

## **Appendix A2**

### **Relevant WIC Policy and Guidance Documents**

**Appendix A2. Relevant WIC Policy and Guidance Documents includes the following:**

1. **Value Enhance Nutrition Assessment (VENA) in WIC. (2006).** *Executive Summary*, p. 3-5. Full text available at:  
[https://wicworks.fns.usda.gov/sites/default/files/media/document/VENA\\_Guidance.pdf](https://wicworks.fns.usda.gov/sites/default/files/media/document/VENA_Guidance.pdf)
2. **“Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Final Rule.”** Federal Register 79:42 (March 4, 2014) p. 12274-12300.

**Value Enhance Nutrition Assessment (VENA) in WIC. (2006).** *Executive Summary*,  
p. 3-5. Full text available at:  
[https://wicworks.fns.usda.gov/sites/default/files/media/document/VENA\\_Guidance.pdf](https://wicworks.fns.usda.gov/sites/default/files/media/document/VENA_Guidance.pdf)

# VENA

VALUE ENHANCED NUTRITION ASSESSMENT IN WIC

## The First Step In Quality Nutrition Services



U.S. Department of Agriculture  
Food and Nutrition Service

**WIC**  
MAKES A DIFFERENCE

# Value Enhanced Nutrition Assessment (VENA) in WIC

## The First Step in Quality Nutrition Services

### Executive Summary

#### What is VENA?

VENA is a new initiative, developed jointly by the Food and Nutrition Service (FNS) and the National WIC Association (NWA), to improve nutrition services in the WIC Program by establishing standards for the assessment process used to determine WIC eligibility *and* to personalize nutrition education, referrals, and food package tailoring. VENA is part of the larger process known as Revitalizing Quality Nutrition Services (RQNS) in WIC.

#### Why is VENA Necessary?

VENA responds to recommendations made in a 2002 Institute of Medicine (IOM) report, *Dietary Assessment in the WIC Program*<sup>1</sup>. In its report, the IOM recommended that all women and children ages 2 to 5 years who meet the eligibility requirements of income, category, and residency status should also be presumed to meet the requirement of nutrition risk through the category of dietary risk based on *failure to meet Dietary Guidelines*.

The IOM made clear in its recommendation that the intent was **not** to affect the current use of other nutrition risk criteria for eligibility determination. That is, information should continue to be collected for the identification of potentially serious nutrition risk factors, such as growth issues, iron deficiency, or predisposing medical conditions related to nutrition. Such information is required for the priority placement of participants, and to provide the necessary referrals and individualize other nutrition services.

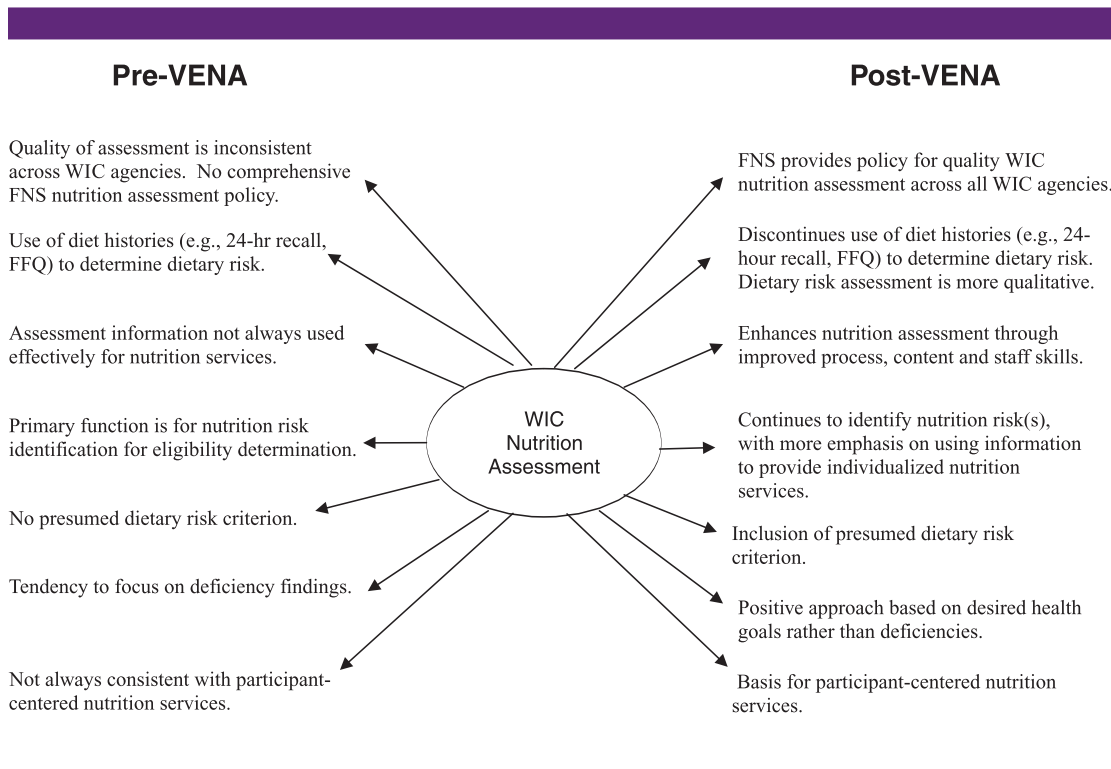
As a result of the IOM report findings and recommendation for a presumed dietary risk criterion, the FNS identified the need to develop comprehensive nutrition assessment guidance. VENA not only serves to enhance the nutrition services of the WIC Program, but also to ensure the integrity of the WIC Program as a premier public health nutrition program.

