

**DEPARTMENT OF AGRICULTURE****Food and Nutrition Service****7 CFR Part 246**

[FNS-2006-0037]

RIN 0584-AD77

**Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages****AGENCY:** Food and Nutrition Service, USDA.**ACTION:** Interim rule.

**SUMMARY:** This interim rule revises regulations governing the WIC food packages to align the WIC food packages with the Dietary Guidelines for Americans (DGA) <sup>1</sup> and current infant feeding practice guidelines of the American Academy of Pediatrics, better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of food, and provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences.

**DATES:** *Effective Date:* This rule is effective February 4, 2008.

*Implementation Date:* State agencies must implement the provisions of this rule no later than August 5, 2009.

*Comment Date:* To be considered, comments on this interim rule must be postmarked on or before February 1, 2010.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>, select "Food and Nutrition Service," from the agency drop-down menu, then click "Submit." In the Docket ID column, select FNS-2006-0037 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "User Tips" link.

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

Comments submitted in response to this interim rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identities of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the comments publicly available on the Internet via <http://www.regulations.gov>. Information regarding the interim rule will be available on the FNS Web site at <http://www.fns.usda.gov/wic>. A regulatory impact analysis has been prepared for this rule. It follows this regulation as an Appendix.

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

**SUPPLEMENTARY INFORMATION:****I. Overview**

This interim rule implements the first comprehensive revisions to the WIC food packages since 1980. These revised food packages were developed to better reflect current nutrition science and dietary recommendations than do current food packages, within the parameters of current program costs.

**II. Background**

The WIC food packages provide supplemental foods designed to address the nutritional needs of low-income pregnant, breastfeeding, non-breastfeeding postpartum women, infants and children up to five years of age who are at nutritional risk. WIC food packages and nutrition education are the chief means by which WIC affects the dietary quality and habits of participants. WIC is a unique nutrition assistance program in that it also serves as an adjunct to good health care during critical times of growth and development to prevent the occurrence of health problems and to improve the health status of Program participants. WIC was never intended to be a primary source of food, nor of general food assistance. Rather, WIC food benefits are scientifically-based and intended to address the supplemental nutritional needs of a specific population—low income pregnant, breastfeeding, non-breastfeeding postpartum women, infants and children up to five years of age who are at nutritional risk. In addition to WIC, the Food and Nutrition Service (FNS) administers a variety of other complementary nutrition

assistance programs that work together to provide a more complete diet to low-income persons. Low-income families can, and frequently do, receive benefits from more than one of these programs. The largest of these programs, the Food Stamp Program, provides general food assistance intended to increase the food buying power of low-income households.

The ability of the WIC food packages to reinforce nutrition education messages provided to participants is critical to affecting the dietary quality and habits of infants, children and mothers served by WIC. The nutrition education provided by WIC enables participants to make informed decisions in choosing foods that, together with the supplemental foods contained in the WIC food packages, can meet their total dietary needs. The intent is to help participants continue healthful dietary practices after leaving the Program.

Since the creation of the WIC Program in the 1970s, and the last major revision of the WIC food packages in the early 1980's, much has been learned about the nutritional needs of Americans, including WIC's target population of pregnant and postpartum women, infants, and preschool aged children. In recent years the ability of the WIC Program to address the supplemental nutritional needs of WIC participants through its food packages and nutrition education has received growing attention. Significant interest in updating the food packages based on new information about the needs of low-income, culturally diverse women, infants, and children has been voiced by WIC Program administrators, the medical and scientific communities, advocacy groups, and Congress.

**III. General Summary of Comments Received on the Proposed Rule To Revise the WIC Food Packages**

The Proposed Rule to revise regulations pertaining to the supplemental foods provided through the WIC Program was published in the **Federal Register** on August 7, 2006 (71 FR 44784), with a 90-day comment period. The proposed rule largely reflected recommendations made by the National Academies' Institute of Medicine (IOM) in its Report "WIC Food Packages—Time for a Change,"<sup>(2)</sup> with modifications found necessary by FNS to ensure cost neutrality.

A total of 46,502 comment letters were received on the Proposed Rule; of those, 23,908 were form letters. A total of 38,257 letters were received from program participants; 18,080 of those were form letters. The remaining comment letters were submitted from a

variety of sources, including WIC State and local agencies and Indian Tribal Organizations, the National WIC Association (NWA), professional organizations and associations, advocacy groups, healthcare professionals (including universities), members of Congress, the food industry, vendors, farmers, and private citizens.

In general, the proposed changes to the WIC food packages garnered broad support from public commenters. A total of 21,042 commenters (8,293 of these form letters) made explicit statements regarding the merits of the proposed rule as a whole. Of those, 20,438 (8,292 of which were form letters) expressed support for the majority of the proposed revisions. A total of 604 commenters (1 of these a form letter) disagreed with the majority of the proposed rule provisions—these letters were primarily from participants who did not want to see any changes to the current WIC food packages. FNS considered all comments without regard to whether they were provided by a single commenter or repeated by many. Importance was given to the substance or content of the comment, rather than the number of times a comment was submitted.

#### **IV. Discussion of the Proposed Provisions**

The following is a discussion of the major provisions set forth in the proposed rule, a brief summary of the comments received that addressed these issues, and FNS' rationale for either modifying each section in the interim rule, or retaining its provisions as initially proposed. Provisions not addressed in the preamble to this interim rule did not receive significant or substantial public comments and are retained in this interim rule as proposed.

This preamble articulates the basis and purpose behind significant changes from the August 7, 2006, proposal. The reasons supporting provisions of the proposed regulations were carefully examined in light of the comments to determine the continued applicability of the justifications. Unless otherwise stated, or unless inconsistent with the interim rule or this preamble, the rationales contained in the preamble to the proposed regulations should be regarded as a basis for the interim rule. Therefore, a thorough understanding of the rationales for the interim regulations may require reference to the preamble of the August 7, 2006 proposal (71 FR 44784).

#### **A. Definitions**

1. *Participation.* FNS proposed to revise the definition for WIC "participation" to include the number of breastfeeding women who receive no supplemental foods or food instruments but whose breastfed infant(s) receives the supplemental foods or food instruments. The definition means, therefore, that a partially breastfeeding woman who requests, after the sixth month postpartum, more than the maximum amount of formula allowed for a partially breastfed infant would no longer receive a food package but would continue to count as a WIC participant and receive other Program benefits and nutrition services (nutrition education, including breastfeeding promotion and support, and referrals to health and social services.) Thirty-two commenters (15 form letters) were opposed to not providing a food package to partially breastfeeding women who request, after the sixth month postpartum, more formula than the maximum.

The IOM recommended that a partially breastfeeding woman who requests, after the sixth month postpartum, more than the maximum amount of formula for a partially breastfed infant, no longer be certified for the WIC Program. However, FNS determined that this approach is incongruous with the definition of breastfeeding in WIC regulations at 7 CFR 246.2—the practice of feeding a mother's breastmilk to her infant(s) on the average of at least once per day. In WIC, this definition is used to determine Program eligibility, and allows all breastfeeding women, regardless of feeding pattern, to participate in the WIC Program, be counted as a breastfeeding woman, and receive supplemental foods, breastfeeding promotion and support, and referrals to health care. The definition recognizes that any breastfeeding, even if only on an average of once a day, provides some immunological and nutritional benefits that would otherwise not be provided to an infant. Rather than adopt IOM's recommendation in its entirety, FNS proposed to revise the definition for WIC "participation" to include breastfeeding women who receive no supplemental foods or food instruments but whose breastfed infant(s) receives supplemental food or food instruments. Counting these women, although they are not receiving a food package, is consistent with the current practice of counting the infants of exclusively breastfeeding women. Therefore, a partially breastfeeding woman who requests, after the sixth month

postpartum, more than the maximum amount of formula allowed for a partially breastfed infant would no longer receive a food package but would continue to count as a WIC participant and receive other Program benefits (nutrition education, including breastfeeding promotion and support, and referrals to health and social services). This would serve to meet the intent of IOM's recommendations within the context of WIC regulations.

As recommended by some commenters, FNS clarifies that breastfeeding women who receive no supplemental foods or food instruments but whose breastfed infant(s) receives the supplemental foods or food instruments continue to be eligible to receive nutrition services, and breast pumps are a part of nutrition services. With this clarification, the definition of participation is retained in this interim rule as proposed at 7 CFR 246.2.

2. *WIC-eligible medical foods.* FNS proposed to revise the definition for "WIC-eligible medical foods" to clarify that medical foods are designed for children 12 months and older and adults and that WIC-eligible medical foods are not conventional foods, drugs, flavorings or enzymes. A few commenters disagreed with the proposed definition for WIC-eligible medical foods stating that the definition as proposed would exclude infants from receiving certain medical foods that are appropriate for them such as modular formulas that are not nutritionally complete but add specific nutrients such as protein, fat, and carbohydrate. FNS acknowledges that certain medical foods exist that are appropriate for use by infants and that medically fragile infants should be included as a participant category in the WIC-eligible medical food definition. Several other commenters believe that FNS should rely on Food and Drug Administration (FDA) expertise for the definition of medical foods since FDA is the regulatory authority for medical foods. FNS acknowledges FDA's role in the regulation of medical foods. However, specific requirements for the safety or appropriate use of medical foods have not yet been established by FDA.

FNS agrees with commenter concerns that the proposed definition for WIC-eligible medical foods excludes infants as a participant category. Therefore, the proposed definition for WIC-eligible medical foods is revised in this interim rule to include infants as a participant category.

### B. General Provisions That Affect All WIC Food Packages

#### 1. Food Lists

The proposed rule would have continued to require State agencies to identify brands and package sizes that are acceptable for use in their States from among those authorized and to provide to local agencies a list of acceptable foods and their maximum monthly allowances in accordance with WIC requirements. This provision is retained in this interim rule at 7 CFR 246.10(b)(2)(i). A conforming amendment in this interim rule at 7 CFR 246.4 clarifies that a copy of the food list must be included in the State Plan.

#### 2. Nutrition Tailoring

Current FNS policy allows both categorical and individual nutrition tailoring of WIC food packages. Categorical nutrition tailoring is the process of modifying the WIC food packages for participant groups or subgroups with similar supplemental nutrition needs, based on scientific nutrition rationale and State established policies. The proposed rule would have prohibited categorical nutrition tailoring, but continue to allow individual nutrition tailoring based on the Competent Professional Authority's assessment of a participant's supplemental nutrition needs.

A total of 528 commenters (of these, 505 were form letters) agreed with the proposal to eliminate State authority to categorically tailor food packages, stating that the careful balance achieved by the IOM's recommendations to revise the WIC food packages should be maintained. In contrast, 187 commenters (of these, 151 were form letters) were opposed to the provision, stating that States need the flexibility to propose modifications to food packages that respond to rapid changes in food industry, science, demographics, and other factors.

As discussed at length in the preamble to the proposed rule, the revised food packages have the potential to address current nutrient inadequacies and excesses; discrepancies between dietary intake and dietary guidance; and current and future health-related problems in WIC's target population. The IOM was also charged with considering the cultural needs of WIC participants and its recommendations for revisions to the WIC food packages, and the proposed rule, reflect those considerations. The IOM had the resources and capacity to conduct an independent, rigorous scientific review of the nutritional needs of WIC participants in each category prior to

recommending the quantities and types of WIC foods to address those needs in its Report.<sup>(2)</sup> Because the IOM based the revisions to the WIC food packages on current nutrition science, FNS proposed that State agencies would no longer be authorized to categorically tailor food packages.

FNS believes that State agencies will best be able to meet the nutritional needs of each WIC participant through nutrition assessment and individual tailoring of the food package. Therefore, the provision to disallow State agency proposals to categorically tailor WIC food packages is retained in this interim rule at 7 CFR 246.10(c). FNS clarifies that, in addition to having the authority to individually tailor food packages, State agencies continue to have the authority to make adjustments to WIC foods for administrative convenience and to control costs. Such adjustments may involve packaging methods, container sizes, brands, types and physical forms of WIC foods.

#### 3. Cultural Food Package Proposals

A total of 174 commenters (of these, 149 were form letters) were opposed to FNS' proposal to no longer consider WIC State agency requests for cultural food substitutions. Commenters cited the need for State agencies to have the flexibility to keep pace with demographic changes in the WIC population.

FNS believes that the increased variety and choice in the supplemental foods in this interim rule provide State agencies expanded flexibility in prescribing culturally appropriate packages for diverse groups. Section 203(c) of Public Law 108-265 amended Section 17(c)(2) of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1786), by requiring the Secretary to conduct, as often as necessary, a scientific review of supplemental foods available under the program and to amend the foods, as needed, to reflect nutrition science, public health concerns, and cultural eating patterns. As such, future reviews of the WIC food packages by FNS will be used to determine the need for additional cultural accommodations. However, in response to requests by commenters to allow State agencies the flexibility to meet unanticipated cultural needs of participants, a new 7 CFR 246.10(i) has been added to this interim rule that allows State agencies to submit to FNS a plan for substitution of food(s) to allow for different cultural eating patterns. The criteria for submitting plans for substitutions for different cultural eating patterns and the criteria FNS will use to evaluate such plans are

the same as those under current WIC regulations at 7 CFR 246.10(e).

#### 4. Medical Documentation and Supervision Requirements

Under the proposed rule, medical documentation would have been required for certain milk alternatives for children and women and for any supplemental foods authorized in proposed Food Package III. Under the proposed rule, medical documentation would continue to be required for any contract brand infant formula that does not meet the requirements of an infant formula as specified in Table 4 of 7 CFR 246.10(e)(12) of the proposed rule, any non-contract brand infant formula, any exempt infant formula, or any WIC-eligible medical food.

Under current WIC regulations, the technical requirements for medical documentation include:

- Brand name of the WIC formula prescribed;
- Medical diagnosis warranting the WIC formula;
- Length of time the prescribed WIC formula is medically required by the participant; and
- Signature (or name, if the initial documentation was received by telephone) of the requesting health care provider.

Under the proposed rule, additional technical requirements would have been added as follows:

- Contact information for the participant's healthcare provider making the medical determination;
- Date of medical determination;
- Name of specific supplemental food(s) to be prescribed;
- Amount prescribed per day of WIC formula and/or supplemental foods;
- Qualifying condition that warrants the issuance of the specific supplemental food(s); and
- Length of time the specific supplemental food(s) is medically required.

A total of 2,107 comment letters (1,945 of these were form letters) opposed the proposed medical documentation, primarily the documentation for children to receive soy-based beverage. Commenter's stated that the medical documentation requirement for soy-based beverage for children would create barriers to services and undermine FNS' efforts to provide foods that meet the cultural needs of participants. A small number of comments received from WIC staff primarily at the local level expressed concern that requiring medical documentation for the additional supplemental foods allowed in proposed Food Package III and requiring

a prescribed amount per day is burdensome to participants, the medical community and WIC agencies.

FNS understands the potential administrative impact of requiring medical documentation for the provision of supplemental foods in Food Package III. However, these medical documentation requirements were proposed to ensure that the participant's healthcare provider, licensed in the State to write prescriptions, has determined that the supplemental foods are not medically contraindicated by the participant's qualifying condition. Participants that receive Food Package III are medically fragile and should be under the care of a healthcare professional for the purpose of close medical supervision essential for the participant's overall dietary management. Participants that receive Food Package III have qualifying medical conditions that preclude or restrict their use of conventional foods. Requiring medical documentation to include the additional supplemental foods allowed in proposed Food Package III and requiring an amount prescribed per day will ensure that the participant's health care provider is aware that WIC is providing supplemental foods that the health care provider has determined are not medically contraindicated by the participant's qualifying medical condition. Requiring the health care provider to designate an amount of WIC formula and the WIC supplemental foods allowed in the participant's diet will help the Certified Professional Authority (CPA) in designing nutrition education and a food package prescription that is appropriate to the participant's medical needs.

FNS acknowledges that some additional administrative tasks will occur because of medical documentation requirements for dairy alternatives. However, requiring medical documentation for soy-based beverage for children ensures that a child's health care provider is aware that the child may be at nutritional risk when milk is replaced by other foods. The DGA<sup>(1)</sup> stress the importance of milk consumption in the development of bone mass for children. The IOM noted that while soy products may be an appropriate choice for children who cannot consume milk, soy should not be made available to satisfy participant preference in the absence of medical need. Therefore, the proposed provisions for medical documentation for certain milk alternatives for children and women and for any supplemental foods authorized in proposed Food Package III are retained in this interim

rule at 7 CFR 246.10(d). Proposed provisions related to revised medical documentation requirements that are not addressed in this preamble did not receive significant or substantial public comments and are retained in this interim rule as proposed.

#### 5. Organic Foods

A number of commenters asked FNS to allow organic products within the authorized categories of foods in the WIC food packages. FNS points out that some organic forms of WIC-eligible foods meet the nutritional requirements set forth in current WIC regulations and are therefore authorized; this interim rule continues to authorize organic forms of foods that meet minimum nutrition requirements described in Table 4 of 7 CFR 246.10(e)(12). However, WIC State agencies are responsible for determining the brands and types of foods to authorize on their State WIC food lists. Some State agencies may allow organic foods on their foods lists, but this will vary by State. The decision may be influenced by a number of factors such as cost, product distribution within a State, and WIC participant acceptance.

#### C. Supplemental Foods and Food Packages

**Note:** In the interest of clarity, specific food package issues are discussed according to food item rather than food package and then the food package categories are discussed. The order of some of the topics in this section is modified from the proposed rule for the purposes of discussion.

#### 1. Fruits and Vegetables in Food Packages III Through VII

The addition of fruits and vegetables to the WIC food packages was the most welcomed provision of the proposed rule across all commenter categories. Of the total of 40,026 comment letters that addressed fruits and vegetables, 39,961 (22,935 of these form letters) were favorable. The majority of the few opposing comments were from participants who did not want to see any changes to the current WIC food packages.

#### a. Maximum Monthly Allowances

The IOM recommended that fruits and vegetables be provided at levels of \$10 per month for women and \$8 per month for children. To achieve cost neutrality, the proposed rule would have established the value of fruit and vegetable vouchers at levels of \$8 per month for women and \$6 per month for children. A total of 3,166 commenters (2,940 of these form letters) asked FNS to increase the cash-value vouchers to

the level recommended by the IOM so that participants could receive one additional serving of fruits and vegetables per day. Commenters cited (1) the important benefits of fruits and vegetables in decreasing high blood pressure, heart disease, obesity, and cancer; (2) the generally low consumption of fruits and vegetables among WIC participants; and (3) the role that WIC can play in helping participants meet the DGA<sup>(1)</sup> for fruit and vegetable intake. Commenters urged FNS to seek additional funds to provide the cash-value vouchers at the level recommended by IOM.

A total of 692 commenters (562 of these form letters) asked FNS to consider, at a minimum, increasing the cash-value fruit and vegetable voucher to \$10 for fully breastfeeding women to further enhance the attractiveness of this package and provide an additional incentive for women to breastfeed.

While FNS is in full agreement with the IOM and commenters regarding the benefits of fruits and vegetables for WIC participants, it is important that revisions to the WIC food packages be cost neutral to protect the program's ability to serve the greatest number of eligible women, infants, and children. For fruits and vegetables, the IOM's intent was to move WIC participants towards some amount of increased fruit and vegetable consumption and, at the same time, reinforce the role of the WIC food packages in nutrition education. The proposed \$8 and \$6 cash-value fruit and vegetable voucher fulfilled this intent while ensuring cost neutrality. Therefore, the provision will be retained in this interim rule as proposed for children and women in Food Packages III–VI in Table 2 of 7 CFR 246.10(e)(10) and Table 3 of 7 CFR 246.10(e)(11). However, FNS has considered the benefits of increasing the value of the vouchers for fully breastfeeding women and has determined that a \$2 increase can be accomplished while maintaining cost neutrality. This provision is therefore revised in the interim rule in Table 2 of 7 CFR 246.10(e)(10) and Table 3 of 7 CFR 246.10(e)(11) to reflect a cash-value voucher of \$10 for fully breastfeeding women in Food Packages III and VII.

Thirty commenters (23 of which were form letters) preferred that a set amount of fruits and vegetables be authorized per month, e.g., 3 pounds for a child, in lieu of a cash-value voucher, for administrative ease and to control costs. FNS disagrees with this approach. A voucher, rather than a more narrowly defined fruit and vegetable option, offers flexibility, ensures participant access, and minimizes costs of

compliance by administrative agencies and WIC-approved vendors. Allowing participants to choose a wide variety of fruits or vegetables is intended to increase consumption by accommodating individual and culturally-based preferences.

(1) *State agency responsibility to make available to participants at least two fruits and two vegetables from the category of fruits and vegetables in each authorized food package.* FNS proposed that State agencies be required to make available at least two fruits and two vegetables to participants in Food Packages III–VII. A total of 487 commenters (of which 418 were form letters) opposed the provision, believing that it undermines the IOM's recommendation to allow participants a wide variety of choices within the authorized fruit and vegetable options by authorizing State agencies to limit the number and variety of fruits and vegetables.

FNS' intention with this proposed provision was to ensure participant choice among the fruit and vegetables authorized by the State agency by expanding current WIC regulations that require State agencies to make available at least one food from each group in each food package. As described in the preamble to the proposed rule, it was FNS' expectation that more than two varieties each of fruits and vegetables would be authorized by State agencies. Therefore, the proposed provision is clarified in the interim rule at 7 CFR 246.10(b)(2)(ii)(B) to ensure its original intent to require State agencies to allow participants to use their cash value vouchers to purchase any WIC-eligible fruits and vegetables from among those authorized in Table 4 of 7 CFR 246.10(e)(12). This allows participants a wide variety of choices within the authorized fruit and vegetable options without restriction, in keeping with IOM recommendations. Further, the proposed provision at 7 CFR 246.10(b)(1)(i) is revised in this interim rule to disallow further restrictions on eligible fruits and vegetables.

(2) *Minimum vendor stocking requirement.* Similarly, at 7 CFR 246.12(g)(3)(i), FNS proposed that WIC authorized vendors carry a minimum of two varieties of fruits and vegetables to ensure participant choice at the retail level, while acknowledging that certain smaller vendors may not be able to stock as wide a variety of fruits and vegetables as larger vendors. A total of 472 commenters (418 form letters) disagreed with this provision, stating that setting a minimum vendor stocking requirement of two fruits and vegetables undermines the IOM recommendation

to allow participants a wide variety of choices. Of these commenters, 269 (221 form letters) stated that State agencies should be allowed to specify minimum stocking requirements.

FNS points out that the proposed provision authorizes State agencies to establish different minimums for different vendor peer groups, thus allowing State agencies the flexibility to work with vendors to provide the maximum number and variety of fruits and vegetables that are locally accessible, culturally appropriate and affordable. However, it is required that all authorized vendors must stock at least two varieties of fruits, two varieties of vegetables, and one whole grain cereal authorized by the State agency. Therefore, the provision at 7 CFR 246.12(g)(3)(i) is retained in the interim rule as proposed; however, a technical oversight in the proposed rule has been corrected by clarifying that authorized vendors must stock at least two different varieties of fruits and two different varieties of vegetables.

#### b. Inflation Adjustment

FNS proposed an option to increase the value of the cash-value fruit and vegetable vouchers by a whole dollar increment. A total of 124 commenters (75 of which were form letters) asked that FNS commit to a yearly inflation adjustment. FNS agrees with commenter that it is important to maintain the value of the vouchers over time. Cash-value vouchers will be set at \$6 for children and \$8 for pregnant and partially breastfeeding and \$10 for fully breastfeeding women in the year in which the food package revisions take effect. This interim rule adds a provision at 7 CFR 246.16(j) to adjust the maximum value of the vouchers in whole dollar increments using the Bureau of Labor Statistics' Consumer Price Index for Fresh Fruits and Vegetables.

#### c. Minimal Restrictions on Authorized Fresh Fruits and Vegetables

To improve the consumption of fresh fruits and vegetables and to appeal to participants of different cultural backgrounds, the proposed rule would have authorized a wide variety of choices within the authorized fruit and vegetable options. To ensure nutritional integrity and cost neutrality, some minimal restrictions were proposed, e.g., no herbs or spices, edible blossoms of flowers, fruit leathers and fruit roll-ups. The majority of commenters favored the provision to authorize a wide variety of fruits and vegetables; however, 9 commenters (1 of which was a form letter) stated the opinion that the

fruit and vegetable selections should be limited to sources of priority nutrients.

As stated in the Regulatory Impact Analysis that was published in the **Federal Register** as an appendix to the proposed rule, FNS considered alternatives to the proposed provision, including authorizing a more restrictive dark green and orange vegetable provision. This alternative was rejected because FNS believes that WIC food packages that reflect the IOM recommendations as closely as possible within the constraints of cost neutrality best reflect current scientific consensus on how to meet the supplemental dietary needs of WIC participants. The IOM chose not to emphasize the dark green and orange vegetable groups that tend to offer the highest concentrations of certain priority nutrients and instead recommended a fruit and vegetable option with few restrictions. Nutrition education offered by local WIC agencies will remain the primary method of encouraging participants to incorporate these high nutrient fruits and vegetables into their diets; under this interim rule participants remain largely free to choose the fruits and vegetables that they find most appealing.

Thirteen commenters (2 of which were form letters) believe that FNS should simplify the proposed minimal restrictions to ease interpretation and implementation for participants, vendors, and staff. A total of 128 commenters (125 of which were form letters) asked FNS to allow State agencies flexibility to promote produce selections that come in standard packages with Universal Product Codes to minimize burden. As stated above, the nutrition education provided to participants is intended not only to encourage participant choice in the selection of fruits and vegetables, but also to provide information on shopping tips to obtain the maximum value of the voucher.

FNS is aware that State agencies will need to provide training and technical assistance to participants and vendors in implementing the food package changes. State agencies generally update their food lists on a biennial basis which requires training for both participants and vendors. Recognizing the extensive changes that will be necessary as a result of this rule, FNS will assist State agencies on vendor training, participant education, and other implementation issues. FNS also encourages State agencies to work with their vendor associations as they develop their new State procedures, particularly in regard to the cash-value fruit/vegetable voucher.

#### d. Disallowance of White Potatoes

Under the proposed rule, white potatoes would have been excluded from authorization in the WIC food packages. A total of 324 commenters (of these 291 were form letters) opposed the restriction of white potatoes. Twenty-four commenters stated that white potatoes should be included in the WIC food packages because they are versatile, economical and contain key nutrients. Thirteen commenters (1 form letter) from WIC State and local agencies stated that the exclusion of white potatoes would be hard to administer.

The restriction of white potatoes, as recommended by the IOM, is based on the amounts suggested in the DGA<sup>(1)</sup> for consumption of starchy vegetables; food intake data indicating that consumption of starchy vegetables meets or exceeds these suggested amounts; and food intake data showing that white potatoes are the most widely used vegetable. Therefore, this provision is retained in the interim rule as proposed in Table 4 of 7 CFR 246.10(e)(12).

#### e. Implementation of Fruit and Vegetable Options

(1) Small dollar denomination of fruit and vegetable food instruments. In the preamble to the proposed rule, FNS encouraged State agencies to issue small denomination, i.e., \$2, cash-value fruit and vegetable food instruments. The small denominations were encouraged so the participant could obtain small amounts of fresh produce at various times during the month, lessening the chance of food spoilage and waste. A total of 200 commenters (of which 133 were form letters) disagreed with FNS' recommendation to provide the fruit and vegetable value in small denominations. The majority of those in opposition were WIC State and local agencies who stated that they should be allowed to determine, in partnership with vendors, the most cost effective method to provide the fruit and vegetable food instrument. FNS clarifies that although State agencies are encouraged to provide the cash-value food instrument in small denominations for the reasons cited above and in the proposed rule, State agencies will determine the dollar denomination that is most beneficial to participants and cost effective given the State agency's infrastructure and environment.

(2) Paying cash with the fruit/vegetable voucher. Nineteen commenters asked that participants be allowed to pay the difference when the purchase exceeds the value of the fruit/vegetable voucher. Under current rules at 7 CFR 246.12(c), State agencies must

ensure that participants receive their authorized supplemental foods free of charge. Such a restriction is necessary with the "traditional" WIC food instrument which reflects a specific quantity of foods that a participant must receive. In contrast, the fruit/vegetable cash-value voucher reflects a maximum dollar allotment for the participant. Because it may be difficult to accurately estimate the exact purchase price of the fruit and vegetable selections, particularly when fresh and canned or frozen items are combined in one purchase, FNS concurs with commenters that participants should be allowed to pay the difference when the purchase of allowable fruits and vegetables exceeds the value of the fruit/vegetable voucher. This option would promote increased consumption of fruits and vegetables because participants would be more likely to utilize the full cash value, rather than partially redeem the voucher for fear of exceeding its cash value. The rule prohibits giving cash or credit to the participant for any unused portion of the fruit/vegetable voucher.

(3) Benefit delivery. While most of the food package changes will be administered via existing State benefit delivery systems, the cash-value fruit/vegetable voucher will require changes to WIC benefit delivery systems to accommodate a more open-ended benefit determined by a cash value rather than a fixed quantity of a specific food item. State agencies and vendors must modify operations and procedures to issue, transact, and process the redemption of a cash value benefit. As described in the proposed rule, options for benefit delivery include Electronic Benefit Transfer (EBT) and farmers' markets.

(4) Farmers' markets. A total of 936 commenters (of which 170 were form letters) agreed with the provision to allow the fruit/vegetable cash-value voucher to be redeemed by farmers at farmers' markets. Eleven commenters disagreed with the provision. Many commenters suggested that FNS "Do no harm to the WIC Farmers' Market Nutrition Program (FMNP)," and that funding for the FMNP not be reduced or procedures established that would adversely affect its operation or effectiveness.

FNS would like to clarify that the regulatory requirements for the FMNP are unchanged by this interim rule. Many commenters incorrectly believed that the proposal would have allowed FMNP coupons to be redeemed at authorized WIC vendors. This is not true; the proposal would have allowed the WIC fruit/vegetable cash-value

voucher to be redeemed at farmers' markets.

Of the commenters supporting the provision to allow farmers at farmers' markets to accept the fruit/vegetable cash-value voucher, clarification was requested on several issues—would State agencies be required to authorize farmers at farmers' markets if they do not currently administer the FMNP; can farmers at farmers' markets be treated as seasonal vendors and only be allowed to accept the fruit/vegetable voucher; can the State agency enter into one contract with the farmer that includes requirements for both WIC and the FMNP; and, can farmers' markets be excluded from the WIC vendor monitoring and audit requirements?

In response to commenter questions, this interim rule will not require State agencies to authorize farmers to accept the WIC fruit/vegetable voucher. If a State agency chooses to authorize farmers at farmers' markets, it may modify its standard vendor agreement to address the unique circumstances of farmers' markets, as allowed by 7 CFR 246.12(h)(2). For example, the farmer's market agreement may only allow the farmer to accept the fruit/vegetable cash-value voucher. In addition, the State agency can choose to enter into one agreement with the farmer that includes the requirements for both the WIC and WIC Farmers' Market Nutrition Programs. Further, farmers would be excluded from the vendor cost containment requirements. The farmers may also be excluded from the WIC monitoring requirements provided that they are included in the sample of farmers upon which the FMNP monitoring requirement is drawn. A new 7 CFR 246.12(v) has been added that specifies the requirements regarding the authorization of farmers at farmers' markets. The rule also adds definitions for cash-value voucher and farmer (the same as that used in the FMNP), and modifies the food instrument requirements to identify the provisions that do not apply to the cash-value voucher. As a result of the addition of the definitions of farmer and cash-value voucher, we have made conforming amendments to the definitions of "compliance buy," "employee fraud and abuse," "participants," "participant violations," "proxy," and "nutrition services and administration" to include these new terms as appropriate.

(5) Electronic Benefit Transfer (EBT). While the majority of State WIC agencies deliver benefits via paper checks or vouchers, 5 States are testing the feasibility of EBT and an additional State has adopted EBT statewide.

Although it will take a number of years to implement WIC EBT fully in all States, the fruit and vegetable benefit may provide opportunities for alternative forms of benefit delivery and allow some States to move toward limited electronic benefit processing prior to the implementation of EBT for all WIC purchases. In an effort to explore the range of possibilities for using existing commercial infrastructure to administer the fruit and vegetable benefit including WIC EBT smartcard and online solutions, commercial debit cards, and other technologies, FNS commissioned a study by the State Information Technology Consortium (SITC). Although the report is not yet final, preliminary findings indicate that for redemption of the fruit/vegetable benefit, paper fruit and vegetable cash-value checks or vouchers appear to be the least costly and easiest to implement by State agencies and food vendors within a 12-month time period. The accountability for purchasing authorized fruits and vegetables remains the same as other food instruments—subject to training store clerks regarding eligible food items and State compliance monitoring.

Debit type cards (EBT or credit/debit) with a magnetic strip offer potentially cost-effective solutions that leverage the widely available card payment infrastructure in the United States. Magnetic strip cards in volume can be purchased for less than 25 cents each. There are, for instance, many large and smaller food vendors that already accept credit card payments or accept EBT cards using a four digit Personal Identification Number (PIN). These vendors include most authorized WIC vendors. Focus groups with participants were favorable to this type of alternative because of lessened stigma while shopping and the ability to purchase foods incrementally rather than forfeiting some items with a paper instrument. Technical standards would need to be modified to enable card use only within authorized WIC vendor locations and there may be a need to define standards to facilitate retailer and/or EBT contractor changes to existing store equipment and software. The accountability for purchasing eligible foods only is similar to paper food instruments.

WIC EBT solutions, on-line using magnetic-strip cards or off-line using smart cards, offer the greatest potential to ensure that only eligible fruits and vegetables are purchased with WIC cash-value vouchers, but it would be more costly for all stakeholders. These solutions would match each item scanned to a State list of authorized

UPC's and/or Price Look-Up codes or PLUs. These solutions require additional investment by State agencies in cards, equipment, and maintenance of a much larger number of product Universal Product Codes and Price Look-Up (PLUs) codes for fresh produce. The fresh produce industry has taken steps to institute greater standardization of PLUs; however, the seasonal and local produce suppliers do not always have means to use PLUs effectively. The draft SITC report suggests that pilot design and development will be necessary to identify cost effective solutions that can be widely adopted by State agencies and authorized vendors.

## 2. Peanut Butter and Legumes

The proposed rule would have added 18 ounces of peanut butter in Food Package V to improve the intake of several nutrients in the diets of pregnant and breastfeeding women. The proposed rule would also add legumes (dried beans/peas or peanut butter) in Food Package VI for postpartum women. Canned beans were proposed as an optional substitute for dry beans in Food Packages III–VII. Of the 3,091 comment letters that addressed these provisions, 3,085 commenters (21 form letters)—a large majority of whom were participants—were in favor of the proposed changes.

Six commenters asked that FNS eliminate peanut butter in the food packages for children because of concerns about peanut allergies. The IOM advised that children should avoid eating peanut butter from a spoon for safety reasons until age 3, but recommended that peanut butter continue to be offered in the WIC food packages for young children from 1 to 5 years of age. IOM has advised FNS that assessing for allergies and tailoring a young child's food package based on such assessment, as is current practice in WIC, is appropriate.

Therefore, the proposed peanut butter and legume provisions are retained in this interim rule as proposed.

## 3. Milk and Milk Alternatives

### a. Maximum Monthly Milk Allowances

The proposed rule would have decreased the maximum monthly allowances for milk in all food packages—for children and postpartum women, from 24 quarts to 16 quarts; for pregnant and partially breastfeeding women, from 28 to 22 quarts; and for fully breastfeeding women, from 28 quarts to 24 quarts of milk. Reducing the amount of milk provided through WIC is consistent with recommended limits

on saturated fat, total fat, and cholesterol consumption put forth in the DGA,<sup>(1)</sup> better aligns the amount of milk provided by WIC with the amounts recommended by the DGA<sup>(1)</sup> and is consistent with the supplemental nature of the WIC Program.

The majority of non-participant commenters were in favor of the proposed reductions in milk. A total of 2,088 non-participant commenters (1,874 of which were form letters) were supportive of the reductions, while 66 commenters were opposed. Commenters opposing the reductions cited the contribution of milk to intakes of priority nutrients for WIC participants, e.g., calcium, Vitamin A, and potassium. Seventeen commenters stated that the food package for postpartum women should be increased to the levels provided to pregnant and partially breastfeeding women. Six commenters urged FNS to maintain milk at current levels and increase funding for other proposed food package provisions.

Comment letters from program participants reflected disappointment with the reductions in milk. A total of 1,831 comment letters were received from program participants who opposed the reductions; 225 participants wrote in favor of the proposed reductions.

FNS believes that the IOM set forth a series of science-based recommendations that, taken together, balance the various supplemental nutritional needs of participants. According to the IOM, amounts of milk provided by the WIC food packages need not exceed amounts recommended by the DGA.<sup>(1)</sup> The proposed dairy levels for children (2 cups/day) and pregnant and breastfeeding women (3 cups/day) provide at least 100 percent of the servings recommended by the DGA.<sup>(1)</sup> The level for non-breastfeeding postpartum women is at least  $\frac{2}{3}$  of the amount set forth by the DGA.<sup>(1)</sup> The proposed maximum monthly allowance of milk allows a more balanced food package to provide the various high priority nutrients within cost constraints. Therefore, the proposed maximum allowances for milk are retained in this interim rule in Table 2 of 7 CFR 246.10(e)(10) and Table 3 of 7 CFR 246.10(e)(11).

### b. Low-Fat Milk

Under the proposed rule, only whole milk (not less than 3.25% milk fat) would have been authorized for children less than 2 years of age. For children two years of age and older and women, the proposed rule would have authorized only milk with no more than 2% milk fat to be consistent with current recommendations of the DGA

2005 to limit saturated fat and dietary cholesterol intake. A total of 3,058 commenters (2,663 of which were form letters) agreed with the provisions as written; 222 (10 of which were form letters) were opposed. One hundred seventy of those opposed were program participants. A total of 1,379 commenters (1,338 of which were form letters) stated that the fat content of milk for children and women should be reduced even further—to no more than 1% of milk fat.

Seventy-eight commenters (23 of which were form letters) asked FNS to allow the CPA the authority to prescribe the type of milk (whole milk or low fat milk) to participants, regardless of age or category, if medically necessary for such reasons as failure to thrive, underweight or overweight. FNS' position is that participants who have medical conditions that lead to a diagnosis of failure to thrive will likely be issued Food Package III. Therefore, to address commenters' concerns, this interim rule will authorize whole milk for children 1 through 4 years of age and women in Food Package III, with medical documentation. As proposed, only milk with no more than 2% milk fat is authorized for children 2 years of age and older and women in Food Packages IV–VII. For these participants, nutrition education directed towards appropriate foods and food amounts should be provided for underweight or overweight participants. Nutrition education and individual tailoring of the food package within authorized parameters remain the most effective tools for WIC staff to use to help participants make appropriate choices based on their specific needs.

#### c. Lactose Free Milk

Under the proposed rule, as long as a milk conforms to the FDA standard of identity for milk as defined by 21 CFR Part 131 and meets WIC Federal requirements, it would be an authorized milk in Food Packages IV, V, VI, and VII. Although not specified in the proposed rule, authorized milks that conform to the FDA standard of identity include, but are not limited to, calcium-fortified, lactose-reduced and lactose-free, acidified, and ultra-high temperature (UHT) milks. FNS clarifies that these products are authorized, and that lactose-free or lactose-reduced dairy products should be offered before non-dairy milk alternatives to those participants with lactose intolerance who cannot drink milk. FNS also clarifies that medical documentation is not required for participants to receive lactose-reduced and lactose-free milk.

#### d. Authorized Substitutions for Milk (Cheese, Tofu, Soy-Based Beverage)

(1) Cheese. The proposed rule would have reduced the amount of cheese that may be substituted for milk to one pound per month for children and pregnant, postpartum and partially breastfeeding women, and two pounds for fully breastfeeding women. Reducing the amount of cheese that may be substituted for milk will reduce saturated fat and total fat intake by children age two and older and women consistent with the DGA<sup>(1)</sup> recommendations. Amounts of cheese that exceed the maximum substitution amounts may be authorized with medical documentation in cases of lactose intolerance or other qualifying conditions.

The majority of non-participant commenters were in favor of the proposed reduced cheese substitution amounts. A total of 754 non-participant commenters (of which 589 were form letters) were supportive of the reduced substitution amounts, while 53 commenters were opposed. A total of 917 comment letters were received from program participants who opposed the proposed cheese allowances; 119 participants wrote to express support for the proposed amounts. Commenters opposing the cheese substitution amounts stated that cheese is culturally acceptable to most populations, and provides nutrients in a convenient and familiar way. Fourteen commenters asked FNS to maintain cheese at its current substitution levels and emphasize or require reduced-fat cheese.

