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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 246

RIN 0584–AB52

Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Requirements for and Evaluation of WIC Program Bid Solicitations for Infant Formula Rebate Contracts

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim rule.

SUMMARY: This rule strengthens and simplifies current bidding requirements for using a single-supplier competitive system to provide a rebate for infant formulas. It also addresses new infant formula cost containment requirements which are needed due to recent changes in the infant formula industry. This rule also requires WIC State agencies to award infant formula rebate contracts based on the lowest net price, allowing the highest rebate as a basis of award only when the weighted average retail prices of the different brands of infant formula vary by 5 percent or less. A proposed rule was published July 16, 1998 and as a result of comments received we are publishing an interim rule.

DATES: *Effective Date:* This rule is effective October 23, 2000.

Implementation Date: This rule must be implemented by November 21, 2000.

Comment Date: To be assured of consideration, written comments on this rule must be postmarked on or before August 23, 2001. Since comments are being accepted simultaneously on several separate rulemakings, commenters on this interim rule are asked to label their comments ''Requirements for and Evaluation of WIC Program Bid Solicitations for Infant Formula Rebate Contracts.''

ADDRESSES: Comments may be mailed to Patricia M. Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 540, Alexandria, Virginia 22302, phone number (703) 305–2746. All written comments will be available for public inspection during regular business hours (8:30 a.m.—5:00 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Patricia O'Kelley, Chief, Program Analysis and Monitoring Branch, Supplemental Food Programs Division, Food and Nutrition Service, USDA, phone number (703) 305–2710. An analysis package is available upon request at the above address.

SUPPLEMENTARY INFORMATION:

Background

The Department's fiscal year 1989 appropriations act (Public Law 100–460) 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 when feasible. Since that time, expenditures for infant formula have decreased from 40 percent of all WIC food costs to approximately 20 percent of all food costs in fiscal year 1997. Our figures show that nearly one out of every four WIC participants is supported with rebate savings. 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.

A key component to the success of infant formula rebates is the requirement in section 17(h)(8)(A) of the Child Nutrition Act of 1966 (42 U.S.C. 1786(h)(8)(A)) that WIC State agencies operating retail food delivery systems must use a competitive bidding system for the procurement of infant formula, or any other infant formula cost containment measure that yields savings equal to or greater than savings generated by a competitive bidding system.

However, the infant formula industry has changed considerably over the past several years. Today there are fewer infant formula manufacturers available to bid on infant formula rebate contracts, yet the product lines of infant formula have expanded along with the selection of packaging sizes offered. In addition, infant formula rebate contract awards are increasingly subject to protests and challenges for a variety of reasons. All of these changes have a potential negative effect on competition for WIC program infant formula rebate contracts.

Another issue regarding competition is the way bids for infant formula rebate contracts are evaluated. Current program regulations allow State agencies to evaluate infant formula rebate contracts by the lowest net wholesale cost or highest rebate per unit of infant formula. However, recognizing that the former method results in a competitive disadvantage to infant formula manufacturers that have significantly lower wholesale prices, the Department's appropriations acts for fiscal years 1997 and 1998, Public Laws 104–180 and 105–86, respectively, along with the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Public Law 105–336) for fiscal year 1999 and beyond, required State agencies to award infant formula rebate contracts on the basis of the lowest net price, unless the State agency demonstrates to the satisfaction of the Secretary of Agriculture that the weighted average retail price for different brands of infant formula in the State does not vary by more than 5 percent.

Therefore, a proposed rule to amend 7 CFR Part 246 (63 FR 38343, July 16, 1998) was published which addressed not only the lowest net price requirement, but also the numerous issues reflecting infant formula industry changes. The rule also included provisions to accommodate future market dynamics.

The proposed rule provided a 60-day comment period that ended on September 14, 1998. Twenty-nine comment letters were received on the proposed rule from the following sources: WIC State and local agencies, public interest groups, industry, and other Federal agencies. Approximately one-fourth of the comments were received after the comment period ended. However, because of the low number of comments received and because the late comments were similar to the ones received on time, we

considered all comments. In addition, WIC staff met with representatives from industry who expressed and reiterated their written comments on the proposed rule. We have given all comments careful consideration in the development of this interim rule and would like to thank all commenters who responded to the proposal.

We have made many changes to the proposed rule as a result of the comments received which clarify current and existing proposed requirements. In addition, we have taken this opportunity to consolidate the cost containment requirements in a new section (7 CFR § 246.16a), and to rewrite the provisions in a question and answer format in order to improve readability.

In light of these changes and due to the complicated nature of infant formula rebate contracting, we have decided to publish this rule as an interim rule, rather than a final rule. This approach permits us to go forward with these long overdue improvements to the cost containment requirements while having the benefit of receiving additional comments based on experience gained during the implementation of this rule. We will accept comments until August 23, 2001 in order to provide plenty of time for comments based on operational experience. We will consider the comments received on this interim rule in developing a final rule.

As noted above, we have consolidated the cost containment requirements in a new section 246.16a. This required us to republish all of the requirements, even those that are otherwise unchanged. However, we ask that commenters focus on the substantive changes made by this rule and the issues addressed in this preamble when developing their comments.

Although this rule takes effect October 23, 2000, these changes are not required to be implemented until November 21, 2000. This means that all bid solicitations issued on or after November 21, 2000 must comply with the requirements of this rule.

The following is a discussion of each proposed provision, comments received, and an explanation of the provisions set forth in this interim rule and/or the our response.

A. Definitions

The proposed rule defined ''infant formula'' and ''exempt infant formula'' to mean the same as they are defined in sections 201(z) and 412 of the Federal Food, Drug, and Cosmetic Act (FDC Act 21 U.S.C. 321(z) and 350a), and the Food and Drug Administration (FDA), U.S. Department of Health and Human Services implementing regulations (21 CFR Parts 106 and 107).

Commenters were in favor of cross-referencing the requirements in the FDC Act and regulations; therefore, no changes were made to the proposed definitions in the rule. However, some of the commenters pointed out that using additional undefined terms in the WIC regulations led to confusion. Therefore, to avoid confusion and to help clarify certain requirements, the interim rule includes three definitions in addition to the proposed definitions of infant formula and exempt infant formula, and amends one existing definition. The following is a summary of the new and modified definitions:

Contract brand infant formula means all of infant formula (as defined in this rule) excluding exempt infant formulas, produced by the manufacturer that has been awarded the contract. However this rule, in section 246.16a(c)(1)(i), requires that State agencies issue solicitations which require bidders that do not produce a soy-based infant formula to subcontract with another manufacturer to provide it under the contract. In this case, any soy-based infant formula that is subcontracted is also considered a contract brand infant formula. In addition, this rule in section 246.16(a)(c)(1)(ii) allows a State agency to solicit separate bids for milk-based and soy-based infant formula. If a State agency elects to solicit separate bids, all relevant infant formulas issued under each contract are considered contract brand infant formulas. Finally, all new infant formulas that are introduced after a contract is awarded are also considered contract brand infant formulas. Such infant formulas must meet the definition of an ''infant formula''. See section D of this preamble for more detailed information regarding these requirements.

Net price is defined in section 17(b)(20) of the Child Nutrition Act of 1966 (42 U.S.C. 1786(b)(20)) and section 246.2 of the current WIC regulations as the difference between the manufacturer's wholesale price for infant formula and the rebate level or the discount offered or provided by the manufacturer under a cost containment contract entered into with the pertinent State agency. In order to ensure that State agencies award contracts in a fair and consistent manner, this rule amends the definition of ''net price'' to clarify that the wholesale price is the lowest national wholesale price for a full truckload of infant formula. We discuss this change in more detail in Section I of the preamble.

Non-contract brand infant formula means all brands of infant formulas, including exempt infant formula, that are not covered by a cost containment contract. If a State agency issues an infant formula or exempt infant formula that is not covered under the contract, it is considered a non-contract brand infant formula, does not generate a rebate, and requires medical documentation for its issuance.

WIC-eligible medical foods means certain enteral products that are specifically formulated to provide nutritional support for individuals with a diagnosed medical condition when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible medical foods may be nutritionally complete or incomplete, but they must serve the purpose of a food, provide a source of calories and one or more nutrients, and be designed for enteral digestion via an oral or tube feeding.

The current food package regulations use the term ''formula'' in some instances to mean just infant formula and in others to mean substitute products for infant formula. After publishing the proposed rule, we discovered that, in addition to incorporating the precise terms of ''infant formula'' and ''exempt infant formula'' into the WIC regulations, we also needed to define what FNS recognizes as allowable alternatives to these infant formulas, especially under Food Package III for women and children with special dietary needs.

The inclusion of definitions for infant formula, exempt infant formula, and WIC-eligible medical foods in program regulations clarifies our historic interpretation of the types of products that may be used as substitutes, when medically warranted and documented, for iron-fortified infant formulas as specified under sections 246.10(c)(1) (in the case of infants 0 through 3 months) and 246.10(c)(2) (in the case of infants 4 through 12 months) or for conventional foods as specified under section 246.10(c)(3) (in the case of children and women with special dietary needs). In addition to the new definition, conforming changes are made to the food package requirements in sections 246.10(c)(1) and (3). As is currently the case, WIC-eligible medical foods may not be used for the sole function of enhancing nutrient intake or managing body weight without an underlying medical condition. Also, WIC-eligible medical foods must be supported with medical documentation.

Readers are reminded that WIC-eligible medical foods and exempt infant formulas are permissible expenses under the Federal Medicaid statute and regulations and are also

reimbursable under some other health care programs. Accordingly, State agencies are encouraged to coordinate with other Federal, State, or local public agencies or with private agencies that operate programs that also provide or reimburse for WIC-eligible medical foods and/or exempt infant formula benefits to WIC participants in order to share the cost whenever possible.

B. Issuance of Kosher Infant Formula

It has come to our attention that the proposed rule, as written, would disallow the issuance of certain types of kosher infant formula if the winning bidder does not offer kosher infant formula in its product line. This is because the proposed rule allows non-contract brand infant formula to be issued only with medical documentation. This was not an issue under the current regulations; if the winning bidder did not produce a suitable infant formula, the State agency could have issued a non-contract brand infant formula without medical documentation. As such, the proposed rule does not accommodate special needs for infant formula based on religious beliefs.

It was not our intent to prevent the issuance of kosher and other types of infant formula to accommodate religious eating patterns. Therefore, section 246.10(c)(1)(iv) of this rule makes clear that local agencies may issue non-contract brand infant formulas to accommodate religious eating patterns. We would like to stress that this is the only reason non-contract brand infant formulas may be issued without medical documentation, as described below. In addition, any non-contract infant formula issued to accommodate religious eating patterns must meet the infant formula requirements in section 246.10(c)(1).

