.16a(c)(2).

October 1, 2004: § 246.2 (Definitions); § 246.4(a)(22); § 246.7(o)(2)(ii) and § 246.7(o)(2)(iv); § 246.12(r)(6); § 246.16a(c)(6)(iii) through (c)(6)(iv); § 246.16a(c)(1)(ii); § 246.16a(k); and § 246.16a(l)(3).

June 23, 2005: § 246.16a(m).

September 20, 2005: § 246.7(d)(2)(iv)(D)(*34*).

December 2, 2005: § 246.8(b).

January 6, 2006 (date of enactment): § 246.7(d)(2)(iv)(D)(*33*).

Additionally, two legislative exclusions from consideration *in determining income eligibility* for the WIC Program are included in this rulemaking. Both of these exclusions were effective immediately upon the date of enactment of their respective laws.

The clarification of an inadvertent inconsistency and omission related to fair hearings and notices of adverse actions as set forth at § 246.9(g) will be effective immediately upon publication of this rule.

Finally, two technical amendments are included in this rule. The first amendment applies specifically to § 246.8, Nondiscrimination, and revises the address and telephone numbers to which complaints of alleged discrimination should be directed. The second amendment provides the new address for the FNS Western Region, as set forth in § 246.27, Program information.

For clarity, the discussions of the regulatory amendments related to each of these major issues are addressed by topic, rather than in strict regulatory sequential order.

1. Expanded Definitions of ''Nutrition Education'' and ''Supplemental Foods''

Nutrition Education (§ 246.2)

Section 203(a)(1) of the Reauthorization Act amends Section 17(b)(7) of the CNA by revising the definition of ''nutrition education'' to include a reference to physical activity. It also removes the term ''socioeconomic'' from the current definition. By law, these changes were effective October 1, 2004. This revision recognizes that physical activity is one of the key recommendations included in the Dietary Guidelines for Americans 2005 (DGA). The DGAs provide the foundation for WIC nutrition education. The promotion of the health benefits of regular physical activity as a component of nutrition education supports the development of lifelong habits for good health. This legislative provision does not change the principles or requirements previously set forth by the Department regarding the allowable costs of physical activity promotion as a component of nutrition education for WIC participants.

Therefore, the definition of ''nutrition education'' in § 246.2 is amended to reflect the exact language set forth in Public Law 108–265. Additionally, regulatory language related to nutrition education at § 246.11(b) is modified to conform to the new definition.

Supplemental Foods (§ 246.2)

Section 203(a)(2) of Public Law 108–265 amends Section 17(b)(14) of the CNA, effective October 1, 2004, by revising the definition of ''supplemental foods'' to include foods that promote health as indicated by relevant nutrition science, public health concerns, and cultural eating patterns. This revision broadens the definition to acknowledge that the identification of supplemental foods provided by WIC should consider relevant nutrition science as well as current public health concerns and cultural eating patterns.

Therefore, the definition of ''supplemental foods'' in § 246.2 is amended to reflect the exact language set forth in Public Law 108–265.

2. New Requirements Affecting Infant Formula Rebate Contracts

a. Primary Contract Infant Formula (§§ 246.2 and 246.16a)

Section 203(a)(3) of the Reauthorization Act amends Section 17(b) of the CNA to add a definition of ''primary contract infant formula''. Although the term ''primary contract infant formula'' is used throughout § 246.16a (Infant formula cost containment), program regulations do not currently include a specific definition of that term. Including a specific definition at § 246.2 is intended to clarify the use of ''primary contract infant formula'' wherever it is used. The definition is the same language set forth in Public Law 108–265.

As of October 1, 2004, ''primary contact infant formula'' is used in the WIC Program to refer to the specific infant formula for which a manufacturer submits a bid to a State agency in response to a rebate solicitation and for which a contract is awarded by the State agency as a result of that bid.

Section 203(e)(4) of the Reauthorization Act also amends Section 17(h)(8)(A) of the CNA by adding language to clarify that the State agency is required to use the primary contract infant formula as the first choice of issuance for all WIC infants receiving infant formula in their prescribed food packages, with all other infant formulas issued as an alternative to the primary contract infant formula. Current regulations at § 246.16a(c)(6) provide the State agency with the discretion to approve for issuance, in addition to the primary contract infant formula(s), none, some, or all of the winning bidder's other infant formulas. These other infant formulas from the winning bidder will be considered contract brand infant formulas. If a State agency issues separate (uncoupled) bid solicitations for milk-based and soy-based infant formula, the State agency will have two primary contract infant formulas, one for each contract. In addition, the State agency may require medical documentation before issuing any contract brand infant formula and must require medical documentation before issuing any non-contract brand infant formula, exempt infant formula, or WIC-eligible medical food.

Effective for all bid solicitations issued on or after October 1, 2004, the State agency must issue the primary contract infant formula, as defined in the Reauthorization Act, as the formula of first choice. The State agency may continue to issue contract brand and non-contract brand alternatives to the primary contract infant formula, if determined to be more appropriate.

b. State Alliance (§§ 246.2, 246.16a)

Section 203(a)(3) of Public Law 108–265 amends Section 17(b) of the CNA to include a definition of ''state alliance.'' While alliances have existed in practice, WIC Program regulations have not contained a specific definition for a State alliance. This rule defines ''State alliance'' in the same manner as set forth in Public Law 108–265.