Reducing the maximum amount of cheese lowers the amount of saturated fat, total fat, and cholesterol in the WIC food packages. Within the context of the proposed revisions to the WIC food packages as a whole, the reductions in the current levels of cheese ensure that FNS is able to provide a more balanced nutrient intake for WIC participants while maintaining cost neutrality. Therefore, the proposed substitution levels for cheese are retained in this interim rule.

(2) Soy-based beverage and tofu. To provide more flexibility for WIC State agencies and more variety and choice for WIC participants, the proposed rule would have authorized soy-based beverage to be substituted for milk for women in Food Packages V, VI and VII at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum allowance of milk. The proposal also would have allowed calcium-set tofu to be substituted at the rate of 1 pound of tofu per 1 quart of

milk. A maximum of 4 quarts of milk could be substituted in this manner in Food Packages V and VI, and a maximum of 6 quarts of milk may be substituted in Food Package VII. Under the proposed rule, soy-based beverage and tofu would not be allowed as substitutes for milk for children in Food Package IV without medical documentation. The qualifying conditions may include, but are not limited to, milk allergy, severe lactose maldigestion, and vegan diets. Amounts of tofu that exceed the maximum substitution amounts may be authorized for women, with medical documentation, in cases of lactose intolerance or other qualifying conditions.

A total of 8,932 commenters (4,615 form letters) were supportive of adding soy-based beverage and tofu to the WIC food packages as milk substitutes; 368 commenters (148 form letters) were not supportive. Comments received on medical documentation requirements for soy-based beverage for children and FNS' rationale for retaining the provision in this interim rule as initially proposed are discussed in section IV.B.4. of this preamble.

As stated in the preamble to the proposed rule, Section 102 of the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265) requires that nondairy beverages offered as an alternative to fluid milk in the National School Lunch Program and School Breakfast Program must be nutritionally equivalent to fluid milk and meet nutritional standards set by the Secretary of Agriculture. FNS, therefore, proposed that authorized soy-based beverage provide, at a minimum, the following nutrients:

Calcium .....	276 milligrams (mg) per cup.
Protein .....	8 grams per cup.
Vitamin A ...	500 International Units (IU) per cup.
Vitamin D ...	100 IU per cup.
Magnesium ..	24 mg per cup.
Phosphorus ..	222 mg per cup.
Potassium ....	349 mg per cup.
Riboflavin ....	0.44 mg per cup.
Vitamin B12 ..	1.1 mcg per cup.

A total of 340 commenters (255 form letters) were opposed to the proposed minimum nutrient standard, stating that fortification at these levels is not necessary, and that soy-based beverage meeting the proposed minimum nutrition standard are not available in the marketplace. FNS believes that it is imperative for WIC and the school nutrition programs to use the same standards for defining allowable soy-based beverage as alternatives to fluid milk. Therefore, the proposed minimum nutrient standard for soy-based beverage

is retained in this interim rule. FNS is aware of at least one soy-based beverage in the marketplace that meets these requirements and anticipates that the marketplace will respond with additional products. To the extent that the marketplace doesn't respond with additional products, other options, such as tofu, are available for participants.

(3) Yogurt. The IOM recommended adding yogurt to the WIC food packages as a milk substitute for children and women. However, in order to maintain cost neutrality, the proposed rule did not include yogurt. Of the 758 commenters that addressed yogurt, 749 (617 form letters) disagreed with FNS' decision not to include yogurt. Commenters stated that yogurt provides priority nutrients, and is convenient, popular, and culturally acceptable to WIC participants.

FNS agrees that yogurt would be a desirable dairy alternative to milk for WIC participants; however, the cost is simply prohibitive (\$413.9 million over 5 years). In addition, FNS has determined that WIC participants will be able to get the calcium provided by yogurt through other foods authorized in these revised food packages. Lactose-free and lactose-reduced dairy products, for example, are readily available in both urban and rural areas for those WIC participants with lactose intolerance. Calcium-set tofu and soy-based beverages are available to accommodate cultural preferences. Also, as noted earlier, a new 7 CFR 246.10(i) has been added to this interim rule to allow State agencies the flexibility to meet unanticipated cultural needs of participants.

It is important that revisions to the WIC food packages be cost neutral to protect the program's ability to serve the greatest number of eligible women, infants, and children. Therefore, FNS is unable to authorize yogurt in the WIC food packages in this interim final rule.

However, FNS solicits comments from State agencies as they implement the provisions of this interim rule about the extent to which WIC participants would benefit from the addition of yogurt, and whether that addition would be achieved in a cost-effective way. In particular, we are interested in the impact of adding yogurt for women in Food Packages V–VII.

FNS also solicits comments as to the feasibility of rebate agreements between yogurt manufacturers and individual States, so that yogurt could be provided to specific participant groups in the WIC program while maintaining cost-neutrality. State agencies are currently encouraged to explore the feasibility of cost containment systems, especially

rebates, and to implement such a system where feasible for other WIC foods. In an effort to use their food grants more efficiently, 13 State agencies, which include 3 multi-State contracts, have rebate contracts for juice (frozen and shelf), infant juice and/or infant cereal. If FNS were to consider including yogurt as a WIC-eligible food through future rulemaking, FNS would be interested in the following types of information:

- Which participant groups would most benefit from having yogurt included as part of their food package?
- Would States be able to secure rebates sufficient enough to add yogurt for all or certain participant groups while maintaining cost-neutrality?

Finally, and as noted earlier, Section 203(c) of Public Law 108–265 amended Section 17(c)(2) of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1786), by requiring the Secretary to conduct, as often as necessary, a scientific review of supplemental foods available under the program and to amend the foods, as needed, to reflect nutrition science, public health concerns, and cultural eating patterns. As such, future reviews of the WIC food packages by FNS will be used to determine the need for yogurt.

#### 4. Eggs

Under the proposed rule, the maximum monthly allowance for fresh shell eggs would have been reduced from the current 2 or 2½ to 1 dozen fresh shell eggs for children and women in Food Packages IV, V, and VI. For fully breastfeeding women in Food Package VII, the maximum monthly allowance was proposed at 2 dozen eggs.

A total of 1,469 commenters (266 of which were form letters) addressed the proposed egg reduction provision. Of the 492 non-participant commenters, 406 were in favor of the proposed reductions. Those opposing stated that eggs provide important nutrients at relatively low cost. Of the 1,009 program participants who commented, 923 were opposed to the reduction in eggs.

The proposed maximum monthly allowance of eggs is consistent with recommendations of the IOM<sup>(3)</sup> and the DGA<sup>(1)</sup> to reduce cholesterol. In addition, the IOM determined that protein is no longer a priority nutrient for the WIC population. Within the context of the proposed revisions to the WIC food packages as a whole, the reductions in the current levels of eggs ensures that FNS is able to provide a more balanced nutrient intake for WIC participants while maintaining cost

neutrality. Therefore, the proposed maximum monthly allowances for eggs are retained in this interim rule.

#### 5. Juice for Children and Adults

The proposed rule would have reduced the maximum allowances of juice for women and children in Food Packages IV–VII. According to the IOM, deleting or reducing the quantity of juice in the WIC food packages helps allow for the inclusion of whole fruits and vegetables while containing food costs, and is consistent with recommendations of the DGA<sup>(1)</sup> and the American Academy of Pediatrics (AAP).

For children, the proposed maximum monthly allowance of juice would have been reduced from 288 fluid ounces to 128 fluid ounces. For pregnant and partially breastfeeding women, the proposed maximum monthly allowance of juice was reduced from 288 fluid ounces to 144 fluid ounces; for postpartum women from 192 fluid ounces to 96 fluid ounces; and for fully breastfeeding women, from 336 fluid ounces to 144 fluid ounces.

A total of 2,256 commenters (846 form letters) addressed the proposed reductions in juice. Of these, 1,610 commenters (846 form letters) were supportive of the juice reductions. Eighty two of those commenters recommended that juice be eliminated entirely from the WIC food packages and replaced with fruits and vegetables. Of the 646 commenters that opposed the reduction in juice, 633 were program participants. Non-participant commenters who opposed the reductions cited the nutritional benefits of juice and stated that the proposed reductions were too drastic.

Reducing the quantity of juice in the WIC food packages helps allow for the inclusion of whole fruits and vegetables while containing food costs. The reduction in the amount of juice provided for children to about 4 ounces per day is consistent with the AAP recommendation for that age group. The AAP also notes that juice does not provide any additional nutritional benefit beyond that of whole fruit. The reduced amount of juice for women is consistent with the recommendation of the DGA<sup>(1)</sup> that whole fruits be used for a majority of the total daily amount of fruit.

Additionally, 34 commenters (14 form letters) expressed concern that juice package sizes need to be considered to ensure the full nutritional benefit of juice is received by participants. Over the years, there have been many changes in package sizes for all WIC-eligible food categories, and FNS has struggled with how to manage these changes

within WIC Program regulations that allow for a monthly maximum allowance of food that cannot be exceeded (except for the rounding option for infant formula and infant foods). It is not practical for FNS to be able to respond to all the variations in package sizing. Basing the maximum monthly allowance on package sizes would not guarantee that those package sizes will not change over time.

Therefore, FNS is retaining the proposed maximum juice allowances for children and women in this interim rule.

#### 6. Whole Grains and Breakfast Cereals

To support the DGA<sup>(1)</sup> recommendations to consume at least 3 servings per day of whole grains to reduce the risk of coronary heart disease and type 2 diabetes, to help with body weight maintenance, and to increase intake of dietary fiber, the proposed rule would have established a whole grain requirement for breakfast cereal in Food Packages III–VII and added whole wheat bread or other whole grain options for children and pregnant and breastfeeding women in Food Packages III, IV, V and VII.

The addition of whole grains to the WIC food packages was popular across all commenter categories. A total of 17,165 comment letters (7,983 form letters) agreed with the whole grain provisions and 113 comment letters (5 form letters) disagreed with the provisions. While strongly supporting FNS' emphasis on whole grains, 876 commenters (764 form letters) expressed concern that the proposed nutritional requirement for whole grain breakfast cereal—using labeling requirements for making a health claim as a “whole grain food with moderate fat content” as defined by the Food and Drug Administration (FDA) in its December 9, 2003, *Health Claim Notification for Whole Grain Foods with Moderate Fat Content* at <http://www.cfsan.fda.gov/~dms/flgrain2.html>—is too restrictive. Commenters stated that the proposed provision would eliminate corn and rice-based cereals that are necessary for participants with wheat allergies or strong preferences for corn and rice-based cereals, as well as severely limit the total variety and choice of WIC-eligible cereals. In addition, 77 commenters (21 form letters) also stated that whole grain foods are less palatable to young children, may not be preferred by certain cultures, and therefore may not be chosen by participants, potentially negating FNS' goal to help participants increase whole grain consumption. Additionally, commenters pointed to (1) potential administrative

difficulties in the identification of whole wheat bread and whole grain cereals by State agency staff when determining which products are WIC-eligible; and (2) confusion by vendors and participants at the point of purchase due to lack of consistency in food labels that do not clearly identify foods as meeting the FDA standard of identity for whole wheat bread or the labeling requirement for making the health claim as “a whole grain with moderate fat content.”

Commenters suggested several alternatives for determining a nutritional standard for whole grain cereals including the elimination of any requirement for whole grain, adoption of an 8-gram per serving standard, and exemption of certain cereals from the whole grain requirement. FNS finds merit in commenters' concerns that the proposed whole grain nutritional requirement for breakfast cereal would eliminate corn and rice-based cereals, as well as severely limit the variety and choice of WIC-eligible breakfast cereals; and that whole grain breakfast cereals may be less palatable to participants, especially children, and less preferred by certain cultures. WIC-eligible breakfast cereals are the major source of iron in the WIC food packages for children and women and research shows that participation in WIC has a positive impact on the iron status of its participants. The IOM pointed out that despite declines in the prevalence of iron-deficiency, this deficiency remains a nutrition-related health risk for children and women of reproductive age.

Acceptability of eligible foods by participants is an important factor in the decision to authorize types and brands of foods for State food lists and therefore, in this interim rule, the provision at 7 CFR 246.10(e)(12) is revised to require that at least one half of the total number of breakfast cereals on the State's authorized food list meet the whole grain requirement using the FDA labeling requirements for making a health claim as a “whole grain food with moderate fat content.” Further, to assist in the identification of whole grain cereals for State agencies, vendors and participants, the interim rule adds the requirement that the primary ingredient by weight must be a whole grain. The remaining authorized breakfast cereals are required to meet only the iron and sugar requirements. State agencies may opt that all or more than half of the cereals on the State's authorized food list meet the whole grain requirement. However, in establishing minimum requirements for the variety and quantity of foods that a

vendor must stock to be authorized, State agencies must require that at least one whole grain cereal be available.

FNS believes that the revisions to the proposed whole grain provisions for cereals in this interim rule will continue to support the goals of the DGA<sup>(1)</sup> for increasing whole grain consumption. State agencies are reminded that 7 CFR 246.10(b)(1)(i) allows the State to establish criteria in addition to the minimum Federal requirements for WIC supplemental foods, e.g., no artificial sweeteners.

FNS also finds merit in commenters' concerns about administrative difficulties in the identification of whole wheat bread and whole grain products. It is important that WIC nutritional requirements be simple and accurate for State agencies to use when determining foods to authorize for State food lists and that authorized whole wheat and whole grain products make significant contributions of whole wheat or whole grain to the WIC food packages. Therefore, the proposed requirements for whole wheat bread—any bread that conforms to the FDA standard of identity for whole wheat bread as defined by 21 CFR 136.180 will be retained in this interim rule. However, to assist in the identification of whole wheat bread products for State agencies, vendors and participants, the interim rule adds the requirement that the primary ingredient by weight must be whole wheat. FNS also clarifies in this interim rule that whole wheat buns and rolls that meet the FDA standard of identity for whole wheat bread, and have whole wheat as their primary ingredient, are WIC-eligible.

The proposed requirements for whole grain breads—any bread product that meets labeling requirements for making a health claim as a “whole grain food with moderate fat content” as defined by FDA in its December 9, 2003, *Health Claim Notification for Whole Grain Foods with Moderate Fat Content* at <http://www.cfsan.fda.gov/~dms/flgrain2.html>—will also be retained in this interim rule. However, the interim rule adds the requirement that the primary ingredient by weight must be whole grain.

The revisions to the whole wheat and whole grain bread requirements will allow products that are 100% whole grain, or are primarily whole wheat or multi-grain, to be WIC-eligible as well as provide an easy way for participants and vendors to identify whole wheat and whole grain bread products by using the food label. The primary ingredient is easily identified on the food label since ingredients are listed in

descending order of predominance by weight.

To ensure that the whole grain options are consistent with the intent of the IOM recommendations, this interim rule also clarifies that the brown rice, bulgur (cracked wheat), oatmeal, and barley (whole-grain) are the whole unprocessed grain, and that soft corn and whole wheat tortillas must have the whole grain as the primary ingredient by weight according to the food label. A technical oversight in the proposed food package rule has been corrected in this interim rule by removing the requirement that authorized soft corn or whole wheat tortillas contain no added fats or oils.

In the interim rule, State agencies will continue to be responsible for determining which types and brands of whole wheat bread and whole grain products and breakfast cereals to authorize on State food lists using the minimum requirements and specifications in Table 4 at 7 CFR 246.10(e)(12). FNS will provide information on label reading and marketplace availability to State agencies to assist in the identification of whole wheat and whole grain foods and on nutrition education that encourages increased consumption of whole grains. The assistance of industry is requested in notifying FNS of whole wheat and whole grain bread products, whole grain cereals, and whole grain options that may meet the newly established nutritional requirements. Information may be mailed or sent electronically to FNS at the addresses provided at the beginning of this preamble.

#### Maximum Monthly Allowance

The proposed rule would have established a maximum monthly allowance of 2 pounds of whole wheat bread or other whole grain options for children in Food Packages III and IV; and 1 pound of whole wheat bread or other whole grain options for women in Food Packages III, V and VII. The rule proposed a maximum monthly allowance of 36 ounces of breakfast cereal for children and women in Food Packages III–VII. While supporting the addition of whole wheat bread and other whole grain options to the WIC food packages, 95 comment letters (38 form letters) expressed concern that the package sizes of bread are not commonly available in either one- or two-pound loaves and that the participants would have difficulty purchasing the maximum monthly allowance for whole wheat bread. FNS has long recognized that package sizes of WIC-eligible foods vary among manufacturers and those manufacturers

may change package sizes at any time. Over the years, there have been many changes in package sizes for all WIC-eligible food categories, and FNS has struggled with how to manage these changes within WIC Program regulations that allow for a monthly maximum allowance of food that cannot be exceeded (except for the rounding option for infant formula and infant foods). It is not practical for FNS to be able to respond to all the variations in package sizing. Basing the maximum monthly allowance on package sizes would not guarantee that those package sizes will not change over time and, therefore, the maximum monthly allowance for whole wheat bread and other whole grain options and breakfast cereal remains as proposed.

#### 7. Canned Fish

The proposed rule would have authorized 30 ounces of a variety of canned fish in Food Package VII for fully breastfeeding women. The following varieties of canned fish were proposed—light tuna, salmon, and sardines. In the proposed rule, FNS solicited input on additional canned fish to offer in Food Package VII.

A total of 3,546 commenters (26 form letters) expressed support for the proposed canned fish provisions; 555 commenters opposed. Of the opposing comment letters received, 506 were variations of one form letter submitted as part of a letter writing campaign initiated by an advocacy organization concerned with the public's exposure to methylmercury. These and other opposing commenters believe that canned light tuna should be eliminated from the WIC food packages until more study is conducted on its mercury content. Two commenters (1 form letter) opposed the omission of albacore tuna from the list of authorized varieties of canned fish.

The IOM recommended that a variety of canned fish that do not pose a mercury hazard be offered in Food Package VII. As identified by federal advisories of the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA),<sup>(4)</sup> canned light tuna, salmon, and sardines are among those fish that are lower in mercury. For ease of administration by State agencies, to accommodate participant preferences, and to minimize intake of mercury, this interim rule retains the proposed varieties of canned fish in Food Package VII for fully breastfeeding women. In response to commenters' requests, canned mackerel—N. Atlantic and Chub (Pacific)—also identified as lower in mercury, has been added in this interim

rule as an authorized canned fish in Food Package VII.

#### 8. Proposed Food Packages I and II for Infants

The rule proposed the following changes in Food Packages I and II for infants:

- Revise age specifications for assignment to infant food packages;
- Delay introduction of complementary food to six months of age;
- Establish 3 feeding options within each infant food package—fully breastfed, partially breastfed, or fully formula fed;
- Revise maximum monthly infant formula allowances;
- Add infant food fruits and vegetables in Food Package II;
- Eliminate juice from both infant food packages;
- Disallow provision of infant formula for breastfed infants during the first month after birth;
- Disallow low iron infant formula;
- Allow commercial infant food meat for fully breastfed infants in Food Package II; and
- Reassign infants with a qualifying condition to proposed Food Package III—Participants With Qualifying Conditions—and authorize the issuance of exempt infant formulas only in Food Package III.

The proposed revisions to Food Packages I and II for infants were designed to better promote and support the establishment of successful long-term breastfeeding among women who choose that feeding method, address differences in nutritional needs of breastfed and formula fed infants, address developmental needs of infants, bring the infant food packages in line with current infant feeding practice guidelines from the AAP, and serve all participants with certain medical conditions under one food package to facilitate efficient management of medically fragile participants.

##### a. Food Package I for Infants Under Six Months

Under current WIC regulations, a maximum formula allowance is specified for all infants assigned to Food Package I, regardless of infant feeding practice; WIC staff may tailor the amount of formula to reflect the individual needs of the infants. The proposed rule would have extended the age range of infants covered by Food Package I by two months, thereby delaying introduction of complementary foods previously offered in this food package (juice and cereal) until six months of age. In proposed Food

Package I, fully formula fed infants four through five months of age would receive a slightly increased amount of infant formula to compensate in part for the decrease in nutrients and calories that results from the omission of juice and infant cereal. Also, to more actively support successful breastfeeding, the proposed rule would set a maximum formula amount for partially breastfed infants in Food Package I that is roughly half the maximum provided to fully formula fed infants.

b. Food Package II for Infants Six Through Eleven Months

Under the proposed rule, the amounts of formula and the amounts and type of infant foods would vary by infant feeding option. Infant food fruits and vegetables would be added to Food Package II, infant juice eliminated, and maximum formula allowances reduced for both partially breastfed and fully formula fed infants.

The majority of commenters were supportive of the revisions to the infant food packages as proposed. The discussion that follows pertains to those provisions that received significant or substantial opposing comments, suggested alternatives, or requests for clarifications. Provisions related to the proposed food packages for infants that are not addressed in this preamble did not receive significant or substantial public comments and are therefore retained in this interim rule as proposed.

c. Breastfeeding Provisions

The proposed food packages for infants and women were designed to strengthen WIC's breastfeeding promotion efforts and provide additional incentives to assist mothers in making the decision to initiate and continue to breastfeed. The IOM's three-pronged approach to better promote and support breastfeeding through the WIC food packages was proposed. The approach focuses on the market value of the package for the mother/infant pair for the first year after birth, addresses differences in supplementary nutrition needs of breastfed and formula fed infants, and considers how to minimize early supplementation with infant formula through continued or increased efforts to promote and support the breastfeeding dyad.

Because early supplementation may contribute to the short duration of breastfeeding, only two infant feeding options were recommended initially after delivery—either full breastfeeding or full infant formula-feeding. The IOM recommended this approach because physiology provides a strong basis for

avoiding supplemental formula. The amount of milk a breastfeeding woman produces depends directly on how often and how long she nurses. Providing supplemental formula to a new breastfeeding mother may interfere with her milk production and success at continued breastfeeding.

The differences in the proposed packages for the mother-infant pairs were based on differences in nutritional needs. For example, fully breastfeeding women require additional calories per day during the first six months postpartum as well as higher levels of most vitamins and minerals. Thus, the package for fully breastfeeding women provides the most food energy and nutrients, and the package for fully formula-feeding women provides the least. Similarly, starting at age six months, the proposed package for fully breastfed infants would have included commercial infant food meats to add a source of iron and zinc.

These proposed food package changes, as recommended by the IOM, were intended to strengthen WIC's efforts to promote and support breastfeeding as the optimal infant feeding choice for WIC mothers.

In general, commenters expressed support for the proposed breastfeeding provisions. Of the 1,057 commenters (774 form letters) that made statements regarding the breastfeeding provisions, 1,017 (753 form letters) were supportive of the provisions, stating that they add value and incentive for mothers to breastfeed and support WIC's efforts to promote breastfeeding as the optimal infant feeding choice.

The largest number of opposing comments on the breastfeeding provisions focused on those related to the establishment of infant feeding options the first month after birth, as described below.

Establishment of Infant Feeding Options—First Month After Birth

To support the successful establishment of breastfeeding, the proposed rule would have established two infant feeding options for the first month after birth, either full breastfeeding or full formula-feeding. Under the proposed rule, infant formula would not be provided for fully or partially breastfeeding infants during the first month of life after birth. The IOM recommended this approach because providing supplemental formula to a new breastfeeding mother may interfere with her milk production and success at continued breastfeeding.

A total of 862 commenters (540 form letters) addressed this provision. Of those, 195 commenters (102 form

letters) agreed with the provision as written. A total of 667 commenters (438 form letters) were opposed. While agreeing with its premise—that early supplementation inhibits the establishment of successful breastfeeding in the critical early weeks of an infants life—opposing commenters expressed concern that some WIC State and local agencies may not be prepared to provide support services (peer counselors, breast pumps, consultation with lactation experts) to the extent necessary to make this provision work for every mother. As a result, a mother who feels less than confident about her ability to breastfeed may choose to either (1) categorize her infant as fully formula fed, thus receiving more formula than is necessary for the breastfeeding infant and further compromising the establishment of successful breastfeeding, or (2) not breastfeed at all. Other commenters pointed to legitimate medical reasons that a breastfeeding mother/infant dyad may have which result in the need for supplemental formula in the early postpartum period, such as infants with metabolic disorders. Commenters urged FNS to consider allowing State agencies the option to provide a small amount of infant formula during the first month in limited situations.

FNS finds the arguments put forth by commenters compelling. Therefore, the provisions at 7 CFR 246.10(e)(1)(ii)(A) and in Table 1 of 7 CFR 246.10(e)(9) are revised as follows. Three infant feeding options will be authorized in the first month after birth—either (1) fully formula feeding; (2) fully breastfeeding; or (3) partially breastfeeding. As proposed, no supplemental formula will be provided for fully breastfeeding infants. The third infant feeding option—partially breastfeeding—will be offered to the infant who is breastfed but also receives not more than 104 reconstituted fluid ounces of formula from the WIC program. Food Package V will be provided to mothers of these partially breastfeeding infants.

Partially breastfed infants ages 0 to 1 month may receive the equivalent of not more than 104 fluid ounces of reconstituted infant formula. This will allow State agencies to issue one can of powder infant formula commonly used in WIC, and is responsive to commenters' requests to make a small amount of infant formula available for partially breastfeeding infants in the first month. Powder infant formula is recommended until the partially breastfed infant reaches four months of age due to its longer shelf life and to minimize waste. The CPA is expected to individually tailor the amount based on

the carefully assessed needs of the individual breastfeeding infant. This means that mothers of partially breastfed infants should not “automatically” be provided a can of formula in the first month of life. If, after a careful assessment, the CPA determines that some formula is appropriate for the infant in the first month, the mother should be advised on the appropriate amount of that one can of formula to feed the infant. The goal is to provide as minimal amount of supplemental formula as is needed, while offering counseling and support, in order to help the mother establish a successful milk supply.

FNS is aware that adequate breastfeeding support for mothers is important for the success of both the partially and fully breastfeeding options in the first month after birth. FNS is committed to strengthening WIC’s efforts to promote and support breastfeeding, through the provision of peer counseling funding to State agencies and other means. Judicious use of NSA funds by State agencies directed toward research-based support known to be effective—i.e., peer counseling, consultation with lactation experts—will further enhance the ability of State and local agencies to assist mothers in establishing and continuing successful breastfeeding in the critical weeks after birth and beyond. FNS’ view is that the provision of a small amount of formula for certain infants in the first month of life is a temporary option that State agencies may invoke to assist breastfeeding mothers who may otherwise choose to fully formula feed. FNS expects that the proportion of participants offered the partially breastfeeding option in the first month will decrease over time as State agencies strengthen their breastfeeding support infrastructure.

#### d. Maximum Monthly Allowances of Infant Formula

Under the proposed rule, the maximum monthly allowance of infant formula would be revised from current levels to reflect the proposed feeding options (fully formula feeding, partially breastfeeding, and fully breastfeeding), physical form of infant formula provided (liquid concentrate, powder,

or ready-to-feed), and the age of the infant. A total of 574 commenters (143 form letters) addressed the maximum monthly allowances of infant formula. Two hundred forty four commenters were opposed to changes in the maximum monthly allowances; of these, 148 were program participants. The majority of comments centered on two specific issues: (1) The variation in amounts of formula provided during the different age specifications; and (2) a decrease in amount of formula available, especially for the 6–12 month old infant. Non-participant commenters in opposition to revising formula allowances stated that reducing formula will result in supplementation with whole milk or inappropriate liquids. Some non-participant commenters stated that formula amounts should stay the same as in current regulations and the CPA should tailor the packages as appropriate for the needs of individual infants. Participant commenters expressed concern that formula is expensive and if WIC reduces the amount provided it will increase their out-of-pocket expenses to purchase the additional formula.

The proposed maximum formula allowances for infants were determined based on a scientific review of the calorie and nutrient needs of infants at different ages. The proposed amounts of infant formula for partially breastfeeding infants in Food Packages I and II are designed to enhance the promotion and support of breastfeeding. The provision is part of the IOM’s comprehensive approach resulting from thorough consideration of scientific research and public comments on how to promote and support breastfeeding. The maximum amount for partially breastfed infants provides approximately half the amount provided to fully formula fed infants—to provide about half of the infant’s nutritional needs to encourage the mother to breastfeed enough to provide at least half of the infant’s nutritional needs. This approach is preferable to current tailoring because it establishes a standard procedure that promotes breastfeeding as the optimal way to feed infants across WIC programs. The addition of infant foods, along with the proposed amount of formula for infants

in Food Package II, provides close to recommended amounts of nutrients, introduces more variety into the infant’s diet and encourages healthy dietary patterns. FNS believes that the nutrition education and anticipatory guidance on infant feeding provided by WIC local agencies will enable participants and caregivers to make informed choices about appropriate liquids for infants.

Other commenters asked for clarification on the maximum monthly allowances of infant formula per physical form and suggested that the maximum monthly allowance for infant formula be the same for all physical forms. The IOM recommended a maximum monthly allowance of liquid concentrate but stated that powder or ready-to-feed formula (RTF) may be substituted for liquid concentrate at rates that provide the approximate number of fluid ounces as the liquid concentrate. The IOM recommended rounding to whole cans to approximate the target amount. FNS recognizes that powder infant formula is an increasingly popular physical form with WIC agencies and participants. In determining the amount of powder formula to authorize, FNS considered the cans sizes commonly used in WIC, their reconstituted yields, and the range of dry powder ounces recommended by the IOM. The maximum monthly allowance of powder infant formula provides at least the number of fluid ounces as the same reconstituted liquid concentrate for the 3 major milk-based infant formulas manufactured that State agencies issue, thereby ensuring a minimum level of nutrition for infants regardless of physical form.

As described in section C.8.c. of this preamble, partially breastfed infants ages 0 to 1 month may receive the equivalent of not more than 104 fluid ounces of reconstituted infant formula. This will allow State agencies to issue one can of powder infant formula commonly used in WIC, and is responsive to commenters’ requests to make a small amount of infant formula available for partially breastfeeding infants in the first month. The maximum allowances of infant formula for infants 1 month and older in Food Package I and II are retained in this interim rule as proposed.

## EXHIBIT A.—MAXIMUM MONTHLY ALLOWANCES FOR FOOD PACKAGE I FOR INFANTS AGES BIRTH TO 6 MONTHS, BY FEEDING OPTION

WIC food	Fully breastfed infants	Partially breastfed infants			Fully formula fed infants	
	0 through 5 months	Birth to one month	1 through 3 months	4 through 5 months	0 through 3 months	4 through 5 months
Infant Formula .....	NA .....	104 fl oz reconstituted powder.	364 fl oz reconstituted liquid concentrate*.	442 fl oz reconstituted liquid concentrate.	806 fl oz reconstituted liquid concentrate.	884 fl oz reconstituted liquid concentrate.

NA= not applicable.

\* The maximum monthly allowance is specified in the liquid concentrate form; however, powder and RTF are allowable substitutes and the powder form is recommended for partially breastfed infants, ages 0 through 3 months of age.

Two technical oversights in the proposed food package rule have been corrected in this interim rule by adjusting the maximum monthly allowance of RTF formula in Food Package I.A. from 800 fluid ounces to 832 fluid ounces, and in Food Package II.A. from 364 fluid ounces to 384 fluid ounces.

#### e. Elimination of Juice for Infants and Addition of Infant Foods in Food Package II

A total of 629 commenters (69 form letters) addressed the elimination of juice from the infant food packages. The majority of commenters were in agreement with the provision to eliminate juice from the infant food packages, stating that juice is not nutritionally valuable or necessary for infants. A total of 242 commenters were opposed; 228 of those opposed were program participants. Twelve non-participant commenters stated that the elimination of juice may lead to substitution of lower-cost sweetened beverages. The IOM specifically recommended that infant food fruits and vegetables replace juice for infants 6 through 12 months of age. An important part of the nutrition education provided by WIC staff to parents and caregivers of infant participants' is information on the timing and types of complementary foods appropriate for infants.

The addition of jarred infant foods (fruits, vegetables, meat) to Food Package II was well received by commenters. Of the 5,953 commenters that addressed infant foods, 5,887 commenters (of these, 131 were form letters) expressed support for the addition of infant foods. Those that opposed asked that fresh, canned, or frozen fruits and vegetables be allowed in Food Package II instead of, or as an option, to jarred infant foods. Some of these commenters believe that jarred infant foods are environmentally wasteful and costly. Others stated that the provision of jarred foods undermines nutrition education

messages about home prepared foods for infants. Some commenters stated that providing a cash value voucher for fruits and vegetables for infants 9–12 months of age may be more developmentally appropriate for this age group.

The IOM specifically recommended “commercial baby food fruits and vegetables and fresh bananas” for (1) early introduction to new flavors and textures over time; (2) nutrient content; (3) availability in developmentally appropriate textures; and (4) food safety. Further, the provision of commercial baby food fruits and vegetables helps ensure that these items are consumed by infants and not other participants, an important consideration since the amount of infant formula in Food Package II is reduced from current levels and replaced with complementary infant foods. Therefore, the proposed provisions about jarred infant foods in Food Package II are retained in this interim rule. FNS does not believe that the provision of jarred infant foods is incompatible with the nutrition education provided by WIC staff related to appropriate food choices and home preparation of foods for infants since the amount of infant foods provided by WIC is supplemental to an infant's entire needs.

(1) Authorized infant meat. A technical oversight in the proposed rule has been corrected in this interim rule by clarifying the minimum requirements and specifications for authorized infant meat as—any variety of commercial infant food meat or poultry, as a single major ingredient, with added broth or gravy. Added sugars or salt (i.e. sodium) are not allowed. Texture may range from pureed through diced.

(2) Infant cereal. As proposed, the maximum quantity of infant cereal was not changed from current WIC regulations. Thirteen commenters believe that the amount of infant cereal should be reduced. These commenters stated that in their experience infants did not eat the volume of infant cereal provided by WIC. The IOM

recommended that the amount of iron-fortified infant cereal for infants six months and older remain at 24 ounces. Therefore, the proposed maximum amount of infant cereal is retained in this interim rule.

#### f. Rounding Up of Infant Foods

Public Law 108–265, the Child Nutrition and WIC Reauthorization Act of 2004, enacted on June 30, 2004, contains a provision that allows a State agency to round up to the next whole can of infant formula to allow all participants to receive the full-authorized nutritional benefit specified by regulation. This provision only applies to infant formula (not exempt infant formula or WIC-eligible medical foods) issued as a result from a solicitation bid on or after October 1, 2004. The proposed rule described the “full-authorized nutritional benefit” as well as a methodology that State agencies would be required to use if choosing to implement the option to round up. Consistent with the authority allowing State agencies to round up infant formula, FNS proposed rounding up of infant foods (infant cereal, fruit, vegetables and meat) to provide administrative flexibility to State agencies to ensure that infants would receive the full nutritional benefit recommended by the IOM.

Of the 139 comments received on this issue, 129 commenters (66 form letters) disagreed with the proposed methodology for rounding up. Seventy-seven commenters (40 form letters) stated that the proposed methodology was confusing and time-consuming to calculate. Twenty-four commenters (21 form letters) urged FNS to allow State agencies to determine their own methodology for rounding up. FNS is sensitive to commenters' concerns and will further assist State agencies that choose to implement the option to round up. FNS believes, however, that a standard methodology for rounding up, uniformly applied across State agencies, is imperative. Therefore, the

rounding up provisions are retained in this interim rule as proposed, except that this interim rule clarifies that the full nutritional benefit for infant formula is provided as a minimum on average during the timeframe that the food package is provided. This means that when the rounding methodology is applied, in some months participants will receive less than the full nutritional benefit amount, and other months will receive more; however, on average, participants will receive the full nutritional benefit. The full nutritional benefit is defined as the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate infant formula for the food package category and feeding option, e.g. partially breastfed infants 4 through 5 months of age.

#### 9. Revisions in Food Package III and Their Effect on Food Packages I and II

Under proposed Food Package III, infants with qualifying conditions would be added and other supplemental foods would be authorized. The revisions were intended to provide flexibility in accommodating the wide range of nutritional needs of participants served by this food package, and facilitate the efficient management and tracking of the costs of providing supplemental foods to persons with the most serious medical conditions. Of the 86 comment letters that addressed the proposed revisions to Food Package III, 74 commenters (38 form letters) agreed with the proposed changes, especially the addition of supplemental foods other than WIC formula, cereal and juice that are currently authorized. Twelve commenters (5 form letters) disagreed with the proposed revisions.

Commenters remarked on a few specific provisions. While agreeing with the majority of provisions, 21 commenters (19 form letters) from State and local agencies asked that FNS clarify the scope of Food Package III since infants receiving an exempt infant formula for a medical condition would now be served under that package rather than under Food Packages I and II as in current regulations. These same commenters wanted clarification on the qualifying conditions that would allow a participant to receive Food Package III. FNS realizes that serving infants with certain medical conditions under Food Package III rather than under Food Packages I and II will be a major change for WIC staff. As stated in the preamble of the proposed rule, only infant formula would be authorized in Food Packages I and II. Infant formula is a food substitute for human milk for

generally healthy, full-term infants. Infant formula includes milk-based, soy-based and lactose-free products. Therefore, infants served under Food Packages I and II will be generally healthy, full-term infants. Conversely, infants with a serious nutritionally-related medical condition that requires an exempt infant formula or WIC-eligible medical food would be served under Food Package III. Women and children with serious medical conditions would also be served under Food Package III. FNS reminds readers that the WIC Works Formula Database, <http://www.nal.usda.gov/wicworks> provides helpful information on the identification and indications for use of infant formulas, exempt infant formulas and WIC-eligible medical foods.

Commenters were also concerned about medically fragile infants 6 months of age or greater whose medical condition prevents them from consuming complementary infant foods. Commenters requested that these infants receive more WIC formula in replacement of the nutrition that would result from the addition of complementary foods. FNS finds merit in this concern and therefore will revise the provision in Table 1 of 7 CFR 246.10(e)(9) to allow medically fragile infants 6 months of age or greater whose medical condition prevents them from consuming complementary infant foods (cereal, fruit and vegetables, and meat) to receive exempt infant formula or WIC-eligible medical foods at the same maximum monthly allowance as infants ages 4 through 5 months of the same feeding option. The provision of exempt infant formula or WIC-eligible medical foods for these infants is in lieu of provision of complementary infant foods.

In the proposed rule, FNS requested comments on WIC-eligible medical foods. Of the 36 comments received, 21 commenters (14 form letters) agreed with the WIC-eligible medical food provisions and 15 (all form letters) disagreed. As discussed in section IV.A. of this preamble, commenters disagreed with the proposed definition for WIC-eligible medical foods.

Of the 27 commenters (14 form letters) who addressed ways to determine nutritional equivalency for other than liquid forms of ready-to-feed (RTF) medical foods, e.g. bars and puddings, 17 commenters (14 form letters) recommended that protein equivalents be used and 10 commenters felt that the CPA, in consultation with the health care provider, should determine the amount of WIC-eligible medical foods to prescribe, based on a thorough nutritional assessment. One

commenter also suggested that FNS consider a serving per day equivalent. FNS has determined that more information is needed about nutritional equivalency for other than liquid RTF forms of WIC-eligible medical foods. FNS will consult with experts from industry as well as the FDA prior to developing guidance for WIC agencies on ways to determine nutritional equivalency for various physical forms of WIC-eligible medical foods.

#### D. Implementation Timeframe for Revised Food Packages

FNS proposed a one-year implementation timeframe for the majority of the revisions to the WIC food packages, with the following exceptions—(1) a six-month timeframe was proposed for the elimination of juice for infants; and (2) a limitation was proposed on the ability to implement the partially breastfeeding food packages for infants and women to not more than 32 sites within up to eight selected State agencies so that FNS could examine the effects of the revisions on the initiation and duration of breastfeeding before allowing full implementation by all State agencies.

Of the 203 commenters (137 form letters) who addressed the proposed one-year implementation of the revised food package changes for pregnant, postpartum, and fully breastfeeding women, fully formula fed and fully breastfeeding infants, children, and participants with certain medical conditions, 191 commenters (135 form letters) were opposed. Commenters asked for a longer implementation timeframe due to the complexity of the provisions, changes to management information systems, and training needs of staff, vendors and participants. FNS is, therefore, extending the timeframe for implementation of these new food packages to 18 months after the effective date of this interim rule.

A total of 611 commenters (501 form letters) addressed the proposed implementation plan for the partially breastfeeding food packages for infants and women. Of these, 590 commenters (501 form letters) were strongly opposed to the plan. Commenters stated that deferring access to these packages denies WIC Programs a vital tool to encourage women to breastfeed and unnecessarily delays participant access to the proposed improvements in these food packages. Commenters also expressed concern that offering both new and old food packages for up to 3 years after implementing the new food packages would create an administrative burden for State agencies and could cause confusion for WIC participants.