C. Medical Documentation Requirements

Current regulations at section 246.10(c)(1) require medical documentation for the issuance of any infant formula that does not meet the nutritional requirements of that section. The proposed rule would also have required medical documentation from a licensed health care professional authorized to write medical prescriptions under State law whenever the State agency issued any non-contract brand infant formula, even if it met the nutritional requirements of section 246.10(c)(1). The documentation required would have included the: brand name of the infant formula prescribed; medical diagnosis warranting the infant formula; length of time the infant formula is medically required by the participant; and signature of the health care professional requesting the infant formula. Medical documentation would not have been required for contract brand infant formulas that meet the nutritional requirements of section 246.10 (c)(1).

A majority of the commenters supported this requirement, stating that such documentation is reasonable and is an important step toward ensuring that non-contract brand infant formulas are issued only when medically necessary. Therefore, this interim rule maintains the medical documentation requirements for the issuance of non-contract infant formula except as discussed in section B of this preamble. Commenters did, however, raise several concerns related to this requirement which are discussed below along with our response.

Issue 1: Medical documentation requirements for soy-based infant formula. A number of commenters found the proposed rule confusing regarding whether medical documentation is required for contract brand soy-based infant formula.

Department Response: We did not intend to mandate medical documentation for any contract brand infant formulas, including soy-based infant formulas, as long as they meet the nutritional requirements in section 246.10(c)(1)(i). Therefore, the interim rule at section 246.10(c)(1)(i) clarifies that all such contract brand infant formulas may be issued without medical documentation. Exempt infant formulas, which are not considered to be contract brand infant formulas, continue to require medical documentation. The interim rule further clarifies at section 246.10(c)(1)(iii) that all non-contract brand infant formulas may be issued only with medical documentation. This clarification is also addressed in section 246.2 by defining contract and non-contract brand infant formulas.

Issue 2: Limiting the issuance of infant formulas. Commenters suggested that regulatory language should be added that would limit the issuance of different types of contract brand infant formulas.

Department Response: Requiring a rebate on the bidder's entire infant formula product line (except exempt infant formula) does not obligate State agencies to approve or issue all of the types of infant formulas produced by a manufacturer. In fact, the best impartial medical evidence strongly demonstrates that milk-based, lactose containing and soy-based, lactose-free infant formulas meet the nutritional needs of almost all infants. State agencies currently have the authority to limit the issuance of both contract brand infant formulas and non-contract brand infant formulas, and we strongly encourage State agencies to exercise this authority. However, to further emphasize this authority, the interim rule at section 246.10(c)(1)(i) states that State agencies may choose to limit the types of contract brand infant formulas that are approved for issuance or may require medical documentation for contract brand infant formulas. This choice is also addressed in section 246.16a(c)(6).

Issue 3: Role of the dietitian. Commenters were also concerned that due to the medical documentation requirement for non-contract brand infant formulas, dietitians (as opposed to health care professionals with prescription-writing authority) would be prevented from prescribing non-contract brand infant formulas. They stressed dietitians are in a better position to counsel parents, investigate infant formula problems, and make infant formula suggestions and are more accessible than physicians. In addition, dietitians are often more aware of the savings rebates provide to the WIC program, and thus would be judicious in ensuring that fewer clients use non-contract brand infant formulas.

Department Response: We would like to emphasize that the role of the dietitian is critical in providing nutrition education not only to parents and/or caretakers, but also in relaying to the medical community the significant savings to the WIC program of using contract brand infant formulas. If there is not an infant formula in the contractor's product line that meets the infant's needs, dietitians are encouraged to work closely with the participant's health care providers who are authorized to make the necessary determinations for medical documentation. We believe requiring medical documentation only strengthens a dietitian's role in ensuring that the most suitable infant formula is issued without compromising an infant's nutritional needs. However, we continue to believe that permitting only health care professionals with prescription-writing authority to authorize non-contract brands of infant formula will ensure that issuance occurs only in exceptional situations with minimal loss of rebate savings.

Issue 4: Allowing medical documentation to be telephoned into clinics. Commenters indicated that the medical documentation requirement may place an infant's urgent nutritional and health needs at risk by delaying services. Commenters recommended

allowing medical documentation to be telephoned to the WIC clinic.

Department Response: The interim rule at section 246.10(c)(1)(v)(B) allows medical documentation to be telephoned into a competent professional authority (CPA) at WIC clinics by a health care professional licensed by the State to write medical prescriptions. However, such verbal confirmation must promptly be transformed into written documentation by the CPA and kept on file at the WIC clinic. This method may only be used until written confirmation is received and only when absolutely necessary to prevent undue hardship to a participant or to prevent a delay in the provision of infant formula that would place the participant at increased nutritional risk. The local clinic must obtain written confirmation of the medical documentation within a reasonable amount of time after accepting the initial medical documentation by telephone (*i.e.*, one or two weeks' time). The written documentation must be kept on file with the initial telephone documentation. The interim rule makes clear that medical documentation may be provided as an original written document, electronically or by facsimile.

Issue 5: Filing of medical documentation. One commenter requested that State agencies be allowed to keep a hard copy of medical documentation on file but not necessarily in the participant's file. Otherwise, requiring medical documentation to be filed in a participant's file is difficult for a paperless system.

Department Response: The interim rule at section 246.10(c)(1)(v)(B) makes allowances for paperless systems by requiring medical documentation to be kept on file at the WIC clinic, instead of requiring the documentation in the participant's certification file.

D. Soliciting Bids for Milk-based Infant Formula

The proposed rule would have required State agencies to solicit and evaluate bids for a single milk-based infant formula only. We received several comments fully supporting this provision; however, many comments were received opposing this provision. See below for more detailed discussion on comments received and our response.

Issue 1: Potential issues as a result of soliciting and evaluating bids for milk-based infant formula only. Several commenters pointed out that a manufacturer that produces only a milk-based infant formula could potentially win the contract because there is no requirement that bidders also produce a soy-based infant formula. In the current marketplace, this is not a problem because all infant formula manufacturers produce a soy-based infant formula. However, in the past not all infant formula manufacturers produced both a milk-based and soy-based infant formula. There is no way to predict what changes may occur in the future. For example, a manufacturer may enter the market that does not produce a soy-based infant formula or a current manufacturer may discontinue producing a soy-based infant formula. If such a manufacturer were to win a WIC infant formula rebate contract, medical documentation would be required for soy-based infant formula. As a result, because of the soy-based infant formula's non-contract status the State agency would be forced to pay the full retail price for this formula, thus eroding rebate savings.

Several commenters also stated that evaluating bids only for a milk-based infant formula and then using that bid as a basis for calculating rebates on all of the winning bidder's other infant formulas would put a State agency at risk of selecting a bidder that does not necessarily offer the lowest total cost to the State. Commenters pointed out that the proposed rule did not consider the variances in wholesale prices between milk-based and soy-based infant formula. Commenters stated that the requirement limiting bids to a single milk-based infant formula would provide an immediate advantage to any manufacturer whose wholesale price relationship between its soy-based and milk-based infant formulas is greatest relative to that for other manufacturers because the discount ratio would have less effect on the net price for its soy-based product. In fact, commenters stated that the requirement may encourage a manufacturer to change its infant formula prices in amounts that would provide a bidding advantage.

Finally, there was concern that limiting bids to a milk-based infant formula would preclude a State agency from issuing separate solicitations for milk-based and soy-based infant formulas. Allowing separate solicitations enables new or smaller manufacturers with a limited product line of infant formula to bid and, as a result, opens the bidding to a larger number of competitors.

Department Response: The interim rule addresses these concerns in two ways. Under the ''single solicitation'' option in section 246.16a(c)(1)(i), the State agency must require any manufacturer who does not produce a soy-based infant formula to contract with another manufacturer to supply a soy-based infant formula. The winning bidder is required to pay a rebate on the contracted soy-based infant formula using the same percentage discount on wholesale price as the winning bidder is required to use for all other infant formulas it produces. This approach recognizes the commenters' point about ensuring the availability of soy-based infant formulas while maintaining the simplified bidding structure of the proposed rule. There will always be some variation between the estimates of the types and amounts of infant formulas that will be issued and the actual types and amounts issued. The unpredictability is further exacerbated when new types of infant formula are introduced. Taking bids for a single milk-based infant formula strikes a balance between simplifying the bidding process without sacrificing rebate savings.

However, we do agree that uncoupled bids can increase competition in some instances. Accordingly, section 246.16a(c)(1)(ii) permits the State agency to issue a separate solicitation for a soy-based infant formula. This solicitation would be in addition to the milk-based infant formula solicitation. This approach is commonly called an ''uncoupled bid.'' Many State agencies have used the uncoupled bid approach when soliciting bids for infant formula rebate contracts. In fact, we have encouraged this approach as a way of allowing all infant formula manufacturers an opportunity to bid and, as a result, increasing competition.

This option results in two contracts with potentially different manufacturers. The winning bidder for the milk-based infant formulas contract must provide a rebate on all the milk-based infant formula it produces, except exempt infant formulas. The winning bidder for the soy-based infant formula must provide a rebate on all the soy-based infant formulas it produces, except exempt infant formulas.

Issue 2: Types of infant formulas vary between bidding manufacturers. One commenter pointed out that the proposed rule did not consider that the types of infant formula vary between bidding manufacturers. For example, all infant formula manufacturers do not offer a milk-based lactose-free infant formula. Consequently, the number of units on which rebates are demanded and the total amount of rebates required are different for each bidder—again, leaving State agencies at risk of selecting a bidder that does not necessarily offer the lowest cost to the State.

Department Response: We acknowledge that the types and forms of infant formula issued will vary depending on which manufacturer is awarded the contract. However, the best medical evidence indicates that almost all infants nutritional needs can be met by the milk-based, lactose-containing and soy-based contract brand of infant formulas. (As discussed above, the winning bidder would be required to provide a soy-based infant formula.) Further, accounting for the various types and forms of infant formula available to State agencies by manufacturer during the bid evaluation process would be a burdensome task that may itself result in an uncompetitive solicitation process. Therefore, in the interest of streamlining the solicitation process and ensuring the continued viability of the competitive bidding process, this interim rule requires the winning bidder to supply and provide a rebate on all infant formula it produces that are issued by the State agency, except exempt infant formulas.

E. Use of Composite Rebate

A few commenters pointed out that there are some State agencies that use a generic food instrument that allows participants to purchase either a milk-based infant formula or a soy-based infant formula. These State agencies evaluate bids based on a composite rebate for both infant formulas, which enables them to invoice one rebate for both products. Commenters stated their current data systems do not include a method for tracking milk-based and soy-based infant formulas separately. In addition, segregating infant formula by type on the food instrument would require extensive computer system changes. As such, the requirement complicates the process of issuance, redemption, and rebate bidding.