<sup>1</sup> Institute of Medicine; Committee on Dietary Risk Assessment in the WIC Program. *Dietary risk assessment in the WIC program*. Washington (DC): National Academy Press; 2002.



## How will VENA Change Current Assessment Procedures?

The *WIC Nutrition Services Standards* (NSS)<sup>2</sup> provide a framework of nutrition assessment components to guide State agencies in establishing policy and practices. The VENA Policy and Guidance builds on the NSS and defines in more detail, the process and content of a quality WIC nutrition assessment upon which nutrition education, food package selection and referrals will be based. In addition, VENA identifies the essential staff competencies necessary to conduct an assessment. The diagram below highlights and summarizes the changes anticipated with the implementation of VENA.



## What are the Anticipated Results of VENA?

The anticipated results of VENA are summarized below:

State agencies will:

- Enhance the nutrition assessment process.
- Empower staff by improving their nutrition assessment skills.
- Enjoy more satisfied staff and participants.

<sup>2</sup> U.S. Department of Agriculture, Food and Nutrition Service, Supplemental Food Programs Division: WIC Nutrition Services Standards, October 2001. Available from: <http://www.fns.usda.gov/wic/benefitsandservices/nutritionservicesstds.HTM>

WIC staff members will:

- Use their limited time to collect relevant nutrition assessment information.
- Use critical thinking skills to link assessment information to a participant's individual needs and concerns.
- Plan a personalized nutrition intervention.
- Engage the participant in dialogue and goal setting.
- Weave nutrition and diet as the common thread throughout the assessment process.

WIC participants will:

- Experience a positive encounter.
- Receive information and services related to their individual needs and concerns.
- Feel involved in goal setting to improve their own health.

### **When will VENA be Implemented?**

Implementation of VENA will be a gradual process determined by each State agency's current staffing and nutrition assessment processes. Initially, State agencies will conduct a self-evaluation of their current nutrition assessment practices to determine areas of strengths and potential areas for enhancement. A summary of the self-evaluation findings will be submitted to the FNS by December 15, 2006. The FNS will provide further guidance on the self-evaluation in a separate communiqué. Subsequently, State agencies will submit a plan for the implementation of VENA in August 2007 with their Fiscal Year 2008 State Plan submissions. The FNS expects that all State agencies will begin the use of their *value enhanced* nutrition assessment processes by Fiscal Year 2010.

**“Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Final Rule.”** Federal Register 79:42 (March 4, 2014) p. 12274-12300.





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Food and Nutrition Service  
7 CFR Part 246

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Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages; Final Rule

**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 (FNS), USDA.**ACTION:** Final rule.

**SUMMARY:** This final rule considers public comments submitted in response to the interim rule revising the WIC food packages published on December 6, 2007. The interim rule implemented the first comprehensive revisions to the WIC food packages since 1980. The interim rule revised regulations governing the WIC food packages to align them more closely with updated nutrition science and the infant feeding practice guidelines of the American Academy of Pediatrics, promote and support more effectively 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. This rule makes adjustments that improve clarity of the provisions set forth in the interim rule.

**DATES:** *Effective Date:* This rule is effective May 5, 2014.

*Implementation Dates:*

- State agencies must implement the provision in Table 2 at 7 CFR 246.10(e)(10) increasing the cash-value voucher for children to \$8 per month no later than June 2, 2014.
- The provision found at 7 CFR 246.12(f)(4) requiring split tender for cash-value vouchers shall be implemented no earlier than October 1, 2014 and no later than April 1, 2015.
- Footnote 11 of Table 2 at 7 CFR 246.10(e)(10) shall be implemented on the later of October 1, 2014, or the date on which the State agency exercises their option to issue authorized soy-based beverage or tofu to children who receive Food Package IV.
- The provisions in Footnote 10 of Table 2 at 7 CFR 246.10(e)(10) and Footnote 12 of Table 3 at 7 CFR 246.10(e)(11) authorizing yogurt for children and women in Food Packages III–VII may be implemented no earlier than April 1, 2015.

**FOR FURTHER INFORMATION CONTACT:**

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

This final rule addresses public comments submitted in response to the interim rule revising the WIC food packages published on December 6, 2007 (72 FR 68966), and makes adjustments that improve clarity of the provisions set forth in the interim rule.

**II. Background**

An interim rule revising the WIC food packages was published in the **Federal Register** on December 6, 2007 (72 FR 68966). The interim rule implemented the first comprehensive revisions to the WIC food packages since 1980 and largely reflected recommendations made by the National Academies' Institute of Medicine (IOM) in its Report "WIC Food Packages: Time for a Change" ("Report").<sup>1</sup> The interim rule aligned the food packages more closely with updated nutrition science, promoted and supported more effectively the establishment of successful long-term breastfeeding, provided WIC participants with a wider variety of food, and provided WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences. WIC State agencies were required to implement the changes by October 1, 2009.

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

The interim rule revising the WIC food packages provided an extensive public comment period to obtain comments on the impact of the changes experienced during implementation of the new food packages. The interim rule comment period ended February 1, 2010.

A total of 7,764 comment letters were received on the interim rule; of those, 111 were form letters. A total of 6,664 of the letters were from program participants, and included comments submitted in Spanish, Chinese, and other languages, in addition to English.

<sup>1</sup> Institute of Medicine, National Academy of Sciences. "WIC Food Packages: Time for a Change," 2005. Available at Internet site: <http://www.fns.usda.gov/wic-food-packages-time-change>.