Finally, commenters pointed out that under the proposed implementation plan, partially breastfed infants 6 months to 11 months old could receive more infant formula than fully formula fed infants.

In light of the viewpoints expressed by commenters, and as a result of further review and determination by FNS, the implementation timeframe for the partially breastfeeding food

packages for infants and women is revised to be concurrent with implementation of the other food packages—18 months from the effective date of this interim rule. FNS remains committed to examining the impact of the significant changes to these food packages on the breastfeeding mother/infant dyad, and is developing a study design that allows an assessment of the effects of these changes without

delaying national implementation. In addition, FNS encourages State WIC agencies to examine the impact of these food package changes in the first month following birth on breastfeeding initiation, intensity and duration and to share the results with FNS and the WIC community.

The following chart summarizes the revised implementation timeframes for all food package changes.

TIMELINES FOR IMPLEMENTATION OF FOOD PACKAGE CHANGES

Food package category	Who must implement	Timeframe for implementation
Pregnant Women	All State Agencies	18 Months from Effective Date of Interim Rule.
Postpartum Women	All State Agencies	18 Months from Effective Date of Interim Rule.
Fully Breastfeeding Women	All State Agencies	18 Months from Effective Date of Interim Rule.
Partially Breastfeeding Women	All State Agencies	18 Months from Effective Date of Interim Rule.
Fully Formula fed Infants	All State Agencies	18 Months from Effective Date of Interim Rule.
Partially Breastfed Infants	All State Agencies	18 Months from Effective Date of Interim Rule.
Fully Breastfed Infants	All State Agencies	18 Months from Effective Date of Interim Rule.
Juice Elimination from Infant Food Packages	All State Agencies	18 Months from Effective Date of Interim Rule.
Children	All State Agencies	18 Months from Effective Date of Interim Rule.
Participants with Certain Medical Conditions (Women, Infants and Children).	All State Agencies	18 Months from Effective Date of Interim Rule.

During the 18-month phase-in period, State agencies are required to issue food benefits based on either the new food packages or current food packages but may not combine the two. For example, a State agency may not add whole wheat bread and fresh fruits and vegetables to the current foods and quantities available under the children’s food package. The State agency may, however, phase-in the new food packages on a participant category basis. To minimize participant and vendor confusion, once the State agency begins issuing the new food packages, it must be done on a Statewide basis. FNS will collaborate with the National WIC Association on developing recommendations and options for rolling out the new food packages, based on ease of administration and other issues. State agencies must, however, roll out the food packages for the partially breastfeed mother/infant dyad concurrently, and are also strongly encouraged to concurrently roll out the food packages for the fully breastfed mother/infant dyad.

**V. Endnotes**

(1) U.S. Department of Health and Human Services/U.S. Department of Agriculture, Dietary Guidelines for Americans, 2005. Available at Internet site: <http://www.healthierus.gov/dietaryguidelines/>.

(2) Institute of Medicine, National Academy of Sciences. “WIC Food Packages: Time for a Change,” 2005. Available at Internet site: [http://www.fns.usda.gov/oane/menu/Published/WIC/FILES/Time4AChange\(mainrpt\).pdf](http://www.fns.usda.gov/oane/menu/Published/WIC/FILES/Time4AChange(mainrpt).pdf).

(3) Institute of Medicine, National Academy of Sciences, 2002a. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, DC: National Academy Press.

(4) Environmental Protection Agency/Food and Drug Administration. “What You Need to Know About Mercury in Fish and Shellfish.” EPA and FDA Advice for: Women Who Might Become Pregnant, Women Who Are Pregnant, Nursing Mothers, and Young Children. 2004. Available at Internet site: <http://www.cfsan.fda.gov/dms/admehg3.html>.

**VI. Procedural Matters**

*Executive Order 12866*

This interim rule has been determined to be economically significant and was reviewed by the Office Management and Budget in conformance with Executive Order 12866.

*Regulatory Impact Analysis*

As required for all rules that have been designated as Significant by the Office of Management and Budget, a Regulatory Impact Analysis (RIA) was developed for this interim rule. It follows this regulation as an Appendix. The conclusions of this analysis are summarized below.

*Need for Action.* As the population served by WIC has grown and become more diverse over the last 20 years, the nutritional risks faced by participants have changed, and though nutrition science has advanced, the WIC supplemental food packages have remained largely unchanged. A rule is needed to implement recommended

changes to the WIC food packages based on the current nutritional needs of WIC participants and advances in nutrition science.

*Benefits.* Benefits of this rule include bringing the WIC food packages in line with the Dietary Guidelines for Americans<sup>(1)</sup> and current infant feeding practice guidelines of the American Academy of Pediatrics, better promoting and supporting the establishment of successful long-term breastfeeding, providing WIC participants with a wider variety of food, providing WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences, and serving all participants with certain medical conditions under one food package to facilitate efficient management of medically fragile participants.

*Costs.* FNS estimates that the provisions in this interim rule will have minimal impact on total costs over 5 years.

*Regulatory Flexibility Act*

This interim rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C 601–612). Nancy Montanez Johner, 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. State and local agencies and WIC participants will be most affected by the rule and WIC authorized vendors and the food industry may be indirectly affected.

Although not required by the Regulatory Flexibility Act, FNS has prepared a Regulatory Flexibility Analysis (RFA) describing the impact of this interim rule on small entities. The RFA reflects comments that were received on the Initial Regulatory Flexibility Analysis that was included in the WIC Food Package Proposed Rule published at 71 FR 44784. Additional analysis of the regulatory flexibility considerations of this interim rule may be found in the Regulatory Impact Analysis section of this preamble and the cited RIA itself.

#### Need For, and Objectives of, the Interim Rule

This interim rule revises regulations governing the WIC food packages to change the maximum monthly allowances and minimum requirements for certain supplemental foods, and add new foods such as fruits, vegetables and whole grains. The revisions largely reflect recommendations made by the Institute of Medicine of the National Academies in its Report "WIC Food Packages: Time for a Change."<sup>(2)</sup> These revisions bring the WIC food packages in line with the Dietary Guidelines for Americans<sup>(1)</sup> and current infant feeding practice guidelines of the American Academy of Pediatrics, better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of food, and provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences.

#### Description and Estimate of Number of Small Entities To Which the Interim Rule Would Apply

This interim rule applies to WIC State agencies with respect to their selection of foods to be included on their food lists. As a result, vendors will be indirectly affected and the food industry will realize increased sales of some foods and decreases in other foods, with an overall neutral effect on sales nationally. The rule may have an indirect economic affect on certain small businesses because they may have to carry a larger variety of certain foods to be eligible for authorization as a WIC vendor. Currently, approximately 46,000 stores are authorized to accept WIC food instruments, some of which are small businesses. With the high degree of State flexibility allowable under this interim rule, small vendors will be impacted differently in each State depending upon how that State chooses to meet the new requirements. It is, therefore, not feasible to accurately

estimate the rule's impact on small vendors. Since neither FNS nor the State agencies regulate food producers under the WIC Program, it is not known how many small entities within that industry may be indirectly affected by the interim rule.

#### Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

This interim rule provides State agencies with greater flexibility in prescribing food packages to WIC participants. The information collection burden estimated for this rule is 14,598 hours. The burden reflects requirements associated with medical documentation for the issuance of any supplemental foods issued to participants who receive Food Package III; any authorized soy-based beverage or tofu issued to children who receive Food Package IV; and, any additional authorized tofu and cheese issued to women who receive Food Packages V and VII that exceeds the maximum substitution rate.

#### Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

FNS has considered significant alternatives in developing this interim rule including those that may reduce the indirect impact on small business. These considerations include (among others) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; the use of performance, rather than design, standards; and an exemption from coverage of the rule, or any part thereof, for small entities.

In general, the alternatives of exempting small entities from the requirements in this interim rule or altering the requirements for small entities were rejected. The WIC food packages provide supplemental foods designed to address the nutritional needs of low-income pregnant, breastfeeding, non-breastfeeding postpartum women, infants and children up to age five who are at nutritional risk. Exempting small entities from providing the specific foods intended to address the nutritional needs of participants or altering the requirements for small entities would undermine the purpose of the WIC Program and endanger the health status of participants.

FNS has, however, modified the new food provision in an effort to mitigate

the impact on small entities. Currently, State agencies must establish minimum requirements for the variety and quantity of foods that a vendor must stock in order to receive WIC Program authorization. This rule adds new food items, such as fruits and vegetables and whole grain breads, which may require some WIC vendors, particularly smaller stores, to expand the types and quantities of food items stocked in order to maintain their WIC authorization. In addition, vendors also have to make available more than one food type from each WIC food category, except for the categories of peanut butter and eggs, which may be a change for some vendors. To mitigate the impact of the fruit and vegetable requirement, the rule allows canned, frozen and dried fruits and vegetables to be substituted for fresh produce.

#### Federal Rules That May Duplicate, Overlap, or Conflict With the Interim Rule

There are no Federal rules that may duplicate, overlap, or conflict with the provisions of this interim rule.

#### *Public Law 104-4, Unfunded Mandates Reform Act of 1995 (UMRA)*

Title II of the UMRA establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, FNS 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 interim rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that impose costs on State, local, or tribal governments or to the private sector of \$100 million or more in any one year. This rule is, therefore, not subject to the requirements of sections 202 and 205 of the UMRA.

#### *Executive Order 12372*

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is listed in the Catalog of Federal Domestic Assistance under

No. 10.557. For reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related Notice (48 FR 29114, June 24, 1983), this Program is included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

#### *Federalism Summary Impact Statement*

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

#### *Prior Consultation With WIC State and Local Agency Officials*

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

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

- Publishing an advanced notice of proposed rulemaking (ANPR) in 2003 to solicit comments to determine if the WIC food packages should be revised to better improve the nutritional intake, health and development of participants; and, if so, what specific changes should be made to the food packages. In response to the ANPR, FNS received 195 total comments;
- Commissioning the National Academies' Institute of Medicine (IOM) to independently review the WIC Food Packages. IOM solicited public comment on revisions to the WIC food packages, via 3 public hearings, letters and e-mail, throughout its 22-month study period. IOM considered these comments, as well as comments FNS received in response to the ANPR, in

developing recommendations to revise the WIC food packages. IOM published its reports of these recommendations on April 27, 2005: "WIC Food Packages: Time for a Change."<sup>(2)</sup> This rule incorporates IOM's recommendations;

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

- Consulting and collaborating with NWA on a wide variety of WIC issues, including those related to the WIC food packages (1983-present). NWA is a non-profit organization that was founded in 1983 by State and local agencies that administer the WIC Program. In 2006, NWA's paid membership included 75 of the 89 WIC State agencies, 675 local agencies, 5 State WIC Associations, and 19 sustaining members (i.e., for-profit and non-profit businesses or organizations). Functioning as a coalition of WIC agencies, NWA is dedicated to maximizing WIC resources through effective management practices. NWA also serves in a leadership role for WIC agencies by developing position papers on issues of concern to the WIC community.

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

- Congress has requested a WIC food package rule that includes fruits and vegetables and allows for cultural food accommodations and responds to the needs of the WIC population.

- The National Advisory Council on Maternal, Infant, and Fetal Nutrition, in its annual Reports to FNS, recommends better accommodation of the nutritional and cultural needs of WIC participants through the WIC food packages; and

- In 1999, NWA (then the National Association of WIC Directors (NAWD)) published a position paper entitled "NAWD WIC Food Prescription Recommendations" and in 2003, NWA published a position paper entitled "NWA WIC Culturally Sensitive Food Prescription Recommendations." NWA's major recommendations in these two reports were to reframe the WIC food packages to be consistent with the Dietary Guidelines for Americans and allow State agencies flexibility to accommodate cultural eating patterns.

Based upon the need to address the nutritional needs of the WIC population given current scientific information and consumption patterns as exemplified by

the concerns and recommendations of NWA, and others, FNS was aware of the need to revise the WIC food packages.

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

FNS has considered the impact of the interim rule on State and local agencies. FNS believes that the rule is responsive to the expressed concerns and requests of commenters representing State and local concerns. A few commenters stated that the Department did not conduct a regulatory risk assessment as required for certain Departmental regulations under section 304 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, Public Law 103-354. However, based on the statutory language and legislative intent, the Department determined that a regulatory risk assessment is not required for this regulation.

#### *Executive Order 12988*

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

#### *Civil Rights Impact Analysis*

FNS has reviewed this interim rule in accordance with FNS Regulation 4300-4, "Civil Rights Impact Analysis," to identify and address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, and the characteristics of WIC Program applicants and participants, FNS has determined that it does not have a deleterious effect on the participation of protected individuals in the WIC Program. All data available to FNS indicate that protected individuals have the same opportunity to participate in the WIC Program as non-protected individuals. FNS specifically prohibits State and local agencies operating the WIC Program from discrimination based on race, color, national origin, sex, age, or disability. Section 246.8(a) of WIC regulations requires State agencies to ensure that no person will be excluded from participation based on race, color,

national origin, age, sex or disability. Where State agencies have options, and they choose to implement a certain provision, they must implement it in such a way that it complies with the regulations at 7 CFR 246.8.

This rule merely addresses revisions to the WIC food packages to bring them into line with the Dietary Guidelines for Americans<sup>(1)</sup> and current infant feeding recommendations from the American Academy of Pediatrics. Several provisions are specifically designed to better accommodate WIC's highly diverse population. This interim rule provides WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences, including allowing participants a broad selection of fruits and vegetables; tofu and soy-based beverage as substitutes for milk; participant choice for whole grains (including tortillas); and salmon and sardines as substitutions for tuna. This interim rule also makes provisions to better accommodate the special dietary needs of high-risk participants served in Food Package III, helping to protect the health and well-being of this nutritionally vulnerable subset of WIC participants.

*Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320) requires that the Office of Management and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. In the publication of the proposed rule on August 7, 2006, FNS solicited comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. FNS received no public comments in response to this solicitation. On November 1, 2006, OMB filed comment in accordance with 5 CFR 1320.11(c), requiring FNS to review public comments in response to the proposed rule and address any such comments in the preamble of the final rule. As a result, FNS has submitted a new clearance package for OMB review and approval. These information collection requirements will not become effective until approved by OMB. When OMB has approved these information collection requirements, FNS will publish separate action in the **Federal Register**.

*E-Government Act Compliance*

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

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

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

■ For reasons set forth in the preamble, 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 new definitions of “Cash-value voucher” and “Farmer” in alphabetical order;

■ b. Amend the definitions of “Compliance buy”, “Employee fraud and abuse”, “Participants” and “Proxy” by removing the words “food instruments” and adding in their place the words “food instruments or cash-value vouchers”;

■ c. Amend the definition “Nutrition Services and Administration (NSA) Costs” by removing the words “food instruments” and adding in their place the words “food instruments and cash-value vouchers”;

■ d. Revise the definition of “Participant violation”;

■ e. Revise the definition of “Participation”;

■ f. Amend the definition of “WIC-eligible medical foods” by removing the words “with a diagnosed medical condition” and adding in their place the words “with a qualifying condition”, and by revising the second sentence.

The additions and revisions read as follows:

**§ 246.2 Definitions.**

\* \* \* \* \*

*Cash-value voucher* means a fixed-dollar amount check, voucher, electronic benefit transfer (EBT) card or other document which is used by a participant to obtain authorized fruits and vegetables.

\* \* \* \* \*

*Farmer* means an individual authorized by the State agency to sell eligible fruits and vegetables to participants at a farmers’ market or roadside stands. Individuals who exclusively sell produce grown by someone else, such as wholesale distributors, cannot be authorized.

\* \* \* \* \*

*Participant violation* means any intentional action of a participant, parent or caretaker of an infant or child participant, or proxy that violates Federal or State statutes, regulations, policies, or procedures governing the Program. Participant violations include intentionally making false or misleading statements or intentionally misrepresenting, concealing, or withholding facts to obtain benefits; exchanging cash-value vouchers, food instruments or supplemental foods for cash, credit, non-food items, or unauthorized food items, including supplemental foods in excess of those listed on the participant’s food instrument; threatening to harm or physically harming clinic, farmer or vendor staff; and dual participation.

*Participation* means the sum of:

(1) The number of persons who received supplemental foods or food instruments during the reporting period;

(2) The number of infants who did not receive supplemental foods or food instruments but whose breastfeeding mother received supplemental foods or food instruments during the report period; and

(3) The number of breastfeeding women who did not receive supplemental foods or food instruments but whose infant received supplemental foods or food instruments during the report period.

\* \* \* \* \*

*WIC-eligible medical foods* \* \* \* Such WIC-eligible medical foods must serve the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme.\* \* \*

■ 3. In § 246.4:

■ a. Revise paragraph (a)(11)(iii).

■ b. Amend paragraph (a)(14)(iii) by revising the heading and the first sentence;

■ c. Revise paragraph (a)(14)(vi);

■ d. Revise paragraph (a)(14)(xi);

■ e. Amend paragraph (a)(14)(xii) by removing the words “food instrument” wherever they appear and adding in their place the words “food instrument and cash-value voucher”;

■ f. Amend paragraph (a)(21) by removing the words “food instruments” and adding in their place the words “food instruments and cash-value vouchers”; and

■ g. Amend paragraph (a)(25)(iii) by removing the words “food instruments” and adding in their place the words “food instruments, cash-value vouchers”.

The revisions read as follows:

**§ 246.4 State plan.**

(a) \* \* \*

(11) \* \* \*

(iii) Instructions concerning all food delivery operations performed at the local level, including the list of acceptable foods and their maximum monthly quantities as required by § 246.10(b)(1).

\* \* \* \* \*

(14) \* \* \*

(iii) *Vendor and farmer agreement.* A sample vendor and farmer, if applicable, agreement, including the sanction schedule, which may be incorporated as an attachment or, if the sanction schedule is in the State agency’s regulations, through citation to the regulations. \* \* \*

\* \* \* \* \*

(vi) *Food instruments and cash-value vouchers.* A facsimile of the food instrument and cash-value voucher, if used, and a description of the system the State agency will use to account for the disposition of food instruments and cash value vouchers in accordance with § 246.12(q);

\* \* \* \* \*

(xi) *Vendor and farmer training.* The procedures the State agency will use to train vendors in accordance with § 246.12(i) and farmers. State agencies that intend to delegate any aspect of training to a local agency, contractor, or vendor representative must describe the State agency supervision and instructions that will be provided to ensure the uniformity and quality of vendor training.

\* \* \* \* \*

■ 4. In § 246.7:

■ a. Amend paragraphs (c)(2)(i) and (f)(2)(i) by removing the words “food or food instruments” and adding in their place the words “ food, cash-value vouchers or food instruments”; and

■ b. Revise paragraphs (f)(2)(iv), (h)(3)(i), (j)(3) and (j)(6).

The revisions read as follows:

**§ 246.7 Certification of participants.**

\* \* \* \* \*

(f) \* \* \*

(2) \* \* \*

(iv) Each local agency using a retail purchase system shall issue a food

instrument(s) and if applicable cash-value voucher(s) to the participant at the same time as notification of certification. Such food instrument(s) and cash-value vouchers shall provide benefits for the current month or the remaining portion thereof and shall be redeemable immediately upon receipt by the participant. Local agencies may mail the initial food instrument(s) and if applicable cash-value vouchers with the notification of certification to those participants who meet the criteria for the receipt of food instruments through the mail, as provided in § 246.12(r)(4).

\* \* \* \* \*

(h) \* \* \*

(3) \* \* \*

(i) A State agency may allow local agencies to disqualify a participant for failure to obtain food instruments, cash-value vouchers or supplemental foods for several consecutive months. As specified by the State agency, proof of such failure includes failure to pick up supplemental foods, cash-value vouchers or food instruments, nonreceipt of food instruments or cash-value vouchers (when mailed instruments or vouchers are returned), or failure to have an electronic benefit transfer card revalidated for purchase of supplemental foods; or

\* \* \* \* \*

(j) \* \* \*

(3) If the State agency implements the policy of disqualifying a participant for not picking up supplemental foods, cash-value vouchers or food instruments in accordance with paragraph (h)(3)(i) of this section, it shall provide notice of this policy and of the importance of regularly picking up cash-value vouchers, food instruments or supplemental foods to each participant, parent or caretaker at the time of each certification.

\* \* \* \* \*

(6) A person who is about to be suspended or disqualified from program participation at any time during the certification period shall be advised in writing not less than 15 days before the suspension or disqualification. Such notification shall include the reasons for this action, and the participant’s right to a fair hearing. Further, such notification need not be provided to persons who will be disqualified for not picking up cash-value vouchers, supplemental foods or food instruments in accordance with paragraph (h)(3)(i) of this section.

\* \* \* \* \*

■ 5. Revise § 246.10 to read as follows:

**§ 246.10 Supplemental foods.**

(a) *General.* This section prescribes the requirements for providing

supplemental foods to participants. The State agency must ensure that local agencies comply with this section.

(b) *State agency responsibilities.* (1) State agencies may:

(i) Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section, except that the State agency may not establish further restrictions on the eligible fruits and vegetables, for the supplemental foods in their States. These State criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal; and

(ii) Make food package adjustments to better accommodate participants who are homeless. At the State agency’s option, these adjustments would include, but not be limited to, issuing authorized supplemental foods in individual serving-size containers to accommodate lack of food storage or preparation facilities.

(2) State agencies must:

(i) Identify the brands of foods and package sizes that are acceptable for use in the Program in their States in accordance with the requirements of this section. State agencies must also provide to local agencies, and include in the State Plan, a list of acceptable foods and their maximum monthly allowances as specified in Tables 1 through 4 of paragraphs (e)(9) through (e)(12) of this section; and

(ii) Ensure that local agencies:

(A) Make available to participants the maximum monthly allowances of authorized supplemental foods, except as noted in paragraph (c) of this section, and abide by the authorized substitution rates for WIC food substitutions as specified in Tables 1 through 3 of paragraphs (e)(9) through (e)(11) of this section;

(B) Make available to participants more than one food from each WIC food category except for the categories of peanut butter and eggs, and any of the WIC-eligible fruits and vegetables (fresh or processed) in each authorized food package as listed in paragraph (e) of this section;

(C) Authorize only a competent professional authority to prescribe the categories of authorized supplemental foods in quantities that do not exceed the regulatory maximum and are appropriate for the participant, taking into consideration the participant’s age and nutritional needs; and

(D) Advise participants or their caretaker, when appropriate, that the supplemental foods issued are only for their personal use. However, the supplemental foods are not authorized for participant use while hospitalized

on an in-patient basis. In addition, consistent with § 246.7(m)(1)(i)(B), supplemental foods are not authorized for use in the preparation of meals served in a communal food service. This restriction does not preclude the provision or use of supplemental foods for individual participants in a nonresidential setting (e.g., child care facility, family day care home, school, or other educational program); a homeless facility that meets the requirements of § 246.7(m)(1); or, at the State agency's discretion, a residential institution (e.g., home for pregnant teens, prison, or residential drug treatment center) that meets the requirements currently set forth in § 246.7(m)(1) and (m)(2).

(c) *Nutrition tailoring.* The full maximum monthly allowances of all supplemental foods in all food packages must be made available to participants if medically or nutritionally warranted. Reductions in these amounts cannot be made for cost-savings, administrative convenience, caseload management, or to control vendor abuse. Reductions in these amounts cannot be made for categories, groups or subgroups of WIC participants. The provision of less than the maximum monthly allowances of supplemental foods to an individual WIC participant in all food packages is appropriate only when:

(1) Medically or nutritionally warranted (e.g., to eliminate a food due to a food allergy);

(2) A participant refuses or cannot use the maximum monthly allowances; or

(3) The quantities necessary to supplement another programs' contribution to fill a medical prescription would be less than the maximum monthly allowances.

(d) *Medical documentation—(1) Supplemental foods requiring medical documentation.* Medical documentation is required for the issuance of the following supplemental foods:

(i) Any non-contract brand infant formula;

(ii) Any infant formula prescribed to a child or adult who receives Food Package III;

(iii) Any exempt infant formula;

(iv) Any WIC-eligible medical food;

(v) Any authorized supplemental food issued to participants who receive Food Package III;

(vi) Any authorized soy-based beverage or tofu issued to children who receive Food Package IV;

(vii) Any additional authorized cheese issued to children who receive Food Package IV that exceeds the maximum substitution rate;

(viii) Any additional authorized tofu and cheese issued to women who

receive Food Packages V and VII that exceeds the maximum substitution rate; and

(ix) Any contract brand infant formula that does not meet the requirements in Table 4 of paragraph (e)(12) of this section.

(2) *Supplemental foods not requiring medical documentation.* (i) State agencies may authorize local agencies to issue a non-contract brand infant formula that meets the requirements in Table 4 of paragraph (e)(12) of this section without medical documentation in order to meet religious eating patterns; and

(ii) The State agency has the discretion to require medical documentation for any contract brand infant formula and may decide that some contract brand infant formula may not be issued under any circumstances.

(3) *Medical Determination.* For purposes of this program, medical documentation means that a health care professional licensed to write medical prescriptions under State law has:

(i) Made a medical determination that the participant has a qualifying condition as described in paragraphs (e)(3) through (e)(7) of this section that dictates the use of the supplemental foods, as described in paragraph (d)(1) of this section; and

(ii) Provided the written documentation that meets the technical requirements described in paragraphs (d)(4)(ii) and (d)(4)(iii) of this section.

(4) *Technical Requirements—(i) Location.* All medical documentation must be kept on file (electronic or hard copy) at the local clinic. The medical documentation kept on file must include the initial telephone documentation, when received as described in paragraph (d)(4)(iii)(B) of this section.

(ii) *Content.* All medical documentation must include the following:

(A) The name of the authorized WIC formula (infant formula, exempt infant formula, WIC-eligible medical food) prescribed, including amount needed per day;

(B) The authorized supplemental food(s) appropriate for the qualifying condition(s) and their prescribed amounts;

(C) Length of time the prescribed WIC formula and/or supplemental food is required by the participant;

(D) The qualifying condition(s) for issuance of the authorized supplemental food(s) requiring medical documentation, as described in paragraphs (e)(3) through (e)(7) of this section; and

(E) Signature, date and contact information (or name, date and contact information), if the initial medical documentation was received by telephone and the signed document is forthcoming, of the health care professional licensed by the State to write prescriptions in accordance with State laws.

(iii) *Written confirmation—(A) General.* Medical documentation must be written and may be provided as an original written document, an electronic document, by facsimile or by telephone to a competent professional authority until written confirmation is received.

(B) *Medical documentation provided by telephone.* Medical documentation may be provided by telephone to a competent professional authority who must promptly document the information. The collection of the required information by telephone for medical documentation purposes may only be used until written confirmation is received from a health care professional licensed to write medical prescriptions and used only when absolutely necessary on an individual participant basis. The local clinic must obtain written confirmation of the medical documentation within a reasonable amount of time (*i.e.*, one or two week's time) after accepting the initial medical documentation by telephone.

(5) *Medical supervision requirements.* Due to the nature of the health conditions of participants who are issued supplemental foods that require medical documentation, close medical supervision is essential for each participant's dietary management. The responsibility remains with the participant's health care provider for this medical oversight and instruction. This responsibility cannot be assumed by personnel at the WIC State or local agency. However, it would be the responsibility of the WIC competent professional authority to ensure that only the amounts of supplemental foods prescribed by the participant's health care provider are issued in the participant's food package.

(e) *Food packages.* There are seven food packages available under the Program that may be provided to participants. The authorized supplemental foods must be prescribed from food packages according to the category and nutritional needs of the participant. The food packages are as follows:

(1) *Food Package I—Infants birth through 5 months—(i) Participant category served.* This food package is designed for issuance to infant participants from birth through age 5

months who do not have a condition qualifying them to receive Food Package III.

(ii) *Infant feeding categories—(A) Birth to one month.* Three infant feeding options are available during the first month after birth—fully breastfeeding, i.e., the infant receives no infant formula from the WIC Program; partially breastfeeding, i.e., the infant receives not more than 104 reconstituted fluid ounces of formula; or fully formula-feeding. Infant formula is not provided during the first month after birth to fully breastfed infants to support the successful establishment of breastfeeding.

(B) *One through 5 months.* Three infant feeding options are available from 1 months through 5 months—fully breastfeeding, fully formula-feeding, or partially breastfeeding, i.e., the infant is breastfed but also receives infant formula from the WIC Program in an amount not to exceed approximately half the amount of infant formula allowed for a fully formula fed infant.

(iii) *Infant formula requirements.* This food package provides iron-fortified infant formula that is not an exempt infant formula. The issuance of any contract brand or noncontract brand infant formula that contains less than 10 milligrams of iron per liter at standard dilution (i.e., approximately 20 kilocalories per fluid ounce of prepared formula) is prohibited. Except as specified in paragraph (d) of this section, local agencies must issue a contract brand infant formula that meets the requirements in Table 4 of paragraph (e)(12) of this section.

(iv) *Physical forms.* Local agencies must issue all WIC formulas (WIC formulas mean all infant formula, exempt infant formula and WIC-eligible medical foods) in concentrated liquid or powder physical forms. Ready-to-feed WIC formulas may be authorized when the competent professional authority determines and documents that:

(A) The participant's household has an unsanitary or restricted water supply or poor refrigeration;

(B) The person caring for the participant may have difficulty in correctly diluting concentrated or powder forms; or

(C) The WIC infant formula is only available in ready-to-feed.

(v) *Authorized category of supplemental foods.* Infant formula is the only category of supplemental foods authorized in this food package. Exempt infant formulas and WIC-eligible medical foods are authorized only in Food Package III.

(2) *Food Package II—Infants 6 through 11 months—(i) Participant*

*category served.* This food package is designed for issuance to infant participants from 6 through 11 months of age who do not have a condition qualifying them to receive Food Package III.

(ii) *Infant feeding options.* Three infant feeding options are available—fully breastfeeding, fully formula-feeding, or partially breastfeeding.

(iii) *Infant formula requirements.* The requirements for issuance of infant formula in Food Package I, specified in paragraphs (e)(1)(iii) and (e)(1)(iv) of this section, also apply to the issuance of infant formula in Food Package II.

(iv) *Authorized categories of supplemental foods.* Infant formula, infant fruits and vegetables, infant meat, and infant cereal are the categories of supplemental foods authorized in this food package.

(3) *Food Package III—Participants with qualifying conditions—(i) Participant category served and qualifying conditions.* This food package is reserved for issuance to women, infants and child participants who have a documented qualifying condition that requires the use of a WIC formula (infant formula, exempt infant formula or WIC-eligible medical food) because the use of conventional foods is precluded, restricted, or inadequate to address their special nutritional needs. Medical documentation must meet the requirements described in paragraph (d) of this section. Participants who are eligible to receive this food package must have one or more qualifying conditions, as determined by a health care professional licensed to write medical prescriptions under State law. The qualifying conditions include but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental formula, and life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or the utilization of nutrients that could adversely affect the participant's nutrition status. This food package may not be issued solely for the purpose of enhancing nutrient intake or managing body weight.

(ii) *Non-authorized issuance of Food Package III.* This food package is not authorized for:

(A) Infants whose only condition is:

(1) A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt infant formula; or

(2) A non-specific formula or food intolerance.

(B) Women and children who have a food intolerance to lactose or milk protein that can be successfully managed with the use of one of the other WIC food packages (i.e., Food Packages IV–VII); or

(C) Any participant solely for the purpose of enhancing nutrient intake or managing body weight without an underlying qualifying condition.

(iii) *Restrictions on the issuance of WIC formulas in ready-to-feed (RTF) forms.* WIC State agencies must issue WIC formulas (infant formula, exempt infant formula and WIC-eligible medical foods) in concentrated liquid or powder physical forms unless the requirements for issuing RTF are met as described in paragraph (e)(1)(iv) of this section. In addition to those requirements, there are two additional conditions which may be used to issue RTF in Food Package III:

(A) If a ready-to-feed form better accommodates the participant's condition; or

(B) If it improves the participant's compliance in consuming the prescribed WIC formula.

(iv) *Unauthorized WIC costs.* All apparatus or devices (e.g., enteral feeding tubes, bags and pumps) designed to administer WIC formulas are not allowable WIC costs.

(v) *Authorized categories of supplemental foods.* The supplemental foods authorized in this food package require medical documentation for issuance and include infant formula (for children or women), exempt infant formula, WIC-eligible medical foods, infant cereal, infant food fruits and vegetables, milk and milk alternatives, cheese, eggs, canned fish, fruits and vegetables, breakfast cereal, whole wheat bread or other whole grains, juice, legumes and/or peanut butter.

(vi) *Coordination with medical payors and other programs that provide or reimburse for formulas.* WIC State agencies must coordinate with other Federal, State or local government agencies or with private agencies that operate programs that also provide or could reimburse for exempt infant formulas and WIC-eligible medical foods benefits to mutual participants. At a minimum, a WIC State agency must coordinate with the State Medicaid Program for the provision of exempt infant formulas and WIC-eligible medical foods that are authorized or could be authorized under the State Medicaid Program for reimbursement and that are prescribed for WIC participants who are also Medicaid recipients. The WIC State agency is responsible for providing up to the

maximum amount of exempt infant formulas and WIC-eligible medical foods under Food Package III in situations where reimbursement is not provided by another entity.

(4) *Food Package IV—Children 1 through 4 years*—(i) *Participant category served*. This food package is designed for issuance to participants 1 through 4 years of age who do not have a condition qualifying them to receive Food Package III.

(ii) *Authorized categories of supplemental foods*. Milk, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. Cheese may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Substitutions exceeding the maximum substitution allowance of cheese, up to the maximum allowance for fluid milk, may be allowed with medical documentation of the qualifying condition. Soy-based beverage and tofu can be substituted for milk only with medical documentation in this food package, in amounts described in Table 2 of paragraph (e)(10) of this section. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a child cannot drink milk and requires soy-based beverage, tofu, or additional cheese as a substitute for milk. Such determination can be made for situations that include, but are not limited to, milk allergy, severe lactose maldigestion, and vegan diets. Medical documentation must meet the requirements described in paragraph (d) of this section.

(5) *Food Package V—Pregnant and partially breastfeeding women*—(i) *Participant category served*. This food package is designed for issuance to women participants with singleton pregnancies who do not have a condition qualifying them to receive Food Package III. This food package is also designed for issuance to breastfeeding women participants, up to 1 year postpartum, who do not have a condition qualifying them to receive Food Package III and whose partially breastfed infants receive formula from the WIC program in amounts that do not exceed the maximum allowances described in Table 1 of paragraph (e)(9) of this section. Women participants breastfeeding more than one infant, and women participants pregnant with more than one fetus, are eligible to receive

Food Package VII as described in paragraph (e)(7) of this section.

(ii) *Authorized categories of supplemental foods*. Milk, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, legumes and peanut butter are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

(6) *Food Package VI—Postpartum women*—(i) *Participant category served*. This food package is designed for issuance to women up to 6 months postpartum who are not breastfeeding their infants, and to breastfeeding women up to 6 months postpartum whose participating infant receives more than the maximum amount of formula allowed for partially breastfed infants as described in Table 1 of paragraph (e)(9) of this section.

(ii) *Authorized categories of supplemental foods*. Milk, breakfast cereal, juice, fruits and vegetables, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation

must meet the requirements described in paragraph (d) of this section.

(7) *Food Package VII—Fully breastfeeding*—(i) *Participant category served*. This food package is designed for issuance to breastfeeding women up to 1 year postpartum whose infants do not receive infant formula from WIC (these breastfeeding women are assumed to be fully breastfeeding their infants). This food package is also designed for issuance to women participants pregnant with two or more fetuses, and women participants partially breastfeeding multiple infants. Women participants fully breastfeeding multiple infants receive 1.5 times the supplemental foods provided in Food Package VII.

(ii) *Authorized categories of supplemental foods*. Milk, cheese, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, legumes, peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

(8) *Supplemental Foods—Maximum monthly allowances, options and substitution rates, and minimum requirements*. Tables 1 through 3 of paragraphs (e)(9) through (e)(11) of this section specify the maximum monthly allowances of foods in WIC food packages and identify WIC food options and substitution rates. Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications of supplemental foods in the WIC food packages.

(9) *Maximum monthly allowances of supplemental foods for infants*. The maximum monthly allowances, options and substitution rates of supplemental foods for infants in Food Packages I, II and III are stated in Table 1 as follows:

TABLE 1.—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR INFANTS IN FOOD PACKAGES I, II AND III

Foods <sup>1</sup>	Fully formula fed (FF)		Partially breastfed (BF/FF)		Fully breastfed (BF)	
	Food packages I-FF & III-FF A: 0 through 3 months B: 4 through 5 months	Food packages II-FF & III-FF 6 through 11 months	Food packages I-BF/FF & III BF/FF A: 0 to 1 month <sup>2</sup> B: 1 through 3 months <sup>2</sup> C: 4 through 5 months	Food packages II-BF/FF & III BF/FF through 11 months	Food package I-BF 0 through 5 months	Food package II-BF 6 through 11 months
WIC Formula <sup>4 5 6 7</sup> ..	A: 806 fl oz reconstituted liquid concentrate or 832 fl oz RTF or 870 fl oz reconstituted powder. B: 884 fl oz reconstituted liquid concentrate or 896 fl oz RTF or 960 fl oz reconstituted powder.	624 fl oz reconstituted liquid concentrate or 640 fl oz RTF or 696 fl oz reconstituted powder	A: 104 fl oz reconstituted powder <sup>3</sup> B: 364 fl oz reconstituted liquid concentrate or 384 fl oz RTF or 435 fl oz reconstituted powder C: 442 fl oz reconstituted liquid concentrate or 448 fl oz RTF or 522 fl oz reconstituted powder	312 fl oz reconstituted liquid concentrate or 320 fl oz RTF or 384 fl oz reconstituted powder		
Infant cereal <sup>8</sup> .....	.....	24 oz .....	.....	24 oz .....	.....	24 oz.
Infant food fruits and vegetables <sup>8 9 10</sup> .	.....	128 oz .....	.....	128 oz .....	.....	256 oz.
Infant food—meat <sup>8 10</sup> .	.....	.....	.....	.....	.....	77.5 oz.

Table 1 Footnotes: (abbreviations in order of appearance in table): FF = fully formula fed; BF/FF = partially breastfed (i.e., the infant is breastfed but also receives formula from the WIC Program); BF = fully breastfed (i.e., the infant receives no formula through the WIC program).

<sup>1</sup> Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.

<sup>2</sup> The powder form is the form recommended for partially breastfed infants ages 0 through 3 months in Food Package I.

<sup>3</sup> Liquid concentrate and ready-to-feed (RTF) may be substituted at rates that provide comparable nutritive value.

<sup>4</sup> WIC formula means infant formula, exempt infant formula, or WIC-eligible medical food. Only infant formula may be issued for infants in Food Packages I and II. Exempt infant formula may only be issued for infants in Food Package III.

<sup>5</sup> The maximum monthly allowance is specified in reconstituted fluid ounces for liquid concentrate, RTF liquid, and powder forms of infant formula and exempt infant formula. Reconstituted fluid ounce is the form prepared for consumption as directed on the container.

<sup>6</sup> If powder infant formula is provided, State agencies must provide at least the number of reconstituted fluid ounces as the maximum allowance for the liquid concentrate form of the same product in the same Food Package up to the maximum monthly allowance for powder. State agencies must issue whole containers that are all the same size.

<sup>7</sup> State agencies may round up and disperse whole containers of infant formula over the food package timeframe to allow participants to receive the full authorized nutritional benefit (FNB). State agencies must use the methodology described in accordance with paragraph (h)(1) of this section.

<sup>8</sup> State agencies may round up and disperse whole containers of infant foods (infant cereal, fruits and vegetables, and meat) over the Food Package timeframe. State agencies must use the methodology described in accordance with paragraph (h)(2) of this section.

<sup>9</sup> Fresh banana may replace up to 16 ounces of infant food fruit at a rate of 1 pound of bananas per 8 ounces of infant food fruit.

<sup>10</sup> In lieu of infant foods (cereal, fruit and vegetables, and meat), infants greater than 6 months of age in Food Package III may receive exempt infant formula or WIC-eligible medical foods at the same maximum monthly allowance as infants ages 4 through 5 months of age of the same feeding option.