Department Response: While we strongly encourage State agencies to identify the type of infant formula prescribed on the food instrument, it was never our intent to prevent State agencies from using a generic food instrument for infant formula. Under this interim rule State agencies may continue to issue a generic instrument that allows participants to purchase more than one type of infant formula. However, these State agencies must still request and evaluate bids for only a milk-based infant formula (unless a State agency elects to issue separate bid solicitations). After a winning bidder is selected, the State agency must determine the rebate for the soy-based infant formula based on the rebate bid for the milk-based infant formula (or use the winning rebate for soy-based infant formula if the State agency elects to issue separate bid solicitations). The State agency must then determine a composite rebate for the generic food instruments using the rebate amounts established for the milk-based and soy-based infant formulas under the contract(s) and the projected usage rate for each type purchased with the generic food instruments.

F. Requiring a Rebate for all Infant Formula Produced by the Manufacturer

The proposed rule would have required the bid solicitations and contracts to require that the winning bidder pay a rebate for any infant formula it produces that is issued by the State agency.

Just over half of the commenters opposed this provision. Supporters stated the requirement would ensure that no manufacturer has an advantage in the bidding process because it offers more types of infant formula than its competitors. This interim rule retains the requirement in section 246.16a(c)(1). See below for further discussion of the comments.

Issue 1: Perception of across-the-board endorsement of infant formulas. Commenters opposing the requirement indicated that it may give the perception of an across-the-board endorsement of infant formulas by the WIC program by providing a marketing opportunity for manufacturers. State agencies are currently under considerable pressure from manufacturers to approve their brands of infant formula. There is concern that if a rebate is required for all infant formulas produced by the winning bidder, it will be very difficult to limit the issuance of these other types of infant formulas. Other opponents also stated that requiring a rebate on all infant formulas produced by the winning bidder would create an impression that the State agency is not maximizing its food dollars if it does not issue an infant formula that generates a rebate.

Department Response: As stated earlier in this preamble, the interim rule codifies the current authority which allows State agencies to limit the types of infant formulas that are issued. Thus, if State agencies do not wish to endorse particular infant formulas, they may elect to exclude such formulas from their approved supplemental food list.

Issue 2: Administrative burden for State agencies. State agencies were also concerned that requiring a rebate on all infant formulas produced by the winning bidder would cause confusion among staff, participants, vendors, and the medical community, which may lead to conflicts, non-compliance and lower rebates.

Department Response: We envision that after a contractor is selected, State agencies will identify the infant formulas in the contractor's product line it will approve for issuance and establish the rebate to be paid on each of these infant formulas. This is the only information that needs to be provided to WIC clinics, health care providers, and vendors and is no different than the process used by State agencies today. If a new infant formula is introduced into the winning bidder's product line or the State agency decides to add more types of infant formulas to its approved list, the State agency need only calculate the rebate for the additional infant formula, notify the affected parties in the WIC community, and bill the manufacturer accordingly when and if that infant formula is issued.

Issue 3: Concerns regarding on which infant formulas a rebate should be paid. Several of the comments we received that opposed the requirement that the winning bidder must pay a rebate on all infant formula it produces were centered on difficulties with who should determine which infant formulas require a rebate. Several commenters indicated that State agencies should be allowed to specify in the bid solicitation the items it seeks to procure (e.g., a milk-based infant formula and at least one lactose-free infant formula).

On the other hand, one infant formula manufacturer stated that within the two categories of milk-based and soy-based infant formulas, each prospective bidder should be allowed to identify its own list of potential infant formulas that would be covered by the contract (i.e., the ''contract brand infant formulas'') at the time of bid submission. This would allow bidders an option to exclude from its list any of its infant formulas with a particularly high cost base.

A second manufacturer believed that manufacturers should not be obligated to provide rebates on any infant formula other than one milk-based lactose containing and one soy-based infant formula. The commenter elaborated that if a manufacturer is willing to supply other infant formulas at its own option and the State agency approved such infant formulas, these formulas should then be included in the contract and should yield the same percentage discount on the wholesale cost as the products they replace. However, if a manufacturer is unwilling to pay a rebate on other infant formulas it produces and other manufacturers have equivalents of such formulas, then issuance of any of these formulas should be on a non-discriminatory basis and

should be subject to the medical documentation requirement.

Department Response: Allowing State agencies to specify in the bid solicitation the types of infant formula requiring a rebate could eliminate from bidding some manufacturers who do not offer certain types of infant formula. Conversely, we believe that if infant formula manufacturers were able to pick which infant formulas would receive a rebate, it would be impossible to equitably assess competing bids. Both bidding options are inconsistent with our effort to streamline the solicitation process and to maximize full and open competition among manufacturers.

Issue 4: Discourages manufacturers from developing new products and packaging. One infant formula manufacturer stated that given the large percentage of total U.S. infants served by the WIC program, imposing a rebate on yet undeveloped infant formulas may create a disincentive for a manufacturer to develop a new or better infant formula(s). Manufacturers may also reduce rebates to allow for the added cost of an advanced product, thereby increasing the chance it will lose the bid. In this case, WIC participants might not receive that manufacturer's advanced product and the successful bid price for a less advanced product could be higher. They further state that manufacturers might also withdraw from the bidding process and focus on only non-WIC business. For example, the manufacturer's research could center on exempt infant formulas or on product packaging that is not appropriate for the WIC program.

Conversely, a second infant formula manufacturer asserted that the rule encourages innovation and competition because it minimizes any bid evaluation inequities. The commenter further stated that removing such inequities gives manufacturers greater incentives to offer new and/or improved products in the United States.

Department Response: In the past, State agencies that have approved for issuance new infant formulas, with and without a rebate and/or medical documentation, have witnessed an increase in the issuance of these new infant formulas—some as high as 7 percent or more. These new products continue to gain popularity and we anticipate new products will continue to be introduced. This requirement enables State agencies to issue a solicitation that is competitive while ensuring a rebate is paid on any infant formula in the winning bidder's product line. The medical documentation requirement prevents a State agency from unnecessarily issuing any non-contract brand infant formula.

G. Clarification of Percentage Discount Rebate

The proposed rule would have required the rebate paid on any infant formula to yield the same percentage discount on its wholesale cost as the rebate for the infant formula for which a bid was submitted.

Issue: Most of the comments received centered on the need for clarification. Specifically, several commenters believed that the rule should be revised to clarify that bidders are not required to offer the same discount on different physical forms of infant formula (e.g., powdered versus concentrated liquid). In addition, commenters requested clarification as to how the percentage discount is to be applied to a new infant formula introduced after the contract is implemented. Comments were also received questioning whether the percentage discount applies to a manufacturer's prices as of the bid opening date, the commencement date of the contract, or after each wholesale price increase or decrease during the contract term.

Department Response: The interim rule clarifies in section 246.16a(c)(2) that different bids may be submitted for each of the physical forms of the milk-based infant formula for which bids are being sought. Section 246.16a(c)(5) then makes clear that in calculating the rebates for other types of infant formula, the percentage discount to be used will depend on the physical form of the infant formula.

For example, if the rebate offered for the concentrated liquid form of the milk-based infant formula is 80 percent of the wholesale price, then the rebate required to be paid for a soy-based infant formula in concentrated liquid form, or any other concentrated liquid infant formulas in the bidder's product line, will be 80 percent of its wholesale price. The same calculation approach holds true for infant formulas in powdered and ready-to-feed forms.

Clarifications also were added to the interim rule in response to commenters' confusion regarding when the discount percentage and resultant rebates are established for each of the infant formula types in the bidder's infant formula product line. The interim rule clarifies at section 246.16a(c)(5) (i) and (ii) that the discount percentages and rebates must be based on the wholesale prices in effect on the date of the bid opening. If a new infant formula product is introduced during the term of the contract, the rebate required for the new product must be calculated using the wholesale price of the new infant formula at the time it is approved for issuance by the State agency.

Currently, all State agencies with competitively-bid infant formula rebate contracts require an inflationary provision ensuring the net cost remain constant. In order to preserve the net cost, this interim rule requires at section 246.16a(c)(5)(iv) that all rebate contracts must include an inflation provision to adjust for price changes subsequent to the date of the bid opening. State agencies may require either a cent-for-cent increase in the rebate amounts whenever there is a change in the wholesale price for infant formula or another method established by the State agency in the bid solicitation.

H. Participation Data and Infant Formula Usage Rates

The proposed rule would have required State agencies to solicit bids based on the estimated total amount of infant formula it expects to issue (by physical form) based on the current number of infant participants, excluding those exclusively breastfed and those issued exempt infant formula. The comments received generally supported this requirement; however, several commenters relayed concerns which are summarized below along with our comments.

Issue: Several commenters suggested that State agencies be allowed to use actual participation and usage rates, rather than estimates.

Department Response: It was not our intention to have State agencies use anything but the most current infant participation available. We believe that due to the fairly stable levels of participation, as compared to past years, a State agency's most current participation figures available give potential bidders the best data for evaluating the amount of infant formula it will be required to provide under the contract. Therefore, this rule does not permit State agencies to use estimates, such as projected participation, to establish infant formula usage data.

The interim regulation clarifies this requirement at sections 246.16a(c) (3) and (4). Section 246.16a(c)(3) requires State agencies to use the most recent available participation data and usage rates in evaluating bids, and section 246.16a(c)(4) requires State agencies to provide the same data to bidders. The word ''estimate'' has been removed to avoid confusion, as neither of these figures are estimates but instead are actual data based on program operation. The rule requires that infant participation data include at least 6

months of the most recent average infant participation information.

We expect that given the wide range of infant formulas that will be available under each contract, only a small portion of infant formula will be issued as non-contract brand infant formula. This is why all infants, except those exclusively breastfed and those issued exempt infant formulas, must be included in the participation data.

We would like to stress that even though bids are solicited for milk-based infant formula only, all types of infant formulas, (including soy-based and milk-based lactose-free infant formulas) issued to infants must be included in the infant formula usage rates. For example, if a State agency issued a total of 1,000 units of concentrated liquid infant formula a month (excluding exempt infant formula), the usage rate must include all possible types of infant formula that were issued in the form of concentrated liquid infant formula, including both contract and non-contract brand infant formula issuance under its current contract. The same approach must be applied for calculating the usage rates for powdered and ready-to-feed infant formula.

All bidders should be reminded that participant data and infant formula usage rates provided include all types of infant formula the State agency currently uses, except exempt infant formula. At the same time, we strongly encourage State agencies to provide their latest invoice information, or comparable information, that categorizes the infant formula usage data by type and form. Providing this data ensures all bidders have the same information as the current contractor has to base bids on.