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, commenters expressed broad support for the changes and reported relatively smooth implementation of the new WIC food packages. Commenters also voiced concerns about various aspects of the interim rule and made recommendations for clarifying or improving specific provisions of the interim rule. Overall, participants expressed overwhelming support for the revised WIC food packages, especially the addition of whole grains and fruits and vegetables. However, many participants who were enrolled in WIC during the transition from the previous food packages to the revised food packages expressed displeasure with changes to fat-reduced milks and less cheese.

FNS considered all timely 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.

WIC State agencies are to be commended for the staff and vendor training that led to successful implementation of the new WIC food packages, as well as nutrition education provided to participants on the benefits of the new foods in the WIC food packages. Successful implementation of the new WIC food packages was further enhanced by the efforts of WIC's partners in the advocacy, retail, and medical communities.

**IV. Discussion of the Final Rule Provisions**

The following is a discussion of the major provisions set forth in this final rule, a brief summary of the comments received on the interim rule that addressed these issues, and FNS' rationale for either modifying or retaining provisions in this final rule. Provisions not addressed in the preamble to this final rule did not receive significant or substantial public comments and remain unchanged.

The preamble to this final rule articulates the basis and purpose behind significant changes from the December 6, 2007 interim rule. The reasons supporting provisions of the interim

regulations were carefully examined in light of the comments received to determine the continued applicability of the justifications. Unless otherwise stated, or unless inconsistent with this final rule or this preamble, the rationales contained in the preamble to the proposed and interim regulations should be regarded as the basis for this final rule. Therefore, a thorough understanding of the rationales for the interim regulations may require reference to the preamble of the August 7, 2006 proposed rule (71 FR 44784) and the December 6, 2007 interim rule (72 FR 68966).

#### A. Definitions

*The following definitions have been added or modified in the final rule.*

**Farmers' market.** As described in a subsequent section of this preamble, this final rule adds the definition of "farmers' markets" at 7 CFR 246.2.

**Full nutrition benefit.** As described in a subsequent section of this preamble, this final rule adds the definition of "full nutrition benefit" at 7 CFR 246.2.

**WIC-eligible medical foods.** Based on review and discussion with the Food and Drug Administration (FDA), this final rule changes the name of the food category "WIC-eligible medical food" to "WIC-eligible nutritional," but does not substantively change this food category. This nomenclature modification better describes the group of special WIC-eligible nutritional products the WIC Program provides to participants with qualifying conditions, and alleviates confusion associated with the use of the term "medical food," which is defined by regulations governing FDA and differs from the WIC use of this term. The FNS definition for "WIC-eligible medical food" and the FDA definition for "medical food" are both comprehensive and detailed. Although the definition of "WIC-eligible medical food" closely aligns with the FDA definition for "medical food," there are slight differences, such that some, but not all "WIC-eligible medical foods" meet FDA's definition of "medical food." In an effort to alleviate confusion, and distinguish between the two product categories and definitions, FNS is modifying the name of the food category from "WIC-eligible medical food" to "WIC-eligible nutritional." Other than the name change, the definition for this food category put forth in the interim rule remains unchanged in this final rule.

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

##### 1. Nutrition Tailoring

Prior to the interim rule, FNS policy allowed 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, public health concerns, cultural eating patterns, and State established policies. The interim rule prohibits categorical nutrition tailoring, but continues to allow individual nutrition tailoring based on the Competent Professional Authority's (CPA) assessment of a participant's supplemental nutrition needs.

A total of 33 commenters (of these, 8 were form letters) opposed the provision that prohibits categorical tailoring, stating that State agencies need the flexibility to propose modifications to food packages that respond to rapid changes in food industry, science, dietary recommendations, demographics, and other factors. Commenters asked that State agencies be able to request approval for categorical tailoring to meet nutritional needs and preferences.

As stated in the preamble to the interim rule, the IOM conducted a full, independent and rigorous scientific review of the nutritional needs of WIC participants prior to recommending the quantities and types of WIC foods to address those needs in its Report. In addition, Section 232 of Public Law 111–296 amended Section 17(f)(11)(C) of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1786), by requiring the Secretary to conduct, as often as necessary, but not less than every 10 years, 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 conducted as needed and used to determine the need for modification of current WIC food packages. FNS believes that this is the appropriate process for changes to the WIC food packages and 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 final rule at 7 CFR 246.10(c).

##### 2. Cultural Food Package Proposals

The interim rule allows State agencies to submit to FNS a plan for substitution of food(s) to allow for different cultural eating patterns. The interim rule includes criteria for submitting plans for substitutions and the criteria FNS will use to evaluate such plans. A total of 26 commenters (8 form letters) asked FNS to change the criterion that "any proposed substitute food must be nutritionally equivalent or superior to the food it is intended to replace" to be less restrictive and easier to satisfy.

The increased variety and choice in the supplemental foods in the interim rule, as recommended by the IOM, provide State agencies expanded flexibility in prescribing culturally appropriate packages for diverse groups. Further, the interim rule allows State agencies flexibility to meet unanticipated cultural needs of participants by submitting plans for substitutions. The criteria are not meant to preclude justifiable cultural substitution proposals submitted by WIC State agencies, but are intended to ensure that WIC food substitutions maintain the nutritional integrity of the WIC foods they replace. FNS will continue to make determinations on proposed plans for cultural substitutions based on existing evaluation criteria as appropriate. Therefore, the criteria for submitting State agency plans for substitutions for different cultural eating patterns and the criteria FNS will use to evaluate such plans are retained at 7 CFR 246.10(i).