(10) Maximum monthly allowances of supplemental foods in Food Packages IV through VII. The maximum monthly allowances, options and substitution rates of supplemental foods for children and women in Food Package IV through VII are stated in Table 2 as follows:

TABLE 2.—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN IN FOOD PACKAGES IV, V, VI AND VII

Foods <sup>1</sup>	Children		Women	
	Food package IV 1 through 4 years	Food package V: Pregnant and partially breastfeeding (up to 1 year postpartum) <sup>2</sup>	Food package VI: Postpartum (up to 6 months postpartum) <sup>3</sup>	Food package VII: Fully breastfeeding (up to 1 year post-partum) <sup>4 5</sup>
Juice, single strength <sup>6</sup> .....	128 fl oz .....	144 fl oz .....	96 fl oz .....	144 fl oz.
Milk, fluid .....	16 qt <sup>7 8 9 10</sup> .....	22 qt. <sup>7 8 11 12</sup> .....	16 qt. <sup>7 8 11 12</sup> .....	24 qt. <sup>7 8 11 12</sup>
Breakfast cereal <sup>13</sup> .....	36 oz .....	36 oz .....	36 oz .....	36 oz.
Cheese .....	N/A .....	N/A .....	N/A .....	1 lb.
Eggs .....	1 dozen .....	1 dozen .....	1 dozen .....	2 dozen.
Fruits and vegetables <sup>14 15</sup>	\$6.00 in cash value vouchers.	\$8.00 in cash-value vouchers.	\$8.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.
Whole wheat bread or other whole grains <sup>16</sup> .	2 lb .....	1 lb .....	N/A .....	1 lb.
Fish (canned) .....	N/A .....	N/A .....	N/A .....	30 oz.

TABLE 2.—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN IN FOOD PACKAGES IV, V, VI AND VII—Continued

Foods <sup>1</sup>	Children	Women		
	Food package IV 1 through 4 years	Food package V: Pregnant and partially breastfeeding (up to 1 year postpartum) <sup>2</sup>	Food package VI: Postpartum (up to 6 months postpartum) <sup>3</sup>	Food package VII: Fully breastfeeding (up to 1 year post-partum) <sup>4,5</sup>
Legumes, dry <sup>17</sup> .....	1 lb .....	1 lb .....	1 lb .....	1 lb.
And/or peanut butter .....	Or 18 oz .....	And 18 oz .....	Or 18 oz .....	And 18 oz.

Table 2 Footnotes: N/A = the supplemental food is not authorized in the corresponding food package.

<sup>1</sup> Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.

<sup>2</sup> Food Package V is issued to two categories of WIC participants: Women participants with singleton pregnancies and breastfeeding women whose partially breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances for Food Packages I-BF/FF-A, I-BF/FF-B, I-BF/FF-C, or II-BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

<sup>3</sup> Food Package VI is issued to two categories of WIC participants: Non-breastfeeding postpartum women and breastfeeding postpartum women whose partially breastfed infants receive more than the maximum infant formula allowances for Food Packages I-BF/FF-A, I-BF/FF-B, I-BF/FF-C or II-BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

<sup>4</sup> Food Package VII is issued to three categories of WIC participants: Fully breastfeeding women whose infants do not receive formula from the WIC Program; women pregnant with two or more fetuses; and women fully or partially breastfeeding multiple infants.

<sup>5</sup> Women fully breastfeeding multiple infants are prescribed 1.5 times the maximum allowances.

<sup>6</sup> Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.

<sup>7</sup> Whole milk, as specified in FDA standards, is the only type of milk allowed for 1-year-old children (12 through 23 months). Reduced fat milks, as specified in FDA standards, i.e., 2% milk fat, are the only types of milk allowed for children ≥ 24 months of age and women.

<sup>8</sup> Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. Dry milk may be substituted at an equal reconstituted rate to fluid milk. When a combination of different milk forms is provided, the full maximum monthly fluid milk allowance must be provided.

<sup>9</sup> For children, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 lb. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese may be substituted in cases of lactose intolerance or other qualifying conditions, up to the maximum allowance for fluid milk.

<sup>10</sup> For children, soy-based beverage and calcium-set tofu may be substituted for milk only with medical documentation for qualifying conditions. Soy-based beverage may be substituted for milk, with medical documentation, for children in Food Package IV on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.

<sup>11</sup> For women, cheese or calcium-set tofu may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this manner in Food Packages V and VI; however, no more than 1 pound of cheese may be substituted for milk. A maximum of 6 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 2 lbs. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese or tofu may be substituted, up to the maximum allowances for fluid milk, in cases of lactose intolerance or other qualifying conditions.

<sup>12</sup> For women, soy-based beverage may be substituted for milk at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum monthly allowance of milk.

<sup>13</sup> At least one-half of the total number of breakfast cereals on the State agency's authorized food list must have whole grain as the primary ingredient and meet labeling requirements for making a health claim as a "whole grain food with moderate fat content" as defined in Table 4 of paragraph (e)(12) of this section.

<sup>14</sup> Processed (canned, frozen, dried) fruits and vegetables may be substituted for fresh fruits and vegetables. Dried fruit and dried vegetables are not authorized for children in Food Package IV.

<sup>15</sup> The monthly value of the fruit/vegetable cash-value vouchers will be adjusted annually for inflation as described in § 246.16(j).

<sup>16</sup> Brown rice, bulgur (cracked wheat), oatmeal, whole-grain barley, soft corn or whole wheat tortillas may be substituted for whole wheat bread on an equal weight basis.

<sup>17</sup> Canned legumes may be substituted for dried legumes at the rate of 64 oz. of canned beans for 1 lb. dried beans. Under Food Packages V and VII, two additional combinations of dry or canned beans/peas are authorized: 1 lb. Dry and 64 oz. Canned beans/peas (and no peanut butter); or 2 lb. Dry or 128 oz. Canned beans/peas (and no peanut butter) or 36 oz. peanut butter (and no beans).

(11) Maximum monthly allowances of supplemental foods for children and women with qualifying conditions in Food Package III. The maximum monthly allowances, options and substitution rates of supplemental foods for participants with qualifying conditions in Food Package III are stated in Table 3 as follows:

TABLE 3.—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN IN FOOD PACKAGE III

Foods <sup>1</sup>	Children	Women		
	1 through 4 years	Pregnant and partially breastfeeding (up to 1 year postpartum) <sup>2</sup>	Postpartum (up to 6 months postpartum) <sup>3</sup>	Fully breastfeeding, (up to 1 year post-partum) <sup>4,5</sup>
Juice, single strength <sup>6</sup> .	128 fl oz .....	144 fl oz .....	96 fl oz .....	144 fl oz.
WIC Formula <sup>7,8</sup> .....	455 fl oz liquid concentrate	455 fl oz liquid concentrate	455 fl oz liquid concentrate	455 fl oz. liquid concentrate.
Milk .....	16 qt <sup>9,10,11,12</sup> .....	22 qt <sup>9,10,13,14</sup> .....	16 qt <sup>9,10,13,14</sup> .....	24 qt. <sup>9,10,13,14</sup>
Breakfast cereal <sup>15,16</sup> .	36 oz .....	36 oz .....	36 oz .....	36 oz.
Cheese .....	N/A .....	N/A .....	N/A .....	1 lb.
Eggs .....	1 dozen .....	1 dozen .....	1 dozen .....	2 dozen.

TABLE 3.—MAXIMUM MONTHLY ALLOWANCES OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN IN FOOD PACKAGE III—Continued

Foods <sup>1</sup>	Children	Women		
	1 through 4 years	Pregnant and partially breastfeeding (up to 1 year postpartum) <sup>2</sup>	Postpartum (up to 6 months postpartum) <sup>3</sup>	Fully breastfeeding, (up to 1 year post-partum) <sup>4 5</sup>
Fruits and vegetables <sup>17 18</sup> ,	\$6.00 in cash value vouchers.	\$8.00 in cash value vouchers.	\$8.00 in cash value vouchers.	\$10.00 in cash value vouchers.
Whole wheat bread <sup>19</sup> .	2 lb .....	1 lb .....	N/A .....	1 lb.
Fish (canned) .....	N/A .....	N/A .....	N/A .....	30 oz.
Legumes, dry <sup>20</sup> .....	1 lb .....	1 lb .....	1 lb .....	1 lb.
and/or Peanut butter.	Or 18 oz .....	And 18 oz .....	Or 18 oz .....	And 18 oz.

Table 3 Footnotes: N/A—the supplemental food is not authorized in the corresponding food package.

<sup>1</sup> Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.

<sup>2</sup> Food Package V is issued to two categories of WIC participants—women participants with singleton pregnancies and breastfeeding women whose partially breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances for Food Packages I–BF/FF–A, I–BF/FF–B, I–BF/FF–C, or II–BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

<sup>3</sup> Food Package VI is issued to two categories of WIC participants—non-breastfeeding postpartum women and breastfeeding postpartum women whose partially breastfed infants receive more than the maximum formula allowances for Food Packages I–BF/FF–A, I–BF/FF–B, I–BF/FF–C or II–BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

<sup>4</sup> Food Package VII is issued to three categories of WIC participants—fully breastfeeding women whose infants do not receive formula from the WIC Program; women pregnant with two or more fetuses; and women fully or partially breastfeeding multiple infants.

<sup>5</sup> Women fully breastfeeding multiple infants are prescribed 1.5 times the maximum allowances.

<sup>6</sup> Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.

<sup>7</sup> WIC formula means infant formula, exempt infant formula, or WIC-eligible medical food.

<sup>8</sup> Powder and Ready-to-Feed may be substituted at rates that provide comparable nutritive value.

<sup>9</sup> Whole milk, as specified in FDA standards, is the only type of milk allowed for 1-year-old children (12 through 23 months). Reduced fat milks, as specified in FDA standards, i.e., 2% milk fat, are the only types of milk allowed for children > 24 months of age and women. With medical documentation, whole milk may be substituted for reduced fat milk for children > 24 months of age and women.

<sup>10</sup> Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. Dry milk may be substituted at an equal reconstituted rate to fluid milk. When a combination of different milk forms is provided, the full maximum monthly fluid milk allowance must be provided.

<sup>11</sup> For children, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 lb. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese may be substituted in cases of lactose intolerance or other qualifying conditions, up to the maximum allowance for fluid milk.

<sup>12</sup> For children, soy-based beverage and tofu may be substituted for milk only with medical documentation for qualifying conditions. Soy-based beverage may be substituted for milk, with medical documentation, for children in Food Package IV on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.

<sup>13</sup> For women, cheese or calcium-set tofu may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this manner in Food Packages V and VI; however, no more than 1 pound of cheese may be substituted for milk. A maximum of 6 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 2 lbs. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese or tofu may be substituted, up to the maximum allowances for fluid milk, in cases of lactose intolerance or other qualifying conditions.

<sup>14</sup> For women, soy-based beverage may be substituted for milk at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum monthly allowance of milk.

<sup>15</sup> 32 dry ounces of infant cereal may be substituted for 36 ounces of breakfast cereal.

<sup>16</sup> At least one half of the total number of breakfast cereals on the State agency's authorized food list must have whole grain as the primary ingredient and meet labeling requirements for making a health claim as a "whole grain food with moderate fat content" as defined in Table 4 of paragraph (e)(12) of this section.

<sup>17</sup> Processed (canned, frozen, dried) fruits and vegetables may be substituted for fresh fruits and vegetables. Dried fruit and dried vegetables are not authorized for children.

<sup>18</sup> The monthly value of the fruit/vegetable cash-value vouchers will be adjusted annually for inflation as described in § 246.16(j).

<sup>19</sup> Brown rice, bulgur (cracked wheat), oatmeal, whole-grain barley, soft corn or whole wheat tortillas may be substituted for whole wheat bread on an equal weight basis.

<sup>20</sup> Canned legumes may be substituted for dried legumes at the rate of 64 oz of canned beans for 1 lb dried beans. Issuance of two additional combinations of dry or canned beans/peas is authorized for the Pregnant and Partially Breastfeeding (up to 1 year postpartum) category and Fully Breastfeeding (Enhanced) (up to 1 year postpartum) category: 1 lb. Dry and 64 oz. Canned beans/peas (and no peanut butter); or 2 lb. Dry or 128 oz. Canned beans/peas (and no peanut butter) or 36 oz. Peanut butter (and no beans).

(12) Minimum requirements and specifications for supplemental foods.

Table 4 describes the minimum requirements and specifications for supplemental foods in all food packages:

TABLE 4.—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS

Categories/foods	Minimum requirements and specifications
WIC formula: Infant formula .....	All authorized infant formulas must (1) meet the definition for an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and meet the requirements for an infant formula under section 412 of the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107;

TABLE 4.—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS—Continued

Categories/foods	Minimum requirements and specifications
	<p>(2) Be designed for enteral digestion via an oral or tube feeding;                      (3) Provide at least 10 mg iron per liter (at least 1.8 mg iron/100 kilocalories) at standard dilution;                      (4) Provide at least 67 kilocalories per 100 milliliters (approximately 20 kilocalories per fluid ounce) at standard dilution.                      (5) Not require the addition of any ingredients other than water prior to being served in a liquid state.</p>
Exempt infant formula .....	<p>All authorized exempt infant formula must (1) meet the definition and requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 350a(h)) and the regulations at 21 CFR Parts 106 and 107; and                      2) Be designed for enteral digestion via an oral or tube feeding.</p>
WIC-eligible medical foods. <sup>1</sup>	<p>Certain enteral products that are specifically formulated to provide nutritional support for individuals with a qualifying condition, when the use of conventional foods is precluded, restricted, or inadequate. Such WIC-eligible medical foods must serve the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provide a source of calories and one or more nutrients; be designed for enteral digestion via an oral or tube feeding; and may not be a conventional food, drug, flavoring, or enzyme.                      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)).</p>
Milk and milk alternatives:	
Cow's milk .....	<p>Must conform to FDA standard of identity for whole, reduced fat, low-fat, or non-fat milks (21 CFR 131.110). Must be pasteurized and contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2000 IU of vitamin A per quart (500 IU per cup).                      May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dried (i.e., powder) (21 CFR 131.147).<sup>2</sup></p>
Goat milk .....	<p>Cultured Milks. Must conform to FDA standard of identity for cultured milk (21 CFR 131.112—cultured buttermilk, kefir cultured milk, acidophilus cultured milk).                      Must conform to FDA standard of identity for whole, reduced fat, low-fat, or non-fat milks (21 CFR part 131). Must be pasteurized and contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2000 IU of vitamin A per quart (500 IU per cup) following FDA fortification standards (21 CFR part 131). May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dried (i.e., powdered) (21 CFR 131.147).<sup>2</sup></p>
Cheese .....	<p>Domestic cheese made from 100 percent pasteurized milk. Must conform to FDA standard of identity (21 CFR Part 133); Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, part-skim or whole Mozzarella, pasteurized processed American, or blends of any of these cheeses are authorized.                      Cheeses that are labeled low, free, reduced, less or light in the nutrients of sodium, fat or cholesterol are WIC-eligible.<sup>3</sup></p>
Tofu .....	<p>Calcium-set tofu prepared with only calcium salts (e.g., calcium sulfate). May not contain added fats, sugars, oils, or sodium.</p>
Soy-based beverage .....	<p>Must be fortified to meet the following nutrient levels: 276 mg calcium per cup, 8 g protein per cup, 500 IU vitamin A per cup, 100 IU vitamin D per cup, 24 mg magnesium per cup, 222 mg phosphorus per cup, 349 mg potassium per cup, 0.44 mg riboflavin per cup, and 1.1 mcg vitamin B12 per cup, in accordance with fortification guidelines issued by FDA.</p>
Juice .....	<p>Must be pasteurized 100% unsweetened fruit juice. Must conform to FDA standard of identity (21 CFR part 146) or vegetable juice must conform to FDA standard of identity (21 CFR part 156) and contain at least 30 mg of vitamin C per 100 mL of juice. With the exception of 100 percent citrus juices, State agencies must verify the vitamin C content of all State-approved juices. Juices that are fortified with other nutrients may be allowed at the State agency's option. Juice may be fresh, from concentrate, frozen, canned, or shelf-stable.                      Vegetable juice may be regular or lower in sodium.<sup>3</sup></p>
Eggs .....	<p>Fresh shell domestic hens' eggs or dried eggs mix (must conform to FDA standard of identity in 21 CFR 160.105) or pasteurized liquid whole eggs (must conform to FDA standard of identity in 21 CFR 160.115).                      Hard boiled eggs, where readily available for purchase in small quantities, may be provided for homeless participants.</p>
Breakfast cereal .....	<p>Breakfast cereals as defined by FDA in 21 CFR 170.3(n)(4) for ready-to-eat and instant and regular hot cereals.                      Must contain a minimum of 28 mg iron per 100 g dry cereal.                      Must contain ≤ 21.2 g sucrose and other sugars per 100 g dry cereal (≤ 6 g per dry oz).                      At least half of the cereals authorized on a State agency's food list must have whole grain as the primary ingredient by weight AND meet labeling requirements for making a health claim as a "whole grain food with moderate fat content":<sup>4</sup></p>
Fruits and Vegetables (fresh and processed) ....	<p>(1) Contain a minimum of 51% whole grains (using dietary fiber as the indicator);                      (2) Meet the regulatory definitions for "low saturated fat" at 21 CFR 101.62 (≤ 1 g saturated fat per RACC) and "low cholesterol" (≤ 20 mg cholesterol per RACC);                      (3) Bear quantitative trans fat labeling; and                      (4) Contain ≤ 6.5 g total fat per RACC and ≤ 0.5 g trans fat per RACC.                      Any variety of fresh whole or cut fruit without added sugars.<sup>5</sup>                      Any variety of fresh whole or cut vegetable, except white potatoes, without added sugars, fats, or oils (orange yams and sweet potatoes are allowed).<sup>5</sup></p>

TABLE 4.—MINIMUM REQUIREMENTS AND SPECIFICATIONS FOR SUPPLEMENTAL FOODS—Continued

Categories/foods	Minimum requirements and specifications
	Any variety of canned <sup>6</sup> fruits (must conform to FDA standard of identity (21 CFR part 145); including applesauce, juice pack or water pack without added sugars, fats, oils, or salt (i.e. sodium). Any variety of frozen fruits without added sugars. <sup>7</sup> Any variety of canned <sup>6</sup> or frozen vegetables (must conform to FDA standard of identity (21 CFR part 155)) except white potatoes (orange yams and sweet potatoes are allowed); without added sugars, fats, or oils. May be regular or lower in sodium. <sup>3 thnsp:7</sup> Any type of dried fruits or dried vegetable without added sugars, fats, oils, or salt (i.e., sodium). <sup>5</sup>
Whole wheat bread/Whole grain bread/Other whole unprocessed grains.	<p style="text-align: center;"><i>Bread</i></p> Whole wheat bread must conform to FDA standard of identity (21 CFR 136.180). (Includes whole wheat buns and rolls.) AND Whole wheat must be the primary ingredient by weight in all whole wheat bread products. Whole grain bread must meet labeling requirements for making a health claim as a “whole grain food with moderate fat content”: <sup>4</sup> (1) Contain a minimum of 51% whole grains (using dietary fiber as the indicator); (2) Meet the regulatory definitions for “low saturated fat” at 21 CFR 101.62 (≤ 1 g saturated fat per RACC) and “low cholesterol” (≤ 20 mg cholesterol per RACC); (3) Bear quantitative trans fat labeling; and (4) Contain ≤ 6.5 g total fat per RACC and ≤ 0.5 g trans fat per RACC. AND Whole grain must be the primary ingredient by weight in all whole grain bread products. <p style="text-align: center;"><i>Other Whole Unprocessed Grains</i></p> Brown rice, bulgur (cracked wheat), oatmeal, and whole-grain barley without added sugars, fats, oils, or salt (i.e., sodium). May be instant-, quick-, or regular-cooking. Soft corn or whole wheat tortillas may be allowed at the State agency’s option. Whole grain must be the primary ingredient by weight.
Canned fish <sup>6</sup> .....	Canned only: Light tuna (must conform to FDA standard of identity (21 CFR 161.190)); Salmon (must conform to FDA standard of identity (21 CFR 161.170)); Sardines; Mackerel (N. Atlantic Scomber scombrus, or Chub Pacific Scomber japonicus); May be packed in water or oil. Pack may include bones or skin. May be regular or lower in sodium content. <sup>3</sup>
Mature legumes (dry beans and peas) .....	Any type of mature dry beans, peas, or lentils in dry-packaged or canned <sup>6</sup> forms. Examples include but are not limited to black beans (“turtle beans”), blackeye peas (cowpeas of the blackeye variety, “cow beans”), garbanzo beans (chickpeas), great northern beans, kidney beans, lima beans (“butter beans”), navy beans, pinto beans, soybeans, split peas, and lentils. All categories exclude soups. May not contain added sugars, fats, oils or meat as purchased. Canned legumes may be regular or lower in sodium content. <sup>3 thnsp:8</sup> Baked beans may be provided for participants with limited cooking facilities. <sup>8</sup>
Peanut butter .....	Peanut butter and reduced fat peanut butter (must conform to FDA Standard of Identity (21 CFR 164.150)); creamy or chunky, regular or reduced fat, salted or unsalted <sup>3</sup> forms are allowed.
Infant Foods: Infant cereal .....	Infant cereal must contain a minimum of 45 mg of iron per 100 g of dry cereal. <sup>9</sup> Any variety of single ingredient commercial infant food fruit without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced. <sup>10</sup> Any variety of single ingredient commercial infant food vegetables without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced. <sup>11</sup> Any variety of commercial infant food meat or poultry, as a single major ingredient, with added broth or gravy. Added sugars or salt (i.e. sodium) are not allowed. Texture may range from pureed through diced. <sup>12</sup>

Table 4 Footnotes: FDA = Food and Drug Administration of the U.S. Department of Health and Human Services; RACC = reference amount customarily consumed.

<sup>1</sup> The following are not considered a WIC eligible medical food: Formulas used solely for the purpose of enhancing nutrient intake, managing body weight, addressing picky eaters or used for a condition other than a qualifying condition (e.g., vitamin pills, weight control products, etc.); medicines or drugs, as defined by the Food, Drug and Cosmetic Act (21 U.S.C. 350a) as amended; enzymes, herbs, or botanicals; oral rehydration fluids or electrolyte solutions; flavoring or thickening agents; and feeding utensils or devices (e.g., feeding tubes, bags, pumps) designed to administer a WIC-eligible formula.

<sup>2</sup> All authorized milks must confirm to FDA, DHHS standards of identity for milks as defined by 21 CFR part 131 and meet WIC’s requirements for vitamin fortification as stated above. Additional authorized milks include, but are not limited to: calcium-fortified, lactose-reduced and lactose-free, acidified, and UHT pasteurized milks. Other milks are permitted at the State agency’s discretion provided that the State agency determines that the milk meets the minimum requirements for authorized milk.

<sup>3</sup> Any of the following lower sodium forms are allowable:  
*Sodium-free*—less than 5 mg sodium per serving;  
*Very low sodium*—35 mg sodium or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 35 mg sodium or less per 50 g of the food;  
*Low-sodium*—140 mg sodium or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 140 mg sodium or less per 50 g of the food;  
*Light in sodium*—at least 50 percent less sodium per serving than average reference amount for same food with no sodium reduction;  
*Lightly salted*—at least 50 percent less sodium per serving than reference amount (If the food is not “low in sodium,” the statement “not a low-sodium food” must appear on the same panel as the Nutrition Facts panel.); and

*Reduced or less sodium*—at least 25 percent less sodium per serving than reference food.

<sup>4</sup> Food and Drug Administration (FDA), *Health Claim Notification for Whole Grain Foods with Moderate Fat Content* at <http://www.cfsan.fda.gov/~dms/flgrain2.html>

<sup>5</sup> Herbs or spices; edible blossoms and flowers, e.g., squash blossoms (broccoli, cauliflower and artichokes are allowed); creamed or sauced vegetables; vegetable-grain (pasta or rice) mixtures; fruit-nut mixtures; breaded vegetables; fruits and vegetables for purchase on salad bars; peanuts; ornamental and decorative fruits and vegetables such as chili peppers on a string; garlic on a string; gourds; painted pumpkins; fruit baskets and party vegetable trays; and items such as blueberry muffins and other baked goods are not authorized. Mature legumes (dry beans and peas) and juices are provided as separate food WIC categories and are not authorized under the fruit and vegetable category.

<sup>6</sup> "Canned" refers to processed food items in cans or other shelf-stable containers, e.g., jars, pouches.

<sup>7</sup> Excludes white potatoes; catsup or other condiments; pickled vegetables, olives; soups; juices; and fruit leathers and fruit roll-ups.

<sup>8</sup> The following canned mature legumes are not authorized: soups; immature varieties of legumes, such as those used in canned green peas, green beans, snap beans, orange beans, and wax beans; baked beans with meat; e.g., beans and franks; and beans containing added sugars (with the exception of baked beans), fats, meat, or oils.

<sup>9</sup> Infant cereals containing infant formula, milk, fruit, or other non-cereal ingredients are not allowed.

<sup>10</sup> Mixtures with cereal or infant food desserts (e.g., peach cobbler) are not authorized; however, combinations of single ingredients (e.g., apple-banana) are allowed.

<sup>11</sup> Combinations of single ingredients (e.g., peas and carrots) are allowed.

<sup>12</sup> No infant food combinations (e.g., meat and vegetables) or dinners (e.g., spaghetti and meatballs) are allowed.

(f) *USDA purchase of commodity foods.* (1) At the request of a State agency, FNS may purchase commodity foods for the State agency using funds allocated to the State agency. The commodity foods purchased and made available to the State agency must be equivalent to the foods specified in Table 4 of paragraph (e)(12) of this section.

(2) The State agency must:

(i) Distribute the commodity foods to its local agencies or participants; and

(ii) Ensure satisfactory storage facilities and conditions for the commodity foods, including documentation of proper insurance.

(g) *Infant formula manufacturer registration.* Infant formula manufacturers supplying formula to the WIC Program must be registered with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). Such manufacturers wishing to bid for a State contract to supply infant formula to the program must certify with the State health department that their formulas comply with the Federal Food, Drug, and Cosmetic Act and regulations issued pursuant to the Act.

(h) *Rounding up.* State agencies may round up to the next whole container for either infant formula or infant foods (infant cereal, fruits, vegetables and meat). State agencies that use the rounding up option must calculate the amount of infant formula or infant foods provided according to the requirements and methodology as described in this section.

(1) *Infant Formula.* State agencies must use the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate infant formula as specified in Table 1 of paragraph (e)(9) of this section as the full nutritional benefit (FNB) provided by infant formula for each food package category and infant feeding option (e.g., Food Package I A fully formula fed, IA–FF).

(i) For State agencies that use rounding up of infant formula, the FNB

is determined over the timeframe (the number of months) that the participant receives the food package. In any given month of the timeframe, the monthly issuance of reconstituted fluid ounces of infant formula may exceed the maximum monthly allowance or fall below the FNB; however, the cumulative average over the timeframe may not fall below the FNB. In addition, the State agency must:

(A) Use the methodology described in paragraph (h)(1)(ii) of this section for calculating and dispersing the rounding up option;

(B) Issue infant formula in whole containers that are all the same size; and

(C) Disperse the number of whole containers as evenly as possible over the timeframe with the largest monthly issuances given in the beginning of the timeframe.

(ii) The methodology to calculate rounding up and dispersing infant formula to the next whole container over the food package timeframe is as follows:

(A) Multiply the FNB amount for the appropriate food package and feeding option (e.g. Food Package I A fully formula fed, IA–FF) by the timeframe the participant will receive the food package to determine the total amount of infant formula to be provided.

(B) Divide the total amount of infant formula to be provided by the yield of the container (in reconstituted fluid ounces) issued by the State agency to determine the total number of containers to be issued during the timeframe that the food package is prescribed.

(C) If the number of containers to be issued does not result in a whole number of containers, the State agency must round up to the next whole container in order to issue whole containers.

(2) *Infant foods.* (i) State agencies may use the rounding up option to the next whole container of infant food (infant cereal, fruits, vegetables and meats)

when the maximum monthly allowance cannot be issued due to varying container sizes of authorized infant foods.

(ii) State agencies that use the rounding up option for infant foods must:

(A) Use the methodology described in paragraph (h)(2)(iii) of this section for calculating and dispersing the rounding up option;

(B) Issue infant foods in whole containers; and

(C) Disperse the number of whole containers as evenly as possible over the timeframe (the number of months the participant will receive the food package).

(iii) The methodology to round up and disperse infant food is as follows:

(A) Multiply the maximum monthly allowance for the infant food by the timeframe the participant will receive the food package to determine the total amount of food to be provided.

(B) Divide the total amount of food provided by the container size issued by the State agency (e.g., ounces) to determine the total number of food containers to be issued during the timeframe that the food package is prescribed.

(C) If the number of containers to be issued does not result in a whole number of containers, the State agency must round up to the next whole container in order to issue whole containers.

(i) *Plans for substitutions.* (1) The State agency may submit to FNS a plan for substitution of food(s) acceptable for use in the Program to allow for different cultural eating patterns. The plan shall provide the State agency's justification, including a specific explanation of the cultural eating pattern and other information necessary for FNS to evaluate the plan as specified in paragraph (i)(2) of this section.

(2) FNS will evaluate a State agency's plan for substitution of foods for different cultural eating patterns based on the following criteria:

(i) Any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace.

(ii) The proposed substitute food must be widely available to participants in the areas where the substitute is intended to be used.

(iii) The cost of the substitute food must be equivalent to or less than the cost of the food it is intended to replace.

(3) FNS will make a determination on the proposed plan based on the evaluation criteria specified in paragraph (i)(2) of this section, as appropriate. The State agency shall substitute foods only after receiving the written approval of FNS.

■ 6. In § 246.12:

■ a. Revise the second sentence of paragraph (a)(1).

■ b. Amend paragraphs (e), (f)(2)(i), (f)(2)(ii), (f)(2)(iv), (h)(3)(ix), (k)(2), and (k)(3), by removing the words “food instrument” wherever they appear and adding in their place the words “food instrument or cash-value voucher”;

■ c. Amend paragraphs (h)(3)(i), (h)(3)(xv), and (i)(2), by removing the words “food instruments” wherever they appear and adding in their place the words “food instruments and cash-value vouchers”;

■ d. Amend paragraphs (l)(1)(i), (l)(1)(ii)(B), (l)(1)(iii)(A), (l)(1)(iii)(D), and (l)(1)(iii)(F), by removing the words “food instruments” wherever they appear and adding in their place the words “food instruments or cash-value vouchers”;

■ e. Revise the heading of paragraph (f), paragraph (f)(1), paragraph (f)(2) introductory text, paragraphs (f)(2)(iii), (f)(3), (g)(3)(i), (h)(3)(ii), and (h)(3)(iv) through (h)(3)(vi), (h)(3)(x), and paragraphs (k)(1), (k)(5), and (o) through (s);

■ f. Amend paragraph (t) by removing the word “vendor” and adding in its place the words “vendor, farmer”;

■ g. Add a new paragraph (v).

The addition and revisions read as follows:

**§ 246.12 Food delivery systems.**

(a) \* \* \*

(1) \* \* \* The State agency may permit only authorized vendors and farmers, home food delivery contractors, and direct distribution sites to accept food instruments and cash-value vouchers.

\* \* \* \* \*

(f) *Retail food delivery systems: Food instrument and cash-value voucher requirements*—(1) *General.* State agencies using retail food delivery systems must use food instruments and cash-value vouchers that comply with

the requirements of paragraph (f)(2) of this section.

(2) *Printed food instruments and cash-value vouchers.* Each printed food instrument and cash-value voucher must clearly bear on its face the following information:

\* \* \* \* \*

(iii) *Last date of use.* The last date on which the food instrument or cash-value vouchers may be used to obtain authorized supplemental foods. This date must be a minimum of 30 days from the first date on which it may be used, except for the participant’s first month of issuance, when it may be the end of the month or cycle for which the food instrument or cash-value voucher is valid. Rather than entering a specific last date of use on each instrument or cash-value voucher, all instruments or cash-value vouchers may be printed with a notice that the participant must transact them within a specified number of days after the first date on which the food instrument or cash-value voucher may be used;

\* \* \* \* \*

(3) *Vendor identification.* The State agency must implement procedures to ensure each food instrument and cash-value voucher submitted for redemption can be identified by the vendor or farmer that submitted the food instrument or cash-value voucher. Each vendor operated by a single business entity must be identified separately. The State agency may identify vendors by requiring that all authorized vendors stamp their names and/or enter a vendor identification number on all food instruments or cash-value vouchers prior to submitting them for redemption.

(g) \* \* \*

(3) \* \* \*

(i) *Minimum variety and quantity of supplemental foods.* The State agency must establish minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized. These requirements include that the vendor stock at least two varieties of fruits, two varieties of vegetables, and at least one whole grain cereal authorized by the State agency. The State agency may not authorize a vendor applicant unless it determines that the vendor applicant meets these minimums. The State agency may establish different minimums for different vendor peer groups.

\* \* \* \* \*

(h) \* \* \*

(3) \* \* \*

(ii) *No substitutions, cash, credit, refunds, or exchanges.* The vendor may

provide only the authorized supplemental foods listed on the food instrument and cash-value voucher. The vendor may not provide unauthorized food items, non-food items, cash, or credit (including rainchecks) in exchange for food instruments or cash-value vouchers. The vendor may not provide refunds or permit exchanges for authorized supplemental foods obtained with food instruments or cash-value vouchers, except for exchanges of an identical authorized supplemental food item when the original authorized supplemental food item is defective, spoiled, or has exceeded its “sell by,” “best if used by,” or other date limiting the sale or use of the food item. An identical authorized supplemental food item means the exact brand and size as the original authorized supplemental food item obtained and returned by the participant.

\* \* \* \* \*

(iv) *Time periods for transacting food instruments and cash-value vouchers.*

The vendor may accept a food instrument or cash-value voucher only within the specified time period.

(v) *Purchase price on food instruments and cash-value vouchers.*

The vendor must ensure that the purchase price is entered on food instruments and cash-value vouchers in accordance with the procedures described in the vendor agreement. The State agency has the discretion to determine whether the vendor or the participant enters the purchase price. The purchase price must include only the authorized supplemental food items actually provided and must be entered on the food instrument or cash-value voucher before it is signed.

(vi) *Signature on food instruments and cash-value vouchers.* For printed food instruments and cash-value vouchers, the vendor must ensure the participant, parent or caretaker of an infant or child participant, or proxy signs the food instrument or cash-value voucher in the presence of the cashier. In EBT systems, a Personal Identification Number (PIN) may be used in lieu of a signature.

\* \* \* \* \*

(x) *No charge for authorized supplemental foods or restitution from participants.* The vendor may not charge participants, parents or caretakers of infant and child participants, or proxies for authorized supplemental foods obtained with food instruments or cash-value vouchers. In addition, the vendor may not seek restitution from these individuals for food instruments or cash-value vouchers not paid or partially paid by the State agency. The

State agency may, however, allow participants, parents or caretakers of child participants to pay the difference when the purchase of authorized fruits and vegetables exceeds the value of the cash-value voucher.

\* \* \* \* \*

(k) \* \* \*

(1) *System to review food instruments and cash-value vouchers for vendor claims.* The State agency must design and implement a system to review food instruments and cash-value vouchers submitted by vendors for redemption to ensure compliance with the applicable price limitations and to detect questionable food instruments or cash-value vouchers, suspected vendor overcharges, and other errors. This review must examine either all or a representative sample of the food instruments and cash-value vouchers and may be done either before or after the State agency makes payments on the food instruments or cash-value vouchers. The review of food instruments must include a price comparison or other edit designed to ensure compliance with the applicable price limitations and to assist in detecting vendor overcharges. For printed food instruments and cash-value vouchers the system also must detect the following errors—purchase price missing; participant, parent/caretaker, or proxy signature missing; vendor identification missing; food instruments or cash-value vouchers transacted or redeemed after the specified time periods; and, as appropriate, altered purchase price. The State agency must take follow-up action within 120 days of detecting any questionable food instruments or cash-value vouchers, suspected vendor overcharges, and other errors and must implement procedures to reduce the number of errors when possible.

\* \* \* \* \*

(5) *Food instruments and cash-value vouchers redeemed after the specified period.* With justification and documentation, the State agency may pay vendors for food instruments and cash-value vouchers submitted for redemption after the specified period for redemption. If the total value of such food instruments or cash-value vouchers submitted at one time exceeds \$500.00, the State agency must obtain the approval of the FNS Regional Office before payment.

\* \* \* \* \*

(o) *Participant, parent/caretaker, proxy, vendor, farmer and home food delivery contractor complaints.* The State agency must have procedures to document the handling of complaints by

participants, parents or caretakers of infant or child participants, proxies, vendors, farmers, home food delivery contractors, and direct distribution contractors. Complaints of civil rights discrimination must be handled in accordance with § 246.8(b).

(p) *Food instrument and cash-value voucher security.* The State agency must develop standards for ensuring the security of food instruments and cash-value vouchers from the time the food instruments and cash-value vouchers are created to the time they are issued to participants, parents/caretakers, or proxies. For pre-printed food instruments or cash-value vouchers, these standards must include maintenance of perpetual inventory records of food instruments or cash-value vouchers throughout the State agency's jurisdiction; monthly physical inventory of food instruments or cash-value vouchers on hand throughout the State agency's jurisdiction; reconciliation of perpetual and physical inventories of food instruments and cash-value vouchers; and maintenance of all food instruments and cash-value vouchers under lock and key, except for supplies needed for immediate use. For EBT and print-on-demand food instruments and cash-value vouchers, the standards must provide for the accountability and security of the means to manufacture and issue such food instruments and cash-value vouchers.

(q) *Food instrument and cash-value voucher disposition.* The State agency must account for the disposition of all food instruments and cash-value vouchers as either issued or voided, and as either redeemed or unredeemed. Redeemed food instruments and cash-value vouchers must be identified as validly issued, lost, stolen, expired, duplicate, or not matching valid enrollment and issuance records. In an EBT system, evidence of matching redeemed food instruments to valid enrollment and issuance records may be satisfied through the linking of the Primary Account Number (PAN) associated with the electronic transaction to valid enrollment and issuance records. This process must be performed within 120 days of the first valid date for participant use of the food instruments and must be conducted in accordance with the financial management requirements of § 246.13. The State agency will be subject to claims as outlined in § 246.23(a)(4) for redeemed food instruments or cash-value vouchers that do not meet the conditions established in paragraph (q) of this section.

(r) *Issuance of food instruments, cash-value vouchers and authorized*

*supplemental foods.* The State agency must:

(1) *Parents/caretakers and proxies.* Establish uniform procedures that allow parents and caretakers of infant and child participants and proxies to obtain and transact food instruments and cash-value vouchers or obtain authorized supplemental foods on behalf of a participant. In determining whether a particular participant or parent/caretaker should be allowed to designate a proxy or proxies, the State agency must require the local agency or clinic to consider whether adequate measures can be implemented to provide nutrition education and health care referrals to that participant or, in the case of an infant or child participant, to the participant's parent or caretaker;

(2) *Signature requirement.* Ensure that the participant, parent or caretaker of an infant or child participant, or proxy signs for receipt of food instruments, cash-value vouchers or authorized supplemental foods, except as provided in paragraph (r)(4) of this section;

(3) *Instructions.* Ensure that participants, parents or caretakers of infant and child participants, and proxies receive instructions on the proper use of food instruments and cash-value vouchers, or on the procedures for obtaining authorized supplemental foods when food instruments or cash-value vouchers are not used. The State agency must also ensure that participants, parents or caretakers of infant and child participants, and proxies are notified that they have the right to complain about improper vendor, farmer and home food delivery contractor practices with regard to program responsibilities;

(4) *Food instrument and cash-value voucher pick up.* Require participants, parents and caretakers of infant and child participants, and proxies to pick up food instruments and cash-value vouchers in person when scheduled for nutrition education or for an appointment to determine whether participants are eligible for a second or subsequent certification period. However, in all other circumstances the State agency may provide for issuance through an alternative means such as EBT or mailing, unless FNS determines that such actions would jeopardize the integrity of program services or program accountability. If a State agency opts to mail food instruments and cash-value vouchers, it must provide justification, as part of its alternative issuance system in its State Plan, as required in § 246.4(a)(21), for mailing food instruments and cash-value voucher to areas where food stamps are not mailed. State agencies that opt to mail food

instruments and cash-value vouchers must establish and implement a system that ensures the return of food instruments and cash-value vouchers to the State or local agency if a participant no longer resides or receives mail at the address to which the food instruments and cash-value vouchers were mailed; and

(5) *Maximum issuance of food instruments and cash-value voucher.* Ensure that no more than a three-month supply of food instruments and cash-value vouchers or a one-month supply of authorized supplemental foods is issued at any one time to any participant, parent or caretaker of an infant or child participant, or proxy.

(s) *Payment to vendors, farmers and home food delivery contractors.* The State agency must ensure that vendors, farmers and home food delivery contractors are paid promptly. Payment must be made within 60 days after valid food instruments or cash-value vouchers are submitted for redemption. Actual payment to vendors, farmers and home food delivery contractors may be made by local agencies.