The exception to the above is when a State agency elects to solicit separate bids for milk-based and soy-based infant formulas. In this case, participation data and usage rates must be calculated the same as above, but broken out by milk-based infant formula (including all types of milk-based infant formula except exempt infant formula) and soy-based infant formula.

I. Lowest Net Price

All but one commenter supported the requirement to award contracts based on the lowest net price for infant formula. This requirement is dictated by statute; therefore, the interim rule retains the lowest net price requirement in section 246.16a(c)(3). However, as explained in this preamble in the definitions section, there was some confusion among commenters regarding the term ''net price'' which is summarized below.

Issue 1: Several commenters stated that if bids are to be evaluated on the basis of lowest net price, it would improve consistency if the basis for the wholesale price is defined. Other commenters asked for clarification in determining the lowest net price. As one manufacturer explained, manufacturers bracket their wholesale prices based on subdivisions of a full truckload, and the ''full truckload price'' is simply the best, or lowest, price they offer to retail and wholesale outlets. However, different manufacturers base their wholesale prices on different truckload weights due primarily to variations in packaging size and weight, and different trucking equipment used to ship product. What matters is that each manufacturer's best full truckload price bracket be used when evaluating bids. Otherwise, bid evaluations may not be evaluated in a fair and consistent manner.

Department Response: In order to clarify the requirement of awarding a contract based on the lowest net price this rule amends the current definition of ''net price.'' State agencies must use a consistent measurement of a common denominator to evaluate all rebates in order to ensure contracts are evaluated in a fair and consistent manner. As such, this rule requires State agencies to use the lowest national wholesale price for a full truckload of the infant formula on which a bid is submitted when evaluating bids and establishing rebates for the manufacturer's full product line. This requirement is reflected in the definition of net price in section 246.2 and in sections 246.16a(c)(3) and 246.16a(c)(5) which describe how to award contracts and to calculate rebates for infant formulas.

Issue 2: One commenter opposing this provision expressed concern that evaluating bids based on the lowest net price using wholesale prices prevents State agencies from recognizing a State agency's true cost of infant formula. The commenter explained that retailers purchase infant formula at different wholesale price tiers depending on the quantity of product purchased, which affects the retail cost of infant formula. As such, the rule should permit a State agency to identify a wholesale pricing level used in evaluating bids that is consistent with the unique characteristics of that State agency. A second commenter, asking for clarification of net price, stated that because manufacturers have different wholesale prices depending upon the quantity they deliver and the geographic area, the net price should be based on the quantity most commonly delivered to vendors participating in the WIC Program.

Department Response: It would be impractical to exactly capture wholesale cost actually paid by vendors or to use retail pricing. Therefore, this rule includes in the definition of net price the national wholesale price for a full truck of infant formula. This definition ensures consistency and simplifies the bidding process. State agencies should recognize that the national wholesale price catalog is used only as a tool in evaluating bids and setting rebate amounts. Infant formula manufacturers do not, and may not, by law, act in concert to influence retail prices for infant formula to retailers. Therefore, they, as a group, have no control over the price that is charged for the infant formula sold by WIC vendors and cannot be held accountable for retail prices charged. On the other hand, the actual price that retailers charge for infant formula falls under the domain of State-agency-managed WIC vendor cost controls. In fact, to promote efficiency and contain costs, the William F. Goodling Child Nutrition Reauthorization Act of 1998 (Public Law 105–336) requires WIC State agencies to consider the prices a store charges for authorized supplemental foods as compared to the prices that other stores charge when selecting vendors.

J. Retail Prices at WIC and Non-WIC Retailers

The proposed rule would have allowed a State agency to evaluate bids by the highest rebate instead of lowest net price if the State agency could demonstrate that the weighted average retail prices for different brands of infant formula in the State vary by 5 percent or less. The retail prices were to reflect both authorized WIC vendors and stores that do not participate in the WIC program.

Issue: Many commenters disagreed with the requirement of including non-WIC stores when demonstrating the differences and/or similarities in retail prices. It was remarked that a number of WIC State agencies currently consider price practices in determining whether a vendor can participate in the WIC program. However, allowing such State agencies to consider pricing practices of non-WIC stores could enable a State agency to demonstrate that retail prices do not vary by more than 5 percent in the State while the prices of WIC vendors do vary by more than 5 percent. Commenters also stated that obtaining price information from non-WIC stores would be a difficult task and a burden on State agencies.

Department Response: As a result of the comments received, the interim rule at section 246.16a(c)(3)(ii) modifies the

highest rebate option to give State agencies the option to evaluate infant formula prices at only authorized WIC vendors or at both WIC vendors and stores that do not participate in the WIC program. State agencies using retail price information from WIC vendors only may find it more difficult to present a compelling argument demonstrating a price differential of less than 5 percent. State agencies are also reminded that price information must be approved by FNS before soliciting bids using an evaluation method of highest rebates offered.

K. Variance in Unit Sizes of Powdered Infant Formula

Some commenters pointed out that powdered infant formula no longer comes in a single standard unit size. One commenter also wrote that although the food package regulations state the maximum amounts of infant formula in dry ounces, not all powdered infant formulas reconstitute at the same rate. That commenter suggested basing rebates on reconstituted ounces of infant formula. These commenters questioned how State agencies should account for differences in the unit size and reconstitution rates when evaluating rebate bids.

The proposed rule, at section 246.16(k)(1)(ii), required bids to be solicited based on an estimated total amount of infant formula the State agency expected to issue; however, the proposed rule was silent on how to account for differing unit sizes when evaluating rebate bids. As discussed in the Background section of this preamble, the infant formula industry has changed considerably over the past several years. Over the past decade, there have been numerous changes in both the packaging and formulation of infant formulas and it is impossible to predict future changes.

Currently, the liquid concentrate and ready-to-feed milk-based lactose containing infant formula is available in the same unit size, regardless of the manufacturer. However, the three primary infant formula manufacturers currently offer milk-based lactose powder in six different unit sizes ranging from 12 ounces to 32 ounces not including single packet sizes. Of the six unit sizes offered for milk-based powder, there is no common size among those three manufacturers.

The current variations in unit sizes for powdered infant formulas create a dilemma for State agencies when evaluating bids because the unit size dictates how many units a State agency can issue to a WIC infant without exceeding the Federal maximum monthly allowance of 8 pounds or 128 dry ounces of powdered infant formula. Consequently, the total number of units of powdered infant formula that can be issued each month depends upon the brand. The table below illustrates how differences in unit sizes for powdered infant formula can affect monthly issuance rates and identifies the total dry ounces of powdered product that can be issued each month for each of the current unit sizes most commonly issued.

Current unit sizes for powdered milk-based lactose containing infant formulas	Total number of units issued each month without exceeding the federal allowance of 128 oz./8 lbs.	Yield per total number of units issued monthly & resulting issuance shortage
12 dry oz.	10 units	120 dry oz. (8 oz. short).
14.1 dry oz.	9 units	126.9 dry oz. (1.1 oz. short).
16 dry oz.	8 units	128 dry oz. (no shortage) .

Currently, many State agencies evaluate rebate bids for powdered infant formula based on the total number of units of infant formula a bidder is able to provide under the contract without exceeding the Federal maximum monthly allowance of 128 dry ounces of powdered product. The smaller the unit size, the greater is the number of units needed to provide up to the Federal maximum monthly allowance. However, this method fails to recognize that State agencies already have the flexibility to provide up to the Federal maximum monthly infant formula averaged over the participant's certification period. It also fails to take into account further potential changes in unit sizes.

In this interim rule, as well as the proposed rule, we are seeking to simplify the bid evaluation process and to set forth standards that will take into account future changes in the infant formula industry, such as changes in unit size. Unfortunately, we cannot address the issue of differing reconstitution rates in this rulemaking. However, we can simplify the bidding process by requiring the bid evaluation to be made on a standardized number of units of infant formula among bidders. Therefore, this interim rule requires at section 246.16a(c)(3) that State agencies evaluate bids for a standardized number of units of infant formula equal to the total maximum allowable amount number of ounces in the infant formula package at section 246.10(c)(1)(vi), rather than the maximum number of units that could be issued in a single month due to unit size limitations and State agency issuance practices.

This standardized number of units of infant formula to be bid upon must contain the equivalent maximum allowable number of ounces of each physical form of infant formula that could be issued to all infants under section 246.10(c)(1)(vi). Since rebate bids are typically made on a per unit basis, it is necessary to convert the maximum allowable number of ounces of each physical form needed to serve all infants into a number of units needed to serve all infants. In order to do so a State agency would first calculate the total number of ounces needed by physical form by multiplying the total number of infants expected to use each physical form of infant formula (based on the most recent available participation and usage data) by the maximum allowable number of ounces for each physical form (e.g., 128 ounces of powdered). Next, the number of units needed to provide the maximum number of ounces of infant formula would be calculated by dividing the total number of ounces calculated by physical form by the number of ounces in the size of the unit being bid. If the number of units calculated is not a whole number, the number would be rounded down to the nearest unit. To calculate the total cost of each bid the State agency would then multiply the per unit net cost (rebate offered minus wholesale price) by the number of units needed to provide the maximum amount of infant formula allowed.

The following is an example of a bid calculation of the standardized number of units in a State agency using the single solicitation method. The example assumes the bids are evaluated by lowest net price, and the most recent available participation and usage data show the State agency issued powdered infant formula to 290 infants, liquid concentrate to 1,000 infants, and ready-to-feed to 10 infants per month.

(A) Unit size & physical form	(B) Max. issuance per infant (oz.)*	(C) Avg. monthly infant participation by form**	(D) Total oz. for bid B*C	(E) Standardized number of units D/A (16, 14.1, 12 oz.)	(F) Whole-sale cost***	(G) Rebate per unit	(H) Net Cost Per Unit F–G	(I) Standardized number of units column E	(J) Net cost H*I
16 oz. powder, or	128	290	37,120	2,320				2,320	
14.1 oz.. powder, or	128	290	37,120	2,633				2,633	
12 oz. powder	128	290	37,120	3,093				3,093	
13 oz. liq. concentrate	403	1,000	403,000	31,000				31,000	
32 oz. RTF	806	10	8,060	252				252	
Total monthly cost									$

*Allowed under Section 246.10(c)(1)(vi) of regulations.
**Excludes only infants exclusively breastfed and issued nonexempt infant formula.
***Lowest national wholesale cost per unit for a full truckload of infant formula.