The interim rule increased the variety and number of substitutions available for several WIC foods. This final rule further increases the number of substitutions and options available, i.e., yogurt, canned jack mackerel, and whole wheat macaroni (pasta) products. These additions are within the context of the IOM recommendations. FNS believes that these changes already provide substantial flexibility for prescribing food packages and that further modifications of the current WIC food packages are best determined through future scientific reviews of the WIC food packages. FNS will, therefore, not accept WIC State agency plans for substitutions of WIC foods for reasons other than to accommodate cultural eating patterns as provided for in 7 CFR 246.10(i).

##### 3. Medical Documentation and Supervision Requirements

###### a. Milk and Milk Alternatives

Under the interim rule, medical documentation by a health care professional licensed to write medical

prescriptions is required for the issuance of certain milk alternatives for children and women. A total of 180 comment letters (53 of these form letters) opposed this requirement, primarily the documentation for children to receive soy-based beverage. Commenters stated that the provision is unnecessary, costly and burdensome for participants and physicians, creates barriers to services, and undermines FNS' efforts to provide foods that meet the cultural needs of participants. The NWA and the American Dietetic Association (now known as the Academy of Nutrition and Dietetics) stressed that WIC dietitians and nutritionists are trained health professionals capable of doing a complete nutrition assessment, selecting WIC foods, and providing appropriate education to participants and caregivers, in consultation with the health care provider when warranted.

Based on the experiences cited by WIC State and local agencies related to medical documentation throughout implementation of the new food packages, FNS will no longer require a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS will no longer require documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance. Instead, consistent with IOM recommendations for documentation from a "WIC recognized medical authority," FNS will allow the CPA to determine and document the need for tofu and soy-based beverage as substitutes for milk for children, as established by State agency policy. Such determination must be based on individual nutritional assessment, as required under the interim rule and retained in this final rule at 7 CFR 246.10(b)(2)(ii)(C), and consultation with the participant's health care provider, as appropriate. Such determination can be made for situations that include, but are not limited to, milk allergy, lactose intolerance, and vegan diets. As previously discussed, the interim rule revised regulations governing the WIC food packages to, among other things, accommodate participants with cultural food preferences. Since cultural practices may affect nutrient intake, FNS will allow soy for cultural practices that prevent participants from including in their diets cow's milk and lactose-free or lactose-reduced fortified dairy

products in amounts that meet their nutritional needs.

FNS will allow the CPA, as established by State agency policy, to determine the need for tofu in quantities that exceed the maximum substitution rates. Such determination can be made for situations that include, but are not limited to, milk allergy, lactose intolerance, and vegan diets.

FNS believes that allowing the CPA to make determinations for milk substitutes is consistent with IOM recommendations for documentation from a "WIC recognized medical authority." Although FNS is no longer requiring documentation from a health care professional licensed to write medical prescriptions, it is incumbent upon WIC State agencies to ensure that participants and caregivers receive education that stresses the importance of milk over milk substitutes, and that appropriate policies and procedures are in place for appropriate issuance of milk substitutes. Parents and caregivers should be made aware that children's diets may be nutritionally inadequate when milk is replaced by other foods, and provided appropriate nutrition education. The value of milk for WIC participants, particularly in the development of bone mass for children, should be emphasized. Lactose-free or lactose-reduced fortified dairy products should be offered before non-dairy milk alternatives to those participants with lactose intolerance that cannot drink milk. Also, if milk is replaced by milk alternatives that are not vitamin D fortified, vitamin D intakes may be inadequate. Thus, replacements for milk are to be approached with caution even if they are rich in calcium.

Therefore, Table 2 of 7 CFR 246.10(e)(10) of this final rule requires that issuance of tofu and soy-based beverage as substitutes for milk for children be based on an individual nutritional assessment by the CPA, in consultation with the participant's health care provider as appropriate. Table 2 of 7 CFR 246.10(e)(10) allows the CPA, as established by State agency policy, to determine the need for women to receive tofu in excess of the maximum substitution allowance.

#### b. Technical Requirements for Medical Documentation

Under the interim rule, technical requirements for medical documentation were established. A total of 51 comments opposed the provision requiring health care providers to prescribe the supplemental foods and quantities appropriate for a participant's qualifying condition in Food Package III (for participants with qualifying

conditions). Commenters believe that medical documentation, especially for authorization of supplemental foods in Food Package III, is burdensome to State agencies, participants and the medical community. Commenters stated that this provision has little value since the foods could otherwise be purchased by the participants at grocery stores. Commenters also stated that the WIC nutritionist or registered dietitian is capable of determining appropriate amounts and types of supplemental foods to issue to participants based on a nutrition assessment of the participant.

Due to the nature of the health conditions of participants who are issued supplemental foods in Food Package III, close medical supervision is essential for each participant's dietary management. FNS considers it appropriate that the responsibility for this close medical supervision remain with the participant's health care provider. Medical documentation requirements for specific supplemental foods that do not usually require a prescription were established to ensure that the participant's healthcare professional has determined that the supplemental foods are not medically contraindicated by the participant's condition. Therefore, FNS retains the technical requirements for medical documentation for supplemental foods in Food Package III as written in the interim rule. However, FNS recognizes that WIC registered dietitians and/or qualified nutritionists play an important role in the continuum of care of medically fragile WIC participants. Therefore, FNS would support State agency policy that allows health care providers to refer to the WIC registered dietitian and/or qualified nutritionist for identifying appropriate supplemental foods (excluding WIC formula) and their prescribed amounts, as well as the length of time the supplemental foods are required by the participant. This arrangement would be supported only in situations where the health care provider has indicated on the medical documentation form that the provider acknowledges referral to the WIC registered dietitian and/or qualified nutritionist for such determinations. This gives the health care provider medical oversight while allowing the WIC registered dietitian and/or qualified nutritionist to determine the appropriate issuance of WIC foods to participants with qualifying conditions in Food Package III.