Section 203(e)(3) of the same law limits the size of State alliances, as defined at § 246.2 of this interim rule, to 100,000 infants served by the participating State agencies as of October 1, 2003, or a subsequent date determined by the Secretary for which data is available.

For many years, WIC State agencies have entered into partnerships to form an alliance for the purpose of promoting competitive bids and administrative simplification. However, an unintended consequence of large alliances is that competition is diminished because not all infant formula manufacturers may be able to compete for larger State alliance contracts due to production capacity. The Department believes that limiting the size of State alliances will help to maintain competition among infant formula manufacturers by ensuring all manufacturers can compete for rebate contracts.

Section 203(e)(3) of Public Law 108–265 allows current State alliances that serve more than 100,000 infant participants to continue to exist, but prohibits them from adding new State agencies to such alliances, except under the following circumstances:

- A State alliance that serves more than 100,000 infants may expand to include additional State agencies if the State agency to be included is an Indian Tribal Organization that is also a WIC State agency or a State agency that serves less than 5,000 infants as of October 1, 2003, or a subsequent date determined by the Secretary for which data is available.
- Public Law 108–265 also allows the Secretary to grant a waiver to the State agency alliance requirements after submitting a written report to the Committee on Education and the Workforce of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate that describes the cost-containment and competitive benefits of the proposed waiver.

Therefore, §§ 246.16a(c)(1)(ii) and 246.16a(c)(2) are amended to include these limitations and their corresponding exceptions. Also, § 246.16a(k) is redesignated as § 246.16a(l), and amended to reflect changes required in Public Law 108–265. This section addresses provisions for a national cost containment bid solicitation and selection.

c. Rebate Invoices (§ 246.16a(k))

Section 203(e)(5) of Public Law 108–265 requires WIC State agencies to have a system that ensures that infant formula rebate invoices, under competitive bidding, provide a reasonable estimate or an actual count of the number of units (i.e., cans) of infant formula purchased by participants with food instruments.

Manufacturers pay rebates to the State agency based on the number of units of contract brand infant formula indicated on monthly rebate invoices. Historically, State agencies have based their rebate invoices on the total number of units of formula authorized on redeemed food instruments. Because WIC participants do not always purchase the total amount of formula authorized, this method inadvertently bills manufacturers for units of formula that were not purchased. Therefore, a system that bases monthly rebate invoices on the number of units of formula authorized on redeemed food instruments may not be a reasonable estimate of the number of units purchased by participants.

To implement this provision, the current § 246.16a(k) is redesignated as § 246.16a(l), and a new paragraph (k) is added that sets forth the requirements for infant formula rebate invoices.

The Department recognizes the challenges some State agencies may face in implementing this requirement. However, over the past few years, many State agencies have worked collaboratively with infant formula manufacturers to develop methodologies that provide a close approximation or reasonable estimate of

the number of units of infant formula purchased with WIC food instruments. State agencies that have not yet developed such methodologies should seek information and advice from the Department, as well as from other WIC State agencies that currently have billing systems based on reasonable estimates or actual counts. In addition, the Department encourages State agencies to work together with manufacturers when developing an acceptable billing system.

Over the past few years, many State agencies have worked collaboratively with infant formula manufacturers to develop methodologies that provide a close approximation or reasonable estimate of the number of units of infant formula purchased with WIC food instruments. State agencies that need further improvements to their methodologies should seek information and advice from the Department, as well as from other WIC State agencies that currently have billing systems based on reasonable estimates or actual counts. In addition, the Department encourages State agencies to work together with manufacturers when developing an acceptable billing system.

d. Uncoupling Milk-Based and Soy-Based Infant Formula Bids (§ 246.16a(c)(1)(ii))

Section 203(e)(6) of Public Law 108–265 requires any WIC State agency or State alliance that served a monthly average of more than 100,000 infants during the preceding 12-month period to solicit separate bids for milk-based and soy-based infant formulas. This provision is implemented by its addition to the WIC Program regulations at § 246.16a(c)(1)(ii).

State agencies have always had the option to solicit separate bids for milk- and soy-based infant formulas. In practice, however, most State agencies do not exercise this option. When State agencies do solicit separate bids, competition is open to manufacturers that otherwise may not be able to bid if the infant formula types were coupled due to factors such as production capacity and/or distribution issues. The intent of this provision is to promote competition among infant formula manufacturers by ensuring all manufacturers are able to compete for rebate contracts. Separate bids for milk- and soy-based infant formulas may result in a State agency having two primary contract infant formulas, one for milk-based and one for soy-based formulas. This provision applies to bid solicitations issued on or after October 1, 2004.

e. Cent-for-Cent Adjustments (§ 246.16a(c)(6)(iv))

Section 203(e)(7) of Public Law 108–265 requires State agencies to adjust for price increases and price decreases subsequent to the bid opening. This provision applies to bid solicitations issued on or after October 1, 2004.