As noted above, this evaluation method is consistent with an issuance option WIC State agencies currently have to average the amount of infant formula issued over the participant's certification period. We are developing guidance that will clarify how under current WIC regulations State agencies can better accommodate the wide variances in both container size and multi-unit packaging configurations of infant formulas, exempt infant formulas and WIC-eligible medical foods. State agencies that elect to make accommodations to their monthly issuance of infant formula due to the unit size limitations of its contract infant formula ensure infants are prescribed an amount of infant formula that best meets their needs.

L. Responsive and Responsible Bidders/ Full and Open Competition

Several commenters relayed concern about the dependence upon a single manufacturer that may not be able to perform the contract requirements. Specific concerns raised were the ramifications of an interruption of infant formula supply due to a manufacturer's inability to perform the job. One State agency relayed that the cost of replacing a contractor goes well beyond the cost of infant formula. Several commenters requested us to explore procurement and contract management policies which would prevent an unreliable entity from winning a contract and, thus, ensuring a bidder that is capable of performing under the contract wins.

Department Response: Section 17(h)(8)(A)(i) of the Child Nutrition Act of 1966 (42 U.S.C. 1786(h)(8)(A)(i)) requires State agencies subject to the infant formula cost containment requirements to use competitive bidding or another method that yields equal or better savings. ''Competitive bidding'' is defined as, among other things, selecting the bidder ''offering the lowest price'' (42 U.S.C. 1786(b)(17)).

We have consistently taken the position that the competitive bidding requirement encompasses both the concepts of requiring that the winning bidder must be responsive and responsible and that the bid solicitation must be conducted in a manner to maximize full and open competition. As a result, we have said that technical requirements are appropriate only if they do not unnecessarily limit competition.

One provision that has caused confusion on this point is the requirement in current section 246.16(n)(2) that prohibits State agencies from issuing bid solicitations or entering into rebate contracts which exclude from consideration in the bidding evaluation any infant formula manufacturer that is in compliance with the Federal Food, Drug, and Cosmetic Act. This provision is based on a requirement in section 17(f)(15) of the Child Nutrition Act of 1966 (42 U.S.C. 1786(F)(15)) which requires companies supplying infant formula to the WIC program to register with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act and to certify to the State Health Department that it is in compliance with that Act and the related regulations. (There is a parallel regulatory provision concerning the registration and certification in section 246.10(f) of the current regulations.) Some have read the provision at section 246.16(n)(2) as meaning that no bidder may be precluded from bidding or contract award if it meets the FDA registration requirement. If read strictly, this requirement could be interpreted to mean that even a bidder that submits a nonresponsive bid may not be precluded from being awarded a contract if the bidder presents the lowest net price.

It was not our intent to totally exclude technical information from the bid evaluation process. We recognize the place that technical specifications have in competitive bidding situations. In fact, section 246.16a(c) of this interim rule requires State agencies to solicit bids from infant formula manufacturers to not only provide a rebate for infant formula, but to also supply such formula. However, we must also bear in mind the extremely small number of infant formula manufacturers and the highly regulated infant formula industry. In addition, care must be taken to ensure that any technical requirements do not unnecessarily limit competition in violation of the statutory requirement for competitive bidding.

As a result, this interim rule includes two provisions. The first (in section 246.16a(c)(3)) makes clear that the contract must be awarded only to a responsive and responsible bidder. To be responsive, a bidder must submit a bid that conforms to the solicitation. To be responsible, a bidder must meet the eligibility requirements under the applicable statute and regulations and any additional technical requirements set forth in the bid solicitation. Any information required to be submitted under a technical requirement must be capable of being evaluated objectively on a yes/no or pass/fail basis.

As we have previously advised, State agencies can address their concerns about possible performance problems by including appropriate contract provisions in their bid solicitations. For example, a State agency could include a clause that requires the winning bidder to pay a rebate on another brand of similar infant formula issued to participants in the event the contract manufacturer's infant formula is unavailable to WIC vendors for a specified period of time (e.g., 5 days).

The second provision, in section 246.16a(c), makes clear that maximizing ''full and open'' competition is an integral part of competitive bidding. The interim rule also removes the confusing and somewhat duplicative provision relating to FDA registration currently at section 246.16(n)(2) and includes

instead a cross reference to the FDA registration/certification requirement in section 246.10(f).

We would also like to emphasize that procurement requirements in 7 CFR 3016.36(a) still pertain to State agencies, whereby a State agency may follow the same policies and procedures it uses for State procurements. However, if State agency policies and procedures are in conflict with Federal requirements such as those in this rule, Federal requirements supersede State requirements.

M. Alternative Cost Containment System and National Bid Solicitation and Selection

One commenter pointed out that the proposed rule failed to make conforming amendments to the requirements for bid evaluation under the comparative method (section 246.16(j)(2)(i)) and under the National Bid Solicitation and Selection (section 246.16(o)). This rule amends these provisions to be consistent with the participation and infant formula usage data required by this rule for the single-supplier competitive system and the lowest net price/highest rebate requirements. These provisions are moved to section 246.16a(d) and (k), respectively.

N. Implementation Time Frames

We have taken this opportunity to update the implementation time frames for infant formula cost containment systems. WIC regulations currently in effect mandate that State agencies must have an infant formula cost containment system in effect as of March 15, 1990, and no later than November 10, 1990. The interim rule clarifies that all WIC State agencies (except Indian State agencies operating a retail food delivery system with fewer than 1,000 participants), must continuously operate a cost containment system in accordance with section 246.16a. This rule also makes conforming changes to the State Plan requirements in section 246.4(a)(14)(x).

O. Miscellaneous Regulation Citations

We have also taken this opportunity to update certain regulation citations in section 246.4.

Executive Order 12866

This rule has been determined to be economically significant and was 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). Shirley R. Watkins, Under Secretary, Food, Nutrition and Consumer Services, has certified that this rule will not have a significant economic impact on a substantial number of small entities. This rule will help ensure that WIC State agencies will be able to serve the maximum number of eligible applicants possible within their grant levels provided by the Federal government by removing current regulatory ambiguities that have resulted in the proliferation of protests of infant formula rebate contract awards. This rule further defines evaluation procedures for WIC State agencies' infant formula rebate contracts. While some WIC local agencies and WIC vendors may be small entities, the changes proposed by this rule will not affect them significantly.

Executive Order 12372

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is listed in the Catalog of Federal Domestic Assistance Programs under No. 10.557. For the reasons set forth in the final rule in 7 CFR 3015, Subpart V, and related Notice (48 FR 29115, June 24, 1983), this Program is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is intended to have a 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. Prior to any judicial challenge to the provisions of this rule or the applications of its provisions, all applicable administrative procedures must be exhausted.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the information collection and recordkeeping requirements included in Section 246.10(c)(1)(i) of this interim final rule have been approved by the Office of Management and Budget (OMB) under control number 0584–0043.

Public Law 104–4

Title II of the Unfunded Mandated 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 202 of the UMRA, 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 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, and tribal governments or the private sector of $100 million or more in any one year. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects in 7 CFR Part 246

Administrative practice and procedure, Civil rights, Food assistance programs, Food and Nutrition Service, Food donations, Grant programs—health, Grant programs—social programs, Indians, Infants and children, Maternal and child health, Nutrition, Nutrition education, Penalties, Reporting and recordkeeping requirements, Public assistance programs, WIC, Women.

Accordingly, 7 CFR Part 246 is 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. add the definitions of *Contract brand infant formula, Exempt infant formula, Infant formula, Non-contract brand infant formula,* and *WIC-eligible medical foods* in alphabetical order; and

b. revise the definition of *Net price.*

The additions and revision read as follows:

§ 246.2 Definitions.

* * * * *

Contract brand infant formula means all infant formulas (except exempt infant formulas) produced by the manufacturer awarded the infant

formula cost containment contract. If under a single solicitation the manufacturer subcontracts for soy-based infant formula, then all soy-based infant formulas covered by the subcontract are also considered contract brand infant formulas (see § 246.16a(c)(1)(i)). If a State agency elects to solicit separate bids for milk-based and soy-based infant formulas, all infant formulas issued under each contract are considered the contract brand infant formula (see § 246.16a(c)(1)(ii)). For example, all of the milk-based infant formulas issued by a State agency that are produced by the manufacturer that was awarded the milk-based contract are considered contract brand infant formulas. Similarly, all of the soy-based infant formulas issued by a State agency that are produced by the manufacturer that was awarded the soy-based contract are also considered to be contract brand infant formulas. Contract brand infant formulas also include all infant formulas (except exempt infant formulas) introduced after the contract is awarded.

* * * * *

Exempt infant formula means an infant formula that meets the requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(h)) and the regulations at 21 CFR parts 106 and 107.

* * * * *

Infant formula means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107.

* * * * *

Net price means the difference between an infant formula manufacturer's lowest national wholesale price per unit for a full truckload of infant formula and the rebate level or the discount offered or provided by the manufacturer under an infant formula cost containment contract.

Non-contract brand infant formula means all infant formula, including exempt infant formula, that is not covered by an infant formula cost containment contract awarded by that State agency.

* * * * *

WIC-eligible medical foods means certain enteral products that are specifically formulated to provide nutritional support for individuals with a diagnosed medical condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible medical foods may be nutritionally complete or incomplete, but they must serve the purpose of a food, provide a source of calories and one or more nutrients, and be designed for enteral digestion via an oral or tube feeding. WIC-eligible medical foods include many, but not all, products that meet the definition of medical food in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).

3. In § 246.4, revise paragraph (a)(14)(xi) to read as follows:

§ 246.4 State plan.

(a) * * *

(14) * * *

(xi) A description of any cost containment system. A State agency must submit a State Plan or Plan amendment if it is attempting to structure and justify a system that is not a single-supplier competitive bidding system for infant formula in accordance with § 246.16a(d); is requesting a waiver for an infant formula cost containment system under § 246.16a(e); or, is planning to change or modify its current system or implement a system for the first time. The amendment must be submitted at least 90 days before the proposed effective date of the system change. The plan amendment must include documentation for requests for waivers based on interference with efficient or effective program operations; a cost comparison analysis conducted under § 246.16a(d)(2); and a description of the proposed cost containment system. If FNS disputes supporting plan amendment documentation, it will deem the Plan amendment incomplete under this paragraph (a), and will provide the State agency with a statement outlining disputed issues within 15 days of receipt of the Plan amendment. The State agency may not enter into any infant formula cost containment contract until the disputed issues are resolved and FNS has given its consent. If necessary, FNS may grant a postponement of implementation of an infant formula cost containment system under § 246.16a(f). If at the end of the postponement period issues remain unresolved the State agency must proceed with a cost containment system judged by FNS to comply with the provisions of this part. If the State agency does not comply, it will be subject to the penalties set forth in § 246.16a(i).