#### 4. Sodium Content of WIC Foods

In its Report, the IOM found that intakes of sodium were excessive in the

diets of WIC participants. The IOM reported that more than 90 percent of WIC children 2 through 4 years and of pregnant, lactating, and non-breastfeeding postpartum women had usual sodium intakes above the Tolerable Upper Intake Level (UL). More than 60 percent of WIC children age 1 year had usual sodium intakes above the UL. As such, the IOM recommended, and the interim rule reflected, reductions in the overall sodium level of WIC food packages. The majority of WIC foods under the interim rule may not contain added salt (sodium).

However, options for some WIC foods, i.e., cheese, vegetable juice, canned vegetables, canned beans, peanut butter, and canned fish include both regular and lower sodium varieties. In an effort to support participants in reducing sodium intake, FNS provided technical assistance to State agencies encouraging them to offer only lower sodium varieties of these foods when these options exist.

FNS encourages WIC State agencies that offer canned vegetables to allow only lower sodium canned vegetables and lower-sodium versions of other WIC-eligible foods, i.e., breads, as they become more widely available in the marketplace. FNS encourages food manufacturers to reduce excess sodium in processed foods and to make a wider variety of these foods available to help WIC achieve its goal to safeguard the health of children and women.

#### 5. Organic Foods

The interim rule authorizes 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 specific brands and types of foods to authorize on their State WIC food lists. Some State agencies allow organic foods on their food 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.

FNS received 52 comments asking that State agencies be required to offer organic foods in the WIC food packages. Many of these comments were from one State where the WIC State agency had recently removed organic milk from its list of authorized WIC foods. This final rule continues to provide State agencies the option to offer organic forms of WIC-eligible foods through the regular WIC food instrument, e.g., milk, eggs, peanut butter, and encourages State agencies to make available authorized foods that are acceptable and will be consumed by participants, including organic varieties.

This final rule clarifies in Table 4 of 7 CFR 246.10(e)(12) that State agencies are required to allow organic forms of fruits and vegetables purchased with the cash-value voucher.

#### C. Supplemental Foods and Food Packages

**Note:** The order of some of the topics in this section is modified from the interim rule for the purposes of discussion.

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

###### a. Dollar Amount of Cash-Value Voucher

In order to maintain cost neutrality, the interim rule published December 2007 (72 FR 68966) only provided fully breastfeeding women with the IOM recommended amount of \$10.00 per month fruit and vegetable cash-value vouchers; all other women participants were provided \$8.00 per month, and children were provided \$6.00. An amendment to the interim rule was published in the **Federal Register** on December 31, 2009 (74 FR 69243) to provide all WIC women participants with \$10.00 per month fruit and vegetable cash-value vouchers, consistent with IOM's recommendations.

A total of 448 commenters (76 form letters) asked FNS to increase the fruit and vegetable cash-value voucher to the IOM recommended level from \$6 to \$8 for children. The Department has responded to commenters' requests under this final rule by increasing the cash-value voucher for children to \$8 per month. This increase will allow State agencies to further efforts to increase fruit and vegetable consumption by children.

A total of 162 commenters (36 form letters) asked FNS to further increase the fruit and vegetable voucher for fully breastfeeding women from \$10 to \$12 to provide incentive for women to choose to fully breastfeed, and to meet the intent of the IOM to provide an enhancement to the food packages for fully breastfeeding women. While FNS understands the benefit of increasing the value of the food package for fully breastfeeding women, it is not possible under this rulemaking to go beyond the dollar value for the cash-value voucher for the fully breastfeeding package due to cost. Therefore, the cash-value voucher remains at \$10 for all women, including fully breastfeeding women, in this final rule. The base year for calculation of the value of the fruit and vegetable voucher and the base value to be used are updated in 7 CFR 246.16(j)(2).

###### b. Clarification of Authorized Fruits and Vegetables

To improve the consumption of fresh fruits and vegetables and to appeal to participants of different cultural backgrounds, the interim rule authorized a wide variety of choices within the authorized fruit and vegetable options. The interim rule reflects the IOM recommendation to provide a cash-value fruit and vegetable benefit to participants with few restrictions. The following is a discussion of clarifications and revisions to the interim rule pertaining to authorized fruits and vegetables. Technical corrections in this final rule clarify that both fresh fruits and fresh vegetables must be authorized by State agencies. This final rule further clarifies that 21 CFR 101.95 defines the term "fresh" when referring to eligible fresh fruits and vegetables.

Technical corrections in this final rule clarify that the cash-value voucher may be redeemed for any eligible fruit and vegetable (refer to Table 4 of 7 CFR 246.10(e)(12) and its footnotes). Except as authorized by this final rule, State agencies may not selectively choose which fruits and vegetables are available to participants. For example, if a State agency chooses to offer dried fruits, it must authorize all WIC-eligible dried fruits, i.e., those without added sugars, fats, oils, or sodium, and may not allow only a single variety of dried fruits. This final rule clarifies that State agencies may, however, invoke their administrative option at 7 CFR 246.10(b)(1)(i) to establish criteria in addition to the minimum Federal requirements in Table 4 of 7 CFR 246.10(e)(12), which could include restricting packaging (such as plastic containers) and package sizes (such as single serving) of processed fruits and vegetables available for purchase with the cash-value voucher. In addition, State agencies may identify specific types of certain processed WIC-eligible fruits and vegetables (e.g., salsas, tomato sauces, stewed and diced tomatoes) on their food lists if they believe there is cause for significant vendor and participant confusion in identifying specific items within those categories that are WIC-eligible.