Current regulations state that bid solicitations must require manufacturers to adjust for price changes subsequent to the bid opening; however, it only mandates that manufacturers provide for cost adjustments as a result of any inflation in the wholesale prices of infant formula. It does not include a corresponding adjustment for decreases in wholesale prices. Section 246.16a(c)(6)(iv) reflects this new requirement of adjusting rebates to reflect both increases and decreases in infant formula prices.

f. Infant Formula Rebate Contracts and Civil Monetary Penalties (§ 246.16a(l))

This regulation also codifies, at § 246.16a(m), a requirement mandated by Section 17(h)(8)(H) of the CNA. The CNA requires any legal entity (i.e., person, company, corporation), shall be ineligible to submit bids for up to 2 years if it discloses the bid amount or discloses the rebate or discount practices in advance of the bid opening. In addition, the legal entity shall be subject to a civil penalty of up to $100,000, as determined by the Secretary, to provide restitution to the program for harm done.

The Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–410, 28 U.S.C. 2461 note (the Act)) as amended, requires Federal agencies periodically to adjust certain civil monetary penalties (CMPs) for inflation. Under the Act, a CMP is defined as any penalty, fine, or other sanction for which a Federal statute specified a monetary amount, including a range of minimum and maximum amounts. Each Executive agency is responsible for adjusting, pursuant to the Act, all CMPs within the agency's jurisdiction.

The Act requires each Executive agency to make an initial inflation adjustment for all applicable CMPs not later than 180 days after the date of enactment of the Debt Collection Improvement Act of 1996 (Pub. L. 104–134)—i.e., April 26, 1996—and subsequent inflation adjustments at least once every 4 years thereafter. USDA published its initial round of inflation adjustments in the **Federal Register** on July 31, 1997, and those adjustments became effective on September 2, 1997 (62 FR 40924, July 31, 1997). USDA's initial CMP adjustments are codified in subpart E of 7 CFR 3.91. Subsequently, 7 CFR 3.91(b) was amended to reflect a second round of inflation adjustments in the **Federal Register** on May 24, 2005, and those adjustments became effective June 23, 2005 (70 FR 29573, May 24, 2005). As a result, when adjusted for inflation, the original $100,000,000 civil penalty increases to $132,000,000. This regulation refers to 7 CFR 3.91 when determining a CMP for any person, company, corporation, or legal entity for violations of § 246.16a(l).

Although the provision for determining CMPs with the necessary adjustments for inflation is not contained in the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265), it is nondiscretionary. Therefore, it is being included with this interim rule because this is the first appropriate rulemaking with implications for infant formula rebate contracts to be promulgated since the enactment of the second round of adjustments pursuant to the Debt Collection Improvement Act of 1996.

3. Additional Exceptions to the Physical Presence Requirement for Certification (§ 246.7(p)(2))

Section 246.7(p)(2)(ii) of the current WIC Program regulations allows a State agency to exempt from being physically present at certification an infant or child who was present at his/her initial WIC certification and has documented ongoing health care from a health care provider other than the WIC local agency (as set forth in § 246.7(p)(1)), if being physically present would pose an unreasonable barrier.

Section 203(b)(2) of the Reauthorization Act amends Section 17(d)(3)(C)(ii) of the CNA to allow a State agency the option to waive the physical presence requirement for an infant or child who was present at his/her initial WIC certification and is receiving ongoing health care. In addition, the Reauthorization Act provides an additional exception from the physical presence requirement for an infant under 8 weeks of age who cannot be present at certification for a reason determined appropriate by the local agency, and for whom all necessary certification information is provided. These changes are intended to reduce the burden on WIC applicants and participants while maintaining program integrity.

Thus, § 246.7(p)(2)(ii) is revised in this rule to incorporate the legislative option for exemption from the physical presence requirement and applies to an infant or child receiving ongoing health care from any health care provider,

including the local WIC agency. The revised regulatory language also includes the new exemption from the physical presence requirement for infants under 8 weeks of age who cannot be present at the time of certification (for a reason determined appropriate by the local agency) and for whom all necessary certification information is provided.

4. New Requirements and Stipulations Regarding Food Delivery Systems (§ 246.12)

a. Participants Allowed To Receive Supplemental Foods From Any Authorized Vendor (§ 246.12(r))

Section 203(c)(1)(A) of Public Law 108–265 amends Section 17(f)(1)(C)(i) of the CNA to require WIC State agencies, effective October 1, 2004, to allow participants to receive supplemental foods from any authorized vendor in the State under retail food delivery systems.

This is a new requirement for WIC State agencies. Previously, State agencies were permitted to implement retail food delivery systems in which the name of a specific authorized store, as designated by the participant, was printed on the WIC food instrument.