\* \* \* \* \*

(v) *Farmers.* The State agency may authorize farmers at farmers markets (or roadside stands) to accept the cash-value voucher for eligible fruits and vegetables. The State agency must enter into written agreements with all authorized farmers. The agreement must be signed by a representative who has legal authority to obligate the farmer and a representative of the State agency. The agreement must be for a period not to exceed three years. Only farmers authorized by the State agency may redeem the fruit and vegetable cash-value voucher. The State agency must require farmers to reapply at the expiration of their agreements and must provide farmers with not less than 15 days advance written notice of the expiration of the agreement.

(1) The agreement must include the following provisions, although the State agency may determine the exact wording. The farmer must:

(i) Assure that the cash-value voucher is redeemed only for eligible fruits and vegetables as defined by the State agency;

(ii) Provide eligible fruits and vegetables at the current price or less than the current price charged to other customers;

(iii) Accept the cash-value voucher within the dates of their validity and submit such vouchers for payment within the allowable time period established by the State agency;

(iv) Redeem the cash-value voucher in accordance with a procedure established by the State agency;

(v) Accept training on cash-value voucher procedures and provide training to any employees with cash-value voucher responsibilities on such procedures;

(vi) Agree to be monitored for compliance with program requirements, including both overt and covert monitoring;

(vii) Be accountable for actions of employees in the provision of authorized foods and related activities;

(viii) Pay the State agency for any cash-value vouchers transacted in violation of this agreement;

(ix) Offer WIC participants, parent or caretakers of child participants or proxies the same courtesies as other customers;

(x) Comply with the nondiscrimination provisions of USDA regulations as provided in § 248.7; and

(xi) Notify the State agency if any farmers' market ceases operation prior to the end of the authorization period.

(2) The farmer must not:

(i) Collect sales tax on cash-value voucher purchases;

(ii) Seek restitution from WIC participants, parent or caretakers of child participants or proxies for cash-value vouchers not paid or partially paid by the State agency;

(iii) Issue cash change for purchases that are in an amount less than the value of the cash-value voucher;

(3) Neither the State agency nor the farmer has an obligation to renew the agreement. Either the State agency or the farmer may terminate the agreement for cause after providing advance written notification.

(4) The State agency may deny payment to the farmer for improperly redeemed cash-value vouchers and may demand refunds for payments already made on improperly redeemed vouchers.

(5) The State agency may disqualify a farmer for WIC Program abuse. The farmer has the right to appeal a denial of an application to participate, a disqualification, or a program sanction by the State agency. Expiration of an agreement with a farmer and claims actions under § 246.23, are not appealable.

(6) A farmer which commits fraud or engages in other illegal activity is liable to prosecution under applicable Federal, State or local laws.

■ 7. In § 246.16, add a new paragraph (j) to read as follows:

**§ 246.16 Distribution of funds.**

\* \* \* \* \*

(j) *Inflation adjustment of the fruit and vegetable voucher.* The monthly cash value of the fruit and vegetable voucher shall be adjusted annually for inflation. Adjustments are effective the first day of each fiscal year beginning on or after October 1, 2008. The inflation-adjusted value of the voucher shall be equal to a base value increased by a factor based on the Consumer Price Index for fresh fruits and vegetables, as provided in this section.

(1) *Adjustment year.* The adjustment year is the fiscal year that begins October 1 of the current calendar year.

(2) *Base value of the fruit and vegetable voucher.* The base value of the fruit and vegetable voucher is the monthly cash value of the voucher for fiscal year 2008. The base value equals:

(i) \$6 for children;

(ii) \$8 for pregnant and postpartum women; and

(iii) \$10 for breastfeeding women.

(3) *Adjusted value of the fruit and vegetable voucher.* The adjusted value of the fruit and vegetable voucher is the cash value of the voucher for adjustment years beginning on or after October 1, 2008. The adjusted value is the base value increased by an amount equal to the base value of the fruit and vegetable voucher:

(i) Multiplied by the inflation adjustment described in paragraph (j)(4) of this section; and

(ii) Subject to rounding as described in paragraph (j)(5) of this section.

(4) *Inflation adjustment.* The inflation adjustment of the fruit and vegetable voucher shall equal the percentage (if any) by which the annual average value of the Consumer Price Index for fresh fruits and vegetables, computed from monthly values published by the Bureau of Labor Statistics, for the twelve months ending on March 31 of the fiscal year immediately prior to the adjustment year, exceeds the average of the monthly values of that index for the twelve months ending on March 31, 2007.

(5) *Rounding.* If any increase in the cash value of the voucher determined under paragraph (j)(3) of this section is not a multiple of \$1, such increase shall be rounded to the next lowest multiple of \$1. However, if the adjusted value of the voucher for the adjustment year, as determined under paragraph (j)(3) of this section, is lower than the adjusted value for the fiscal year immediately prior to the adjustment year, then the adjusted value of the voucher will remain unchanged from that immediate prior fiscal year.

■ 8. In § 246.18:

■ a. Amend paragraph (a)(1)(iii)(G) by removing the words "food instrument"

and adding in their place the words “food instrument or cash-value voucher”;

- b. Add a new paragraph (a)(4);
- c. Revise the introductory text of paragraph (b);
- d. Amend paragraph (d) by removing the words “local agency or a vendor” and adding in their place the words “local agency, farmer or vendor”;
- e. Amend paragraph (e) by removing the words “vendor or the local agency” and adding in their place the words “vendor, farmer or local agency”; and
- f. Amend paragraph (f) by removing the words “vendor or local agency” wherever they appear and adding in their place the words “vendor, farmer or local agency”.

The addition and revision read as follows:

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

(a) \* \* \*

(4) *Farmer appeals*—(i) *Adverse Actions*. The State agency shall provide a hearing procedure whereby farmers adversely affected by certain actions of the State agency may appeal those actions. A farmer may appeal an action of the State agency denying its application to participate, imposing a sanction, or disqualifying it from participation in the program. Expiration of an agreement is not subject to appeal.

(ii) *Effective date of adverse actions against farmers*. The State agency must make denials of authorization and disqualifications effective on the date of receipt of the notice of adverse action. The State agency must make all other adverse actions effective no earlier than 15 days after the date of the notice of the adverse action and no later than 90 days after the date of the notice of adverse action or, in the case of an adverse action that is subject to administrative review, no later than the date the farmer receives the review decision.

(b) *Full administrative review procedures*. The State agency must develop procedures for a full administrative review of the adverse actions listed in paragraphs (a)(1)(i), (a)(3) and (a)(4) of this section. At a minimum, these procedures must provide the vendor, farmer or local agency with the following:

- 9. In § 246.23, revise paragraph (a)(4) to read as follows:

**§ 246.23 Claims and penalties.**

(a) \* \* \*

(4) FNS will establish a claim against any State agency that has not accounted for the disposition of all redeemed food instruments and cash-value vouchers

and taken appropriate follow-up action on all redeemed food instruments and cash-value vouchers that cannot be matched against valid enrollment and issuance records, including cases that may involve fraud, unless the State agency has demonstrated to the satisfaction of FNS that it has:

- (i) Made every reasonable effort to comply with this requirement;
- (ii) Identified the reasons for its inability to account for the disposition of each redeemed food instrument or cash-value voucher; and
- (iii) Provided assurances that, to the extent considered necessary by FNS, it will take appropriate actions to improve its procedures.

\* \* \* \* \*

Dated: November 21, 2007.

**Nancy Montanez Johner,**  
*Under Secretary for Food, Nutrition and Consumer Services.*

**Appendix**

**Note:** This appendix will not be published in the Code of Federal Regulations.

**Regulatory Impact Analysis**

*7 CFR Part 246: Special Supplemental Nutrition Program for Women, Infants, and Children (WIC): Revisions in the WIC Food Packages*

Interim Rule

**Executive Summary**

The WIC program addresses the supplemental nutritional needs of at-risk groups through the distribution of supplemental food packages, and a program of nutrition education that includes counseling, health and social service referrals, and breastfeeding promotion and support. WIC nutrition education provisions are governed by broad regulatory language that allows nutrition education provided to participants to respond to the supplemental nutrition needs of participants in light of changes in dietary and health research. In contrast, WIC supplemental food packages are defined very specifically in regulatory language. Consequently, as the population served by WIC has grown and become more diverse over the last 27 years and as food consumption habits have changed, the nutritional risks faced by participants have changed. Also, though nutrition science has advanced, the WIC supplemental food packages have remained largely unchanged.

The interim rule modifies regulations governing the WIC food packages to implement recommended changes based on the current supplemental nutritional needs of WIC participants and advances in nutrition science. Specifically, the interim rule: revises the maximum monthly allowances and minimum requirements for certain supplemental foods; revises the substitution rates for certain supplemental foods and allows additional foods as alternatives; revises age specifications for assignment to infant food packages; modifies food packages

to promote breastfeeding; adds foods to children and women food packages; and, addresses general provisions that apply to all food packages. The revisions reflect recommendations made by the Institute of Medicine of the National Academies in its Report *WIC Food Packages: Time for a Change*, comments received on the Proposed Rule published in the **Federal Register** on August 7, 2006 (71 FR 44784), and certain administrative revisions found necessary by the Department.

The revisions also bring the WIC food packages in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics to: better promote and support the establishment of successful long-term breastfeeding; provide WIC participants with a wider variety of food; provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences; and, serve all participants with certain medical provisions under one food package to facilitate efficient management of participants with special dietary needs.

This impact analysis specifically addresses significant or substantial public comments and Department modifications from the provisions as initially proposed in the Proposed Rule. Unless otherwise stated, the provisions stated in the impact analysis for the Proposed Rule should be regarded as the basis for the impact analysis of the interim rule. Under the interim rule, revisions to the WIC food packages are cost-neutral to the Federal Government. Specifically, FNS estimates that the changes will decrease costs by \$29.7 million over five years, a negligible amount relative to the program’s annual cost of more than \$5 billion.

While the additional program costs from the rule change are negligible, the changes in food packages that will result represent important improvements in the program’s alignment with current dietary guidance, increase the variety and appropriateness of foods provided to clients, and better promote healthy eating behaviors. These benefits will improve the program relative to current rules for years to come.

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*Title:* 7 CFR Part 246: Special

Supplemental Nutrition Program for Women,  
 Infants, and Children (WIC): Revisions in the  
 WIC Food Packages.

#### Action

A. Nature: Interim Rule.

B. Need: The WIC program addresses the supplemental nutritional needs of at-risk groups through the distribution of age and condition specific food packages, and a program of nutrition education that includes counseling, health and social service referrals, and breastfeeding promotion and support. WIC nutrition education provisions are governed by broad regulatory language that allows nutrition education provided to participants to respond to changes in dietary and health research. In contrast, WIC supplemental food packages are defined very specifically in the regulatory language. Consequently, as the population served by WIC has grown and become more diverse over the last 27 years, the nutritional risks faced by participants have changed, and though nutrition science has advanced, the WIC supplemental food packages have remained largely unchanged. This rule is needed to implement recommended changes to the WIC food packages based on the current supplemental nutritional needs of WIC participants and advances in nutrition science.

C. Affected Parties: The program affected by this rule is the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The parties affected by this

regulation are the USDA's Food and Nutrition Service (FNS), State and local agencies that administer the WIC Program, retail vendors, food producers and manufacturers, and WIC participants.

#### Effects

The following analysis describes the potential economic impact of the interim rule. This rule is needed due to changes in the population served by WIC, and advances in nutrition and knowledge about the supplemental nutritional needs of those served by WIC. The changes in this rule are significant to the costs or overall operations to the program. The potential effects of these changes are highlighted below.

#### A. Background

The WIC program was established in the 1970s to address the special supplemental nutritional needs of low-income pregnant and postpartum women, infants, and children up to age five who are determined to be at nutritional risk. Regulations governing the WIC program recognize a broad range of nutritionally related medical conditions for purposes of establishing program eligibility. These include anemia, low birth weight, chronic infections, overweight, underweight, and similar manifestations of poor nutrition suitable for direct measurement or diagnosis.<sup>1</sup> WIC regulations also recognize that personal medical histories, dietary patterns, and economic circumstances may put otherwise healthy women or children at nutritional risk. Certification may therefore be extended to women facing high-risk pregnancies, pregnant women or mothers who abuse alcohol or drugs, homeless women and children, and infants and children with congenital malformations or other medical conditions that may interfere with adequate nutrient intake or absorption.

WIC addresses the supplemental nutritional needs of at-risk groups through the distribution of age- and condition-specific food packages, and a program of nutrition education that includes counseling, health and social service referrals, and breastfeeding promotion and support. Supplemental foods are currently offered to WIC participants in one of seven packages designed for the special supplemental nutritional needs of the following sub-populations:

- I. Infants under four months old
- II. Infants from four to twelve months old
- III. Children and women with special dietary needs
- IV. Children from one to five years old
- V. Pregnant and breastfeeding women
- VI. Non-breastfeeding postpartum women
- VII. Exclusively breastfeeding women

Inadequate nutrition was the prime motivating factor behind the enactment of the WIC program.<sup>2</sup> Nutrition research in the 1970s pointed to calcium, iron, high quality protein, and vitamins A and C as nutrients most likely to be lacking in the diets of low-income women, infants, and children. Current WIC food packages reflect that early

research. Today's packages include some combination of: iron-fortified infant formulas, iron-fortified cereals, vitamin C rich juice, vitamin A and D fortified milk, eggs, cheese, dried beans or peas, peanut butter, tuna, and carrots. Other factors that contributed to the selection of these foods are their nutrient density, modest cost, wide availability, and broad acceptance by the WIC-eligible population.

WIC's nutrition education provisions are governed by broad regulatory language that seeks to promote "proper nutrition," "optimal use" of WIC's supplemental foods, and appropriate advice concerning non-WIC foods.<sup>3</sup> Compliance with this regulatory mandate presumes that nutrition education will respond to the supplemental nutrition needs of participants based on advances in dietary and health research. The U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS) provides for provision of nutrition education to WIC participants that is consistent with the Dietary Guidelines for Americans.

The statute governing WIC directs the Secretary of Agriculture to prescribe supplemental food packages for the program.<sup>4</sup> As a result, the content of WIC food packages is defined with specificity in program regulations; the regulatory flexibility that characterizes WIC nutrition education does not extend to the prescription of individual food packages. The list of WIC-approved foods provides select, nutrient-rich foods; allowed substitutions provide only limited room for participant-specific food package tailoring.

The population served by the WIC program has grown in size and diversity over time and the frequency of nutritional risks faced by WIC participants have changed. White and Black participants represented 72% of the WIC population in 1992; by 2004, just 56% of WIC participants fell into one of those two racial/ethnic groups.<sup>5</sup> WIC's Hispanic population, itself a diverse group, has grown from the third largest to the largest over the same period. Greater ethnic diversity increases the demand for additional food options consistent with cultural preferences.

In addition, the nutritional risks faced by the low-income population of the 1970s have changed. Although inadequate intake of some nutrients remains a concern,<sup>6</sup> improved diets have reduced the prevalence of once relatively common deficiency diseases and

<sup>3</sup> 7 CFR 246.11.

<sup>4</sup> 42 U.S.C. 1786(b)(14).

<sup>5</sup> U.S. Department of Agriculture, Food and Nutrition Service, Office of Analysis, Nutrition and Evaluation, WIC Participant and Program Characteristics 1992, Abt Associates. Alexandria, VA: 1994. U.S. Department of Agriculture, Food and Nutrition Service, Office of Analysis, Nutrition and Evaluation, WIC Participant and Program Characteristics 2004, Abt Associates. Alexandria, VA: 2005. The program characteristics studies performed prior to 1992 did not include participant data from Alaska, Hawaii, Puerto Rico, or U.S. territories. The racial/ethnic breakdowns from those earlier reports should not be directly compared to the ones contained in reports from 1992 forward.

<sup>6</sup> National Academies, Institute of Medicine (IOM). *WIC Food Packages: Time for a Change*, Washington, DC: The National Academies Press, 2005. pp. 31, 64.

<sup>1</sup> 7 CFR 246.7(e).

<sup>2</sup> See 42 U.S.C. 1786(a).

underweight in at-risk groups. A WIC program that now assists nearly eight million individuals monthly, including about half of the nation's infants,<sup>7</sup> supplements the diets of an at-risk population with the very types of iron-fortified, nutrient-dense foods associated with this changed health picture. WIC's current food packages, little modified since the 1970s, were appropriately designed to address the recognized nutritional priorities of that time. But today's WIC population, like the U.S. population as a whole, faces a reordered set of priorities. Excessive intakes of some nutrients, including saturated fat, and of food energy have taken a place among the nation's top public health concerns.<sup>8</sup> Other nutrients, including vitamin E, and fiber, have since been identified as lacking in the diets of WIC-eligible sub-populations.<sup>9</sup> While current WIC food packages continue to address important health risks of undernutrition, they do not target all identified inadequacies, and they may contribute to the risks associated with excessive intake of some nutrients.

Medical consequences of improper diets include fetal or infant lead toxicity tied to low calcium intake by pregnant and breastfeeding women, birth defects caused by inadequate folate consumption early in pregnancy, iron-deficiency anemia, and heart disease, diabetes, stroke, and cancer, all linked to obesity and excessive intake of saturated fat.<sup>10</sup> Adjustments to the WIC food packages that move individual consumption of these priority nutrients closer to Recommended Dietary Allowances (RDAs) and Adequate Intake (AIs) levels of the Institute of Medicine's Dietary Reference Intakes may reduce the nutrition-related medical health risks of WIC participants.

#### B. Summary of Rule and Benefits

FNS contracted with the National Academies' Institute of Medicine (IOM) in 2003 to assess the nutritional health profile of the current WIC population, and to recommend changes in the content of the program's food packages. The Proposed Rule largely reflected recommendations made by the National Academies' Institute of Medicine (IOM) in its Report *WIC Food Packages: Time for a Change*, with certain

cost containment and administrative modification found necessary by the Department to ensure cost neutrality.

The Proposed Rule detailed the first comprehensive revisions to the WIC food packages since 1980. The revised food packages were developed to better reflect current nutrition science and dietary recommendations than do current food packages, without impacting overall program costs. Compared to current WIC packages, the proposal:

Provides greater consistency with the Dietary Guidelines for Americans. The interim rule adds fruits and vegetables, and whole grains to the packages for the first time. The revised packages include foods from each food group except oils and allow variety and choice within the groups. Reductions are made to the amounts provided for certain foods in the current packages in order to be more consistent with the amounts of these foods recommended in the 2005 Dietary Guidelines for Americans and WIC's role as a supplemental nutrition program.

Supports improved nutrient intakes. The interim rule adds additional foods and modifies amounts of current foods support overall improvement in nutrient consumption and reduction in the prevalence of inadequate or excessive nutrient intakes. Compared with the current food packages, the revised packages are estimated to provide greater amounts of nearly all the nutrients identified by the IOM as often lacking in the diets of the WIC-eligible population, such as iron, fiber, and vitamin E. The revised food packages for women and children also provide less saturated fat, cholesterol, total fat and sodium than the current packages.

Provides greater consistency with established dietary recommendations for infants and children under 2, including encouragement and support for breastfeeding. The revised infant food packages improve overall nutrient density compared to current packages while keeping caloric content the same or slightly lower. The revised packages change age specification for assignment as well as establish three feeding categories to better address current dietary recommendations of the American Academy of Pediatrics (AAP) and promote breastfeeding. The packages for breastfeeding infant-mother pairs are revised to provide stronger incentives for continued breastfeeding, including providing less formula to partially breastfed infants than current packages, and providing additional quantities/types of food for breastfeeding mothers. For older infants, the proposal delays the introduction of complementary foods, consistent with AAP, from four to six months of age and modifies formula amounts. Infant foods are added and juice eliminated in the packages for older infants in order to promote healthy dietary patterns.

Addresses Emerging Public Health Nutrition-Related Issues. The prevalence of overweight and obesity in adults, adolescents, and children have increased dramatically, with direct implications for WIC participants. For example, childhood overweight has been linked to adverse health outcomes including elevated blood pressure,

hyperinsulinemia, glucose intolerance, type 2 diabetes, dyslipidemia, and other early risks for chronic disease. The addition of fruits and vegetables and the emphasis on whole grains are consistent with recommendations for food patterns that may contribute to a healthy body weight. Compared to the current food packages, the revised food packages provide less saturated fat and cholesterol than the current packages for women and children. In addition, the revised food packages are designed to encourage breastfeeding and thus may contribute to a reduced risk of overweight in children.

Provides Wide Appeal to Diverse Populations. The proposed additional foods are the foods most often requested over the years by a variety of stakeholders such as the National WIC Association, WIC participants, WIC State and local agencies, industry and health professionals, and would provide more participant choice and a wider variety of foods than the current food packages. The increased variety and choice will provide State agencies increased flexibility in prescribing culturally appropriate food packages.

The Proposed Rule was published in the **Federal Register** on August 7, 2006 (71 FR 44784), with a 90-day comment period. A total of 46,502 comment letters were received on the Proposed Rule; of those, 23,908 were form letters. Comments were submitted by a variety of stakeholders, including program participants, WIC State and local agencies and Indian Tribal Organizations, the National WIC Association, professional organizations and associations, advocacy groups, healthcare professionals (including universities), members of Congress, the food industry, vendors, farmers, and private citizens.

With few changes, the provisions in the Proposed Rule have been adopted as this interim rule. This impact analysis specifically addresses significant or substantial public comments and Department modifications from the provisions as initially proposed. Unless otherwise stated, the provisions stated in the impact analysis for the Proposed Rule<sup>11</sup> should be regarded as the basis for the impact analysis of the interim rule. The provisions of the rule and the related changes are summarized below.

#### 1. Food Package I—Infants Under Six Months

*Proposed rule: Tie maximum infant formula prescriptions to breastfeeding practice*

- Establish fully breastfed, partially breastfed, and fully formula-fed categories, and set maximum formula allowances for each. Food Package I currently specifies a single maximum formula amount for all Package I recipients; local WIC staff may tailor the amount of formula to reflect individual participant needs, based on frequency of breastfeeding. The new rule sets a maximum formula amount for partially breastfed infants age one month and older that is roughly half the maximum provided to fully formula fed infants.

<sup>11</sup> 71 FR 44784: Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages: Proposed Rule, August 7, 2006, p. 44825.

<sup>7</sup> U.S. Department of Agriculture, Food and Nutrition Web site, July 2005. [www.fns.usda.gov/wic/FAQs/FAQ.HTM](http://www.fns.usda.gov/wic/FAQs/FAQ.HTM).

<sup>8</sup> See U.S. Department of Health and Human Services and U.S. Department of Agriculture, *Dietary Guidelines for Americans*, 2005, 6th edition, Washington DC: U.S. Government Printing Office, January 2005. (USDHHS/USDA, 2005)

<sup>9</sup> IOM, p. 59. Note, however, that these conclusions are based on self-reported food consumption data from the Continuing Survey of Food Intakes by Individuals (1994–1996 and 1998.) Underreporting of food intakes is suspected by women involved in the survey. And, the data do not include nutrients consumed in the form of dietary supplements. These factors may overstate the problem of nutrient inadequacies, and may understate the problem of excessive intakes.

<sup>10</sup> See IOM, p. 63; see also "High Costs of Poor Eating Patterns in the United States," Elizabeth Frazão, in *America's Eating Habits: Changes and Consequences*, Elizabeth Frazão, ed., Economic Research Service, U.S. Department of Agriculture, Washington, DC, 1999.

- Powder formula alone is recommended for partially breastfed infants. Powder and non-powder options remain available for fully formula fed infants.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Delay introduction of complementary foods.* Extend the age range of infants covered by Food Package I by two months. Currently, Food Package I supplements the diets of infants from birth through three months. Under the proposed rule, Food Package I would be provided to infants through five months of age. Under both the current and proposed rules, Food Package I contains no complementary foods. Extending the age range of infants served by Food Package I removes complementary foods (juice and infant cereal) from the food packages for four and five-month-old infants, which is consistent with current infant feeding practice guidelines.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Increase maximum formula prescription at four months.* Increase the maximum amount of formula allowed for four and five-month-old infants (relative to the amount allowed under current rules.)

*Interim rule: No change from Proposed Rule.*

*Proposed rule: No partially breastfed category for infants under one month.* Do not provide formula to breastfed infants under one month old. Infants under one month will be recognized as either fully breastfed or fully formula-fed. No infant will be prescribed formula in the amount specified by Food Package I for partially breastfed infants until he or she reaches one month.

*Interim rule: Provide formula to partially breastfed infants under one month.* Partially breastfed infants ages 0 through 1 month may receive the equivalent of not more than 104 fluid ounces of reconstituted infant formula, approximately one can of powder infant formula.

*Rationale:* The interim rule intends to encourage mothers to continue a practice of breastfeeding that may have begun at the hospital. However, FNS recognizes the need for States to have the flexibility to provide a small amount of formula in the first month of life, if necessary, to assist breastfeeding mothers who may otherwise choose to formula feed. Powder infant formula is recommended due to its longer shelf life and to minimize waste. Individual amounts may be tailored by a Competent Professional Authority based on the assessed needs of the breastfeeding infant.

*Proposed rule: No low iron formula.* Discontinue the prescription of low iron infant formula for infants of all ages.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Reclassify prescriptions of exempt infant formula under Package III.* Administer exempt formulas, other than those prescribed for common food allergies, under Food Package III. Currently, all infants are classified as recipients of Food Packages I or II. This proposal would simply reclassify certain Package I (and II) recipients as Package III recipients; it is not intended to alter the types of foods prescribed to infants with qualifying conditions.

*Interim rule: No change from Proposed Rule.*

## 2. Food Package II—Infants 6 Through 11 Months

*Proposed rule: Delay introduction of complementary foods.* Delay the age at which infants become eligible for Food Package II. Infants are currently made eligible for Food Package II and its complementary foods at four months of age. The proposed rule would make infants age one month or older eligible for Package II foods at six months of age.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Tie maximum formula prescription to breastfeeding practice.* Establish fully breastfed, partially breastfed, and fully formula-fed categories, and set maximum formula allowances for each. The new rule sets a maximum formula amount for partially breastfed infants that is roughly half the maximum provided to fully formula-fed infants.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Reduce maximum formula prescription amounts.* Reduce the amount of formula, relative to current rules, for partially breastfed and fully formula-fed infants.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Replace infant's juice with fruits and vegetables*

- Eliminate juice from Food Package II. Add infant food fruits and vegetables to the package. Allow fresh bananas as a substitute for a portion of the infant food fruits and vegetables.

- Provide more infant food fruits and vegetables to fully breastfed infants than to partially breastfed or fully formula-fed infants.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Provide infant food meat to fully breastfed infants.* Add infant food meat to Package II for fully breastfed infants.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: No low iron formula.* Discontinue the prescription of low iron infant formula.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Reclassify prescriptions of exempt infant formula under Package III.* Administer exempt formulas to infants under Food Package III.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Disallow prescription of infant cereal with added ingredients.* Infant cereal with added fruit, milk, formula, or other non-grain foods may not be prescribed under Food Package II.

*Interim rule: No change from Proposed Rule.*

## 3. Food Package III—Medically Fragile Participants

*Proposed rule: Administer exempt formulas to infants with qualifying conditions under Package III*

Infants with a qualifying condition (see below) who currently receive exempt infant formulas would be moved from Package I or Package II to Package III.

*Interim rule:* In addition to the provisions of the Proposed Rule, the interim rule will allow medically fragile infants 6 months of age or greater whose medical condition prevents them from consuming complementary infant foods (cereal, fruit and vegetables, and meat) to receive exempt infant formula or WIC-eligible medical foods at the same maximum monthly allowance as infants ages 4 through 5 months of the same feeding option.

*Rationale:* Comments expressed concern about medically fragile infants 6 months of age or greater whose medical condition prevents them from consuming complementary infant foods. The allowance of exempt infant formula or WIC-eligible medical foods will replace nutrition that would result from the addition of complementary foods.

*Proposal Rule: Clarify language governing Package III's purpose and scope*

- The proposed rule would provide additional guidance to States on the nature of medical conditions that qualify a WIC participant for Package III medical foods.

- Prescription of a medical food would also require additional justification and instructions by a licensed health care professional.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Make non-Package III foods available to Package III recipients.* In addition to the medical foods and exempt formulas currently prescribed to Package III recipients, the proposed rule would offer these individuals all of the foods in the packages to which they would have been eligible in the absence of their special medical needs.

*Interim rule:* No change from Proposed Rule, with the exception of whole milk. Whole milk will be authorized for children 1 through 4 years of age and women receiving Food Package III, with medical documentation.

## 4. Food Package IV—Children From Age One up to Age Five

*Proposed rule: Reduce the prescribed amount of milk; modify substitution options*

- The maximum amount of milk that may be prescribed to children would be reduced from 24 quarts to 16 quarts per month.

- Under current rules, cheese may be prescribed as a substitute for up to 12 quarts of milk. The proposed rule would allow cheese to replace up to three quarts of milk. The substitution rate of one pound of cheese for three quarts of milk would remain unchanged.

- Soy products will be allowed as a milk substitute on a restricted basis; soy may only be prescribed to children with a documented medical need.

*Interim rule:* In addition to the provisions of the Proposed Rule, the interim rule clarifies the authorization of lactose-reduced and lactose-free milk, and that these products should be offered before other authorized milk substitutes to those participants who cannot drink milk due to lactose intolerance. The interim rule also clarifies that medical documentation is not required for participants to receive lactose-reduced and lactose-free milk.

**Rationale:** The IOM emphasized the importance of milk in the diets of WIC participants, and approached the issue of milk substitutes with caution. The IOM considered and rejected the substitution of soy products for milk in the revised childrens' food package without documented medical need.

**Proposed rule: Provide only fat-reduced milk to older children.** Prescribe only fat-reduced milk to children age two and above. Prescribe only whole milk to children under age two.

**Interim rule: No change from Proposed Rule.**

**Proposed rule: Modify/clarify reconstitution rates for dry and evaporated milk.** The reconstitution rate for evaporated milk is changed from 13 to 16 ounces of evaporated milk per reconstituted quart. The reconstitution rate for powdered milk is restated in terms of fluid ounces rather than quarts; this change does not alter the reconstitution rate itself.

**Interim rule: No change from Proposed Rule.**

**Proposed rule: Reduce juice prescriptions; add fruits and vegetables.**

- Reduce monthly maximum juice prescription from 288 fluid ounces to 128. Clarify that juice must be 100% unsweetened fruit or vegetable juice, that it contain a minimum of 30 milligrams of vitamin C per 100 milliliters, and that it be pasteurized.

- Add a \$6 monthly voucher to the package for the purchase of any combination of fresh or processed fruits and vegetables other than white potatoes.

**Interim rule: No change from Proposed Rule.**

**Proposed rule: Add whole grain breads; add whole grain requirement to cereal.**

- Add two pounds of whole grain bread to the food package. Only bread meeting U.S. Food and Drug Administration (FDA) standards for whole grain labeling would be allowed.<sup>12</sup>

- Several whole grain products would be allowed as substitutions for bread. These include brown rice, bulgur, and whole grain barley without added sugar, fat, oil, or sodium. Soft corn or whole wheat tortillas would be allowed as an additional substitute at the option of State agencies. States may limit or completely eliminate substitutes if needed to control food costs.

- Require that WIC authorized breakfast cereals<sup>13</sup> meet the same whole grain requirements as bread.

**Interim rule: Revise proposed whole grain requirements.**

- The cereal whole grain requirement in the Proposed Rule will be modified to require that at least one half of the total number of breakfast cereals on a State's authorized food list meet the whole grain requirement as defined in the interim rule, and that vendors be required to stock at least one whole grain

cereal. The remaining authorized breakfast cereals are required to meet only the iron and sugar requirements.

- To assist in the identification of whole grain bread, cereal, and whole grain foods, the interim rule adds the requirement that a whole grain must be the primary ingredient by weight in all bread, cereal and whole grain products.

**Rationale:**

- Comments expressed concern that the proposed nutritional requirement for whole grain breakfast cereal (using FDA's Health Claim<sup>14</sup>) is too restrictive and would eliminate corn and rice-based cereals that are necessary for those participants with wheat allergies or strong preferences for corn and rice-based cereals. In addition, commenters stated that whole grain cereals are less palatable to young children.

- Comments expressed concern about administrative difficulties in the identification of whole wheat bread and whole grain foods. To ensure State agencies determine the correct foods to authorize for State food lists, the Department has determined that whole-grain foods must have a whole-grain as the primary ingredient. This will allow products that are 100 percent whole grain, or are primarily whole wheat or multi-grain, to be WIC-eligible as well as provide an easy way for participants and vendors to identify most whole grain bread products by using the food ingredient label.<sup>15</sup>

**Proposed rule: Reduce maximum egg prescription.**

Reduce the maximum egg prescription from two and one-half dozen per month<sup>16</sup> to one dozen.

**Interim rule: No change from Proposed Rule.**

**Proposed rule: Allow canned beans as a substitute for dry beans.**

Allow canned beans as a substitute for dry at the rate of sixty-four ounces per pound.

**Interim rule: No change from Proposed Rule.**

#### 5. Food Package V—Pregnant and Partially Breastfeeding Women Up to One Year Postpartum

**Proposed rule: Condition eligibility for Package V on breastfeeding practice.**

Mothers who request, and are prescribed, more than the maximum amount of formula allowed for partially breastfed infants will no longer be eligible for Food Package V. Currently, women who breastfeed at least once per day are eligible for this package. Reclassified as non-breastfeeding for purposes of WIC food package issuance, these women will be assigned Food Package VI up to six months postpartum; they will receive no food package after six months.

**Interim rule: No change from Proposed Rule.**

**Proposed rule: Reduce the prescribed amount of milk; introduce new substitution options.**

- The maximum amount of milk that may be prescribed to Package V recipients would be reduced from 28 quarts to 22 quarts per month.

- Under current rules, cheese may be prescribed as a substitute for up to 12 quarts of milk. The proposed rule would allow cheese to replace just three quarts of milk. The substitution rate of one pound of cheese for three quarts of milk would remain unchanged.

- Calcium-set tofu<sup>17</sup>, and calcium and vitamin D fortified soy beverage would be introduced as new milk substitutes. Each pound of tofu would replace one quart of milk. For most women, cheese and tofu, combined, could replace no more than four quarts of milk; women with documented medical needs may be prescribed these substitutes in amounts that exceed the four quart maximum. No more than one pound of cheese may be substituted for milk.

- Soy beverage would be allowed as a substitute for Package V's entire milk allowance.

- IOM recommended yogurt as an alternative to fluid milk. To ensure cost neutrality yogurt was omitted as a fluid milk substitution. (See discussion of yogurt as a milk substitute in Section F, Item 1.)

**Interim rule:** In addition to the provisions of the Proposed Rule, the interim rule clarifies the authorization of lactose-reduced and lactose-free milk, and that these products should be offered before other authorized milk substitutes to those participants who can not drink milk due to lactose intolerance. The interim rule also clarifies that medical documentation is not required for participants to receive lactose-reduced and lactose-free milk.

**Rationale:** Lactose-reduced and lactose-free milks conform to the FDA standard of identity. The authorization of these milks was not specified in the Proposed Rule.

**Proposed rule: Reduce maximum juice prescription; add fruits and vegetables.**

- Reduce monthly maximum juice prescription from 288 fluid ounces to 144. Clarify that juice must be 100% unsweetened fruit or vegetable juice, that it contain a minimum of 30 milligrams of vitamin C per 100 milliliters, and that it be pasteurized.

- Add an \$8 monthly voucher to the package for the purchase of any combination of fresh or processed fruits and vegetables other than white potatoes.

**Interim rule: No change from Proposed Rule.**

**Proposed rule: Add whole grain breads; add whole grain requirement to cereal.**

- Add one pound of whole grain bread to the food package. Only bread meeting U.S. Food and Drug Administration (FDA) standards for whole grain labeling would be allowed.<sup>18</sup>

- Several whole grain products would be allowed as substitutions for bread. These include brown rice, bulgur, and whole grain barley without added sugar, fat, oil, or

<sup>12</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/dms/flgrain2.html>.

<sup>13</sup> The proposed rule would also replace the existing terms "cereal (hot or cold)" and "adult cereal (hot or cold)" with "breakfast cereal" in 7 CFR 246.10(c).

<sup>14</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/dms/flgrain2.html>.

<sup>15</sup> Baked in-store breads generally have no label.

<sup>16</sup> Some states currently allow just two dozen as the monthly maximum.

<sup>17</sup> Tofu prepared with only calcium salts.

<sup>18</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/dms/flgrain2.html>.

sodium. Soft corn or whole wheat tortillas would be allowed as an additional substitute at the option of State agencies. States may limit or completely eliminate substitutes if needed to control food costs.

- Require that WIC authorized breakfast cereals meet the same whole grain requirements as bread.

*Interim rule: Revise proposed whole grain requirements.*

- The cereal whole grain requirement in the Proposed Rule will be modified to require that at least one half of the total number of breakfast cereals on a State's authorized food list meet the whole grain requirement as defined in the interim rule, and that vendors be required to stock at least one whole grain cereal. The remaining authorized breakfast cereals are required to meet only the iron and sugar requirements.

- To assist in the identification of whole grain bread and whole grain foods, the interim rule adds the requirement that a whole grain must be the primary ingredient by weight in all bread products.

*Rationale:*

- Comments expressed concern that the proposed nutritional requirement for whole grain breakfast cereal (using FDA's Health Claim <sup>19</sup>) is too restrictive and would eliminate corn and rice-based cereals that are necessary for those participants with wheat allergies or strong preferences for corn and rice-based cereals.

- Comments expressed concern about administrative difficulties in the identification of whole wheat bread and whole grain foods. To ensure State agencies determine the correct foods to authorize for State food lists, the Department has determined that whole-grain foods must have a whole-grain as the primary ingredient. This will allow products that are 100 percent whole grain, or are primarily whole wheat or multi-grain, to be WIC-eligible as well as provide an easy way for participants and vendors to identify whole grain bread products by using the food label.

*Proposed rule: Reduce maximum egg prescription.*

Reduce the maximum egg prescription from two and one-half dozen per month to one dozen.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Allow canned beans as a substitute for dry beans.*

Allow canned beans as a substitute for dry at the rate of sixty-four ounces per pound.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Increase total amount of peanut butter and beans.*

Peanut butter is currently offered as a substitute for dry beans. The proposal would provide both one pound of dry beans and 18 ounces of peanut butter to Package V recipients. The rule also clarifies that Package V recipients may replace both dry beans and peanut butter with canned beans.

*Interim rule: No change from Proposed Rule.*

6. Food Package VI—Postpartum Women (Up to Six Months Postpartum)

*Proposed rule: Reduce the prescribed amount of milk; introduce new substitution options.*

- The maximum amount of milk that may be prescribed to Package VI recipients would be reduced from 24 quarts to 16 quarts per month.

- Under current rules, cheese may be prescribed as a substitute for up to 12 quarts of milk. The proposed rule would allow cheese to replace just three quarts of milk. The substitution rate of one pound of cheese for three quarts of milk would remain unchanged. Calcium-set tofu, and calcium and vitamin D fortified soy beverage would be introduced as new milk substitutes. Each pound of tofu would replace one quart of milk. For most women, cheese and tofu, combined, could replace no more than four quarts of milk; women with documented medical needs may be prescribed these substitutes in amounts that exceed the four quart maximum. No more than one pound of cheese may be substituted for milk.

- Soy beverage would be allowed as a substitute for Package VI's entire milk allowance.

- IOM recommended yogurt as an alternative to fluid milk. To ensure cost neutrality yogurt was omitted as a fluid milk substitution. (See discussion of yogurt as a milk substitute in Section F, Item 1.)

*Interim rule:* In addition to the provisions of the Proposed Rule, the interim rule clarifies the authorization of lactose-reduced and lactose-free milk, and that these products should be offered before other authorized milk substitutes to those participants who can not drink milk due to lactose intolerance. The interim rule also clarifies that medical documentation is not required for participants to receive lactose-reduced and lactose-free milk.

*Rationale:* Lactose-reduced and lactose-free milks conform to the FDA standard of identity. The authorization of these milks was not specified in the Proposed Rule.

*Proposed rule: Reduce maximum juice prescription; add fruits and vegetables.*

- Reduce monthly maximum juice prescription from 192 fluid ounces to 96. Clarify that juice must be 100% unsweetened fruit or vegetable juice, that it contain a minimum of 30 milligrams of vitamin C per 100 milliliters, and that it be pasteurized.

- Add an \$8 monthly voucher to the package for the purchase of any combination of fresh or processed fruits and vegetables other than white potatoes.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Add whole grain requirement to cereal.*

- Require that WIC authorized breakfast cereals meet the same whole grain requirements as bread.