A technical correction has been made in Table 4 of 7 CFR 246.10(e)(12) to clarify that the following products are not allowed: Dried white potatoes, mixed vegetables containing white potatoes, noodles, nuts or sauce packets, and decorative flowers and blossoms. Canned tomato sauce and tomato paste without added sugar, fats, oils are authorized. Salsa and spaghetti sauce

without added sugar, fats, and oils are also authorized.

This final rule clarifies that the fruit or vegetable must be listed as the first ingredient in WIC-eligible processed fruits and vegetables. In addition, it clarifies that frozen fruits may not contain added fats, oils, salt (i.e., sodium) or added sugars.

For the reasons described in section IV.B.4 of this preamble, Table 4 of 7 CFR 246.10(e)(12) will be revised to allow State agencies the option to offer only lower sodium canned vegetables for purchase with the cash-value voucher.

#### c. White Potatoes

The interim rule excludes the purchase of white potatoes with the cash-value voucher. A total of 266 (of these, 213 were form letters) opposed the restriction of white potatoes. Commenters stated that white potatoes should be included in the WIC food packages because they are versatile, economical, contain key nutrients, and are preferred by participants. Thirty-two commenters (20 form letters) stated that the exclusion of white potatoes is difficult to administer.

The restriction of white potatoes, as recommended by the IOM, is based on data indicating that consumption of starchy vegetables meets or exceeds recommended amounts, and food intake data showing that white potatoes are the most widely used vegetable. Including white potatoes in the WIC food packages would not contribute towards meeting the nutritional needs of the WIC population and would not support the goal of expanding the types and varieties of fruits and vegetables available to program participants, as recommended by the IOM. Therefore, the provision to exclude white potatoes from the WIC food packages is retained in this final rule. The Department recognizes that white potatoes can be a healthful part of one's diet. However, WIC food packages are carefully designed to address the supplemental nutritional needs of a specific population. Although white potatoes are not offered in the WIC food package, nutrition education provided to WIC participants will continue to include white potatoes as a healthy source of nutrients and an important part of a healthful diet.

#### d. Dried Fruit and Dried Vegetables for Children

As recommended by the IOM, the interim rule disallows dried fruits and vegetables to be purchased with the cash-value voucher for children because of the risk of choking. FNS received a

small number of comments asking that dried fruits be allowed for children, citing a lack of evidence that they pose choking hazards for all children. Recommendations made by IOM for the Child and Adult Care Food Program allow dried fruits for children as long as they do not pose a choking hazard.<sup>2</sup> Therefore, at the State agency's option, this final rule authorizes dried fruits and dried vegetables to be purchased with the cash-value voucher for children. Nutrition education regarding choking hazards, developmental readiness, proper food preparation, and oral health care should be provided to caregivers of young children.

#### e. Standards of Identity for Canned Fruits and Canned Vegetables

Two technical corrections have been made in Table 4 of 7 CFR 246.10(e)(12) related to the standards of identity for canned fruits and canned vegetables. This final rule corrects the specifications for WIC-eligible canned fruits to reflect that only those WIC-eligible canned fruits that have a standard of identity, as listed at 21 CFR Part 145, must conform to the FDA standard of identity. Similarly, this final rule corrects the specifications for WIC-eligible canned vegetables to reflect that only those WIC-eligible canned vegetables that have a standard of identity, as listed at 21 CFR Part 155, must conform to the FDA standard of identity. The provision that WIC-eligible canned vegetables contain no added sugars, fats, and oils remains unchanged. This final rule clarifies that home-canned and home-preserved fruits and vegetables are not authorized.

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

(1) Paying the difference with the cash-value voucher. The interim rule authorized State agencies the option to allow participants to pay the difference if the fruit and vegetable purchase exceeds the value of the cash-value voucher, a transaction known as "split tender." A total of 116 commenters (59 form letters) asked FNS to require all State agencies to allow split tender transactions to ensure that participants are able to maximize use of their cash-value voucher. Because it may be difficult for participants to accurately estimate the exact purchase price of the fruit and vegetable selections, particularly when fresh, canned, dried,

or frozen items are combined in one purchase or when items are purchased in bulk, FNS agrees that all participants should be allowed to pay the difference when the purchase of allowable fruits and vegetables exceeds the value of the fruit/vegetable cash-value voucher. Therefore, this final rule adds a provision at 7 CFR 246.12(f)(4) to require State agencies to allow split tender transactions with the cash-value voucher.

(2) Minimum vendor stocking requirements. A technical oversight in the interim rule has been corrected at 7 CFR 246.12(g)(3)(i) by clarifying that authorized vendors must stock at least two *different* fruits and two *different* vegetables.

(3) Authorizing farmers' markets. The interim rule gave State agencies the option to allow farmers at farmers' markets to accept cash-value vouchers. FNS received 29 comments (mostly form letters) recommending that farmers' market organizations, rather than the individual farmer, be authorized to accept cash-value vouchers, as is permitted under the WIC Farmers' Market Nutrition Program (FMNP). Sixty-nine commenters (mostly form letters) additionally recommended that the WIC Program regulations be more closely aligned with the FMNP. Commenters stated that consistency between the two programs would make FMNP participation easier both for WIC participants and authorized farmers. Many of the comments suggested that State agencies be allowed to authorize farmers' markets in addition to the current provision (7 CFR 246.12(v)) that allows State agencies the flexibility to authorize farmers at farmers' markets or roadside stands. FNS finds merit in such a provision; this also would provide more consistency between WIC and FMNP.