State agencies are no longer allowed to operate such ''vendor-specific'' retail food delivery systems, i.e., systems that specify the vendor on the food instrument or otherwise require transaction of the food instrument at a designated vendor, even if the participant is provided an opportunity to choose the vendor to be so designated. Therefore, § 246.12(r) is revised to add a requirement that WIC State agencies must establish policy and revise their retail food delivery systems to ensure that WIC participants are allowed to transact their food instruments at any retail store authorized by the State agency.

b. Processing Vendor Applications Outside Established Timeframes (§ 246.4)

Section 203(c)(1) of the Reauthorization Act amends Section 17(f)(1)(C) of the CNA by adding a new provision requiring State agencies to include in their State plans procedures for accepting and processing vendor applications outside the established timeframes if the State agency determines that there will otherwise be inadequate participant access to the WIC Program. This includes instances in which a previously authorized vendor sells a store under circumstances that do not permit timely notification to the State agency of the change in ownership. By law, this provision was effective October 1, 2004.

Currently, § 246.12(g)(7) of the WIC regulations requires the State agency to develop procedures for processing vendor applications outside of its established timeframes when it determines there will be inadequate participant access unless additional vendors are authorized, and § 246.4(a)(14) requires a description of the participant access criteria to be included in the State Plan of Operations. Also, § 246.12(h)(3)(xvii) provides the State agency the discretion to determine the length of advance notice required for vendors reporting changes in ownership. Thus, all State Plans must currently describe participant access criteria, and many State Plans also address vendor application processing timeframes.

This provision reinforces the existing regulatory provisions by adding the requirement for a description of these procedures as part of the State Plan to § 246.4(a)(22).

c. Prohibition Against Imposition of EBT Costs on Vendors (§ 246.12(g)(4))

Section 203(e)(11) of Public Law 108–265 amended Section 17(h)(12) of the CNA, by replacing it with a new provision that prohibits the Secretary from imposing or allowing a State agency to impose the cost of electronic benefit transfer (EBT) equipment, systems, or processing on retail vendors as a condition for authorization or participation in the program. By law, this provision was effective June 30, 2004. Such costs include EBT equipment, systems, or processing which are directly attributable to a WIC EBT system and used solely for the WIC Program. Retailers may, however, continue to provide funding for WIC EBT on a voluntary basis, as a number of retailers have already done. WIC EBT is intended to improve program efficiency, and retailers may make a business decision to share in the costs of WIC EBT.

EBT processing is the automated data processing in support of WIC EBT purchase transactions and the associated reimbursement to retailers for their daily WIC EBT business. These activities may be carried out by the State agency or a State agency's contracted EBT processor and/or payment processor.

It is customary practice for commercial processors that support retailer credit, debit, and food stamp EBT transactions to charge processing fees. Banks also charge fees for automated credits to their customers' accounts. These types of processing fees result from specific retailer business decisions; thus, if a retailer decides to participate in a State EBT system, this cost would not be imposed by the State agency, but would result in a cost to the retailer as part of its commercial relationships.

In response to the legislative provisions contained in Public Law 108–265, § 246.12(g) is amended to prohibit a State agency from imposing the costs of EBT equipment, systems, or processing on retail vendors.

5. Expanded Allowances in Funding and Financial Management (§§ 246.14(e) and 246.16(b))

a. Use of Local Agency Claims (§ 246.14(e))

Section 203(c)(3) of Public Law 108–265 amended Section 17(f)(21) of the CNA to allow the WIC State agency to use funds collected through claims assessed against local agencies in the same manner that it uses claims collected from vendors and participants. WIC Program regulations at § 246.14(e) allow the State agency to keep vendor and participant collections and use these funds in the fiscal year in which the initial obligation was made, in which the claim arose, in which the funds are collected, or after the funds are collected, provided certain conditions are met. Before the State agency may credit such recoveries, it must provide vendors and participants with a means to appeal the claim action. For vendor claims, the State agency must provide vendors with an opportunity to justify or correct the claim (§ 246.12(k)(3)); for participant claims, the State agency must provide participants with an administrative hearing (§ 246.9). Because regulations at § 246.18 do not require the State agency to provide the local agency with a full administrative review for local agency claims, unless a claim affects the local agency's participation, the State agency has the discretion to determine the level of review provided for local agency claims. The State agency's review process for local agency claims should be specified or referenced in its local agency agreement. Consequently, a paragraph was added to the regulations to permit the State agency to credit recoveries of local agency claims only after any administrative review requested by the local agency in accordance with the local agency agreement has been completed, making this provision consistent with the requirements for vendor and participant claims.

In addition, the paragraphs in the regulations containing the reporting and

documentation requirements (§ 246.14(e)(4) through (e)(5)) for vendor and participant claims were revised to include local agency claims. Further guidance regarding State agency reporting of local agency collections is provided in the WIC Reporting Guide.

b. Spendforward Authority (§ 246.16(b))

Section 203(f) of Public Law 108–265 amended Section 17(i)(3)(A)(ii)(I) of the CNA to increase the State agency's spendforward authority for nutrition services and administration (NSA) funds from one percent to three percent of its total grant. Regulations at § 246.16(b)(3)(ii) specify the requirements that a State agency must follow to spend forward NSA funds into the next fiscal year. This legislative provision simply increased the spendforward authority without altering any of the other requirements regarding spendforward funds. Consequently, the regulations prohibiting food fund conversions from being spent forward, as well as those allowing an additional one-half of one percent to be spent forward for the development of management information and EBT systems, remain in effect.