*Interim rule: Add whole grain requirement to cereal.*

The cereal whole grain requirement in the Proposed Rule will be modified to require that at least one half of the total number of breakfast cereals on the State's authorized food list meet the whole grain requirement as defined in the interim rule, and that vendors

be required to stock at least one whole grain cereal. The remaining authorized breakfast cereals are required to meet only the iron and sugar requirements. To assist in the identification of whole grain cereal, the interim rule adds the requirement that a whole grain must be the primary ingredient by weight.

*Rationale:*

Comments expressed concern that the proposed nutritional requirement for whole grain breakfast cereal (using FDA's Health Claim <sup>20</sup>) is too restrictive and would eliminate corn and rice-based cereals that are necessary for those participants with wheat allergies or strong preferences for corn and rice-based cereals. Comments also expressed concern about administrative difficulties in the identification of whole wheat bread and whole grain foods. To ensure State agencies determine the correct foods to authorize for State food lists, the Department has determined that whole-grain foods must have a whole-grain as the primary ingredient.

*Proposed rule: Reduce maximum egg prescription.*

Reduce the maximum egg prescription from two and one-half dozen per month to one dozen.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Add beans and peanut butter to the food package.*

One pound of dry beans or 18 ounces of peanut butter would be added to Package VI. The same canned bean substitution option added to Packages IV, V, and VII would be extended to Package VI recipients as well.

*Interim rule: No change from Proposed Rule.*

7. Food Package VII—Exclusively Breastfeeding Women

*Proposed rule: Reduce the prescribed amount of milk; introduce new substitution options.*

- The maximum amount of milk that may be prescribed to Package VII recipients would be reduced from 28 quarts to 24 quarts per month.

- Under current rules, cheese may be prescribed as a substitute for up to 12 quarts of milk. The proposed rule would allow cheese to replace just six quarts of milk. The substitution rate of one pound of cheese for three quarts of milk would remain unchanged.

- Calcium-set tofu, and calcium and vitamin D fortified soy beverage would be introduced as new milk substitutes. Each pound of tofu would replace one quart of milk. For most women, cheese and tofu, combined, could replace no more than six quarts of milk; women with documented medical needs may be prescribed these substitutes in amounts that exceed the six quart maximum. No more than two pounds of cheese may be substituted for milk.

- Soy beverage would be allowed as a substitute for Package VII's entire milk allowance.

- IOM recommended yogurt as an alternative to fluid milk. To ensure cost

<sup>19</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/dms/flgrain2.html>.

<sup>20</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/dms/flgrain2.html>.

neutrality yogurt was omitted as a fluid milk substitution. (See discussion of yogurt as a milk substitute in Section F, Item 1.)

*Interim rule:* In addition to the provisions of the Proposed Rule, the interim rule clarifies the authorization of lactose-reduced and lactose-free milk, and that these products should be offered before other authorized milk substitutes to those participants who can not drink milk due to lactose intolerance. The interim rule also clarifies that medical documentation is not required for participants to receive lactose-reduced and lactose-free milk.

*Rationale:* Lactose-reduced and lactose-free milks conform to the FDA standard of identity. The authorization of these milks was not specified in the Proposed Rule.

*Proposed rule: Reduce maximum juice prescription; add fruits and vegetables.*

- Reduce monthly maximum juice prescription from 336 fluid ounces to 144. Clarify that juice must be 100% unsweetened fruit or vegetable juice, that it contain a minimum of 30 milligrams of vitamin C per 100 milliliters, and that it be pasteurized.

- Add an \$8 monthly voucher to the package for the purchase of any combination of fresh or processed fruits and vegetables other than white potatoes.

- Eliminate the separate prescription of carrots.

*Interim rule:* The provision of an \$8 monthly voucher has been revised to reflect a \$10 monthly voucher.

*Rationale:* IOM recommended cash-value food instruments for fruits and vegetables at the level of \$10 per month for women. To ensure cost neutrality, cash-value food instruments for fruits and vegetable was decreased to \$8 per month for women. However, FNS has considered the benefits of increasing the value of the vouchers for fully breastfeeding women and has determined that a \$2 increase can be accomplished while maintaining cost neutrality. In addition, the increase further enhances the attractiveness of the fully breastfeeding package and provides an additional incentive for women to breastfeed.

*Proposed rule: Add whole grain breads; add whole grain requirement to cereal.*

- Add one pound of whole grain bread to the food package. Only bread meeting U.S. Food and Drug Administration (FDA) standards for whole grain labeling would be allowed.<sup>21</sup>

- Several whole grain products would be allowed as substitutions for bread. These include brown rice, bulgur, and whole grain barley without added sugar, fat, oil, or sodium. Soft corn or whole wheat tortillas would be allowed as an additional substitute at the option of State agencies. States may limit substitutes if needed to control food costs.

*Interim rule: Revise proposed whole grain requirements.*

- The cereal whole grain requirement in the Proposed Rule will be modified to require that at least one half of the total number of

breakfast cereals on the State's authorized food list meet the whole grain requirement as defined in the interim rule, and that vendors be required to stock at least one whole grain cereal. The remaining authorized breakfast cereals are required to meet only the iron and sugar requirements.

- To assist in the identification of whole grain bread and whole grain foods, the interim rule adds the requirement that a whole grain must be the primary ingredient by weight in all bread products.

*Rationale:*

- Comments expressed concern that the proposed nutritional requirement for whole grain breakfast cereal (using FDA's Health Claim<sup>22</sup>) is too restrictive and would eliminate corn and rice-based cereals that are necessary for those participants with wheat allergies or strong preferences for corn and rice-based cereals.

- Comments expressed concern about administrative difficulties in the identification of whole wheat bread and whole grain foods. To ensure State agencies determine the correct foods to authorize for State food lists, the Department has determined that whole-grain foods must have a whole-grain as the primary ingredient. This will allow products that are 100% whole grain, or are primarily whole wheat or multi-grain, to be WIC-eligible as well as provide an easy way for participants and vendors to identify whole grain bread products by using the food label.

*Proposed rule: Reduce maximum egg prescription.*

Reduce the maximum egg prescription from two and one-half dozen per month to one dozen.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Allow canned beans as a substitute for dry beans.*

Allow canned beans as a substitute for dry at the rate of sixty-four ounces per pound. Also clarifies that Package VII recipients may replace both dry beans and peanut butter with canned beans.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Modify Package VII's canned fish provision.*

- Increase the maximum canned fish prescription to 30 ounces. Clarify that fish packaged in foil pouches meets WIC requirements.

- Allow three varieties of canned fish (light tuna, salmon and sardines) that are cost-effective and do not pose a mercury hazard as identified by federal advisories of the Food and Drug Administration and the U.S. Environmental Protection Agency for breastfeeding women.

*Interim rule:* The interim rule allows canned mackerel in addition to canned salmon and sardines, and light tuna.

*Rationale:* In response to comment requests, the interim rule also allows canned mackerel. The rule specifies two species of mackerel, both of which are also cost-

effective and identified by the EPA and FDA as having "lower levels of mercury."

8. Other Provisions (Non Food-Package Specific)

*Proposed rule: Clarifies the right of States to impose restrictions on WIC foods.*

States retain the right to exclude particular products, by brand or variety, from the food packages distributed to their residents. States are authorized to set standards for WIC foods that are more restrictive than those set by the federal government; however, they may not authorize the prescription of foods that do not meet minimum WIC-eligibility requirements set forth in regulations. The States may take into account issues of cost, nutrition, statewide availability, and participant appeal in setting these restrictions.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Ends the state practice of categorical nutritional tailoring.*

States will no longer be permitted to construct their own standardized set of food packages for WIC subpopulations with common supplemental nutritional needs. The full maximum monthly allowances of all foods in all packages must be made available to participants if medically or nutritionally warranted. However, State agencies have the authority to make adjustments to WIC foods for administrative convenience and to control costs. Such adjustments may involve packaging methods, container sizes, brands, types and physical forms of WIC foods.

*Interim rule: No change from Proposed Rule.*

*Proposed rule: Prohibit States from proposing new food package substitutions.*

The increased variety and choice in the supplemental foods in the Proposed Rule is based on IOM recommendations and the consideration of cultural appropriate packages for diverse groups. Therefore, WIC State agency proposal for cultural food substitutions will no longer be considered. Future reviews of the WIC food packages by FNS will be used to determine the need for additional cultural accommodations.

*Interim rule:* State agencies may submit to FNS a plan for substitution of foods to allow for different cultural eating patterns. The plan shall provide the State agency's justification, including a specific explanation of the cultural eating pattern and other information necessary for FNS to evaluate the plan. FNS will evaluate a State agency's plan for substitution of foods for different cultural eating patterns based on the following criteria: (1) Any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace; (2) The proposed substitute must be widely available to participants in the areas where the substitute is intended to be used; and (3) The cost of the substitute must be equivalent to or less than the cost of the food it is intended to replace. These criteria are the same as those under current WIC regulations at 7 CFR 246.10(e).

*Rationale:* Comments requested that the interim rule allow States the flexibility to meet unanticipated cultural needs of participants.

<sup>21</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/~dms/flgrain2.html>.

<sup>22</sup> See 21 CFR Part 136, Section 136.180, and FDA's Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/~dms/flgrain2.html>.

*Proposed rule: Rounding up for infant food and infant cereal*

A state agency may round up to the next whole container for either infant formula or infant foods (infant cereal, fruits and meats) if needed to provide at least the maximum authorized amount of these foods. For infant formula, state agencies must issue the whole containers that provide at the least the full

nutritional benefit (the maximum allowance of reconstituted fluid ounces of liquid concentrate) but not more than the maximum allowance of infant formula for each food package category and infant feeding option.

*Interim rule: No change from Proposed Rule.*

*C. Summary of Key Provisions*

The expected impact of the interim rules on the federal government, state and local WIC agencies, vendors, manufacturers, and program participants is summarized in Table 1. Overall economic effects are noted with a “+” for cost increases, and a “-” for cost savings. A more detailed examination of strictly economic effects follows Table 1.

TABLE 1.—SUMMARY OF KEY PROVISIONS

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Current rule:</p> <ol style="list-style-type: none"> <li>1. Food Package I serves infants from birth through three months. Formula is the only food prescribed under Package I.</li> <li>2. Infants from four through eleven months are eligible for juice and infant cereal, in addition to formula, under Package II. The maximum formula prescription in packages I and II are the same.</li> </ol> <p>Interim rule:</p> <ol style="list-style-type: none"> <li>1. Expand Food Package I to serve infants up to six months. Delay the introduction of complementary foods by two months.</li> <li>2. Increase formula prescriptions at four months to offset lost food energy.</li> </ol>	<p>Reduces cost of infant food packages. Interim packages for four and five month old infants (which reduce calories slightly) are less expensive than current Food Package II.</p>	<p>Changes to current rules will require the implementation of new state and local administrative procedures.</p>	<p>May increase the sale of infant formula at the expense of juice and infant cereal.</p>	<p>Provides a food package that conforms more closely to the diet recommended by health professionals for four and five month old infants.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>—\$</p> <p>Current rule: Under Food Package I, an infant can receive up to the maximum infant formula for the package. Since the rule does not separate partially and fully formula fed infants, a single package maximum applies to all partially and fully formula-fed infants from birth through three months. Food Package V is provided to pregnant women and to all new mothers, up to one year postpartum, if they breastfeed at least once per day. Food Package VII is provided to fully breastfeeding mothers.</p> <p>Interim rule: Infants and mothers will be assigned food packages based on the mother's reported breastfeeding practice. The corresponding amount of formula prescribed will distinguish infants less than 4 months of age as partially breastfed or fully formula-fed. The rule would provide a full formula-feeding package to some infants currently considered partially breastfed; it would move some mothers from Package V to Package VI. Partially breastfed infants under one month of age would be allowed to receive limited infant formula; this would move some mothers from Package VI or VII to Package V.</p> <p>—\$</p> <p>Current rule:</p>	<p>If breastfeeding increases enough to keep an infant classified as partially breastfed who would have been classified as fully formula fed otherwise, then formula costs are reduced and there is no change in the mother's status. For partially breastfed infants under one month of age, the low formula limit provided during that first month, paired with the net effect of mothers and infants switching from fully-formula feeding or fully breastfeeding to partially breastfeeding during the first month may reduce costs during the infant's first month. However, a sustained increase in breastfeeding during an infant's first year will affect the food package eligibility of both the mother and the infant. Although the economic effect of such a sustained increase is dependent on both breastfeeding duration and on the relative rates of partial and exclusive breastfeeding, the net economic effect is likely to be a reduction in cost.</p>	<p>State and local agencies must develop new guidelines to implement and communicate this policy.</p>	<p>Negligible effect on the sale of infant formula for newborn infants. But, the rule provides an incentive to breastfeed, which may ultimately reduce formula sales beyond the infants' first month. Moving mothers from the fully formula fed package to the partially or exclusively breastfeeding packages, may slightly increase food sales to breastfeeding mothers.</p>	<p>Although some participants may receive less food or formula under the interim packages, in general, WIC infants and mothers will benefit from the enhanced packages and package assignment method. Breastfeeding education and limited formula provided to new mothers by WIC staff may successfully increase breastfeeding rates. This is consistent with the recommendations of nutrition experts. However, it is uncertain whether this will have a significant impact on the number of WIC women who breastfeed.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>The current infant food packages do not distinguish between fully and partially formula-fed infants. Infants receive infant formula based on an assessment of their supplemental nutritional needs, subject to a single package maximum. Food Package V is provided to pregnant women and to all new mothers, up to one year postpartum, if they breastfeed at least once per day and their infant receives some formula.</p> <p>Interim rule:            Infants and mothers will be assigned food packages based on the mother's reported breastfeeding practice. The corresponding amount of formula prescribed will distinguish infants between partially breastfed and fully formula-fed. The rule would provide a full formula-feeding package to some infants currently considered partially breastfed; it would move some mothers from Package V to Package VI, or after six months of participation, to no package at all, depending on the amount of formula requested.</p> <p>—\$</p> <p>Current rule:            Currently, the definition of breastfeeding in WIC regulations allows women who breastfeed once a day to be eligible for the WIC program and receive supplemental foods.</p> <p>Interim rule:</p>	<p>If the interim rule has no direct effect on the initiation and duration of breastfeeding, the cost of providing food packages to women will drop; the cost of providing infant formula will remain unchanged. If breastfeeding increases enough to keep an infant classified as partially breastfed who would have been classified as fully formula fed otherwise, then formula costs are reduced and there is no change in the mother's status. Both result in cost reductions.</p>	<p>State and local agencies must conform to a new definition of breastfeeding for WIC food package purposes. Will also encourage changes in the approach to nutrition education; places greater emphasis on breastfeeding promotion. Implementing new procedures will initially increase administrative burden.</p>	<p>Negligible effect in the absence of changes in breastfeeding behavior. Increased breastfeeding would reduce formula sales but might modestly increase the sale of infant food fruits, vegetables and meat to WIC's fully breastfed population.</p>	<p>Although the WIC food benefit received by women who do not fully breastfeed may be reduced, in general, WIC infants and mothers will benefit from the enhanced packages and package assignment method. The interim packages encourage breastfeeding consistent with the best advice of nutrition science. However, breastfeeding is a behavior with many complex determinants, and it is unlikely that the food package changes alone will alter breastfeeding practices.</p>
<p>Interim rule:</p>	<p>These women are already counted as participants when they receive food benefits as breastfeeding women, so the net effect of the change in the definition of participation is minimal. These women will continue to be included in participation numbers and State agencies will be provided NSA funds.</p>	<p>State agencies will be provided NSA funds for a very small number of women who are receiving WIC benefits (nutrition education/ breastfeeding support and referrals to health and social services), but not receiving supplemental foods.</p>	<p>Negligible effect because it applies only to the few women who breastfeed for longer than six months but request the full formula fed amount of infant formula for their infant. These mothers once received supplemental foods but will no longer be eligible for these foods. They will still be visiting WIC approved vendors to obtain infant formula.</p>	<p>Encourages more intensive breastfeeding for WIC women after six months of participation.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Revise the definition for WIC participation to include the number of breastfeeding women who receive no supplemental foods or food instruments but whose breastfed infant(s) receives supplemental foods or food instruments.</p> <p>–\$</p> <p>Current rule: Infants from 4–11 months are eligible for Food Package II. That food package includes juice and infant cereal, as well as formula.</p>	<p>The net effect of these changes increases the cost of Food Package II.</p>	<p>Implementing new procedures, such as setting state policy on allowed varieties of infant food, will increase short-term administrative burden. MIS systems will need to be revised for new foods (infant fruits and vegetables), quantities, and the new age range. Need to train WIC staff, vendors and participants on new foods.</p>	<p>May increase sales of infant food and decrease sales of juice and formula if participants were not already using the quantities in the interim rule. Some vendors may need to stock additional infant food varieties that meet the specific specifications set by the states. Vendors will need to train personnel to identify the newly WIC-eligible infant foods.</p>	<p>Restructures the infant package according to the recommendations of current nutrition science. Increases benefits by adding fruits and vegetables, but decreases maximum allowance of infant formula and eliminates juice. Encourages good infant feeding practices and the consumption of fruits and vegetables.</p>
<p>Interim rule: The following changes are made to Food Package II:</p> <ol style="list-style-type: none"> <li>1. Change age eligibility to 6–11 months.</li> <li>2. Eliminate juice.</li> <li>3. Add infant food fruits and vegetables.</li> <li>4. Reduce maximum formula amount.</li> </ol> <p>+\$</p> <p>Current rule: All infants are eligible for the same amounts of formula, juice, and infant cereal under Food Package II.</p>	<p>The cost of the fully breastfed package for infants age six months and older is increased significantly.</p>	<p>Implementing new procedures, such as setting state rules on permissible varieties of infant food meat, will increase short-term administrative burden. Need to train WIC staff, vendors and participants on new foods. MIS systems will need to be revised.</p>	<p>Increase in sales of infant food meat is likely to be negligible. The number of fully breastfed WIC infants age six months and over is small. Vendors will need to train personnel to identify the newly WIC-eligible infant foods and distinguish them from similarly packaged ineligible items.</p>	<p>Provides added iron and zinc to the diet of fully breastfed infants age six months and older. Also encourages breastfeeding by increasing benefits. Both are consistent with the recommendations of current nutrition science.</p>
<p>Interim rule: Provide relatively more infant food fruit and vegetables to fully breastfed infants at six months than to partially breastfed or fully formula-fed infants. Also provide infant food meat to this group.</p> <p>+\$</p> <p>Current rule:</p>				

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>1. Low iron infant formula may be prescribed with medical documentation.</p> <p>2. Infant cereal must be iron-fortified; WIC regulations contain no other specifications.</p> <p>Interim rule:</p> <p>1. Disallow the prescription of low iron infant formula.</p> <p>2. Disallow the prescription of infant cereal with added ingredients. (minimal economic effect)</p> <p>Current rule:</p> <p>Children and women with special dietary needs are prescribed WIC-eligible medical foods under Food Package III. Infants with special dietary needs are provided exempt infant formula under Food Packages I or II.</p> <p>Interim rule:</p> <p>Serve infants with special dietary needs who receive exempt infant formulas under Food Package III. —\$</p> <p>Current rule:</p> <p>Current practice allows some women and children with certain dietary restrictions, but without serious medical conditions, to be prescribed medical foods under Food Package III.</p> <p>Interim rule:</p> <p>Clarify language governing the purpose and scope of Package III eligibility. —\$</p> <p>Current rule:</p>	<p>These changes are expected to have little effect on the foods actually prescribed to WIC infants. The infant cereal rule simply formalizes what has been federal policy since 1980.</p> <p>The rule is intended to reduce administrative costs and facilitate program management.</p> <p>Clarifies who is eligible for Food Package III and what foods may be distributed as part of that package. These clarifications are generally aimed at tightening these criteria. Will, if anything, reduce Package III costs by moving some participants to food packages more appropriate for their needs. But, given the size of the current Package III population (roughly 1% of all WIC participants) these savings will be small.</p>	<p>The states will incur minimal short-term administrative burden as they implement these minor rule changes. Local WIC agencies will need to communicate the “no low iron infant formula from WIC” concept to the local medical community and some participants. MIS systems will need to be revised.</p> <p>The rule is intended to facilitate program management. It may also allow improved service to WIC beneficiaries. MIS systems will need to be revised.</p> <p>The rule may reduce administrative burden by eliminating Package III eligibility issues. But, it may require state efforts to educate local WIC officials, WIC participants, and health care professionals on the eligibility criteria.</p>	<p>Sales of low iron formula and certain infant cereal varieties will be reduced slightly, if at all, by these rules.</p> <p>No impact.</p> <p>Possible minimal reduction in the sale of medical foods due to eligibility requirements.</p>	<p>The very few WIC participants who have been receiving low iron formula from WIC will either need to purchase the product or work with their medical provider to change to an iron fortified infant formula authorized by WIC.</p> <p>No direct impact. Improved service at the state and local level may result, to the benefit of WIC participants.</p> <p>Some current participants receiving Package III may be served under food packages more appropriate to their needs.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Package III recipients are prescribed medical foods only; they do not receive any of the standard food package foods.</p> <p>Interim rule: Make other WIC foods available to Package III recipients. +\$</p> <p>Current rule: Food Packages IV through VII provide WIC beneficiaries with 24 to 28 quarts of milk per month. Cheese may be substituted for milk at a rate of one pound per three quarts; cheese may replace a total of 12 quarts of milk.</p> <p>Interim rule: Reduce maximum milk prescription amounts to WIC children and women. Add new milk substitution options (tofu, cheese and soy beverage), but reduce the maximum amount of cheese substitution allowed. -\$</p> <p>Current rule:</p>	<p>This rule will increase costs in those cases where Food Package III recipients are able to consume the foods contained in the regular WIC food packages to which they would otherwise be eligible. But, the Package III population is small. The costs will be modest.</p> <p>The net effect of this provision will be a reduction in overall cost, due to the reduction in quantities allowed and reduced substitution amounts.</p>	<p>Administrative burden of implementing the new rule will be incurred in the short run. Local agencies will need to determine which WIC foods can be purchased to each Food Package III recipient. MIS systems will need to be revised.</p> <p>The states will need to establish new specifications and restrictions for the new milk substitutes. They will also incur administrative burden in implementing changes to reflect reduced milk prescription maximums and substitution limits. Local agencies will need to educate WIC vendors and participants on new food items. MIS systems will need to be revised.</p>	<p>May have a small positive effect on the sale of some secondary WIC foods. Will not affect sales of infant formula.</p> <p>The rule may result in reduced milk and cheese sales to WIC participants. It may lead to increased sales of tofu and soy beverage. Vendors may need to stock new items that match the specific product requirements set by the states. Rule proposes nutritional standards for soy milk that are currently not met by many products on the market. Because these standards will also apply to the school meals programs, vendors are likely to change fortification so that the variety of available soy beverages that can be authorized improves over time.</p>	<p>For those Package III recipients able to consume at least some non-Package III WIC foods, this rule will provide them with additional food.</p> <p>Reduces dairy component of WIC benefit. WIC participants who are unable to drink milk may benefit most by the addition of these new substitutes. Others with individual or cultural preferences will also benefit by the added choices. All WIC participants will benefit from a package lower in saturated and total fat, consistent with the recommendations of current nutrition science.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Juice may be prescribed under Food Packages IV through VII at maximum levels that range from 192 to 336 fl. oz. per month.</p> <p>Interim rule: Reduce maximum juice prescription amounts in food packages for children and women. Add a voucher for fruits and vegetables (other than white potatoes) to those packages. +\$</p> <p>Current rule: Eggs are provided under Food Packages IV through VII. States may set their monthly maximums at either 2 or 2½ dozen per month.</p> <p>Interim rule: 1. Reduce maximum egg prescription in all food packages for women and children. -\$</p> <p>Current rule:</p>	<p>The fixed dollar values of the fruit and vegetable vouchers in the interim rule are greater than the offsetting savings that will be realized through reduced juice amounts.</p> <p>Reducing the maximum egg prescription will produce a modest reduction in food package costs. That reduction is used to help offset costs of new foods and substitution options.</p>	<p>States will need to authorize and develop a structure to distribute and redeem fruit and vegetable vouchers, which will be a new component of the programs. This administrative burden will be on-going but part of the current banking and MIS systems. State and local agencies will incur administrative burden in developing educational messages for WIC participants concerning the selection of nutritious fruits and vegetables. Need to train WIC staff, vendors and participants on new food amounts. MIS systems will need to be revised.</p> <p>State and local administrative burden will be incurred in the short term as new procedures are put in place. Local agencies will need to educate WIC vendors and participants on new food amounts. MIS systems will need to be revised.</p>	<p>Juice sales to WIC participants may decline. Sales of fruits and vegetables may increase. Costs will be incurred by vendors as they learn to accommodate the new WIC vouchers. Some WIC authorized vendors may need to add fruits and vegetables to their stocks in fresh, frozen, or canned form. Emphasis on fresh fruits and vegetables may encourage states to authorize and participants to shop at farmers markets more often. (See Market Analysis discussion in Section G).</p> <p>Sales of eggs to WIC participants will decline. Market effects will be minimal.</p>	<p>Expands WIC benefits by adding fruits and vegetables, while reducing juice amounts. The addition of fruits and vegetables to the WIC food packages responds to the recommendations of nutrition science. And the flexibility of a voucher will provide access to a variety of fruits and vegetables, in some form, year round, in all markets.</p> <p>This change reduces food energy, cholesterol, and fat content of the WIC food packages. The changes are consistent with the advice of current nutrition science. The reduction in food energy also makes room for the introduction of new foods that address priority nutrient needs.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>There are no restrictions on the fat content allowed in milk.</p> <p>Interim rule:</p> <ol style="list-style-type: none"> <li>1. Provide only fat reduced milk to women as well as children age two and older.</li> <li>2. Provide only whole milk to children one year of age.</li> </ol> <p style="text-align: center;">–\$</p> <p>Current rule:</p> <p>Grains are included in the current food packages for women and children in the form of breakfast cereal. Current regulations do not specify a minimum whole grain content for that product.</p>	<p>Prescribing only fat reduced milk to women and children age two and older will have a negligible effect on cost.</p>	<p>State and local administrative burden will be incurred in the short term as new procedures are put in place. Local agencies will need to educate WIC vendors and participants on new food amounts. MIS systems will need to be revised.</p>	<p>Market effects will be minimal. Vendors will need to train personnel to allow the type of milk specified on the food instruments.</p>	<p>This proposal reduces total fat and saturated fat content of the WIC food packages. The change is consistent with the advice of current nutrition science.</p>
<p>Interim rule:</p> <ol style="list-style-type: none"> <li>1. Add whole grain bread to Food Packages IV, V, and VII. Allow substitutions of other whole grain foods for bread.</li> <li>2. Require that at least 50 percent of breakfast cereals on State agency food lists must have whole grain as the primary ingredient and meet FDA labeling requirements for making a health claim as whole grain food of moderate fat content.<sup>23</sup> State agencies must require vendors to stock at least one whole grain cereal.</li> </ol> <p style="text-align: center;">+\$</p> <p>Current rule:</p>	<p>The addition of whole grain bread to Packages IV, V, and VII increases the cost of those packages. The requirement for 50 percent of available cereals for children and women to be classified as whole grain will have a minor effect on cost.</p>	<p>State and local agencies will incur administrative burden to implement the new rules. States will incur administrative burden in establishing specifications and restrictions for the new foods and substitution options and local clinics will incur additional administrative burden to explain food options to participants. Local agencies will need to educate WIC vendors and participants on new food amounts and how to distinguish them from similarly packaged ineligible items. MIS systems will need to be revised.</p>	<p>Manufacturers may respond by reformulating popular WIC-approved cereals in whole grain form. Smaller vendors may need to modify stocks to include whole grain bread varieties and at least one whole grain cereal. All vendors will need to train personnel to readily identify WIC-eligible breads and grains.</p>	<p>WIC participants will benefit from food packaged enhanced with whole grain cereals and food products. The addition of whole grains to the WIC packages is consistent with 2005 Dietary Guidelines for Americans that encourage increased consumption of these foods.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Dry beans are included in Food Packages IV, V, and VII. Canned beans may be prescribed, instead of dry, to WIC participants who lack cooking facilities.</p> <p>Interim rule:</p> <ol style="list-style-type: none"> <li>1. Allow canned beans as a substitute for dry in all food packages for children and women.</li> <li>2. Allow both Package V and Package VII recipients to replace both their dry bean and peanut butter allocations with canned beans.</li> </ol> <p style="text-align: center;">+ \$</p> <p>Current rule:</p> <p>Beans and peanut butter are not included in Food Package VI. Package V currently provides a pound of dry beans; those can be replaced with 18oz of peanut butter.</p> <p>Interim rule:</p> <ol style="list-style-type: none"> <li>1. Add one pound of beans, with an 18oz peanut butter substitution option, to Food Package VI.</li> <li>2. Increase the amount of beans and peanut butter allowed under Food Package V; allow the prescription of both one pound of beans and 18oz of peanut butter.</li> </ol> <p style="text-align: center;">+ \$</p> <p>Current rule:</p> <p>26 oz of tuna is made available to exclusively breastfeeding women in Food Package VII. White, light, or dark tuna, packed in water or oil, is allowed.</p> <p>Interim rule:</p>	<p>The rate of substitution between canned and dry beans in the interim rule will increase costs. However, the cost of beans in the food packages is relatively small and this change will have a relatively modest effect on overall program cost.</p> <p>The costs of food packages V and VI are increased.</p> <p>Costs will increase slightly. While the new substitution option may increase the cost of individual prescriptions, the number of WIC participants eligible for Food Package VII is very small.</p>	<p>The option in the interim rule will prompt states to set specifications and restrictions. Other short-term administrative burden will be incurred as the new rule is put in place. Local agencies will need to educate WIC vendors and participants on new food amounts. MIS systems will need to be revised.</p> <p>Neither of these changes introduces foods not already included in other WIC packages. Local agencies will need to educate WIC vendors and participants on new food amounts. MIS systems will need to be revised.</p> <p>States and local agencies will incur administrative burden in implementation. State agencies will adopt specifications and restrictions for the new substitution option. Local agencies will need to educate WIC vendors and participants on new food amounts. MIS systems will need to be revised.</p>	<p>Market effects will be minimal. But, as with the addition of any WIC substitution option, small vendors may need to add new items to their stocks, and all vendors will need to train personnel to identify the newly-eligible WIC foods.</p> <p>Minimal market impact.</p> <p>Minimal market impact. But, may force small vendors to stock additional types of canned fish and will require all vendors to train personnel to identify newly-eligible WIC foods.</p>	<p>By adding variety and convenience, the canned bean option should increase the appeal of that food. It may also encourage greater consumption, replacing less healthy foods in the diets of WIC participants.</p> <p>The addition of beans and peanut butter increases benefits to WIC participants. These changes supplement the diets of breastfeeding and postpartum women with several of the priority nutrients identified by the IOM.</p> <p>These changes add new choices that may encourage consumption. The rule also responds to medical advice that breastfeeding women avoid fish species that are high in mercury.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Authorize a variety of canned fish that do not pose a mercury hazard to fully breastfeeding women. Slightly increase the maximum amount allowed to 30 ounces.</p> <p style="text-align: center;">+ \$</p> <p>Current rule: State WIC agencies impose restrictions on some foods by brand or variety in order to limit cost or ensure statewide product availability. The practice is accepted but not formally authorized by regulation.</p> <p>Interim rule: Clarifies the right of States to restrict WIC foods by variety or brand. (minimal economic impact)</p> <p>Current rule: States are permitted to prescribe foods to WIC participants in quantities that are less than the package maximums when nutritionally warranted. States may also standardize these reductions and apply the reduced amounts consistently to like groups of WIC participants. Such categorical food package tailoring may be done for nutritional reasons, but not to achieve cost reductions.</p> <p>Interim rule: Ends the practice of categorical tailoring of WIC food packages by States.</p> <p style="text-align: center;">- \$</p> <p>Interim rule:</p>	<p>This simply clarifies what is already accepted policy. The policy is an effective way to control costs. Since the rule represents no change from current practice, it results in no economic impact.</p> <p>Assures more consistent WIC benefits are delivered across States.</p>	<p>States are given formal approval for current practice. States should incur little or no administrative burden in implementation.</p> <p>The rule reduces the level of work currently undertaken by State officials. Administrative burden will decrease to the extent that states will not undertake their own review of WIC prescription maximums in response to the federal revisions to the WIC food packages. In the absence of this rule, States may have incurred administrative burden.</p>	<p>If States adopt restrictions on the brands or varieties of foods newly added to the WIC food packages, then participants who already purchase those foods may switch their selection of brands or varieties to the WIC-approved choices. A measurable shift in consumption by brand or variety may result.</p> <p>Minimal effect on vendors and producers.</p>	<p>WIC participants may need to switch brands or varieties of foods that they currently consume to brands and varieties consistent with those added to the WIC packages.</p> <p>Assures more consistent WIC benefits are delivered across States. IOM has based food prescription quantities on current nutritional science rendering food package tailoring unnecessary.</p>

TABLE 1.—SUMMARY OF KEY PROVISIONS—Continued

Current and interim rules:	Effect of interim rule on:			
	USDA/Federal gov't	State/local agencies	Vendors/industry	WIC participants
<p>Allow State agencies to round up to the next whole container of infant foods if needed to provide the maximum authorized amount of these foods.</p> <p style="text-align: center;">+ \$</p> <p>Interim rule: Allow State agencies to propose plans for additional package substitutions to meet unanticipated cultural needs of participants. State agencies will only substitute foods after receiving written approval from FNS.</p>	<p>Minimal cost given the small container sizes involved. Rounding up is likely to require the addition of little jarred infant food to the food packages; containers are typically just 4oz. The current infant cereal maximum of 24oz is a multiple of a commonly prescribed package size; 8oz boxes are among the standard package sizes.</p> <p>Will increase administrative costs of considering proposals but little effect on program costs since very few package substitutions have ever been approved.</p>	<p>States may incur some administrative burden to implement, particularly if manufacturers change container sizes in response to this rule. Local agencies will need to educate WIC vendors and participants on rounded formula amounts. MIS systems will need to be revised.</p> <p>Because of the interim rule's flexibility in food offerings, States will no longer have as much, if any, need to request substitutions to meet cultural preferences. Administrative savings will accrue for those States that do not pursue substitutions.</p>	<p>Unless manufacturers change container sizes to achieve greater product sales, no impact is expected.</p> <p>Minimal since very few food package substitutions have ever been permitted.</p>	<p>Will ensure WIC participants get the full nutritional benefit authorized.</p> <p>Minimal since very few food package substitutions have ever been permitted.</p>

D. Costs

1. Interim Rule

Under the interim rule, FNS estimates that the revisions to the WIC food packages will be cost-neutral. FNS estimates that the

changes will decrease costs by \$29.7 million over five years.

The economic effects of the interim rule on the federal government over a five-year period are summarized in Table 2, which presents the impacts of the revisions by food package type. These figures are limited to

food costs; no additional funds will be provided to States or local clinics to implement this rule. The costs have been adjusted for the rule's phased-implementation schedule. Current and interim food package costs are provided in Tables A1-A3 in Appendix A.

TABLE 2.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS  
[in millions]

Food package	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2008–FY 2012
I—Infants (0–5.9 months)	–\$12.6	–\$44.4	–\$53.4	–\$55.8	–\$58.3	–\$224.5
II—Infants (6–11.9 months)	23.9	84.2	101.2	105.8	110.4	425.4
III—Participants with qualifying conditions	3.0	10.6	12.8	13.4	14.0	53.8
IV—Children (1–4.9 years)	–18.4	–71.0	–92.0	–102.7	–113.8	–398.0
V—Pregnant and Partially Breastfeeding Women	6.5	20.8	22.6	21.2	19.7	90.9
VI—Postpartum Women	0.5	0.4	–0.9	–2.3	–3.8	–6.3
VII—Exclusively Breastfeeding Women	2.1	6.7	7.2	6.7	6.1	28.9
Total	5.0	7.3	–2.5	–13.9	–25.6	–29.7

Negative values are cost reductions. Column and row totals may not be exact due to rounding. FY08 begins with December 2007.

2. Major Cost Drivers

Table 3 shows the major cost drivers for each food package; provisions listed do not

reflect total food costs and savings. Total costs are for FY08-FY12 and have not been

adjusted for the rule's phased implementation.

TABLE 3.—MAJOR COST DRIVERS OF WIC FOOD PACKAGES

Food package	Major cost drivers (2008–2012)
I .....	<ul style="list-style-type: none"> <li>• Formula is reduced for partially breastfed infants and eliminated for fully breastfed infants (–\$172 million post rebate).</li> </ul>
II .....	<ul style="list-style-type: none"> <li>• Formula is reduced for fully formula and partially breastfed infants and is eliminated for fully breastfed infants (–\$516 million post rebate).</li> <li>• Juice is eliminated for all infants (–\$163 million).</li> <li>• Infant fruits and vegetables are added along with infant meats for fully breastfed infants (+\$1,117 million).</li> </ul>
III .....	<p>Package III recipients are eligible for foods in the other packages. Under the interim rule, nearly 76% of Package III recipients are infants, and 24% are children; fewer than 1% are women. (+\$62 million).</p>
IV .....	<ul style="list-style-type: none"> <li>• Juice is reduced (–\$930 million).</li> <li>• Milk is reduced (–\$895 million),</li> <li>• Cheese is reduced (–\$559 million).</li> <li>• Eggs are reduced (–\$215 million).</li> <li>• Whole grains added (+\$703 million).</li> <li>• \$6 cash-value instrument for fruits and vegetables is added (+\$1,314 million).</li> </ul>
V .....	<ul style="list-style-type: none"> <li>• Juice is reduced (–\$305 million).</li> <li>• Cheese is reduced (–\$219 million).</li> <li>• Milk is reduced (–\$219 million).</li> <li>• Beans are increased (+\$113 million).</li> <li>• Milk substitutions are added (soy beverage and tofu) (+\$180 million).</li> <li>• \$8 cash-value instrument for fruits and vegetables is added (+\$486 million).</li> </ul>
VI .....	<ul style="list-style-type: none"> <li>• Milk is reduced (–\$166 million).</li> <li>• Juice is reduced (–\$124 million).</li> <li>• Cheese is reduced (–\$99 million).</li> <li>• \$8 cash-value instrument for fruits and vegetables is added (+\$272 million).</li> </ul>
VII .....	<ul style="list-style-type: none"> <li>• Juice is reduced (–\$124 million).</li> <li>• Milk is reduced (–\$75 million).</li> <li>• \$10 cash-value instrument for fruits and vegetables is added (+\$175 million).</li> </ul>

Negative values (–) are cost reductions, positive values (+) are cost increases. There are a total of \$581 million in increases and \$239 million in decreases that are not reflected in this table.

3. Fruit and Vegetable Option

Due to the seasonal fluctuation in price and availability of fresh fruits and vegetables, and the inability to purchase them in uniform weight units, it is difficult to set quantity terms for fruits and vegetables and still estimate the cost of the WIC food packages. In order to accurately capture the cost of providing fresh fruits and vegetables in WIC Food Packages III-VII, the interim rule includes fruit and vegetable vouchers. Due to the administrative ease of implementation, the IOM recommended cash-value instruments be issued.<sup>24</sup> The IOM also recommended that states provide fruit and vegetable vouchers at the level of \$10 per month for women and \$8 per month for children. However, to achieve cost neutrality with the changes, FNS set the vouchers at the level of \$8 per month for pregnant, partially breastfeeding and postpartum women and \$6 per month for children in the year in which the food package revisions take effect. Fully breastfeeding women receive the recommended \$10 voucher as part of WIC’s breastfeeding promotion initiatives. Vouchers will be adjusted for inflation. The effects of inflation will be accrued annually, but not realized until the cumulative increase in the CPI is sufficient to raise the voucher’s value by a dollar. Inflation is measured as the change in the Consumer Price Index (CPI) for fresh fruits and vegetables, as detailed in the interim rule.

4. Cost Estimate Methodology

Overview

The impacts of the interim rule on Federal expenditures are projected by comparing

current policy to the interim rule with regard to total food costs. (Administrative funds are excluded; as noted above, no increase in funds will be provided to States or local clinics to implement this rule.)

For both current and new rules, food costs are calculated as the sum of the aggregate annual expenditures on each available food package. These expenditures are calculated separately as the product of:

- Participants—the number of women, infants, and children who receive each WIC food package;
- Food Prescriptions—the specific types and quantities of food contained in each package distributed to WIC participants; and
- Food Prices—the cost of the food items contained in WIC food packages.