Seventy-eight comments went on to suggest that the authorization of farmers' markets should be a Federal requirement, rather than a State agency option. FNS believes that State agencies are in the best position to determine what works for their individual benefit delivery systems, taking into consideration such factors as participant access, the availability of farmers, and the administrative burdens of monitoring and authorization. Therefore, the final rule amends 7 CFR 246.12 to allow WIC State agencies to authorize farmers or farmers' markets to accept WIC cash-value vouchers, but such authorization will remain as a State agency option. As a result of the addition of farmers' markets, conforming amendments have been

<sup>2</sup> Institute of Medicine, National Academy of Sciences. "Child and Adult Care Food Program: Aligning Dietary Guidance for All," 2010. Available at Internet site: <http://www.fns.usda.gov/child-and-adult-care-food-program-aligning-dietary-guidance-all>.

made in 7 CFR 246.2, 246.4, 246.18, and 246.23.

A number of comments were received recommending that the Federal WIC regulations be modified to be consistent with the fruits and vegetables eligible for purchase under the FMNP. FNS makes every effort to ensure that both programs are aligned in most areas, to the extent possible. However, each program has different statutory objectives. Thus, FNS is convinced that it is critical for each program to maintain its separate identity. As stated previously, FNS found merit in allowing farmers' markets to redeem WIC cash-value vouchers, an example of aligning both programs. FNS finds no need to make any further operational changes in this area through this final rule. A technical amendment is added to 7 CFR 246.4(a)(14) to correct a cross-reference to 7 CFR 246.12 that addresses the State agency options regarding vendor sanctions.

## 2. Mature Legumes (Dry Beans, Peas and Lentils) and Peanut Butter

### a. Clarification of Allowable Mature Legumes

Technical corrections have been made to the list of authorized mature legumes in Table 4 of 7 CFR 246.10(e)(12). Refried beans, without added sugars, fats, oils, vegetables or meat, have been added to the examples of allowable legumes in Table 4 of 7 CFR 246.10(e)(12). The specification in Table 4 also clarifies that mature legumes issued via the WIC food instrument may not contain added vegetables or fruits.

### b. Issuance of Mature Legumes (Dry Beans and Peas)

The interim rule includes mature dry beans, peas, or lentils in dry-packaged or canned forms as a WIC food category. Items in this food category are issued via the regular WIC food instrument. FNS provided technical assistance to State agencies on the interim rule clarifying that beans and peas that do not qualify under this category may be purchased only with the cash-value voucher. A total of 23 commenters (8 of which were form letters) asked FNS to allow all mature varieties and forms of dry beans and peas to be purchased with both the cash-value voucher and the WIC food instrument to eliminate confusion on the part of participants and vendors.

The nutritional profile of mature dry legumes is different than that for immature varieties and FNS believes it is important to maintain this distinction. Mature legumes are excellent sources of plant protein, and

also provide other nutrients such as iron and zinc. Mature dry beans and peas are similar to meats, poultry, and fish in their contribution of these nutrients. In WIC, they are offered as a separate food category from the fruit and vegetable category. Therefore, mature legumes in dry-packaged and canned forms, without added vegetables, fruits, meat, sugars, fats, or oils, are the only dry beans and peas authorized to be issued via the WIC food instrument.

### c. Disallowed Ingredients in Peanut Butter

A technical oversight has been corrected in Table 4 of 7 CFR 246.10(e)(12) to disallow peanut butter with added marshmallows, honey, jelly, chocolate/or similar ingredients.

## 3. Fruit and Vegetable Juice

Technical corrections have been made in Table 4 of 7 CFR 246.10(e)(12) related to the standard of identities for canned fruit and vegetable juices. This final rule corrects the specifications for WIC-eligible canned fruit juice and vegetable juice to reflect that only those WIC-eligible juices that have a standard of identity, as listed at 21 CFR Part 146 and 21 CFR Part 156, must conform to these FDA standards of identity.

## 4. Milk and Milk Alternatives

a. Whole milk for participants greater than 2 years of age. Under the interim rule, and as recommended by the IOM, whole milk is not authorized for children greater than 2 years of age and women in Food Packages IV–VII. Under the interim rule, whole milk may be issued to medically fragile children older than 2 years of age and women only in Food Package III for participants with qualifying conditions. A total of 216 commenters, primarily local agency WIC staff, asked FNS to allow the CPA to prescribe whole milk for participants in any food package if necessary for participants who have medical or nutritional reasons for requiring additional calories.

FNS believes that WIC staff can assist participants in Food Packages IV–VII in meeting their nutritional needs through fat-reduced milks and other foods. Whole milk adds unnecessary saturated fat and cholesterol to the diets of 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. Therefore, the provision to authorize whole milk for children greater than 2 years of age and women only in Food Package III is retained in

this final rule in Table 3 of 7 CFR 246.10(e)(11).

### b. Fat-Reduced Milks for Children 12 Months to 2 Years of Age in Food Package III and IV

Under the interim rule, children 12 months to 2 years of age may only be issued whole milk. A total of 332 commenters (34 form letters) want flexibility in this provision, citing American Academy of Pediatrics (AAP) policy,<sup>3</sup> recommending fat-reduced milks for children over the age of 1 for whom overweight or obesity is a concern.

In light of current AAP policy, FNS will allow, at State agency option, fat-reduced milks to be issued to 1-year-old children (12 months to 2 years of age) for whom overweight or obesity is a concern. Under Food Package IV, FNS will allow the CPA to make a determination for the need for fat-reduced milks for young children based on an individual nutritional assessment and consultation with the child's health care provider if necessary, as established by State agency policy. FNS will provide technical assistance for issuing fat-reduced milks to children 12 months to 2 years of age in Food Package IV. Due to the medically fragile qualifying conditions of children 12 months to 2 years of age, FNS will continue to require medical documentation for issuance of WIC-eligible formula and foods, including fat-reduced milks, under Food Package III.