6. Income Exclusions in Determining WIC Eligibility (§ 246.7(d))

a. Family Subsistence Supplemental Allowance (FSSA) Payments

Public Law 108–375, the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, excluded FSSA payments, which are provided to certain members of the Armed Forces and their families, as income in determining eligibility for a number of child nutrition programs, including the WIC program. This provision would have expired September 30, 2006. However, Public Law 109–163, the National Defense Authorization Act for Fiscal Year 2006, made the FSSA, and the exclusion of FSSA assistance from income under other programs, permanent. Therefore, the exclusion of FSSA payments as income for child nutrition programs, including the WIC Program, is also permanent. In determining income eligibility for the WIC Program, WIC State agencies must exclude the FSSA payment. FSSA payments have been made to certain members of the Armed Forces by the Department of Defense (DOD) since May 2001.

b. National Flood Insurance Program Payments

Public Law 109–64, enacted September 20, 2005, which amends the National Flood Insurance Act of 1968, states that payments made under the National Flood Insurance Program for flood mitigation activities shall not be counted as income or resources of the owner of the property when determining eligibility for any Federal means-tested program. The Federal Emergency Management Agency awards grants to States and communities, which distribute the funds to individuals and businesses for activities that reduce the risk of repetitive flood damage. Therefore, in determining income eligibility for the WIC Program, State agencies must exclude payments received by property owners under the National Flood Insurance Program.

These income exclusions are added to § 246.7(d)(2)(iv)(D) as paragraphs (d)(2)(iv)(D)(*33*) and (d)(2)(iv)(D)(*34*), respectively.

7. Fair Hearings and Adverse Action Notification Requirements

Prior to the publication of the WIC Miscellaneous Final Rule (71 FR 56708, September 27, 2006), § 246.9(g) of the WIC Program regulations required a participant to request a fair hearing within the 15-day advance adverse action notification period in order to continue receiving WIC benefits pending the outcome of the hearing, or expiration of the certification period, whichever comes first. This requirement was inadvertently removed from the regulations when regulatory language was added to avoid the incorrect impression that a participant must always request a fair hearing within the 15-day advance notice period, instead of within the 60-day period required at § 246.9(e).

However, it was not the intention of the Department to rescind this requirement; as indicated in the preamble to the Miscellaneous Final Rule (71 FR 56718), the requirement continues to be in effect. A participant may request a fair hearing within 60 days of the notification of adverse action, but § 246.9(g) should have stated in the Miscellaneous Final Rule that benefits will be continued only if the fair hearing is requested within the 15-day advance adverse action notice period. This rule clarifies the requirement concerning continuation of benefits during the fair hearing period by restoring the provision in question in this interim rule in § 246.9(g).

8. Technical Amendments

a. Complaints Alleging Discrimination in the WIC Program

Section 246.8(b) of the WIC regulations contains instructions on how discrimination complaints should be filed. The address and telephone numbers to which such complaints should be directed have been changed, and these changes have been included in this rule.

b. New Address for FNS Western Regional Office

The FNS Western Regional Office was relocated in March of 2007. This regulatory amendment updates the contact information provided in § 246.27(g) by providing the new address.

List of Subjects in 7 CFR Part 246

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

■ Accordingly, the WIC Program regulations at 7 CFR part 246 are 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 § 246.2:

■ a. Revise the definitions of ''Nutrition education'' and ''Supplemental foods''; and

■ b. Add in alphabetical order the new definitions ''Primary contract infant formula'', and ''State alliance''.

The additions and revisions read as follows:

§ 246.2 Definitions.

* * * * *

Nutrition education means individual and group sessions and the provision of materials that are designed to improve health status and achieve positive change in dietary and physical activity habits, and that emphasize the relationship between nutrition, physical activity, and health, all in keeping with the personal and cultural preferences of the individual.

* * * * *

Primary contract infant formula means the specific infant formula for which manufacturers submit a bid to a State agency in response to a rebate solicitation and for which a contract is awarded by the State agency as a result of that bid.

* * * * *

State alliance means two or more State agencies that join together for the purpose of procuring infant formula

under the Program by soliciting competitive bids for infant formula.

* * * * *

Supplemental foods means those foods containing nutrients determined by nutritional research to be lacking in the diets of pregnant, breastfeeding and postpartum women, infants, and children, and foods that promote the health of the population served by the WIC Program as indicated by relevant nutrition science, public health concerns, and cultural eating patterns, as prescribed by the Secretary in § 246.10.

* * * * *

■ 3. In § 246.4, redesignate paragraphs (a)(15) through (a)(27) as paragraphs (a)(16) through (a)(28), and add a new paragraph (a)(15), to read as follows:

§ 246.4 State plan.

(a) * * *

(15) The State agency's procedures for accepting and processing vendor applications outside of its established timeframes if the State agency determines there will otherwise be inadequate participant access to the WIC Program.

* * * * *

■ 4. In § 246.7:

■ a. The word ''and'' is removed from the end of paragraph (d)(2)(iv)(D)(*31*);

■ b. Paragraph (d)(2)(iv)(D)(*32*) is amended by removing the period at the end of the paragraph and adding in its place a semicolon.