The data sources and assumptions used in projecting each of these elements are summarized briefly here. Greater detail is provided on the pages that follow.

i. *Participation*—Participation statistics are remitted by State WIC agencies to FNS on a monthly basis. These are the product of routine recordkeeping by WIC clinics. They include counts of the number of women, infants, and children who receive WIC services. FNS collects additional program-relevant participant demographic characteristics such as age and life stage data through biennial data collections from WIC State agencies, as well as supplemental data on current breastfeeding practice. Participants are distributed as recipients of specific food packages under the current and new rules. Growth in program participation is based on projection of historical participation figures alone.

ii. *Prescriptions*—FNS gathers detailed information on the amount of food prescribed

to individual WIC participants through the same survey of WIC providers that serves as FNS’s source for participant demographics. FNS uses these current prescription records, plus a set of explicit assumptions about participant preferences, to generate prescription totals for each of the foods in the interim rule’s revised packages.

iii. *Prices*—FNS tabulated average prices for each of the foods contained in the current and revised food packages from AC Nielsen’s calendar year 2005 Homescan dataset. The final prices used in the cost estimate are these tabulated figures, adjusted for inflation and for rebates negotiated with infant formula manufacturers.

FNS has posted these participation, prescription, and price figures on its Web site (<http://www.fns.usda.gov>), in Microsoft Excel format. Separate figures are given for each of the current and proposed food packages, and for each of the five fiscal years 2008 through 2012.

The posted data will permit interested parties to reproduce the results of the cost estimate presented here. FNS encourages interested parties to examine the spreadsheet after reading the more detailed methodology that follows.<sup>25</sup>

a. Food Package Costs

i. Prescriptions

FNS’s primary data source for participant prescription data is its 2002 WIC Participant and Program Characteristics (“PC2002”) dataset. PC2002 is the eighth in a series of biennial reports and datasets on WIC

<sup>25</sup> Additional information on the posted data, or on any other aspect of this cost estimate, is available from FNS on request.

<sup>24</sup> IOM, p. 172

participant and program characteristics. PC2002 employs the reporting system developed by FNS in 1992, which compiles key features of WIC participant information from State WIC agencies. The current system for reporting participant data is based on the automated transfer of an agreed upon set of data elements held in State management information systems. As part of the documentation needed to process the WIC PC participant data, each State also provides a food package code list which shows types and amounts of WIC food prescribed along with the State coding scheme.

PC2002 summarizes demographic characteristics of WIC participants nationwide as of April 2002, along with information on participant income and nutrition risk characteristics. PC2002 contains information on a near-census of WIC enrollees for whom food benefits were made available in WIC management information systems in April 2002.<sup>26</sup> The dataset and the report's tabulations are based on over 8 million records.<sup>27</sup>

FNS used prescription data from the PC2002 dataset to establish a baseline food cost and to estimate the costs of the package revisions. Actual participant-level prescriptions provide a useful starting point for this analysis. Data at the participant level captures the preferences and dietary restrictions of the current WIC population. Assuming little change in the distribution of the WIC population by life stage, food preference, or supplemental dietary need over the short term, the 2002 prescription data offers the best opportunity for estimating likely prescription amounts under the interim food package rule.<sup>28</sup> FNS estimated participant-specific prescription amounts for each of the foods in the packages other than infant formula. In an effort to reflect the interim rule's requirements that (1) participants be issued prescriptions at the maximum level per package, unless that level for one or more items is medically contraindicated, or the participant declines to accept the item; and (2) States may no longer adjust or "tailor" packages categorically, but that WIC professionals may do so, the following assumptions guided this analysis:<sup>29</sup>

- For foods that are part of both the current WIC packages and the revised packages:
- WIC participants currently prescribed none of that food will continue to be prescribed none (presumed medically contraindicated).

<sup>26</sup> For the month of April 2002, each State WIC agency was required to submit MDS data on a census of its WIC participants. All but 4 of the eighty-eight State WIC agencies (Mississippi, Choctaw Nation (OK), Eastern Shoshone and Rosebud Sioux) were able to provide sufficient data for tabulation in PC2002.

<sup>27</sup> Fewer participants—approximately 7.5 million—actually picked up their vouchers in April 2002 and were counted according to WIC regulations as participants for WIC administrative funding purposes.

<sup>28</sup> Due to insignificant differences in the PC2002 and PC2004 data, this analysis was not updated with the PC2004 dataset.

<sup>29</sup> The description that follows is a simplification of the process used to develop the estimated prescriptions.

- If the participant's current prescription exceeds the interim rule's maximum for the item, then the participant will be prescribed the new maximum amount.

- If the participant's current prescription is less than the maximum amount allowed by the state under current rules, and less than the interim rule's amount, then the participant's prescription will remain unchanged.

- For foods newly added to the WIC packages by the interim rule:

- Generally, prescription rates are set to observed rates for comparable foods already contained in the WIC packages.<sup>30</sup>

- Foods newly added to the WIC packages as substitutes for standard WIC foods were prescribed to a subset of the WIC population equal to the percent of all low income U.S. households that currently purchase those items.<sup>31</sup> For example, market consumption data indicates that about 3% of U.S. households with WIC-eligible incomes purchased tofu, so 3% of WIC participants are assumed to be prescribed tofu.<sup>32</sup> Participants prescribed one of the new substitutes will be provided with the maximum required under the interim rule given any other substitutions allowed.

- Fruit and vegetable vouchers are assumed to be prescribed to all participants at the full amount.

This methodology tends to produce prescription estimates that are at or near the maximum quantities specified in the revised packages. (See Table 4.)

#### ii. Infant Formula and Rounding

In this analysis, infant formula and infant foods were treated slightly differently than the other foods. Using a micro-simulation program with PC2002 data to model prescription amounts for infant formula and foods would not account for "rounding up". Rounding up refers to the ability of state agencies to round up to the next whole container to provide the maximum infant formula allowance. State agencies may only include an option to round-up in infant formula contracts renewed on or after October 1, 2004. The interim rule extends this rounding option to infant foods (cereal, fruit and vegetables, and meat).

Since the PC2002 data do not reflect the costs of states rounding up, the cost estimates of the current and interim rule packages use a different approach to factor in the cost of states rounding up. Given current container sizes, rounding up is only required when

<sup>30</sup> For example, the prescription rates for whole grain bread and bread substitutes are set to the observed prescription rates for cereal. The April 2002 Food Package IV cereal prescription rate was applied to Package IV bread prescriptions; the average Package V and Package VII cereal prescription rate was used to estimate Package V and Package VII bread prescriptions.

<sup>31</sup> Market consumption data is based on 2003 AC Nielsen Homescan survey data.

<sup>32</sup> This method of identifying general consumer preferences for particular items cannot be used to estimate the share of the infant population that consumes fresh bananas. It is assumed, then, that infants will be prescribed bananas as a substitute for jarred infant food fruits and vegetables at the average prescription rate for all foods across all food packages.

issuing powder infant formula and infant fruit and vegetables. The maximum allowances for liquid concentrate infant formula, ready-to-feed infant formula, infant cereal and infant meat are evenly divisible by whole containers. To capture the effect of rounding, the following assumptions have been made:

- Current Food Packages I and II
- Estimated infant formula prescription amounts for Packages I and II incorporate rounding because the estimated reconstituted amounts fall below the package maximum. Estimated prescribed amounts for Packages I and II are set at the maximum amounts of 806 reconstituted liquid ounces for liquid concentrate and ready to feed infant formulas; for powder infant formula the current 8 pound limit is used.

- The reconstituted fluid ounces from powder infant formula is a weighted average of the powder container yield for the three infant formula brands with which state agencies have rebate contracts: Mead Johnson, Ross and Nestle (as determined by State agency contracts as of February 2007.)<sup>33</sup>

- Total infant formula allowance for each package is weighted by the percentage of infants receiving each of the three forms (liquid concentrate, ready to feed, and powder) as distributed in the WIC participant characteristic data set.

- Interim Food Packages I and II
- Infant Formula:

- All packages are set at the maximum monthly allowance for liquid concentrate, ready to feed and powder infant formulas as detailed in the interim rule.

- Powder infant formula is rounded up to meet the Full Nutritional Benefit (the maximum monthly allowance of reconstituted liquid concentrate), but to not exceed the maximum monthly powder infant formula limit.

- The reconstituted fluid ounces from powder infant formula is a weighted average of the powder container yield for the three formula brands with which state agencies have rebate contracts: Mead Johnson, Ross and Nestle (as determined by state agency contracts as of February 2007).<sup>34</sup>

- Interim Food Package I BF/FF-A assumes 100 percent powder infant formula. This is consistent with IOM recommendations.

- Total infant formula allowance for each package is weighted by the percentage of infants receiving each of the three forms (liquid concentrate, ready to feed, and powder) as distributed in the WIC participant characteristic data set.

- Infant Foods:
- Only Package II has infant foods.

Container sizes are based on IOM assumptions: infant fruits and vegetables amounts are determined using Gerber

<sup>33</sup> The primary DHA/ARA enhanced powder formulas prescribed by WIC clinics for each of the manufacturers was used in computing the weighted average.

<sup>34</sup> The primary DHA/ARA enhanced powder formulas prescribed by WIC clinics for each of the manufacturers was used in computing the weighted average.

container sizes weighted over the 6 month package period.<sup>35</sup>

- Bananas are allowed to be substituted for infant fruit at the rate of 2 pounds per 16 ounces of fruit. The interim package cost estimate assumes 1.8 pounds of bananas as substitution.

The interim rule requires State agencies to issue at least the full nutritional benefit of infant formula but not more than the maximum monthly allowance for the food package category and infant feeding option. However, rounding up to the whole container to meet the full nutritional benefit under the interim rule, when compared to the maximum monthly allowance under the current rule, provides more containers per month, which in turn results in higher costs. In addition, under both the current and interim packages, the round up provision is assumed to apply in all States at full implementation beginning in FY08. Therefore, this analysis provides the most conservative estimate of the additional cost

due to rounding (assuming container sizes do not change), as there is no way to accurately determine which States will elect to include a round up provision in their infant formula rebate contract and opt to round up going forward.

iii. Redemption rates

Tables 4 and 5 show the maximum amount per food category and estimated average prescribed amounts used to calculate costs for the food packages under the interim rule and under the current rule, respectively. Each table includes the individual food package component and its corresponding unit of measurement.

WIC foods are provided by quantity, except for the fruit and vegetable voucher. As stated in the interim rule, participants will be given a fruit and vegetable voucher with a fixed dollar value which can be used to purchase fruit and vegetables. Because the fruit and vegetable voucher provides WIC benefits in a different form than is currently used, different redemption behavior is to be

expected. Therefore, in developing a cost estimate for the rule, it is assumed that these vouchers will be redeemed at a rate of 87.5 percent, which is consistent with an evaluation of a WIC fruit and vegetable intervention in Los Angeles in 2004.<sup>36</sup> Per participant, a redemption value of \$5.25 for children, \$7.00 for pregnant, partially breastfeeding and postpartum women, and \$8.75 for fully breastfeeding women was included in the cost of the respective food package.

All other WIC foods are assumed to be redeemed at a 100% rate. The assumption of 100% redemption rates for other WIC foods reflects research findings which indicate that redemption rates for current WIC foods are high and vary little by food item (ranging from 94–99 percent).<sup>37</sup> Variation in the quantity of foods purchased by participants is reflected in the prescription rates. Thus a simplifying assumption of 100 percent redemption rates was used for WIC foods prescribed by quantity.

TABLE 4.—PRESCRIPTION ESTIMATES UNDER INTERIM RULE<sup>38</sup>

Food package	Units <sup>39</sup>	Maximum amount per food category <sup>40</sup>	Estimated average prescribed amount
<b>Infants: Food Package I</b>			
I–FF–A (0–3.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	806	842.65
I–FF–B (4–5.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	884	931.37
I–BF/FF–A (0–0.9 mo):			
Formula (post-rebate) <sup>41</sup> .....	reconstituted fluid oz .....	104	0.00
I–BF/FF–B (1–3.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	364	390.14
I–BF/FF–C (4–5.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	442	470.66
I–BF–A (0–3.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	0	0.00
I–BF–B (4–5.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	0	0.00
<b>Infants: Food Package II</b>			
II–FF (6–11.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	624	656.66
Cereal .....	oz .....	24	20.10
Baby fruits & vegetables .....	oz .....	128	105.37
Bananas .....	lb .....		1.80
II–BF/FF (6–11.9 mo):			
Formula (post-rebate) .....	reconstituted fluid oz .....	312	355.32
Cereal .....	oz .....	24	20.93
Baby fruits & vegetables .....	oz .....	128	105.37
Bananas .....	lb .....		1.80
II–BF (6–11.9 mo):			
Cereal .....	oz .....	24	22.27
Baby fruits & vegetables .....	oz .....	256	225.03
Bananas .....	lb .....		1.80
Infant food meat .....	oz .....	77.5	73.06
<b>Children: Food Package IV</b>			
IV–A (1–1.9 yrs):			
Juice .....	oz .....	128	127.59

<sup>35</sup> The prescription rates for infant cereal, fruit and vegetables, and meat are set to the average prescription rate of juice across all of the women’s food packages. The estimate assumes that no state will authorize rounding of infant foods.

<sup>36</sup> Herman, Dena and Harrison, Gail, “Are Economic Incentives Useful for Improving Dietary Quality among WIC participants and their Families?” ERS, USDA, 2004.

<sup>37</sup> Food and Nutrition Service, U.S. Department of Agriculture, “National Survey of WIC Participants”, October 2001.

TABLE 4.—PRESCRIPTION ESTIMATES UNDER INTERIM RULE<sup>38</sup>—Continued

Food package	Units <sup>39</sup>	Maximum amount per food category <sup>40</sup>	Estimated average prescribed amount
Milk (whole) .....	qt .....	16	13.01
Cheese .....	lb .....	.....	0.96
Cereal .....	oz .....	36	34.39
Eggs .....	doz .....	1	1.00
Whole grain bread .....	lb .....	2	1.22
Other grains .....	lb .....	.....	0.69
Beans, dried <sup>42</sup> .....	lb .....	1	0.30
Beans, canned .....	oz .....	.....	19.54
Peanut butter .....	oz .....	.....	6.27
Fruit and vegetable voucher. <sup>43</sup> .....	voucher (\$) .....	6.00	5.25
<b>IV-B (2–4.9 yrs):</b>			
Juice .....	oz .....	128	127.59
Milk, fat-reduced .....	qt .....	16	13.01
Cheese .....	lb .....	.....	0.96
Cereal .....	oz .....	36	34.39
Eggs .....	doz .....	1	1.00
Whole grain bread .....	lb .....	2	1.22
Other grains .....	lb .....	.....	0.69
Beans, dried .....	lb .....	1	0.30
Beans, canned .....	oz .....	.....	19.54
Peanut butter .....	oz .....	.....	6.27
Fruit and vegetable voucher. <sup>43</sup> .....	voucher (\$) .....	6.00	5.25
<b>Women: Food Package V</b>			
<b>V:</b>			
Juice .....	oz .....	144	143.40
Milk, fat-reduced .....	qt .....	22	16.90
Soy beverage .....	qt .....	.....	1.66
Tofu .....	lb .....	.....	0.05
Cheese .....	lb .....	.....	0.97
Cereal .....	oz .....	36	35.09
Eggs .....	doz .....	1	1.00
Whole grain bread .....	lb .....	1	0.63
Other grains .....	lb .....	.....	0.35
Beans, dried <sup>44</sup> .....	lb .....	1	0.60
Beans, canned .....	oz .....	.....	38.63
Peanut butter .....	oz .....	18	13.41
Fruit and vegetable voucher. <sup>43</sup> .....	voucher (\$) .....	8.00	7.00
<b>Women: Food Package VI</b>			
<b>VI:</b>			
Juice .....	oz .....	96	95.54
Milk, fat-reduced .....	qt .....	16	11.68
Soy beverage .....	qt .....	.....	1.29
Tofu .....	lb .....	.....	0.02
Cheese .....	lb .....	.....	0.95
Cereal .....	oz .....	36	34.70
Eggs .....	doz .....	1	0.95
Beans, dried <sup>44</sup> .....	lb .....	1	0.23
Beans, canned .....	oz .....	.....	14.69
Peanut butter .....	oz .....	.....	9.06
Fruit and vegetable voucher. <sup>43</sup> .....	voucher (\$) .....	8.00	7.00
<b>Women: Food Package VII</b>			
<b>VII:</b>			
Juice .....	oz .....	144	143.64
Milk, fat-reduced .....	qt .....	24	17.51
Soy beverage .....	qt .....	.....	1.46
Tofu .....	lb .....	.....	0.01
Cheese .....	lb .....	.....	1.60
Cheese .....	lb .....	1	1.00
Cereal .....	oz .....	36	35.87
Eggs .....	doz .....	2	1.98
Whole grain bread .....	lb .....	1	0.63
Other grains .....	lb .....	.....	0.35
Canned fish .....	oz .....	30	.....
Tuna .....	oz .....	.....	22.44

TABLE 4.—PRESCRIPTION ESTIMATES UNDER INTERIM RULE <sup>38</sup>—Continued

Food package	Units <sup>39</sup>	Maximum amount per food category <sup>40</sup>	Estimated average prescribed amount
Salmon, sardines, mackerel .....	oz .....	.....	6.11
Beans, dried <sup>44</sup> .....	lb .....	1	0.60
Beans, canned .....	oz .....	.....	38.63
Peanut butter .....	oz .....	18	13.41
Fruit and vegetable voucher. <sup>43</sup> .....	voucher (\$) .....	10.00	8.75

TABLE 5.—PRESCRIPTION ESTIMATES FOR CURRENT FOOD PACKAGES

Food package	Units <sup>45</sup>	Maximum amount per food category	Estimated average prescribed amount
<b>Infants: Food Package I</b>			
I—Fully breast-fed:			
Formula .....	reconstituted fluid oz .....	806	79.58
I—Partially breast-fed:			
Formula .....	reconstituted fluid oz .....	806	546.55
I—Fully formula-fed:			
Formula .....	reconstituted fluid oz .....	806	906.33
<b>Infants: Food Package II</b>			
II—Fully breast-fed 4–6.9 mo:			
Formula .....	reconstituted fluid oz .....	806	77.38
Juice .....	oz .....	96	34.09
Cereal .....	oz .....	24	20.63
II—Partially breast-fed 4–6.9 mo:			
Formula .....	reconstituted fluid oz .....	806	613.76
Juice .....	oz .....	96	53.80
Cereal .....	oz .....	24	16.60
II—Fully formula-fed 4–6.9 mo:			
Formula .....	reconstituted fluid oz .....	806	906.33
Juice .....	oz .....	96	41.93
Cereal .....	oz .....	24	16.99
II—Fully breast-fed 7–11.9 mo:			
Formula .....	reconstituted fluid oz .....	806	77.12
Juice .....	oz .....	96	81.15
Cereal .....	oz .....	24	22.28
II—Partially breast-fed 7–11.9 mo:			
Formula .....	reconstituted fluid oz .....	806	637.89
Juice .....	oz .....	96	69.30
Cereal .....	oz .....	24	21.08
II—Fully formula-fed 7–11.9 mo:			
Formula .....	reconstituted fluid oz .....	806	906.33
Juice .....	oz .....	96	76.42
Cereal .....	oz .....	24	20.27

<sup>38</sup>The only significant change to Food Package III in the interim rule is the proposed addition of foods to these recipients' packages when their medical circumstances allow it. The PC2002 data set indicates that about 1 percent of WIC participants receive Food Package III. FNS assumes that half of them will be able to and will choose to receive all of the other foods available to them under the proposed rule. Therefore, we do not calculate prescription rates for Food Package III.

<sup>39</sup>Units are expressed in: fluid ounces (fluid oz); ounces (oz); pounds (lb); quarts (qt); and, dozens (doz).

<sup>40</sup>Infant formula amounts are expressed in the full nutritional benefit amount of reconstituted liquid concentrate required for that age group. The interim rule details the maximum formula amounts allowed for each form of infant formula.

<sup>41</sup>Although partially breastfed infants will be allowed up to 104 reconstituted fluid ounces in the first month following birth in the interim rule, this

analysis does not estimate a prescribed amount. For more discussion, see Section E, Item 3.

<sup>42</sup>Total ounces for dried beans, canned beans and peanut butter exceed 1lb because participants can substitute 64 ounces of canned beans or 18 ounces of peanut butter for 1lb of dried beans.

<sup>43</sup>Prescribed amount for fruit and vegetable vouchers is the redemption rate as discussed in 3a (iii) within this section.

<sup>44</sup>Total ounces for dried and canned beans exceed 1lb because participants can substitute 64 ounces of canned beans for 1lb of dried beans.

TABLE 5.—PRESCRIPTION ESTIMATES FOR CURRENT FOOD PACKAGES—Continued

Food package	Units <sup>45</sup>	Maximum amount per food category	Estimated average prescribed amount
<b>Children: Food Package IV</b>			
IV:			
Juice .....	oz .....	288	232.77
Milk .....	qt .....	24	16.58
Cheese .....	lb .....	.....	1.57
Cereal .....	oz .....	36	34.39
Eggs .....	doz .....	2.5	1.83
Beans, dried .....	lb .....	1	0.61
Peanut butter .....	oz .....	.....	6.27
<b>Women: Package V</b>			
V:			
Juice .....	oz .....	288	267.83
Milk .....	qt .....	28	20.94
Cheese .....	lb .....	.....	1.84
Cereal .....	oz .....	36	35.09
Eggs .....	doz .....	2.5	1.99
Beans, dried .....	lb .....	1	0.55
Peanut butter .....	oz .....	.....	7.29
<b>Women: Package VI</b>			
VI:			
Juice .....	oz .....	192	185.54
Milk .....	qt .....	24	17.15
Cheese .....	lb .....	.....	1.65
Cereal .....	oz .....	36	34.70
Eggs .....	doz .....	2.5	1.78
<b>Women: Package VII</b>			
VII:			
Juice .....	oz .....	336	319.32
Milk .....	qt .....	28	22.28
Cheese as milk substitute .....	lb .....	.....	1.65
Cheese .....	lb .....	1	1.00
Cereal .....	oz .....	36	35.87
Eggs .....	doz .....	2.5	2.00
Beans, dried .....	lb .....	1	1.20
Peanut butter .....	oz .....	18	13.41
Tuna .....	oz .....	26	24.75
Carrots .....	lb .....	2	1.99

## iv. Food Prices

The price data used in this analysis is based primarily on tabulations from the calendar year 2005 AC Nielsen Homescan dataset.<sup>46</sup> Homescan data is captured by AC Nielsen panel members who record their purchases at home with handheld scanners. This type of panel data is well-suited to the WIC food package analysis. Unlike data gathered from point of sale scanners, panel data is potentially more comprehensive; it is able to capture purchases from retailers of every size and type, including supermarkets, convenience stores, drug stores, and vendors

<sup>45</sup> Units are expressed in fluid ounces (fluid oz), ounces (oz), pounds (lb), quarts (qt), and dozens (doz).

<sup>46</sup> Prices displayed in Table 6 are inflated to FY 2006 levels using Bureau of Labor Statistics CPI estimates.

who lack checkout scanning equipment.<sup>47</sup> In addition, demographic information collected from Homescan panelists allows FNS to distinguish shoppers with WIC-eligible incomes from the rest of the population.

Homescan panels are geographically and demographically stratified random samples of individuals weighted to represent all U.S. households. A few of the demographic strata used by Nielsen are household size, household income, household race, and several characteristics of the head of household. Nielsen monitors and evaluates the performance of panelists, and data collected by panelists undergo various internal consistency checks. (No commenters on the proposed rule raised questions or identified potential limitations with regard to AC Nielsen Homescan data.)

<sup>47</sup> Homescan data also captures purchases of non-UPC coded (non-scannable) random weight items such as fresh produce.

FNS had access to two Homescan panel samples. The 39,000 panelists in the first sample record calendar year 2005 purchases of all scannable products. A smaller subsample of 8,200 panelists record purchases of all items, including random weight, non-UPC-coded items. Most of the foods in the current and interim rule food packages are UPC-coded, standard-weight, pre-packaged (i.e., scannable) items. For that reason, most of the prices computed by FNS are taken from purchases recorded by the larger Homescan panel.

FNS focused its analysis on purchases by individuals with WIC-level incomes. FNS generated its own subsamples of panelists whose reported household size and annual income indicate that they are WIC income-eligible. The income-eligible working dataset drawn from the larger of the two Homescan panels (used for most of FNS's price computations) contains 8,400 panelists. The working dataset drawn from the smaller

panel (used in few of FNS's price computations) contains 1,600 panelists.

a. Computation of Average Prices

For each of the food items in the current or interim packages, FNS computed the average price paid by households with WIC-eligible incomes. All prices are weighted by the aggregate volumes purchased by WIC-eligible product variety, container size, flavor, brand, etc.

Product descriptions captured by Nielsen sometimes lack the detail necessary to separate WIC-eligible items from non-eligible items. For this reason, the selection of products from the Nielsen datasets necessitates some compromise. The average

prices computed by FNS and a brief description of FNS's product selection criteria are shown in Table 6.

Food prices obtained from AC Nielsen Homescan data are inflated to FY 2006 levels with CPI estimates published by Bureau of Labor Statistics. Food items or category-specific inflation estimates were used, when available. For years after FY 2006, food costs are inflated by the Office of Management and Budget's November, 2006 Thrifty Food Plan (TFP) index except for the fruit and vegetable vouchers which are inflated by the USDA's agricultural baseline projections for retail fruit and vegetable prices. (See Tables B and C in Appendix A for more detail.)

In each case, prices are computed only for products in container sizes consistent with current WIC regulations, typical state agency requirements, or the interim rule. Products identified as organic were excluded; states typically disallow organic varieties for cost reasons. FNS also adjusted infant formula prices to account for State agencies prescribing infant formulas enhanced with DHA/ARA, which tend to cost WIC more than non-enhanced infant formulas. This analysis provides a conservative estimate that assumes all states will issue enhanced infant formulas exclusively during the five-year period.<sup>48</sup>

TABLE 6.—WIC FOODS: FOOD ITEM, SELECTION CRITERIA, UNITS, AND PRICES PER UNIT

Food item	Retail sales database selection criteria	Units	Price per unit (inflated to FY06)
Infant formula (post rebate): <sup>49</sup>			
Powdered .....	Enhanced formulas <sup>50</sup> in powdered, liquid concentrate, and ready-to-feed forms.	oz .....	\$0.0312
Weighted average of all forms. <sup>51</sup> .....		oz .....	0.0331
Infant cereal (post rebate) .....	Dry grains without added fruit or other flavors .....	oz .....	0.125
Infant food:			
Infant fruit and vegetables .....	Any texture; plain fruits or vegetables .....	oz .....	0.122
Infant food meat .....	All plain meat varieties .....	oz .....	0.346
Bananas .....	Fresh. ....	lb .....	0.456
Milk:			
Whole .....	Fresh dairy milk only, 1/2 gallon or gallon containers. Reduced fat includes skim milk and milk identified as 2% or lower milk fat.	qt .....	0.767
Reduced fat .....		qt .....	0.708
Cheese .....	Processed American and domestic natural cheddar, Colby, mozzarella, brick, Monterey jack. Sliced or un-sliced varieties.	lb .....	3.292
Yogurt .....	Quart sized containers and larger. Plain, vanilla, and fruit flavors.	qt .....	2.068
Tofu .....	Plain varieties .....	lb .....	1.467
Soy beverage .....	Half gallon or larger sizes. Plain varieties. <sup>52</sup> .....	qt .....	1.370
Juice .....	Apple, grape, orange, grapefruit, tomato. Unsweetened 100% juice.	oz .....	0.032
Adult cereal .....	Weighted average of cereals commonly prescribed by state WIC agencies and whole-grain varieties. Hot or ready-to-eat.	oz .....	0.159
Eggs .....	Large or medium, white. One-dozen containers only	doz .....	0.931
Beans:			
Dry .....	Most varieties, excluding string beans and immature peas. Not mixed with other foods.	lb .....	0.805
Canned .....		oz .....	0.037
Peanut butter .....	All forms and varieties. Not mixed with jelly .....	oz .....	0.094
Whole-grain bread .....	Wheat or grain bread .....	lb .....	1.422
Brown rice .....	Instant or regular .....	lb .....	1.178
Tuna .....	Chunk light, canned .....	oz .....	0.101
Other canned fish .....	Salmon, sardines and mackerel, canned .....	oz .....	0.114
Carrots .....	Fresh, frozen, canned .....	lb .....	0.953

<sup>48</sup>This assumption is based on the percentage of States exclusively issuing enhanced formula as of the February 2007 rebate contract summary of 94%. Based on current trends, FNS believes the percentage of States exclusively issuing enhanced formula will be 100% at the time of implementation.

<sup>49</sup>The average prices computed for infant formula are based on a range of container sizes commonly prescribed by WIC clinics. Formula prices, unlike

the prices computed for other products in this analysis, are based on purchases by all individuals, not just those with WIC-eligible incomes. This has little consequence on the average price since more than half of the infant formula purchased in the U.S. is purchased by WIC participants.

<sup>50</sup>The term "enhanced formulas" means formulas that have been enhanced with two fatty acids, DHA and ARA.

<sup>51</sup>The weighted average price is used throughout this analysis except when pricing the value of formula prescriptions, under the interim rule, for partially breastfeeding infants age 0–3 months. For that one group, the interim rule recommends the prescription of powder alone.

<sup>52</sup>The price reflects purchases by individuals at all income levels. The dataset contained too few sample records when limited to purchases by individuals with WIC-eligible incomes.

#### v. Participant Projections

For this analysis, FNS makes the straightforward assumption that overall WIC participation will grow at a fixed 2.08% annual rate from February 2007 through the end of fiscal year 2012. 2.08% is a simple average of the annual observed rates of growth for each of the seven years that ended in January 2007. The participant data used to generate this growth rate is remitted by the States to FNS on a monthly basis. Participant data are reviewed for possible collection, transmission, or keying errors, but are otherwise unadjusted by FNS. The participant growth assumption used in this analysis is intended to illustrate the potential cost impacts of the revised food package over time and should not be construed as reflecting any policy or projection of future WIC participation.

Consistent with the IOM assumptions, we do not assume any changes in participation under the interim rule due to potential participants finding the revised package more or less attractive. (For more detail on participation levels by food package see Tables D and E in Appendix A.)

Many of the package changes were intended to encourage breastfeeding. However, it is important to note that this analysis does not provide an estimate of the increase in the number of breastfed infants or the additional length of time that infants will be breastfed. Due to the complex set of factors (demographic, social, environment, clinical, etc.) that influence breastfeeding duration, we are unable to estimate the number of infant/mother pairs that will switch food packages as their feeding practices change. This is consistent with the analysis provided by IOM.

The assumption of no change in breastfeeding patterns yields the most conservative cost estimate, as the net impact of increases in breastfed infants and breastfeeding women participants reduces the costs of this proposal. IOM conducted a sensitivity analysis by simulating possible shifts in participation rates. Shifting infant/mother pairs from the fully formula-fed package to the breastfeeding packages has the effect of moving infant/mother pairs from the most expensive set of packages to less

expensive ones. A constant shift of 30 percent for one to 11 months of age from partial to full breastfeeding and a smaller range of shifts from full formula feeding to full breastfeeding (with an appropriate shift in the mother's classification) decreased the average package cost by nearly two percent.<sup>53</sup>

#### vi. Phased Implementation

The analysis assumes the rule takes effect in December 2007 (FY08). During the phase-in period, State agencies will be required to issue food benefits based on either the new food packages or current food packages but cannot combine the two. State agencies may also phase-in new food packages on a participant category basis.

Based on comments from State and local agencies, the interim rule's phased-in period has been revised to reflect an 18-month period, six months longer than the implementation period in the proposed rule. In the interim rule, the elimination of juice from the infant food packages is phased-in over 18 months, rather than six months as stated in the proposed rule, from publication of the rule.

All phase-in effects are reflected in the cost estimates contained in Table 2. This analysis assumes that the remaining provisions of the rule will be phased-in over the course of 18 months beginning December 2007. It is assumed, as above, that States will implement the provisions of the rule throughout the phase-in period; the effective rate of implementation is averaged over the course of 18 months.<sup>54</sup> The rule's phase-in schedule reduces total costs in FY 2008 by \$11.1 million. FY 2009 costs are reduced by an estimated \$1.1 million.

#### vii. State Cost Variation

This analysis is based on national average prescription and price data, which indicates that program-wide, the changes are cost neutral. States may vary somewhat in their implementation experiences, depending on how closely their prescription practices and prices correspond to the national averages. WIC funding rules help address these implementation issues. The food funding formula provides mechanisms for transferring funds from States which are not fully utilizing their grants to those with need for additional funding, and these mechanisms have been successfully used in the past to address variations in States' funding needs.

#### b. Administrative Costs

State agencies and local WIC providers will incur some new costs to implement the rule. A total of six State agencies provided comments on the proposed rule that specifically addressed costs associated with implementation. In general, these States believed that additional nutrition services and administration (NSA) funds would be needed to update and enhance MIS systems,

train staff, participants and vendors, and update food lists. However, none of these commenters attempted to quantify their expected costs.

Many of the costs of implementation are similar in type to the routine recurring costs of operating a WIC program. These include training WIC clinic and administrative staff, and the periodic review and updating of WIC-approved food lists to assist vendors with their own staff training. Much of the training-related cost that State and local agencies will incur as a result of the rule will therefore displace similar recurring expenses during the phase-in period.

Other costs, such as modifying MIS systems, are non-routine expenses tied exclusively to the transition to a new set of food packages. However, MIS systems vary greatly across the States, and the effort needed to modify these systems will vary as well. FNS is not in a position to assess the level of work faced by State and local agencies. As a result, the cost of modifying State MIS systems cannot be estimated.

Despite their concerns, States were overwhelmingly supportive of the proposed changes; one State comment stated directly the judgment that the benefits from implementing the new packages will outweigh the effort needed to implement the changes.

FNS believes that State agencies and local WIC providers will be able to absorb the burden associated with implementing this rule within current NSA funds. State and local agencies have substantial flexibility in how they spend their NSA funds and may need to reprioritize or postpone some initiatives to undertake the implementation activities associated with this rule. Given the extremely positive response that this rule has received within the WIC community at both the State and local levels, we fully expect that implementation will be a priority.

#### E. Uncertainties

The estimate developed above is sensitive to changes in several key assumptions. A few of the most significant are discussed here.

##### 1. Price Volatility in the Dairy Market

Instability in dairy prices over the last several years presents a major element of uncertainty in the cost estimate. However, the maximum amount of milk available in each of the food packages is reduced. The total amount of milk that can be replaced with more expensive substitutes has been reduced as well. These factors make the revised food packages less sensitive to dairy price fluctuations than the current WIC packages. FNS examined the impact of a 10% increase and a 10% decrease in the price of milk and cheese. Since the amount of milk and cheese is being reduced in the interim packages, higher dairy prices would produce a net savings. That is, while higher dairy prices would increase the absolute cost of the interim rule's food packages, an equivalent dairy price increase would increase the absolute cost of the current rule's packages by an even greater amount. Because the increased cost is relatively smaller under the interim rule, a dairy price increase will reduce the cost of adopting the rule; the \$29.7 million savings under our baseline

<sup>49</sup> The average prices computed for infant formula are based on a range of container sizes commonly prescribed by WIC clinics. Formula prices, unlike the prices computed for other products in this analysis, are based on purchases by all individuals, not just those with WIC-eligible incomes. This has little consequence on the average price since more than half of the infant formula purchased in the U.S. is purchased by WIC participants.

<sup>50</sup> The term "enhanced formulas" means formulas that have been enhanced with two fatty acids, DHA and ARA.

<sup>51</sup> The weighted average price is used throughout this analysis except when pricing the value of formula prescriptions, under the interim rule, for partially breastfeeding infants age 0-3 months. For that one group, the interim rule recommends the prescription of powder alone.

<sup>52</sup> The price reflects purchases by individuals at all income levels. The dataset contained too few sample records when limited to purchases by individuals with WIC-eligible incomes.

<sup>53</sup> See IOM, p. 140.

<sup>54</sup> If the phase-in rate increases linearly, the rule would not be fully effective until July 2009. As a rough approximation, it is assumed that the effective rate of implementation of all provisions throughout FY 2008 averages 31 percent, with the remainder realized in the first eight months of FY 2009.

assumptions would become a \$222.5 million savings. Similarly, lower dairy prices would increase the cost of adopting the interim rule.

The impact of these price changes is summarized in the following table:

TABLE 7.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS, ASSUMING A 10% INCREASE OR A 10% DECREASE IN DAIRY PRICES

[In \$ millions]

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Cost/Savings of Rule with 10% Increase in Dairy Prices .....	-\$5.8	-\$30.8	-\$48.4	-\$61.8	-\$75.7	-\$222.5
Cost/Savings of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference Between Base Assumption and 10% Price Increase .....	10.8	38.2	45.9	47.9	50.0	192.8
Cost/Savings of Rule with 10% Decrease in Dairy Prices .....	15.8	45.5	43.3	34.0	24.4	163.1
Cost/Savings of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference Between Base Assumption and 10% Price Decrease .....	-10.8	-38.2	-45.9	-47.9	-50.0	-192.8

Negative values are cost reductions. Differences may not be exact due to rounding.

2. Assumed Preference for Soy Beverage

FNS estimates that as many as 10% of women will request soy beverage in place of liquid milk, if provided the choice.<sup>55</sup> The IOM cites high rates of lactose maldigestion and low rates of cultural acceptability of milk among African American and Asian women as important factors in its decision to introduce substitutes for milk.<sup>56</sup> African American women are represented in the WIC population at a level disproportionate to their share of the general population. In part for that reason, it is appropriate to assume a WIC participant preference for soy beverage at or near the upper range of estimates of soy beverage consumption in the U.S. as a whole. And because WIC participants may choose freely between milk and the more expensive soy substitute, without regard to cost, a natural response is consumption at a rate above the rate of those whose choice between the two products has personal cost impact.

FNS determined which women in the 2002 WIC prescription dataset were provided neither milk nor cheese. Those individuals, as a group, are assumed to be the WIC participants most inclined to request a prescription of soy beverage in place of milk. FNS' simulation model prescribes an amount of soy beverage to those individuals equal to the maximum allowed under their respective food packages. The program then substitutes soy beverage for the existing milk prescriptions of other WIC participants to the extent necessary to reach the 10% participant target. The program prescribes cheese and tofu before soy beverage; it does not replace the prescription of those milk substitutes with soy beverage. IOM took a similar approach in developing its cost estimate; it assumed that soy beverage would replace 10% of liquid milk prescriptions. In IOM's analysis, 8.7% of all milk and milk substitutes prescribed to women is in the

form of soy beverage. FNS' methodology, which incorporates the more detailed data available from PC2002, results in a somewhat lower 7.6% substitution rate for soy beverage.

Precise data on which to base a soy beverage consumption rate for adult women is not available; it is not known whether consumption is appreciably higher or lower among women than among the population generally. For these reasons, the cost of the interim rule has been re-estimated using two alternate assumptions. If soy beverage is prescribed to only 5% of women, the average Package V, VI, and VII soy beverage substitution rate is 3.8%. Conversely if soy beverage is prescribed to approximately 15% of women, the average Package V, VI, and VII soy beverage substitution rate is 11.4%. Given the high cost of soy beverage relative to milk, this uncertainty would have cost implications.

TABLE 8.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS, ASSUMING 5% OR 15% OF WOMEN ARE PRESCRIBED SOY BEVERAGE

[in \$ millions]

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Cost/Savings of Rule with alternate 5% prescription rate .....	\$1.5	-\$4.9	-\$17.2	-\$29.2	-\$41.6	-\$91.4
Cost/Savings of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference Between Base Assumption and 5% Prescription Rate ..	3.5	12.2	14.7	15.3	16.0	61.6
Cost/Savings of Rule with alternate 15% prescription rate .....	8.4	19.5	12.1	1.4	-9.6	31.9
Cost/Savings of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference Between Base Assumption and 15% Prescription Rate	-3.5	-12.2	-14.7	-15.3	-16.0	-61.6

Negative values are cost reductions. Differences may not be exact due to rounding.

3. State option to provide formula for infants 0–0.9 months of age

The proposed rule put forth three options for infant feeding within the first month of birth: (1) Fully formula feeding; (2) fully breastfeeding; or (3) partially breastfeeding. The Proposed Rule did not allow formula to be provided for partially breastfed infants under one month of age. This interim rule will allow partially breastfed infants in the

first month of life to receive no more than 104 reconstituted fluid ounces of infant formula. Food Package V will be provided to mothers of these partially breastfeeding infants.