* * * * *

4. In § 246.10:

a. revise paragraph (c)(1)(i);

b. redesignate paragraph (c)(1)(ii) as paragraph (c)(1)(vi) and add a heading;

c. add four new paragraphs (c)(1)(ii) through (c)(1)(v);

d. revise paragraph (c)(2)(i); and

e. revise paragraph (c)(3) introductory text and paragraph (c)(3)(i).

The revisions and additions read as follows:

§ 246.10 Supplemental foods.

* * * * *

(c) * * *

(1) *Food Package I—Infants 0 Through 3 Months.* (i) *Iron-fortified infant formula—requirements and routine issuance.* Except as specified in paragraphs (c)(1)(iii) through (c)(1)(v) of this section, local agencies must issue a contract brand infant formula that meets the requirements of paragraph (c)(1)(i) of this section. The supplemental food for this food package is an iron-fortified infant formula that is not an exempt infant formula. The iron-fortified infant formula must be nutritionally complete, not requiring the addition of any ingredients other than water prior to being served in a liquid state. It also must contain at least 10 milligrams of iron per liter at standard dilution and supply 67 kilocalories per 100 milliliters (i.e., approximately 20 kilocalories per fluid ounce of infant formula) at standard dilution. Medical documentation is not required for any contract brand infant formula authorized for issuance by the State agency, including the soy-based contract brand of infant formula. However, the State agency may require medical documentation for any contract brand infant formula even though it meets these requirements and may decide that some contract brand infant formulas may not be issued under any circumstances.

(ii) *Physical forms.* Local agencies must issue all WIC formulas (WIC formula means all infant formulas, including exempt infant formulas, and WIC-eligible medical foods) in concentrated liquid or powdered physical forms. Ready-to-feed WIC formulas may be authorized when the competent professional authority determines and documents that the participant's household has an unsanitary or restricted water supply or poor refrigeration, the participant or person caring for the participant may have difficulty in correctly diluting concentrated forms or reconstituting powdered forms, or the WIC formula is only available in ready-to-feed form.

(iii) *WIC formulas requiring medical documentation.* Local agencies may issue the following WIC formulas, but only with medical documentation:

(A) Any contract brand infant formula that does not meet the requirements of paragraph (c)(1)(i) of this section (e.g., low-iron, low-calorie, or high-calorie infant formulas);

(B) Any non-contract brand infant formula (even if it meets the requirements for an iron-fortified infant formula in paragraph (c)(1)(i) of this section);

(C) Any exempt infant formula; and

(D) any WIC-eligible medical food.

(iv) *Religious eating patterns exception.* Local agencies may issue a non-contract brand infant formula that meets the requirements of paragraph (c)(1)(i) of this section without medical documentation in order to meet religious eating patterns. However, if the non-contract brand infant formula does not meet the requirements of paragraph (c)(1)(i) of this section, medical documentation must be provided. Documentation of the basis of the substitution must be kept on file at the local clinic.

(v) *Medical documentation.* (A) *Determination.* For purposes of this food package, medical documentation means a determination by a licensed health care professional authorized to write medical prescriptions under State law. A licensed health care professional must make a medical determination that an infant has a medical condition that dictates the use of the following: a contract brand infant formula that does not meet the requirements of paragraph (c)(1)(i) of this section; a non-contract brand infant formula; an exempt infant formula; or a WIC-eligible medical food. These conditions include, but are not limited to: those that contraindicate the use of iron-fortified infant formula, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes, and food allergies. Low-calorie WIC formulas may not be issued solely for the purpose of managing body weight.

(B) *Technical requirements.* Medical documentation must include the brand name of the WIC formula prescribed; medical diagnosis warranting the issuance of WIC formula; length of time the prescribed WIC formula is medically required by the participant; and signature or name (if the initial medical documentation was received by telephone) of the requesting health care professional. Medical documentation may be provided as an original written document, electronically, or by facsimile. Medical documentation also may be provided by telephone to a competent professional authority who must promptly document the information which must be kept on file at the local clinic. However, this method may only be used until written confirmation is received and only when absolutely necessary on an individual participant basis to prevent undue hardship to a participant or to prevent a delay in the provision of infant formula that would place the participant at increased nutritional risk. The local clinic must obtain written confirmation of the medical documentation within a reasonable amount of time (i.e., one or two weeks' time) after accepting the initial medical documentation by telephone. The written documentation must be kept on file with the initial telephone documentation.

(vi) *Quantities and types of supplemental foods.****

(2) *Food Package II—Infants 4 through 12 months.* (i) Infant formula as specified in paragraphs (c)(1)(i) through (c)(1)(v) of this section.

* * * * *

(3) *Food Package III—Children/Women with Special Dietary Needs.* Local agencies may issue this food package to women and children only with medical documentation. The supplemental foods in Food Package III are set forth in paragraphs (c)(3)(i) through (c)(3)(iv) of this section. For purposes of this food package, medical documentation means a determination by a licensed health care professional authorized to write medical prescriptions under State law that the child or woman has a medical condition that dictates the use of a WIC formula (WIC formula means all infant formulas, including exempt infant formulas, and WIC-eligible medical foods) because the use of conventional foods is precluded or restricted. These medical conditions include, but are not limited to, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes and food allergies. This food package may not be issued solely for the purpose of enhancing nutrient intake or managing body weight. Medical documentation for WIC formulas must meet the technical requirements described in paragraph (c)(1)(v)(B) of this section.

(i) WIC formulas (i.e., an infant formula, exempt infant formula, or WIC-eligible medical food).

* * * * *

§ 246.16 [Amended]

5. In § 246.16:

a. In § 246.16, remove paragraphs (j) through (p).

6. Add a new § 246.16a to read as follows:

§ 246.16a Infant formula cost containment.

(a) *Who must use cost containment procedures for infant formula?* All State agencies must continuously operate a cost containment system for infant formula that is implemented in accordance with this section except:

(1) State agencies with home delivery or direct distribution food delivery systems;

(2) Indian State agencies with 1,000 or fewer participants in April of any fiscal year, which are exempt for the following fiscal year;

(3) State agencies granted a waiver under paragraph (e) of this section; and

(4) State agencies granted a postponement under paragraph (f) of this section.

(b) *What cost containment procedures must be used?* State agencies must use either a single-supplier competitive system as outlined in paragraph (c) of this section, or an alternative cost containment system as outlined in paragraph (d) of this section.

(c) *What is the single-supplier competitive system?* Under the single-supplier competitive system, a State agency solicits sealed bids from infant formula manufacturers to supply and provide a rebate for infant formulas. The State agency must conduct the procurement in a manner that maximizes full and open competition consistent with the requirements of this section.

(1) *How must a State agency structure the bid solicitation?* (i) *Single solicitation.* Under the single solicitation system, the State agency's bid solicitation must require the winning bidder to supply and provide a rebate on all infant formulas it produces that the State agency chooses to issue, except exempt infant formulas. Rebates must also be paid on any new infant formulas that are introduced after the contract is awarded. The solicitation must require bidders that do not produce a soy-based infant formula to subcontract with another manufacturer to supply a soy-based infant formula under the contract. In this case, the bid solicitation must require that the winning bidder pay the State agency a rebate on the soy-based infant formula supplied by the subcontractor that is issued by the State agency. The bid solicitation must require all rebates (including those for soy-based infant formula supplied by a subcontractor) to be calculated in accordance with paragraph (c)(5) of this section. All of these infant formulas are called contract brand infant formulas.

(ii) *Separate solicitations.* Under the separate solicitation system, a State agency issues two bid solicitations. The

first solicitation must require the winning bidder to supply and provide a rebate on all milk-based infant formulas it produces that the State agency chooses to issue, except exempt infant formulas. Rebates must also be paid on any new milk-based infant formulas that are introduced by the manufacturer after the contract is awarded. These infant formulas are considered to be contract brand infant formulas. The second bid solicitation must require the winning bidder to supply and provide a rebate on all soy-based infant formulas it produces that the State agency chooses to issue. Rebates must also be paid on any new soy-based infant formulas that are introduced by the manufacturer after the contract is awarded. These infant formulas are also considered to be contract brand infant formulas.

(2) *On what types and physical forms of infant formula must bids be solicited?* The bid solicitation must require bidders to specify a rebate for each of the types and physical forms of infant formulas specified in the following chart. These rebates apply proportionally to other infant formulas produced by the winning bidder(s) (see paragraph (c)(5) of this section). For purposes of this section the infant formula on which bids are solicited is the primary contract brand infant formula.

Type of infant formula	Physical forms of infant formula	Infant formula requirements
(i) For a single solicitation, the solicitation must require bidders to specify a rebate amount for the following:		
A single milk-based infant formula (primary contract brand infant formula); bidders must specify the brand name of the milk-based infant formula for which the rebate is being specified.	Concentrated liquid, powdered, and ready-to-feed.	Meets requirements under § 246.10(c)(1)(i) and suitable for routine issuance to the majority of generally healthy, full-term infants.
(ii) For separate solicitations, the solicitation must require bidders to specify a rebate amount for the following:		
(A) A single milk-based infant formula (primary milk-based contract brand infant formula); bidders must specify the brand name of the milk-based infant formula for which the rebate is being specified.	Concentrated liquid, powdered, and ready-to-feed.	Meets requirements under § 246.10(c)(1)(i) and suitable for routine issuance to the majority of generally healthy, full-term infants.
(B) A single soy-based infant formula (primary soy-based contract brand infant formula); bidders must specify the brand name of the soy-based infant formula for which the rebate is being specified.	Concentrated liquid, powdered, and ready-to-feed.	Meets requirements under § 246.10(c)(1)(i).

(3) *How are contracts awarded?* A State agency must award the contract(s) to the responsive and responsible bidder(s) offering the lowest total monthly net price for infant formula or the highest monthly rebate (subject to paragraph (c)(3)(ii) of this section) for a standardized number of units of infant formula. The State agency must calculate the lowest net price using the lowest national wholesale cost per unit for a full truckload of the infant formula on the date of the bid opening.

(i) *Calculating the standardized number of units of infant formula.* The State agency must specify a standardized number of units (*e.g.,* cans) of infant formula by physical form (*e.g.,* concentrated liquid, powdered, and ready-to-feed) to be bid upon. The standardized number of units must contain the equivalent of the total number of ounces by physical form needed to give the maximum allowance to the average monthly number of infants using each form. The number of infants does not include infant participants who are exclusively breastfed and those who are issued exempt infant formula. The average monthly number of infant using each physical form must be based on at least 6 months of the most recent participation and issuance data. In order to calculate the standardized number of units of infant formula by form to be bid upon, the average monthly number of infants using each physical form is multiplied by the maximum monthly allowable number of ounces for each form (as allowed under § 246.10(c)(1)(vi)), and divided by the corresponding unit size (*i.e.,* number of ounces per unit being bid). In order to compare bids, total cost is calculated by multiplying this standardized number of units by the net price for each physical form. Alternative calculations that arrive at a mathematically equivalent result are acceptable.