■ c. New paragraphs (d)(2)(iv)(D)(*33*) and (d)(2)(iv)(D)(*34*) are added;

■ d. Paragraph (o)(2)(ii) is revised; and

■ e. A new paragraph (o)(2)(iv) is added.

The revision and additions read as follows:

§ 246.7 Certification of participants.

* * * * *

(d) * * *

(2) * * *

(iv) * * *

(D) * * *

(*33*) Payments received by members of the Armed Forces and their families under the Family Supplemental Subsistence Allowance from the Department of Defense (Pub. L. 109–163, sec. 608); and

(*34*) Payments received by property owners under the National Flood Insurance Program (Pub. L. 109–64).

* * * * *

(o) * * *

(2) * * *

(ii) *Receiving ongoing health care.* The State agency may exempt from the physical presence requirement, if being physically present would pose an unreasonable barrier, an infant or child who was present at his/her initial WIC certification and is receiving ongoing health care.

* * * * *

(iv) *Infants under 8 weeks of age.* The State agency may exempt from the physical presence requirement an infant under eight (8) weeks of age who cannot be present at certification for a reason determined appropriate by the local agency, and for whom all necessary certification information is provided.

* * * * *

■ 5. In § 246.8, the first sentence of paragraph (b) is revised to read as follows:

§ 246.8 Nondiscrimination.

* * * * *

(b) * * * Persons seeking to file discrimination complaints should write to USDA, Director, Office of Adjudication and Compliance, 1400 Independence Avenue, SW., Washington, DC 20250–9410, or call (800) 795–3272 (voice) or (202) 720–6382 (TTY). * * *

* * * * *

■ 6. In 246.9, revise paragraph (g) to read as follows:

§ 246.9 Fair hearing procedures for participants.

* * * * *

(g) *Continuation of benefits.* Participants who appeal the termination of benefits within the 15 days advance adverse action notice period provided by § 246.7(j)(6) must continue to receive Program benefits until the hearing official reaches a decision or the certification period expires, whichever occurs first. This does not apply to applicants denied benefits at initial certification, participants whose certification periods have expired, or participants who become categorically ineligible for benefits. Applicants who are denied benefits at initial certification, participants whose certification periods have expired, or participants who become categorically ineligible during a certification period may appeal the denial or termination within the timeframes set by the State agency in accordance with paragraph (e) of this section, but must not receive benefits while awaiting the hearing or its results.

* * * * *

■ 7. In § 246.10:

■ a. Amend paragraph (d)(2)(ii) by adding the words ''other than the primary contract infant formula'' immediately after the words ''any contract brand infant formula''; and

■ b. Revise the third sentence of paragraph (e)(1)(iii) to read as follows:

§ 246.10 Supplemental foods.

* * * * *

(e) * * *

(1) * * *

(iii) * * * Except as specified in paragraph (d) of this section, local agencies must issue as the first choice of issuance the primary contract infant formula, as defined in § 246.2, with all other infant formulas issued as an alternative to the primary contract infant formula.

* * * * *

§ 246.11 [Amended]

■ 8. In § 246.11:

■ a. Remove the word ''Stress'' in paragraph (b)(1), and add in its place the word ''Emphasize'';

■ b. Further amend paragraph (b)(1) by removing the words ''proper nutrition and good health'' in paragraph (b)(1), and adding in their place the words ''nutrition, physical activity and health''; and

■ c. In the first sentence of paragraph (b)(2), remove the words ''in achieving a positive change in food habits, resulting in improved nutritional status'', and add in their place the words ''in improving health status and achieving a positive change in dietary and physical activity habits,''.

■ 9. In § 246.12:

■ a. Redesignate paragraphs (g)(5) through (g)(9) as paragraphs (g)(6) through (g)(10);

■ b. Add a new paragraph (g)(5); and

■ c. Add a new paragraph (r)(6).

The additions read as follows:

§ 246.12 Food delivery systems.

* * * * *

(g) * * *

(5) *No imposition of EBT costs on retail vendors.* The State agency may not impose the costs of EBT equipment, systems, or processing required for electronic benefit transfers on any retail store authorized to transact food instruments, as a condition for authorization or participation in the program. The State agency may allow retailers to contribute to such costs on a voluntary basis.

* * * * *

(r) * * *

(6) *Any authorized vendor.* Each State agency shall allow participants to receive supplemental foods from any vendor authorized by the State agency under retail delivery systems.

* * * * *

■ 10. In § 246.14:

■ a. Revise the heading to paragraph (e);

■ b. Revise the first sentence of paragraph (e)(1);

■ c. Remove the word ''or'' at the end of paragraph (e)(3)(i);

■ d. Remove the period at the end of paragraph (e)(3)(ii) and add in its place the word ''; or'';
■ e. Add paragraph (e)(3)(iii); and
■ f. Revise paragraphs (e)(4) and (e)(5).

The revisions and addition read as follows:

§ 246.14 Program costs.