As shown in Table 9, the low amount of formula provided to partially breastfeeding infants under one month of age and the difference in the women's packages provides a cost savings when infant/mother pairs

move to the partially breastfeeding packages during the first month after birth. FNS does not know how many fully formula feeding and fully breastfeeding mothers would opt to partially breastfeed during the infant's first month. However, given that the monthly cost of the food packages for a partially breastfeeding pair is less than the cost of the packages for either a fully breastfeeding or fully formula feeding pair, even a relatively

<sup>55</sup> AC Nielsen Homescan data indicate that approximately 10% of households with WIC-eligible incomes purchased some type of soy beverage during FY 2003. Soy beverage cannot be identified precisely in the AC Nielsen dataset. The

10% consumption figure is based on a broad product definition that includes soy beverage varieties that are not WIC-eligible under the interim rule. FNS sought to identify women who might request plain soy beverage if it is offered, cost-free,

as a milk substitute. The estimate developed here assumes that this group will include some women who are current consumers of more popular soy beverage varieties.

<sup>56</sup> IOM, p. 119.

large shift to the partially breastfeeding

packages does not threaten the overall cost neutrality of the interim rule.

TABLE 9.—COMBINED MONTHLY FOOD PACKAGE COSTS FOR INFANT/MOTHER PAIRS OF INFANTS 0–0.9 MONTHS, ASSUMING ONE CAN OF FORMULA FOR PARTIALLY BREASTFEEDING INFANTS IN FIRST MONTH

	Monthly food package costs (FY 2006)		
	Mother	Infant	Pair
Fully Formula Fed Feeding Pair .....	\$31.23	\$27.90	\$59.14
Partially Breast Fed Feeding Pair .....	40.09	3.25	43.34
Cost/Savings of Moving to Partially Breast Fed Packages .....	\$8.86	–\$24.66	–\$15.80
Fully Breast Fed Feeding Pair .....	51.30	0.00	51.30
Partially Breast Fed Feeding Pair .....	40.09	3.25	43.34
Cost/Savings of Moving to Partially Breast Fed Packages .....	–\$11.21	\$3.25	–\$7.96

4. Prescription Assumptions for Whole Grain Bread and Bread Substitutes

Because whole grain bread and bread substitutes are new additions to the WIC food packages, FNS had to develop prescription assumptions for these foods without the benefit of historic prescription data. For

purposes of this cost estimate FNS assumed that whole grain bread and bread substitutes would be prescribed to WIC participants at rates comparable to the observed prescription rates for breakfast cereal, the most closely related food in the current WIC packages.<sup>57</sup> For children’s Package IV, FNS applied an observed cereal prescription rate of 95.4%.

For packages V and VII, FNS applied an observed average rate of 97.7%.

Table 10 recomputes the cost effect of the interim rule under the alternate assumptions that the actual whole grain bread prescription rates for food packages IV, V, and VII will be as low as 90%, or as high as 100%.

TABLE 10.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS ASSUMING 90% AND 100% WHOLE GRAIN PRESCRIPTION RATES

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Cost/Savings of Rule with 90% Whole Grain Prescription Rate .....	\$2.6	\$1.2	–\$12.8	–\$24.6	–\$36.8	–\$72.9
Cost/Savings of Interim Rule .....	5.0	7.3	–2.5	–13.9	–25.6	–29.7
Difference Between Base Assumption and 90% Prescription Rate .....	\$2.4	\$8.5	\$10.3	\$10.7	\$11.2	\$43.1
Cost/Savings of Rule with 100% Whole Grain Prescription Rate .....	6.8	13.7	5.1	–5.9	–17.3	2.5
Cost/Savings of Interim Rule .....	5.0	7.3	–2.5	–13.9	–25.6	–29.7
Difference Between Base Assumption and 100% Prescription Rate .....	–\$1.8	–\$6.4	–\$7.7	–\$8.0	–\$8.4	–\$32.3

5. Prescription Assumptions for Infant Food Fruits and Vegetables, and Infant Food Meat

Jarred infant foods, like whole grain breads, are new additions to the WIC food packages. Without the benefit of historic prescription rates for these foods, FNS had to look elsewhere for a prescription assumption to use in its cost estimate. FNS considered

and rejected infant fruit juice prescriptions as a proxy, despite the fact that the jarred food benefit is comprised primarily of fruits and vegetables. Infant juice prescriptions fall well below 100%, largely because states recognize that the current package maximums exceed amounts recommended by current nutrition science. FNS believes that the interim rule’s infant foods will be prescribed at a much

higher rate. For this reason, FNS assumes that the jarred infant food prescription rate will match the observed 94.3% prescription rate for fruit juice across WIC’s women’s food packages.<sup>58</sup>

Table 11 recomputes the cost effect of the interim rule under the alternate assumptions that jarred infant food prescriptions will be as low as 90%, or as high as 100%.

TABLE 11.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS ASSUMING 90% AND 100% JARRED INFANT FOOD PRESCRIPTIONS

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Cost/Savings of Rule with 90% Infant Food Prescription Rate .....	\$2.1	–\$2.7	–\$14.6	–\$26.5	–\$38.8	–\$80.4
Cost/Savings of Interim Rule .....	5.0	7.3	–2.5	–13.9	–25.6	–29.7
Difference Between Base Assumption and 90% Prescription Rate .....	2.8	10.0	12.0	12.6	13.1	50.6
Cost/Savings of Rule with 100% Infant Food Prescription Rate .....	8.7	20.4	13.1	2.5	–8.6	36.0
Cost/Savings of Interim Rule .....	5.0	7.3	–2.5	–13.9	–25.6	–29.7
Difference Between Base Assumption and 100% Prescription Rate .....	–3.7	–13.0	–15.6	–16.3	–17.1	–65.8

<sup>57</sup> Observed rates were taken from PC2002.

<sup>58</sup> Because the estimate assumes no rounding up of jarred infant foods, the net average prescription

rate is slightly less than 94.3% for baby food fruits and vegetables. The average prescription for baby food meat is a full 94.3%, however, because the

maximum monthly allowance of 77.5 oz is evenly divisible by the most commonly marketed jar size.

6. Changes in Current Food Package Sizes  
 The current and interim rules specify maximum food allowances in units of weight or volume. Several comments on the Proposed Rule asked that food allowances be expressed in package units, such as number of jars or containers, or that maximum weights and volumes match package sizes currently available. Specifically, issues were raised regarding current package sizes of juice, jarred infant foods and whole grain bread (further discussed in Section F, Item 2).  
 FNS recognizes that package sizes of WIC-eligible foods vary among manufacturers as well as regions. FNS also recognizes that manufacturers may change package sizes at any time. However, basing the maximum allowances in the interim rule on package sizes does not reduce the possibility of future changes in package sizes. This cost estimate

does not incorporate any potential changes in package sizes but assumes that the maximum monthly allowance will be able to accommodate future changes to food packages sizes.

7. Uncertainties Summary

Table 12 presents two additional cost estimates that reflect the potential aggregated effect of these alternative assumptions. The first assumes that all of the cost increasing alternate assumptions discussed above are realized. The second assumes that all of the cost decreasing alternate assumptions are realized.

- Scenario 1:
  - a. Jarred infant foods will be prescribed at a 100% rate to eligible infants
  - b. Whole grain bread and bread substitutes will be prescribed at a 100% rate

- c. 15% of women will be prescribed some soy beverage as a milk substitute
  - d. Dairy prices will decrease by 10%
- Scenario 2:
- a. Jarred infant foods will be prescribed at a 90% rate to eligible infants
  - b. Whole grain bread and bread substitutes will be prescribed at a 90% rate
  - c. 5% of women will be prescribed some soy beverage as a milk substitute
  - d. Dairy prices will increase by 10%
- The resulting combined range of uncertainty based on these assumptions is from a savings of \$342 million to a cost of \$359 million over five years, or -1.1% to +1.2% of total projected WIC program costs during that period, relative to the base assumptions.

TABLE 12.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS UNDER ALTERNATE EXTREME ASSUMPTIONS

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Cost of Rule Under Scenario 1 .....	\$25.1	\$78.4	\$82.9	\$75.4	\$67.6	\$329.3
Cost/Savings of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference Between Base Assumption and Scenario 1 .....	-20.1	-71.0	-85.4	-89.3	-93.2	-359.1
Savings of Rule Under Scenario 2 .....	-14.2	-60.3	-83.8	-98.8	-114.3	-371.4
Cost/Savings of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference Between Base Assumption and Scenario 2 .....	19.2	67.6	81.3	84.9	88.7	341.6

F. Alternatives

Based on comments received, FNS considered several alternatives to the Proposed Rule. Some of these alternatives are discussed below. Each of these alternatives was ultimately rejected because FNS believes that a food package which reflects the IOM recommendations as closely as possible within the constraint of cost neutrality best reflects current scientific consensus on how to meet the dietary needs of WIC participants.

1. Include Yogurt as a Milk Substitute for Food Packages IV–VII

For Food Packages IV–VII, the IOM identified yogurt, tofu, and soy beverage as

new milk substitutes to help ensure adequate calcium intake by those who cannot consume milk and to accommodate cultural preferences. Under the current rule cheese is also available as a milk substitute for up to three quarts of milk. IOM's recommendation specifically called for substituting one quart of yogurt or tofu for one quart of milk, and for limiting substitutions of cheese, yogurt, and tofu to four quarts of milk for Food Packages IV, V and VI, and six quarts of milk for Food Package VII. Soy beverage would be allowed for the entire milk allowance for Food Packages V, VI, and VII.

In order to maintain cost-neutrality, the Proposed Rule eliminated yogurt as a milk substitute, but allows the substitution of tofu,

cheese and soy beverages up to the IOM maximum substitution level. As shown in Table 13, the price of yogurt, \$2.07 per quart, as compared to \$.71 per quart for reduced-fat milk, considerably increases the monthly cost of Food Packages IV–VII. Soy beverage and tofu also have higher per unit costs than milk; however, the estimated amount of tofu purchased by WIC participants is substantially lower than that of yogurt, and soy beverage is priced lower than yogurt (\$.70 less per quart) making it a more cost-efficient substitute.

TABLE 13.—PROJECTED COST OF YOGURT AS A MILK SUBSTITUTE

Food package	Estimated average prescribed amount (qt.)	Price per unit (inflated to FY06)	Cost per food package
IV .....	0.86	\$2.07	\$1.78
V .....	0.84	2.07	1.74
VI .....	0.66	2.07	1.37
VII .....	0.83	2.07	1.72

The economic impact of including yogurt as a milk substitute is shown in Table 14. The five year cost of the rule, as modified by

this alternative, is \$384.0 million. The cost of the interim rule without yogurt is -\$29.7 million (see Table 2). Therefore, the

elimination of yogurt is retained in this interim rule.

TABLE 14.—PROJECTED COST OF WIC FOOD PACKAGE REVISIONS, INCLUDING YOGURT AS A MILK SUBSTITUTE  
[In \$ millions]

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Total Cost of Rule with Alternate Assumption .....	\$28.2	\$89.2	\$95.9	\$88.9	\$81.8	\$384.0
Total Cost of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference .....	-23.2	-81.9	-98.4	-102.8	-107.4	-413.7

Negative values are cost reductions. Differences may not be exact due to rounding.

2. Increase the Whole Grain Maximum Allowance for Women to 24 Ounce Increments

The Proposed Rule established a maximum of whole wheat bread or other whole grain—rice, barley (whole-grain), bulgur (cracked wheat), oatmeal and soft corn tortillas—monthly allowance of two pounds for children in Food Package IV and one pound for women in Food Packages V and VII. As recommended by the IOM, this is an

enhancement to the current food packages which do not provide whole grains (except in breakfast cereals).

Some comments on the Proposed Rule stated that most bread loaves are not sold in one or two pound packages and participants would have difficulty purchasing the maximum monthly allowance. In order to accommodate current bread package sizes the maximum allowance for whole grains would need to be increased to 48 ounces for children and 24 ounces for women. Not only

would changing the whole grain maximum allowance to accommodate package sizes currently available in the market significantly increase the overall cost of the interim rule (as shown in Table 15), it is not administratively practical for FNS to change maximum allowances based on current manufacturer packaging as they may vary by region and may change in future years. Therefore, whole grain maximum allowances set in the Proposed Rule are retained in this interim rule.

TABLE 15.—PROJECTED COST (+) / SAVINGS (-) ASSOCIATED WITH INCREASING THE WHOLE GRAIN MAXIMUM ALLOWANCE FOR WOMEN AND CHILDREN  
[In \$ millions]

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Total Cost of Rule with Alternative .....	\$25.2	\$78.7	\$83.3	\$75.8	\$68.0	\$331.1
Total Cost of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference .....	-\$20.2	-\$71.4	-\$85.8	-\$89.7	-\$93.7	-\$360.8

Negative values are cost reductions. Differences may not be exact due to rounding.

3. Fresh Fruits and Vegetables for Infants

The Proposed Rule added jarred infant fruits and vegetables to Food Package II and jarred infant meats to Food Package II for fully breast fed infants. Food Package II also provides a maximum allowance of two pounds of fresh bananas. Comments on the Proposed Rule asked that fresh, canned or

frozen fruits and vegetables be allowed in Food Package II instead of or as an option to jarred infant fruits and vegetables.

The estimate shown below assumes that cash value vouchers replace the interim rule's current infant fruit and vegetable provision. The initial value of the vouchers are set to the nearest whole dollar equivalent of the interim rule's recommended quantity

of infant fruits and vegetables. It is assumed that the vouchers are redeemed and inflated in the same manner as the fruit and vegetable vouchers for women and children. In place of the interim rule's current provision, a fruit and vegetable voucher for infants would reduce the overall cost of the rule by \$133.2 million over five years.<sup>59</sup>

TABLE 16.—PROJECTED COST (+) / SAVINGS (-) ASSOCIATED WITH ISSUING FRESH FRUIT AND VEGETABLE VOUCHERS TO INFANTS 6–11.9 MONTHS OF AGE  
[In \$ millions]

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	Total
Total Cost of Rule with Alternative .....	\$1.0	-\$11.0	-\$27.6	-\$44.6	-\$50.9	-\$133.2
Total Cost of Interim Rule .....	5.0	7.3	-2.5	-13.9	-25.6	-29.7
Difference .....	4.0	18.3	25.0	30.8	25.3	103.5

Negative values are cost reductions. Differences may not be exact due to rounding.

The IOM recommended that commercial baby food fruits and vegetables and fresh bananas replace juice in the current package. The IOM encourages the continuation of full

breastfeeding past 6 months, and recommended that higher amounts of baby food fruits and vegetables and baby food meats be provided to fully breastfeeding

infants. Commercial baby foods were recommended due to nutrient content, availability in developmentally appropriate textures, and food safety.<sup>60</sup> In addition, the

<sup>59</sup>The savings is a consequence of two factors. The first is the assumption that fruit and vegetable vouchers for infants will be issued at their full values, but redeemed at a rate of just 87.5% (the same assumption that applies to fruit and vegetable vouchers for women and children in the baseline estimate.) The jarred fruit and vegetable benefit, by

contrast, is assumed to be prescribed at an average rate equal to 94.3% of the package maximum (95.8% after rounding up to an even number of jars) and redeemed by beneficiaries at 100%. The second factor which makes the voucher option relatively less expensive is the voucher inflation and rounding rule which limits future increases to

whole dollar increments. The effects of inflation are accrued annually, but not realized until the cumulative increase in the CPI is sufficient to raise the voucher's value by a dollar. See interim rule section 246.16(j).

<sup>60</sup>IOM, p. 103.

provision of commercial baby food fruits and vegetables helps ensure that these items are consumed by infants and not other household members. FNS believes that nutrition education provided by WIC staff related to appropriate food choices and home preparation of foods for infants is compatible with provision of jarred infant foods. Therefore, this alternative was rejected.

4. Soy Beverage Substitution for Children Without Medical Documentation

The Proposed Rule allowed State agencies to authorize, with medical documentation, soy-based beverages and tofu substitutions for milk for children in Food Package IV. Some comments received on the Proposed Rule expressed opposition to the medical documentation requirement citing that it creates barriers for children to obtain foods that meet cultural needs.

Requiring medical documentation for dairy alternatives ensures that a health care provider is aware that children may be at nutritional risk when milk is replaced by other foods. The IOM recommended that soy beverage not be made available to children to satisfy participant preference in the absence of medical need.

Research suggests that up to 4% of children consume some sort of soy beverage and that percentage increases as they get older.<sup>61</sup> FNS does not collect data on the percentage of WIC children who request milk alternatives, and the percentage of children that would request soy beverage in place of milk is difficult to estimate. However, given

the price differential between reduced fat milk (\$.71 per quart) and soy beverage (\$1.37 per quart), and the number of WIC-eligible children, substitution of soy beverage for milk without medical documentation could result in a significant increase to the overall cost of the rule.

On both economic grounds and on the expert recommendation of the IOM, FNS retains the medical documentation requirement for soy beverage in the children's food package.

G. Market Share Analysis

The changes in the quantities and types of foods provided by the WIC program should result in changes in the quantities and types of foods that WIC participants buy with their WIC vouchers. The complete market impact of this rule is difficult to accurately quantify because we do not know the extent to which WIC foods substitute for purchases WIC participants would have otherwise made with their own funds. Empirical research on this issue is inconclusive.<sup>62</sup> Because of this uncertainty, we present two scenarios. In the first (Table 17), we assume full substitution—that is, all foods purchased with WIC vouchers under the current packages would otherwise be purchased with the participants' own funds under the interim rule. In the second (Table 18), we assume the alternate—that none of the foods purchased with WIC vouchers would otherwise be purchased with the participants' own funds. In both scenarios, the potential impact of the interim rule on the total market size for most

foods is relatively modest, as is the impact on WIC's share of the total market.

We estimated the total value of WIC sales<sup>63</sup> for each food item and the total annual U.S. retail sales for each WIC food item. To estimate WIC sales, we multiplied the average unit price per food item by an estimate of the quantity of food purchased by WIC participants (the average estimated participation multiplied by the amount of food prescribed to a participant throughout the course of a year).<sup>64</sup> To estimate total annual sales, 2005 AC Nielsen Productscan data was used to calculate total volume and annual grocery store sales of the different categories of food products.<sup>65</sup> We used calendar year (CY) 2005 participation, cost and sales estimates for our market share analysis. Although the rule does not take effect until FY2008, we cannot reliably make projections about the overall sales of WIC food items for the next two years; we believe the CY2005 data provides a good indication of the relative impact of the rule's changes on each food item.

It is important to note that this approach understates the size of the total markets for WIC food items (and thus overstates both WIC's market share and the potential impact of the changes on WIC food markets), because the data used to estimate total market size is limited to grocery store sales. Data on sales through other outlets was not available, but would likely significantly increase the estimated size of the total market for WIC foods.

TABLE 17.—ESTIMATED TOTAL ANNUAL SALES, WIC SALES, AND WIC PERCENT OF MARKET FOR CURRENT FOOD PACKAGE AND INTERIM FOOD PACKAGE, ASSUMING FULL SUBSTITUTION OF WIC FOODS IN TOTAL ANNUAL SALES, CY2005

WIC food item	Current food package			Interim food package		
	Estimated total annual sales (\$)	Estimated total WIC sales (\$) <sup>66</sup>	WIC % of market <sup>67</sup>	Estimated total annual sales (\$)	Estimated total WIC sales (\$) <sup>66</sup>	WIC % of market <sup>67</sup>
Formula .....	3,600,257,587	2,533,590,541	70.4	3,600,257,587	2,025,525,861	56.3
Beans .....	874,176,643	32,179,354	3.7	874,176,643	82,632,904	9.5
Peanut butter .....	1,133,273,041	40,935,940	3.6	1,133,273,041	54,492,515	4.8
Milk .....	16,043,036,006	975,287,323	6.1	16,043,036,006	712,840,678	4.4
Adult cereal .....	9,697,058,781	399,336,655	4.1	9,697,058,781	399,336,655	4.1
Juice .....	14,203,760,671	556,756,383	3.9	14,203,760,671	281,143,313	2.0
Rice .....	737,198,377	0	.....	737,198,377	43,442,898	5.9
Fruit and vegetables .....	15,761,934,300	7,512,820	0.0	15,761,934,300	431,691,818	2.7
Eggs .....	2,959,401,900	120,241,255	4.1	2,959,401,900	67,192,054	2.3
Cheese .....	12,329,016,799	386,210,204	3.1	12,329,016,799	247,273,210	2.0
Bread .....	17,028,860,749	0	.....	17,028,860,749	93,740,564	0.6
Canned fish .....	1,917,928,393	9,191,549	0.5	1,917,928,393	10,885,456	0.6
Infant cereal <sup>68</sup> .....	.....	56,640,143	.....	.....	42,641,463	.....
Baby food <sup>68</sup> .....	.....	0	.....	.....	185,899,515	.....
Tofu <sup>68</sup> .....	.....	0	.....	.....	1,088,288	.....
Soy beverage <sup>68</sup> .....	.....	0	.....	.....	49,561,168	.....

<sup>61</sup> United Soybean Board, Current Knowledge on Soy and Children's Diets, August 2004, prepared by N. Chapman and Associates. [http://www.soyfoods.org/wp-content/uploads/2006/11/soy\\_and\\_child\\_diet.pdf](http://www.soyfoods.org/wp-content/uploads/2006/11/soy_and_child_diet.pdf).

<sup>62</sup> Mary Kay Fox, William Hamilton, Biing-Hwan Lin, *Effects of Food Assistance and Nutrition Programs on Nutrition and Health, Volume 3, Literature Review, Economic Research Service*, U.S. Department of Agriculture, Food Assistance and

Nutrition Research Report Number 19-3. October 2004.

<sup>63</sup> WIC sales refer only to sales produced by the use of WIC vouchers, not the total sales from all purchases made by WIC participants.

<sup>64</sup> Prescription amounts used in this market share analysis are the same as those used in the cost analysis.

<sup>65</sup> Total annual sales include foods that fit in the category of food product, but may not be WIC

eligible (i.e., within cereal, total sales include cereals of any sugar content and cereals without whole grains). This was done to accurately portray the impact of the proposed food package on the whole market and not just the narrow sub-market of "WIC eligible" food. Because AC Nielsen Productscan data covers approximately 70% of the total grocery market, total annual sales were adjusted by dividing by 70%.

TABLE 17.—ESTIMATED TOTAL ANNUAL SALES, WIC SALES, AND WIC PERCENT OF MARKET FOR CURRENT FOOD PACKAGE AND INTERIM FOOD PACKAGE, ASSUMING FULL SUBSTITUTION OF WIC FOODS IN TOTAL ANNUAL SALES, CY2005—Continued

WIC food item	Current food package			Interim food package		
	Estimated total annual sales (\$)	Estimated total WIC sales (\$) <sup>66</sup>	WIC % of market <sup>67</sup>	Estimated total annual sales (\$)	Estimated total WIC sales (\$)	WIC % of market <sup>67</sup>
Total .....	96,285,903,247	5,117,882,167	6.4	96,285,903,247	4,729,388,359	4.6

TABLE 18.—ESTIMATED TOTAL ANNUAL SALES, WIC SALES, AND WIC PERCENT OF MARKET FOR CURRENT FOOD PACKAGE AND INTERIM FOOD PACKAGE, ASSUMING NO SUBSTITUTION OF WIC FOODS IN TOTAL ANNUAL SALES, CY2005

WIC food item	Current Food Package			Interim food package		
	Estimated total annual sales (\$)	Estimated total WIC sales (\$) <sup>69</sup>	WIC % of market <sup>70</sup>	Estimated total annual sales (\$)	Estimated total WIC sales (\$)	WIC % of market <sup>70</sup>
Formula .....	3,600,257,587	2,533,590,541	70.4	3,092,192,907	2,025,525,861	65.5
Beans .....	874,176,643	32,179,354	3.7	924,630,192	82,632,904	8.9
Peanut butter .....	1,133,273,041	40,935,940	3.6	1,146,829,616	54,492,515	4.8
Milk .....	16,043,036,006	975,287,323	6.1	15,780,589,361	712,840,678	4.5
Adult cereal .....	9,697,058,781	399,336,655	4.1	9,697,058,781	399,336,655	4.1
Juice .....	14,203,760,671	556,756,383	3.9	13,928,147,601	281,143,313	2.0
Rice .....	737,198,377	0	.....	780,641,275	43,442,898	5.6
Fruit and vegetables .....	15,761,934,300	7,512,820	0.0	16,186,113,298	431,691,818	2.7
Eggs .....	2,959,401,900	120,241,255	4.1	2,906,352,699	67,192,054	2.3
Cheese .....	12,329,016,799	386,210,204	3.1	12,190,079,804	247,273,210	2.0
Bread .....	17,028,860,749	0	.....	17,122,601,313	93,740,564	0.5
Canned fish .....	1,917,928,393	9,191,549	0.5	1,919,622,300	10,885,456	0.6
Infant cereal <sup>71</sup> .....	.....	56,640,143	.....	.....	42,641,463	.....
Baby food <sup>71</sup> .....	.....	0	.....	.....	185,899,515	.....
Tofu <sup>71</sup> .....	.....	0	.....	.....	1,088,288	.....
Soy beverage) <sup>71</sup> .....	.....	0	.....	.....	49,561,168	.....
Total .....	96,285,903,247	5,117,882,167	6.4	95,674,859,149	4,729,388,359	4.7

It is important to note that the numbers in Tables 17 and 18 differ from the costs reported in Table 3 mainly because the market analysis uses pre-rebate formula and cereal costs as compared to the cost estimate which factors in the post-rebate savings. In addition, the data in the market impact analysis is based on 2005 participation, whereas the cost estimate uses the projected participation estimates for 2008 and beyond. Finally, the market analysis does not take into account any phase-in period.

Overall, the changes in the WIC food package will have a modest impact on WIC sales as a percentage of total annual sales of these food item categories. Market shares are

slightly higher under the no substitution scenario. (See Table 17.) For the foods that are currently part of the food package, the interim food package has the largest dollar impact on the infant formula and beans markets. Under the interim food package, the market share of WIC sales for infant formula is less than with the current food package. The decline is mostly due to a reduction in the maximum allowance of infant formula for partially breastfed and fully formula-fed infants 6 through 11 months of age (Food Package II FF). The market share of beans will increase from 3.7% to 8.9%–9.5%. The majority of this impact stems from the fact that participants can now substitute canned

beans, which are more expensive, for dried beans.

The other markets that will be impacted and are currently part of the food package are the milk, juice, eggs, cheese, peanut butter, and fruit and vegetable markets. The market share of these items will change slightly. The items that will have decreases are milk, juice, eggs, and cheese, while the items that will have increases are peanut butter, and fruits and vegetables. The WIC market share of milk will change from 6.1% to 4.4%–4.5% due to lower prescription amounts and the ability of participants to substitute tofu, and soy beverage for fluid milk. The decline in cheese is also due to these reasons. The share of the juice market shifts from 3.9% to 2.0%,

<sup>66</sup> Total WIC sales reported here are less than the \$5.3 billion (pre-rebate) reported in WIC 2005 food costs. The estimates of total WIC food sales for the current and proposed packages are likely to be lower than actual WIC food expenditures because the AC Nielsen Productscan and Homescan data used to estimate food prices may not fully capture the higher prices charged by WIC vendors such as small, non-chain, convenience and “WIC-Only” stores.

<sup>67</sup> “WIC % of Market” estimates are calculated only for items for which we have both a numerator and denominator.

<sup>68</sup> We were unable to assess the market impact of infant cereal, baby food, tofu and soy beverage items in the WIC food package. These items are not included in the Productscan data; however, we are able to estimate WIC sales because these items are part of the Homescan data, which is our source for item price data.

<sup>69</sup> Total WIC sales reported here are less than the \$5.3 billion (pre-rebate) reported in WIC 2005 food costs. The estimates of total WIC food sales for the current and proposed packages are likely to be lower than actual WIC food expenditures because the AC Nielsen Productscan and Homescan data used to estimate food prices

may not fully capture the higher prices charged by WIC vendors such as small, non-chain, convenience and “WIC-Only” stores.

<sup>70</sup> “WIC % of Market” estimates are calculated only for items for which we have both a numerator and denominator.

<sup>71</sup> We were unable to assess the market impact of infant cereal, baby food, tofu and soy beverage items in the WIC food package. These items are not included in the Productscan data; however, we are able to estimate WIC sales because these items are part of the Homescan data, which is our source for item price data.

while the share of the egg market shifts from 4.1% to 2.3%. Both of these declines stem from changes in the package that are designed to improve the overall nutritional benefit of the package. Participants will be receiving less juice, but more fruits and vegetables. The amount of eggs will be lowered consistent with recommendations of the IOM on cholesterol intake and to permit a wider variety of foods to be included in the WIC food packages. The market share of peanut butter will increase from 3.6% to 4.8%. Lastly, the WIC percent of the fruit and vegetable market will increase from 0% to 2.7%. This is due to the fact that the only fruit or vegetable that WIC participants currently receive are carrots and only exclusively breastfeeding mothers receive them. Under the new rule, the fruit and vegetable vouchers will encourage WIC's women and children participants to consume these foods.

For the foods being added to the WIC food package, the WIC market share percentages are, for the most part, small, 0.5%–0.6% and 5.6%–5.9%, for bread and rice, respectively. We were unable to assess the market impact of baby food, infant cereal, tofu and soy

beverage. These items are not included in the Productscan data; however, we are able to estimate WIC sales because these items are part of the Homescan data, which is our source for item price data.

Given the changes in market share and potential changes in total market demand, changes in the purchases of WIC-provided foods could theoretically have an impact on prices for WIC foods. However, because the demand impacts for most foods are small and impossible to estimate precisely, we are unable to determine the potential price effects.

WIC purchases of infant formula represent a larger share of the total market of WIC-provided foods than do WIC purchases of the other WIC foods. The Economic Research Service (ERS) recently studied the relationship between retail prices of infant formula and demand for WIC-provided formula. ERS findings suggest that the amount of WIC-provided formula purchased has an effect on retail prices; specifically, larger WIC demand leads to higher retail prices for non-WIC consumers who purchase the state's contract brand of formula.<sup>72</sup> ERS estimates, for example, that a non-WIC family

in a State whose WIC program serves two-thirds of all formula fed infants would spend roughly \$3 to \$5 more, per month, on contract brand powder formula for their child than a family in a State whose WIC program serves just half of formula-fed infants.

However, it is difficult to project the exact impact of the reduction in WIC demand for infant formula under the interim rule based on this study. The ERS analysis was limited to formulas sold in supermarkets, whereas projecting the impact of the rule on overall demand would require an analysis of the behavior of non-WIC consumers, which have more diverse purchasing habits. For instance, many non-WIC formula purchases are at prices below that of supermarkets from mass merchandisers that do not participate in the WIC Program. In addition, the change in WIC formula sales as a percentage of retail grocery sales due to this interim rule (from 70.4% to 56.3%–65.5%) is smaller than the changes in WIC sales examined in the ERS report (from 50% to 66%).

**Appendix A: Additional Cost Estimate Assumptions**

**TABLE A1.—FY 08 FOOD PACKAGE COSTS**  
[Monthly costs, post-rebate]

Food package	Current	Interim
I—0 to 5.9 month infants <sup>73</sup>	\$24.49	\$20.84
II—6 to 11.9 month infants	33.32	41.06
III—Participants with qualifying conditions <sup>74</sup>	0.00	21.07
IV—Children 1 to 4.9 years	35.18	34.49
V—Women: Pregnant and partially breastfeeding	39.82	42.66
VI—Women: Postpartum	32.15	33.38
VII—Women: Fully breastfeeding	51.23	54.56

**TABLE A2.—ANNUAL CURRENT FOOD PACKAGE COSTS (POST-REBATE) FY08–FY12**  
[In \$ millions]

Food package	FY08 <sup>75</sup>	FY09	FY10	FY11	FY12
I	\$272.18	\$342.02	\$357.69	\$373.79	\$390.35
II	331.53	416.59	435.68	455.29	475.46
III <sup>74</sup>	0.00	0.00	0.00	0.00	0.00
IV	1,454.11	1,827.21	1,910.94	1,996.95	2,085.41
V	456.17	573.22	599.49	626.47	654.22
VI	206.42	259.39	271.27	283.48	296.04
VII	169.47	212.95	222.71	232.74	243.05

<sup>72</sup> Victor Oliveira, Mark Prell, David Smallwood, Elizabeth Frazão, *WIC and the Retail Price of Infant Formula*, Economic Research Service, U.S. Department of Agriculture, May 2004, p. 60.

<sup>73</sup> To permit a direct comparison against the current rule, average food package costs under the current rule are weighted by the number of children who fall into the age categories that correspond to the interim rule food packages. Although the current cost figures for infants do not correspond to the food package definitions under the interim rule, the average costs of foods prescribed to infants

within the stated age categories are correct. That is, the cost of monthly food prescriptions to infants up to 5 months old is lower under the interim rule by approximately \$3.60.

[Current Food Package I is for infants 0–3.9 months of age; interim Food Package I is for infants 0–5.9 months of age. Current Food Package II is for infants 4–11.9 months of age; interim Food Package II is for infants 6–11.9 months of age. Food package costs are weighted by the respective age groups as shown in Tables D and E in Appendix A.]

<sup>74</sup> Current Food Package III is \$0 because the analysis only considers the incremental costs associated with the proposal. Interim Food Package III represents the incremental costs as a result of the changes in the proposed rule. FNS does not have comprehensive data on the current cost of medical foods provided in Food Package III. However, the medical foods associated with this package are assumed to stay the same under the current and interim rules. The incremental cost is extending foods from other packages to Food Package III recipients.

TABLE A3.—ANNUAL INTERIM FOOD PACKAGE COSTS (POST-REBATE) FY08–FY12  
[In \$ millions]

Food package	FY08 <sup>75</sup>	FY09	FY10	FY11	FY12
I .....	\$259.58	\$297.59	\$304.29	\$317.98	\$332.07
II .....	355.40	500.78	536.88	561.05	585.90
III <sup>74</sup> .....	3.02	10.64	12.79	13.36	13.95
IV .....	1,435.66	1,756.20	1,818.93	1,894.24	1,971.64
V .....	462.71	594.06	622.09	647.66	673.95
VI .....	206.88	259.75	270.33	281.14	292.25
VII .....	171.61	219.70	229.93	239.41	249.14

TABLE B.—CY05 TO FY06 PRICE INFLATION ASSUMPTIONS—FOOD SPECIFIC CPIS

Food item	Inflation rate (percent)
Infant Formula .....	1.3
Infant cereal .....	-1.7
Infant food fruit and vegetables .....	2.5
Infant food meat .....	2.5
Bananas .....	4.2
Milk:	
Whole .....	-0.7
Reduced fat .....	-0.5
Cheese .....	-0.9
Yogurt .....	-0.3
Tofu .....	1.3
Soy beverage .....	1.3

TABLE B.—CY05 TO FY06 PRICE INFLATION ASSUMPTIONS—FOOD SPECIFIC CPIS—Continued

Food item	Inflation rate (percent)
Juice .....	3.9
Adult cereal:	
Whole grain .....	-1.7
Current WIC cereals .....	-1.7
Eggs .....	2.9
Beans:	
Dry .....	1.0
Canned .....	1.0
Peanut butter .....	0.9
Whole grain bread .....	3.2
Brown rice .....	3.7
Tuna .....	2.5
Canned Fish .....	2.5
Carrots .....	3.4

TABLE C.—INFLATION ASSUMPTIONS, FY05–FY12

Year	Thrifty food plan (% change)	CPI: fruit and vegetables (% change)
FY05*	-0.32	3.74
FY06*	-0.75	4.76
FY07*	2.05	1.03
FY08	2.62	1.96
FY09	2.58	1.88
FY10	2.45	1.92
FY11	2.37	1.92
FY12	2.30	1.92

\*Actual WIC Food Package Inflation as of January 2007.

TABLE D.—PROJECTED PARTICIPATION IN THE WIC PROGRAM, BY FOOD PACKAGE TYPE: CURRENT PACKAGES

Food package	FY08	FY09	FY10	FY11	FY12
<b>I</b>					
0–3.9 month Infants:					
Fully formula-fed .....	426,994	435,882	444,956	454,218	463,674
Partially breast-fed .....	112,821	115,169	117,567	120,014	122,513
Fully breast-fed .....	199,996	204,159	208,409	212,747	217,176
Subtotal .....	739,810	755,211	770,932	786,980	803,362
<b>II</b>					
4–5.9 month Infants:					
Fully formula-fed .....	283,539	289,441	295,466	301,617	307,895
Partially breast-fed .....	31,566	32,223	32,894	33,579	34,278
Fully breast-fed .....	56,262	57,433	58,628	59,849	61,095
6–11.9 month Infants:					
Fully formula-fed .....	840,456	857,952	875,811	894,043	912,654
Partially breast-fed .....	56,380	57,554	58,752	59,975	61,224
Fully breast-fed .....	98,114	100,156	102,241	104,369	106,542
Subtotal .....	1,366,316	1,394,759	1,423,793	1,453,432	1,483,687
Participants with qualifying conditions <sup>76</sup> .....	92,470	94,395	96,360	98,366	100,414
<b>IV</b>					
Children: 1–4.9 years .....	4,133,746	4,219,798	4,307,640	4,397,311	4,488,849
<b>V</b>					
Women:					
Pregnant .....	958,254	978,202	998,564	1,019,351	1,040,571
Partially breastfeeding .....	187,421	191,323	195,305	199,371	203,521
Subtotal .....	1,145,675	1,169,524	1,193,870	1,218,722	1,244,092

<sup>75</sup> For both the current and interim rules, FY 08 figures represent just 10 months (the interim rule

will be effective for just 10 months of the year.) The

interim rule figures are not fully phased-in until FY 2010.

TABLE D.—PROJECTED PARTICIPATION IN THE WIC PROGRAM, BY FOOD PACKAGE TYPE: CURRENT PACKAGES—Continued

Food package	FY08	FY09	FY10	FY11	FY12
VI Women: Postpartum .....	642,045	655,410	669,054	682,981	697,198
VII Women: Fully breastfeeding .....	330,813	337,700	344,730	351,906	359,231
Total .....	8,450,876	8,626,796	8,806,378	8,989,698	9,176,834

TABLE E.—PROJECTED PARTICIPATION IN THE WIC PROGRAM, BY FOOD PACKAGE TYPE: INTERIM RULE

Food package	FY08	FY09	FY10	FY11	FY12
I 0–3.9 month Infants:					
Fully formula-fed .....	426,994	435,882	444,956	454,218	463,674
Partially breast-fed .....	112,821	115,169	117,567	120,014	122,513
Fully breast-fed .....	199,996	204,159	208,409	212,747	217,176
4–5.9 month Infants:					
Fully formula-fed .....	283,539	289,441	295,466	301,617	307,895
Partially breast-fed .....	31,566	32,223	32,894	33,579	34,278
Fully breast-fed .....	56,262	57,433	58,628	59,849	61,095
Subtotal .....	1,111,176	1,134,307	1,157,920	1,182,024	1,206,630
II 6–11.9 month Infants:					
Fully formula-fed .....	840,456	857,952	875,811	894,043	912,654
Partially breast-fed .....	56,380	57,554	58,752	59,975	61,224
Fully breast-fed .....	98,114	100,156	102,241	104,369	106,542
Subtotal .....	994,950	1,015,662	1,036,805	1,058,387	1,080,420 *
III Participants with qualifying conditions <sup>76</sup>	92,470	94,395	96,360	98,366	100,414
IV Children:					
1–1.9 years .....	1,364,955	1,393,369	1,422,374	1,451,984	1,482,209
2–4.9 years .....	2,768,791	2,826,428	2,885,265	2,945,327	3,006,639
Subtotal .....	4,133,746	4,219,798	4,307,640	4,397,311	4,488,849
V Women:					
Pregnant .....	958,254	978,202	998,564	1,019,351	1,040,571
Partially breastfeeding .....	187,421	191,323	195,305	199,371	203,521
Subtotal .....	1,145,675	1,169,524	1,193,870	1,218,722	1,244,092
VI Women: Postpartum .....	642,045	655,410	669,054	682,981	697,198
VII Women: Fully breastfeeding .....	330,813	337,700	344,730	351,906	359,231
Total .....	8,450,876	8,626,796	8,806,378	8,989,698	9,176,834

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<sup>76</sup> The interim rule moves infants with qualifying medical conditions from Food Packages I and II to a revised Food Package III. The number of Package III beneficiaries shown here includes those who are reassigned to Package III as a result of the interim rule. Individuals who are currently Package III

recipients, and those who are newly moved to Package III by the interim rule, are affected differently by the interim rule than are other participants. The current and newly assigned Package III recipients are also handled differently than other participants throughout this cost

analysis. For purposes of clarity and consistency, all of these individuals are shown as Package III recipients from the first through the final steps of the analysis.