(ii) *Determining the lowest total monthly net price or highest rebate.* To determine the lowest total monthly net price a State agency must multiply the net price per unit by the established standardized amount of infant formula to be bid upon as calculated in paragraph (c)(3)(i) of this section. If the bid evaluation is based on highest rebate offered, the State agency must multiply the rebate offered by the established amount of infant formula to be bid upon as calculated in paragraph (c)(3)(i) of this section.

(iii) *Highest rebate limitation.* Before issuing the bid solicitation, a State agency that elects to evaluate bids by highest rebate must demonstrate to FNS' satisfaction that the weighted average retail prices for different brands of infant formula in the State vary by 5 percent or less. The weighted average retail price must take into account the prices charged for each type and physical form of infant formula by authorized vendors or, if a State agency elects, it may include stores that do not participate in the WIC program in the State. The State agency must also base calculations on the proportion of each type and physical form of infant formula the State agency issues based on the data provided to bidders pursuant to paragraph (c)(4) of this section.

(4) *What data must be provided to bidders?* The State agency must provide as part of the bid solicitation the participation and infant formula usage data and the standardized number of ounces by physical form of infant formula to be used in evaluating bids as described in paragraph (c)(3) of this section. The State agency must notify bidders that the participation and infant formula usage data does not necessarily reflect the actual issuance and redemption that will occur under the contract.

(5) *How is the rebate to be calculated on all other contract brand infant formulas?* All bids must specify the rebates offered by each bidder for the

primary contract brand infant formula(s). After the contract is awarded, the State agency must calculate the percentage discount for all other contract brand infant formulas (*i.e.,* all other infant formulas produced by the bidder other than exempt infant formulas) approved for issuance by the State agency. The State agency must use the following method in calculating the rebates:

(i) *Calculation of percentage discounts.* Rebates for contract brand infant formulas, other than the primary contract brand infant formula(s) for which bids were received, must be calculated by first determining the percentage discount for each physical form (*e.g.,* concentrated liquid, powdered, and ready-to-feed) of the primary contract brand infant formula(s). The percentage discount must be calculated by dividing the rebate for the primary contract brand infant formula by the manufacturer's lowest national wholesale price per unit, as of the date of the bid opening, for a full truckload of the primary contract infant formula. The percentage discounts must be used to determine the rebate for all other contract brand infant formulas approved for issuance by the State agency.

(ii) *Calculation of rebate amount.* The rebate for each type and form of all other contract brand infant formulas must be calculated by multiplying the percentage discount by the manufacturer's lowest national wholesale price per unit, as of the date of the bid opening, for a full truckload of the other contract brand infant formula. The percentage discount used for each of the other contract brand infant formulas depends on the physical form of the infant formula. For example, if the percentage discount provided for the primary contract brand powdered infant formula is 80 percent of its wholesale price, the same percentage discount must be applied to all other contract brand powdered infant formulas. The rebate for any types or forms of contract brand infant formulas that are introduced during the contract period must be calculated using the wholesale prices of these new contract brand infant formulas at the time the infant formulas are approved for issuance by the State agency.

(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 inflation adjustments required in paragraph (c)(5)(iv) of this section.

(iv) *Inflation provisions.* Bid solicitations must require the manufacturer to adjust for price changes subsequent to the bid opening. The inflation provision may require either a cent-for-cent increase in the rebate amounts whenever there is any change in the lowest national wholesale price for a full truckload of the particular infant formula, or may require another equally effective cost adjustment mechanism for inflation as established by the State agency in the bid solicitation.

(6) *Does a State agency have to approve the issuance of all contract brand infant formulas?* No, the State agency may choose to approve for issuance, in addition to the primary contract brand infant formula(s), none, some, 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 (see § 246.10(c)(1)(i)) and must require medical documentation before issuing any WIC formula covered by § 246.10(c)(1)(iii).

(d) *What is an alternative cost containment system?* Under an alternative cost containment system, a State agency elects to implement an infant formula cost containment system of its choice. The State agency may only implement an alternative system if such a system provides a savings equal to or greater than a single-supplier competitive system. A State agency must conduct a cost comparison demonstrating such savings as described in paragraphs (d)(1) and (d)(2) of this section.

(1) *How must the State agency structure the bid solicitation?* The State agency must solicit bids simultaneously using the single-supplier competitive system described in paragraph (c) of this section and the alternative cost containment system(s) the State agency has selected. The State agency may prescribe standards of its choice for the alternative cost containment system(s), provided that conditions established for each system addressed in the bid solicitation include identical bid specifications for the contract period length and the types and forms of infant formula(s) to be included in the systems. In addition, the alternative cost containment system must cover the types and forms of infant formulas routinely issued to the majority of generally healthy, full-term infants. The State agency must use the procedure outlined in paragraph (d)(2) of this section in conducting a cost comparison to determine which system offers the greatest savings over the entire contract period specified in the bid solicitation.

(2) *How does the State agency conduct the cost comparison?* (i) *Establishing infant formula cost containment savings.* (A) *Savings under the single-supplier competitive system.* The State agency must project food cost savings in the single-supplier competitive system based on the lowest monthly net price or highest monthly rebate, as described in paragraph (c)(3) of this section.

(B) *Savings under an alternative cost containment system.* The State agency must project food cost savings under alternative cost containment systems based on the lowest monthly net cost or highest monthly rebate, as described in paragraph (c)(3) of this section. Food cost savings must be based on the standardized amount of infant formula expected to be issued as calculated for a single-supplier competitive system, prorated by the percentage of anticipated total infant formula purchases attributable to each manufacturer. The State agency must use the aggregate market share of the manufacturers submitting bids in calculating its cost savings estimate.

(C) *General.* In establishing the potential food cost savings under each system, the State agency must take into consideration in its estimate of savings any inflation factors which would affect the amount of savings over the life of the contract. Further, the State agency must not subtract any loss of payments which would occur under the terms of a current contract as a result of any State agency action to be effective after expiration of the contract.

(ii) *Nutrition services and administration cost adjustment.* The State agency must deduct from the food cost savings projected for each system under this paragraph (d) the nutrition services and administration costs associated with developing and implementing—but not operating—each cost containment system. This includes any anticipated costs for modifying its automated data processing system or components of its food delivery system(s), and of training participants, local agencies, vendors, and licensed health care professionals on the purpose and procedures of the new system. For contracts of two years or less, such costs must be proportionately distributed over at least a two year period. The State agency must not deduct any costs associated with procurement. The State agency must itemize and justify all nutrition services and administration cost adjustments as necessary and reasonable for the development and implementation of each system.

(iii) *Final cost comparison.* The State agency must calculate the food costs

savings and deduct the appropriate nutrition services and administration costs for each system for which bids were received. The State agency must implement the single-supplier competitive system, unless its comparative cost analysis shows that, over the length of the contract stipulated in the bid solicitation, an alternative cost containment system offers savings at least equal to, or greater than, those under the competitive single-supplier system. If the comparative cost analysis permits selection of the alternative cost containment system and the State agency wishes to implement that system, it must first submit a State Plan amendment with the calculations and supporting documentation for this cost analysis to FNS for approval. Only after the calculations are approved by FNS may the State agency award the contract or contracts under the alternative cost containment system.

(e) *How does a State agency request a waiver of the requirement for a single-supplier competitive system?* A State agency which, after completing the cost comparison in paragraphs (d)(2)(i) through (d)(2)(iii) of this section, is required to implement the single-supplier competitive cost containment system for infant formula procurement, may request a waiver from FNS to permit it to implement an alternative system. State agencies must support all waiver requests with documentation in the form of a State Plan amendment as required under § 246.4(a)(14)(xi) and may submit such requests only in either of the following circumstances:

(1) The difference between the single-supplier competitive system and the alternative cost containment system is less than 3 percent of the savings anticipated under the latter system and not more than $100,000 per annum.

(2) The single-supplier competitive system would be inconsistent with the efficient or effective operation of the program. Examples of justifications FNS will not accept for a waiver, include, but are not limited to: preservation of participant preference for otherwise nutritionally equivalent infant formulas; maintenance of health care professionals' prerogatives to prescribe otherwise nutritionally equivalent infant formulas for non-medical reasons; potential loss of free or otherwise discounted materials to WIC clinics and other health care facilities; potential inability of a manufacturer selected in accordance with applicable State procurement procedures to supply contractually-specified amounts of infant formula; and the possibility of interrupted infant formula supplies to retail outlets as a consequence of entering into a contract with a single manufacturer.

(f) *How does a State agency request a postponement of the requirement for a continuously operated cost containment system for infant formula?* A State agency may request a postponement of the requirement to continuously operate a cost containment system for infant formula that has been implemented in accordance with this section. However, a State agency may only request a postponement when it has taken timely and responsible action to implement a cost containment system before its current system expires but has been unable to do so due to procurement delays, disputes with FNS concerning cost containment issues during the State Plan approval process or other circumstances beyond its control. The written postponement request must be submitted to FNS before the expiration of the current system. The postponement period may be no longer than 120 days. If a postponement is granted, the State agency may extend, renew or otherwise continue an existing system during the period of the postponement.

(g) *May a State agency implement cost containment systems for other supplemental foods?* Yes, when a State agency finds that it is practicable and feasible to implement a cost containment system for any WIC food other than infant formula, the State agency must fully implement that system in accordance with the time frames established by the State agency and notification must be given to FNS by means of the State agency's State Plan.

(h) *What are the implementation time frames for Indian State agencies that lose their exemption from the infant formula cost containment requirement?* If an Indian State agency operating a retail food delivery system expands its program participation above 1000 and thereby loses its exemption from the requirements of paragraph (a) of this section regarding the method of cost containment for infant formula, then the Indian State agency must begin compliance with paragraph (a) of this section in accordance with time frames established by FNS.

(i) *What are the penalties for failure to comply with the cost containment requirements?* Any State agency that FNS determines to be out of compliance with the cost containment requirements of this part must not draw down on or obligate any Program grant funds, nor will FNS make any further Program funds available to such State agency, until it is in compliance with these requirements.

(j) *What provisions are prohibited to be included in cost containment contracts?* A State agency may not issue bid solicitations or enter into contracts which:

(1) Prescribe conditions that would void, reduce the savings under or otherwise limit the original contract if the State agency solicited or secured bids for, or entered into, a subsequent cost containment contract to take effect after the expiration of the original contract;

(2) Does not include the registration and certification requirements in § 246.10(f); or

(3) Require infant formula manufacturers to submit bids on more than one of the systems specified in the invitation for bids.