* * * * *

(e) *Use of funds recovered from vendors, participants, or local agencies.* (1) The State agency may keep funds collected through the recovery of claims assessed against vendors, participants, or local agencies. * * *

* * * * *

(3) * * *

(iii) In the case of a local agency claim, any administrative review requested in accordance with the local agency agreement has been completed.

(4) The State agency must report vendor, participant, and local agency recoveries to FNS through the normal reporting process;

(5) The State agency must keep documentation supporting the amount and use of these vendor, participant, and local agency recoveries.

■ 11. In § 246.16, revise the first sentence of paragraph (b)(3)(ii)(A) to read as follows:

§ 246.16 Distribution of funds.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(A) The State agency may spend forward NSA funds up to an amount equal to three (3) percent of its total grant (NSA plus food grants) in any fiscal year. * * *

* * * * *

■ 12. In § 246.16a:
■ a. Remove the words ''primary contract brand infant formula'' wherever they appear and add in their place the words ''primary contract infant formula'';
■ b. Amend paragraph (c)(1)(i) by removing the reference ''(c)(5)'' in the 5th sentence and adding in its place the reference ''(c)(6)'';
■ c. Add a new sentence between the first and second sentences in paragraph (c)(1)(ii);
■ d. Redesignate paragraphs (c)(2) through (c)(6) as paragraphs (c)(3) through (c)(7);
■ e. Add a new paragraph (c)(2);
■ f. Amend newly redesignated paragraph (c)(3) by removing the reference ''(c)(5)'' in the second sentence and adding in its place the reference ''(c)(6)'';
■ g. Remove the last sentence of newly redesignated paragraph (c)(3);
■ h. Amend the introductory text of newly redesignated paragraph (c)(4) by removing the reference ''(c)(3)(ii)'' and adding in its place the reference ''(c)(4)(ii)'';
■ i. Amend newly redesignated paragraph (c)(4)(ii) by removing the reference ''(c)(3)(i)'' wherever it appears, and adding in its place the reference ''(c)(4)(i)'';
■ j. Amend the last sentence of newly redesignated paragraph (c)(4)(iii) by removing the reference ''(c)(4)'' and adding in its place the reference ''(c)(5)'';
■ k. Amend newly redesignated paragraph (c)(5) by removing the reference ''(c)(3)'' in the first sentence and adding in its place the reference ''(c)(4)'';
■ l. Revise newly redesignated paragraphs (c)(6)(iii) and (c)(6)(iv);
■ m. Revise newly redesignated paragraph (c)(7);
■ n. Add a new paragraph (c)(8);
■ o. Amend paragraph (d)(2)(i)(A) and (d)(2)(i)(B) by removing the reference ''(c)(3)'' wherever it appears and adding in its place the reference ''(c)(4)'';
■ p. Redesignate paragraph (k) as paragraph (l);
■ q. Add a new paragraph (k);
■ r. In newly redesignated paragraph (l):
■ (i) Remove the reference ''(k)'' wherever it appears and add in its place the reference ''(l)'';
■ (ii) Amend the last sentence of newly redesignated paragraph (l)(3) by removing the references ''(k)(2)(ii), (k)(2)(iii) and (k)(2)(iv)'' and adding in their places the references ''(l)(2)(ii), (l)(2)(iii) and (l)(2)(iv)'';
■ (iii) Amend the first sentence of newly redesignated paragraph (l)(4) by removing the references ''(k)(2) and (k)(3)'' and adding in their places the references ''(l)(2) and (l)(3)'';
■ (iv) Amend the second sentence of newly redesignated paragraph (l)(5)(iii) by removing the reference ''(k)(5)(iii),'' and adding in its place the reference ''(l)(5)(iii)'';
■ (v) Amend the second sentence of newly redesignated paragraph (l)(8) by removing the reference ''(k)(7)'' and adding in its place the reference ''(l)(7)'';
■ (vi) Amend newly redesignated paragraph (l)(9) by removing the references ''(k)(7) and (k)(8)'' whenever they appear, and adding in their places the references ''(l)(7), and (l)(8)'';
■ (vii) Revise newly redesignated paragraph (l)(3); and
■ s. Add a new paragraph (m).

The revisions and additions read as follows:

§ 246.16a Infant formula cost containment.

* * * * *

(c) * * *

(1) * * *

(ii) * * * Any State agency or alliance that served a monthly average of more than 100,000 infants during the preceding 12-month period shall issue separate bid solicitations for milk-based and soy-based infant formula. * * *

(2) W*hat is the size limitation for a State alliance?* A State alliance may exist among State agencies if the total number of infants served by States participating in the alliance as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, does not exceed 100,000. However, a State alliance that existed as of July 1, 2004, and serves over 100,000 infants may exceed this limit to include any State agency that served less than 5,000 infants as of October 1, 2003, or such subsequent date determined by the Secretary for which data is available, and/or any Indian State agency. The Secretary may waive these requirements not earlier than 30 days after submitting to the Committee on Education and the Workforce of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a written report that describes the cost-containment and competitive benefits of the proposed waiver.

* * * * *

(6) * * *

(iii) *Calculation of rebates during contract term.* The rebates resulting from the application of the percentage discount must remain the same throughout the contract period except for the cent-for-cent rebate adjustments required in paragraph (c)(6)(iv) of this section.