(k) *What are the requirements for the national cost containment bid solicitation and selection for infant formula?* FNS will solicit and select bids for infant formula rebates on behalf of State agencies with retail food delivery systems based on the following guidelines:

(1) FNS will solicit bids and select the winning bidder(s) for infant formula cost containment contracts only if two or more State agencies with retail food delivery systems request FNS to conduct bid solicitation and selection on their behalf. FNS will conduct the bid solicitation and selection process only and will not award or enter into any infant formula cost containment contract on behalf of the individual State agencies. Each State agency will individually award and enter into infant formula cost containment contract(s) with the winning bidder(s). State agencies must obtain the rebates directly from the infant formula manufacturer(s). FNS will conduct the bid solicitation in accordance with this paragraph (k) and the competitive bidding procurement procedures of the State agency with the highest infant participation in the bid group on whose behalf bids are being solicited. Any bid protests and contractual disputes are the responsibility of the individual State agencies to resolve.

(2) FNS will make a written offer to all State agencies to conduct bid solicitation and selection on their behalf at least once every 12 months. FNS will send State agencies a copy of the draft Request for Rebates when making the offer to State agencies. Only State agencies that provide the information required by this paragraph (k)(2) in writing, signed by a responsible State agency official, by certified mail, return receipt requested or by hand delivery with evidence of receipt within 15 days of receipt of the offer will be included

in the national bid solicitation and selection process. Each interested State agency must provide:

(i) A statement that the State agency requests FNS to conduct bid solicitation and selection on its behalf;

(ii) A statement of the State agency's minimum procurement procedures applicable to competitive bidding (as defined in § 246.2) for infant formula cost containment contracts and supporting documentation;

(iii) A statement of any limitation on the duration of infant formula cost containment contracts and supporting documentation;

(iv) A statement of any contractual provisions required to be included in infant formula cost containment contracts by the State agency;

(v) The most recent available average monthly number of infant participants less those infant participants who are exclusively breastfed and those who are issued exempt infant formula. The average monthly participation level must be based on at least 6 months of participation data.

(vi) Infant formula usage rates by type (e.g., milk-based or soy-based), form (e.g., concentrated, powdered, ready-to-feed), container size, and supporting documentation;

(vii) A statement of the termination date of the State agency's current infant formula cost containment contract; and

(viii) Any other related information that FNS may request.

(3) If FNS determines that the number of State agencies making the request provided for in paragraph (k)(2) of this section so warrants, FNS may, 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 (k)(2)(ii), (k)(2)(iii) and (k)(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.

(4) For each bid group formed pursuant to paragraphs (k)(2) and (k)(3) of this section, FNS will use for soliciting bids the competitive bidding procurement procedures of the State agency in the group with the highest infant participation. To the extent not inconsistent with the requirements of this paragraph (k), FNS will use that set of procedures in soliciting the bids for that bid group of State agencies. FNS will notify each State agency in the bid group of the choice and provide them each a copy of the procurement procedures of the chosen State agency. Each State agency must provide FNS a written statement, signed by a responsible State agency official, by certified mail, return receipt requested or by hand delivery with evidence of receipt stating whether that State agency is legally authorized to award an infant formula cost containment contract pursuant to that set of procedures within 10 days of the receipt of the notification. If the State agency determines it is not legally authorized to award an infant formula cost containment contract pursuant to those procedures, that State agency may not continue in that round of the national bid solicitation and selection.

(5) At a minimum, in soliciting bids FNS will address the following:

(i) Unless FNS determines that doing so would not be in the best interest of the Program, bids will be solicited for either:

(A) A single contract for each State agency under which the winning bidder will be required to supply and provide rebates on all infant formulas produced by that manufacturer (except exempt infant formulas) that are issued by the State agency. If that manufacturer does not produce a soy-based infant formula, the winning bidder will be required to subcontract with another manufacturer for a soy-based infant formula and the winning bidder will be required to pay a rebate on the soy-based infant formula; or

(B) Two separate contracts for each State agency. Under the first contract, the winning bidder will supply and provide a rebate on all the milk-based infant formulas the winning bidder produces (except exempt infant formulas) that are issued by the State agency and under the second contract the winning bidder will supply and provide a rebate on all the soy-based infant formulas the winning bidder produces (except exempt infant formulas) that are issued by the State agency.

(ii) The infant formula cost containment contract(s) to be entered into by the State agencies and infant formula manufacturers must provide for a constant net price for infant formula for the full term of the infant formula cost containment contract(s).

(iii) The duration of the infant formula cost containment contracts for each bid group will be determined by FNS in consultation with the State agencies. The term will be for a period of not less than 2 years, unless the law applicable to a State agency regarding the duration of infant formula cost containment contracts is more restrictive than this paragraph (k)(5)(iii). In such cases, the term of the contract for only that State agency will be for one year, with the option provided to the State agency to extend the contract for a specified number of additional years (to be determined by FNS in consultation with the State agency). The date on which the individual State agencies' current infant formula cost containment contracts terminate may vary, so the infant formula cost containment contracts awarded by the State agencies within a bid group may begin on different dates.

(iv) FNS will not prescribe conditions that are prohibited under paragraph (j) of this section.

(v) FNS will solicit bids for rebates only from infant formula manufacturers. FNS may limit advertising to contacting in writing each infant formula manufacturer which has registered with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

(6) FNS will select the winning bidder(s). The winning bidder(s) will be the responsive and responsible bidder(s) meeting the specifications and all bid terms and conditions which offers the lowest net price weighted to take into account infant formula usage rates and infant participation. In all instances the winning bidder(s) will be those which singly or in combination yield the greatest aggregate savings based on the net price weighted to take into account the infant formula usage rates. To break a tie between 2 equally low bids, FNS will select the bidder to be awarded the infant formula cost containment contract by a drawing by lot limited to the bidders which submitted those bids.

(7) Once FNS has conducted bid selection, a State agency may decline to award the infant formula cost containment contract(s) only if the State agency determines that awarding the contract(s) would not be in the best interests of its Program, taking into account whether the national bid solicitation and selection would achieve a lower aggregate savings.

(8) As soon as practicable after selecting the winning bid(s), FNS will notify the affected State agencies in writing of the bid results, including the name(s) of the winning bidder(s). If a State agency chooses to request approval to decline to award the infant formula cost containment contract(s) in accordance with paragraph (k)(7) of this section, it must notify FNS in writing, signed by a responsible State agency official, together with supporting documentation, by certified mail, return receipt requested or by hand delivery with evidence of receipt within 10 days of the State agency's receipt of this notification of bid results.

(9) If FNS approves any State agency's request to decline to award the infant formula cost containment contract(s) in accordance with paragraphs (k)(7) and (k)(8) of this section, FNS will notify the bidders of the decision. If two or more State agencies remain in the group, FNS will require the bidders to indicate in writing whether they wish to withdraw or modify their bids within 5 days of receipt of this notification. FNS will again permit State agencies to decline to award the infant formula cost containment contract(s) in accordance with paragraphs (k)(7) and (k)(8) of this section. If FNS approves these additional State agency requests to decline contract awards, FNS may conduct a resolicitation of bids in accordance with this paragraph (k).

Dated: August 10, 2000.

Shirley R. Watkins,

Under Secretary, Food, Nutrition and Consumer Services.

[FR Doc. 00–21423 Filed 8–22–00; 8:45 am]

BILLING CODE 3410–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NE–05–AD; Amendment 39–11804; AD 2000–13–05]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc. RB211 Trent 768–60, Trent 772–60, and Trent 772B–60 Turbofan Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2000–13–05 applicable to Rolls-Royce plc. (RR) RB211 Trent 768–60, Trent 772–60, and Trent 772B–60 turbofan engines that was published in the **Federal Register** on July 3, 2000 (65 FR 40983). The statement regarding the reports of fan blade failures in the Summary section and the Internet address for AD comments in the Addresses section are incorrect. This document corrects that statement and that address. In all other respects, the original document remains the same.

EFFECTIVE DATE: August 23, 2000.

FOR FURTHER INFORMATION CONTACT: James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone 781–238–7176; fax 781–238–7199.

SUPPLEMENTARY INFORMATION: A final rule airworthiness directive applicable to Rolls-Royce plc. (RR) RB211 Trent 768–60, Trent 772–60, and Trent 772B–60 turbofan engines, was published in the **Federal Register** on July 3, 2000 (65 FR 40983).

The following corrections are needed:

1. On page 40983, in the second column, in the **SUMMARY** section, in the eleventh and twelfth lines, ''fan blade failures due to dovetail root cracks.'' is corrected to read ''fan blade root cracks in a factory engine.''.

2. On page 40983, in the second column, in the **ADDRESSES** section, in the first paragraph, in the ninth and tenth lines, ''9-ad-engineprop@faa.gov'' is corrected to read ''9-ane-adcomment@faa.gov''.

Issued in Burlington, MA, on August 16, 2000.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 00–21314 Filed 8–22–00; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–AGL–02]

Modification of Class E Airspace; Marquette, MI; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects two errors in the legal description of a final rule that was published in the **Federal Register** on Wednesday, July 26, 2000 (65 FR 45842), Airspace Docket No. 00–AGL–02. The final rule modified Class E Airspace at Marquette, MI.

EFFECTIVE DATE: 0901 UTC, October 5, 2000.

FOR FURTHER INFORMATION CONTACT: Dennis C. Burke, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, IL 60018; telephone: (847) 294–7477.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 00–18893, Airspace Docket No. 00–AGL–02, published on July 26, 2000 (65 FR 45842), modified Class E Airspace at Marquette, MI. Two errors in the legal description for the Class E airspace for Marquette, MI, were published. This action corrects those errors.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the legal description for the Class E airspace, Marquette, MI, as published in the **Federal Register** July 26, 2000 (65 FR 45842, FR Doc. 00–18893), is corrected as follows:

PART 71—[CORRECTED]

§ 71.1 [Corrected]

On page 45842, Column 3, line 9 from the top of the column, correct ''7.1-miles'' to read ''7.1-mile'' and on page 45842, Column 3, line 16 from the top of the column, correct ''east'' to read ''west''.

Christopher R. Blum,

Manager, Air Traffic Division.

[FR Doc. 00–21492 Filed 8–22–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 1880

[WO–880–9500–PF–24–1A]

RIN 1004–AD23

Financial Assistance, Local Governments

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This final rule revises the regulations governing procedures for disbursing Payments in Lieu of Taxes (PILT) to units of general local government for entitlement lands within their boundaries. In addition, this final rule incorporates statutory changes to the authorizing legislation.