(iv) *Cent-for-cent rebate adjustments.* Bid solicitations must require the manufacturer to adjust rebates for price changes subsequent to the bid opening. Price adjustments must reflect any increase and decrease, on a cent-for-cent basis, in the manufacturer's lowest national wholesale prices for a full truckload of infant formula.

(7) *What is the first choice of issuance for infant formula?* The State agency must use the primary contract infant formula(s) as the first choice of issuance (by physical form), with all other infant formulas issued as an alternative (see § 246.10(e)(1)(iii)).

(8) *Under what circumstances may the State agency issue other contract brand formulas?* Except as required in paragraph (c)(7) of this section, the State agency may choose to approve for issuance some, none, or all of the winning bidder's other infant

formula(s). In addition, the State agency may require medical documentation before issuing any contract brand infant formula, except as provided in paragraph (c)(7) of this section (see § 246.10(c)(1)(i)) and must require medical documentation before issuing any WIC formula covered by § 246.10(c)(1)(iii).

* * * * *

(k) *What are the requirements for infant formula rebate invoices?* A State agency must have a system in place that ensures infant formula rebate invoices, under competitive bidding, provide a reasonable estimate or an actual count of the number of units purchased by participants in the program.

(l) * * *

(3) If FNS determines that the number of State agencies making the request provided for in paragraph (l)(2) of this section does not comply with the requirements of paragraph (c)(2) of this section, FNS shall, in consultation with such State agencies, divide such State agencies into more than one group and solicit bids for each group. These groups of State agencies are referred to as ''bid groups.'' In determining the size and composition of the bid groups, FNS will, to the extent practicable, take into account the need to maximize the number of potential bidders so as to increase competition among infant formula manufacturers and the similarities in the State agencies' procurement and contract requirements (as provided by the State agencies in accordance with paragraphs (l)(2)(ii), (l)(2)(iii), and (l)(2)(iv) of this section). FNS reserves the right to exclude a State agency from the national bid solicitation and selection process if FNS determines that the State agency's procurement requirements or contractual requirements are so dissimilar from those of the other State agencies in any bid group that the State agency's inclusion in the bid group could adversely affect the bids.

* * * * *

(m) *What are the penalties for disclosing the amount of the bid or discount practices prior to the time bids are opened?* Any person, company, corporation, or other legal entity that submits a bid in response to a bid solicitation and discloses the amount of the bid, or the rebate or discount practices of such entities, in advance of the time the bids are opened by the Secretary or the State agency, shall be ineligible to submit bids to supply infant formula to the program for the bidding in progress for up to 2 years from the date the bids are opened. In addition, any person, company, corporation, or other legal entity shall be subject to a civil money penalty as specified in § 3.91(b)(3)(iv) of this title, as determined by the Secretary to provide restitution to the program for harm done to the program.

§ 246.27 [Amended]

■ 13. In § 246.27, amend paragraph (g) by removing the words ''550 Kearny Street, room 400, San Francisco, California 94108'', and adding in their place the words ''90 Seventh Street, Suite #10–100, San Francisco, California 94103''.

Dated: February 20, 2008.

Nancy Montanez Johner,

Under Secretary, Food, Nutrition, and Consumer Services.

[FR Doc. E8–3880 Filed 2–29–08; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

RIN 0563–AC00

Common Crop Insurance Regulations; Cultivated Wild Rice Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) finalizes the Cultivated Wild Rice Crop Insurance Provisions to convert the cultivated wild rice pilot crop insurance program to a permanent insurance program for the 2009 and succeeding crop years.

DATES: *Effective Date:* May 2, 2008.

FOR FURTHER INFORMATION CONTACT: Erin Albright, Risk Management Specialist, Product Management, Product Administration & Standards Division, Risk Management Agency, United States Department of Agriculture, Beacon Facility—Mail Stop 0812, Room 421, PO Box 419205, Kansas City, MO 64141–6205, telephone (816) 926–7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule is non-significant for the purpose of Executive Order 12866 and, therefore, it has not been reviewed by OMB.

Paperwork Reduction Act of 1995

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collections of information in this rule have been approved by OMB under control number 0563–0053 through June 30, 2008.

E-Government Act Compliance

FCIC is committed to complying with the E-Government Act of 2002, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This 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. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 13132

It has been determined under section 1(a) of Executive Order 13132, Federalism, that this rule does not have sufficient implications to warrant consultation with the States. The provisions contained in this rule will not have a substantial direct effect on States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

FCIC certifies that this regulation will not have a significant economical impact on a substantial number of small entities. Program requirements for the Federal crop insurance program are the same for all producers regardless of the size of their farming operation. For instance, all producers are required to submit an application and acreage report to establish their insurance guarantees and compute premium amounts, and all producers are required to submit a notice of loss and production information to determine the amount of an indemnity payment in the event of an insured cause of crop loss. Whether a producer has 10 acres or 1000 acres, there is no difference in the kind of information collected. To ensure crop insurance is available to small entities, the Federal Crop Insurance Act authorizes FCIC to waive collection of administrative fees from limited resource farmers. FCIC believes this