### c. Fat Content of Milk for Children Over 2 Years of Age and Women

Under the interim rule, children  $\geq 24$  months of age and women may be issued a variety of milk types (i.e., nonfat, lowfat (1%) and reduced fat (2%) milk). Seven commenters recommended the issuance of only nonfat or lowfat (1%) milk to children  $\geq 24$  months of age and women to be consistent with the Dietary Guidelines for Americans. FNS notes that State agencies already have policies to ensure that CPAs issue the appropriate milk to participants based on the assessed nutritional needs of individual participants. Since 1995 the Dietary Guidelines for Americans have recommended consumption of nonfat and lowfat milk and milk products. In technical assistance provided to State agencies on the interim rule, FNS supported and encouraged State agencies to issue only nonfat and lowfat

<sup>3</sup> American Academy of Pediatrics. Policy Statement Lipid Screening and Cardiovascular Health in Childhood, *Pediatrics* Vol. 122 No. 1 July 2008, pp. 198–208.

milk to children and women unless otherwise indicated by nutrition assessment. As such, FNS finds merit in adding a provision that nonfat and lowfat (1%) milks are the standard issuance for children  $\geq 24$  months of age and women in Food Packages IV–VII. Reduced fat (2%) milk is authorized only for participants with certain conditions, including but not limited to, underweight and maternal weight loss during pregnancy. The need for reduced fat (2%) milk for children  $\geq 24$  months of age (Food Package IV) and women (Food Packages V, VI, VII) will be determined as part of the careful nutrition assessment completed by the CPA, as established by State agency policy.

#### d. Fortification of Whole Milk

This final rule clarifies the minimum nutrient requirements for all milks listed in Table 4 of 7 CFR 246.10(e)(12). The table restates the milk specifications to make it clearer that vitamin A fortification is not required for whole milk.

#### e. Provision of Maximum Monthly Allowance of Milk

Under the interim rule, the maximum monthly allowance of milk must be provided to participants, as the WIC benefit to participants is the full authorized amount. The interim rule allows a substitution rate of 1 pound of cheese for 3 quarts of milk, leaving a quart of milk or milk substitute that must be provided to participants issued this option to fulfill the maximum allowance in the food package.

A total of 17 commenters (6 of these form letters) asked FNS to drop the “dangling quart” or allow State agencies to round the quantity of milk up when substituting cheese for milk because of limited availability and higher costs of milk in quart size containers. A total of 20 commenters (6 of these form letters) asked FNS to allow State agencies to issue 12 ounce cans of evaporated milk, which are the largest size available in the marketplace and which reconstitute to 24 fluid ounces, as the “dangling quart.”

The IOM cited milk as an important source of calcium and vitamin D for WIC participants, and this food category should not be shortchanged. Therefore, the “dangling quart” may not be ignored. This final rule will continue to require that State agencies provide the maximum allowance of milk to participants if cheese is substituted for milk in order for participants to obtain their full milk benefit.

State agencies continue to have the option to make available other

authorized milk substitutes to fulfill the maximum allowance. Because milk in quart sizes has become more widely available as States have implemented the interim rule, and this final rule allows the option of providing a quart of yogurt for children and women (as described in a subsequent section of this preamble), and allows issuance of a 12 ounce can of evaporated milk to substitute for the “dangling quart,” State agency concerns about difficulty providing the full milk benefit to participants who substitute cheese for milk should be alleviated. State agencies also have the option to prescribe half gallon containers of milk every other month for participants in lieu of the “dangling quart.”

#### f. Cheese in Excess of Maximum Substitution Rates

Under the interim rule, cheese may be substituted for milk. The IOM set a substitution rate for cheese for milk, but put a cap on the amount that can be substituted to control total and saturated fat content of the food packages. Under the interim rule, FNS allowed, with medical documentation, additional amounts of cheese to be issued beyond the substitution rate to provide State agencies with flexibility to accommodate participants with lactose intolerance. This accommodation was made because, at the time, milk alternatives for participants with lactose intolerance were more limited. Few soy-based beverages that met FNS’ nutritional standards were available, and the interim rule did not authorize yogurt, which had been recommended by IOM as a milk substitute. Since that time, more soy-based beverages that meet the nutritional standards established by FNS are available in the marketplace, and this final rule authorizes yogurt for children and women. As a result, State agencies have increased flexibility, in addition to offering lower lactose milks, to accommodate lactose intolerance with substitutes other than cheese, as recommended by the IOM. Therefore, this final rule will no longer allow cheese to be issued beyond established substitution rates, even with medical documentation, which is consistent with the recommendation of the IOM.

#### g. Yogurt

The IOM recommended adding yogurt to the WIC food packages as a partial milk substitute for children and women. However, under the interim rule, FNS determined that the addition of yogurt to the WIC food packages was cost prohibitive. The interim rule solicited comments from State agencies about the

extent to which WIC participants would benefit from the addition of yogurt, and whether that addition could be achieved in a cost-effective manner.

A total of 304 comment letters (63 of these form letters) encouraged FNS to allow yogurt as a milk substitute, emphasizing that yogurt provides priority nutrients and is convenient, popular, and culturally acceptable to WIC participants. Commenters also cited a pilot study, conducted by the California WIC Program in conjunction with the National Dairy Council, which demonstrated the feasibility of providing yogurt in WIC food packages.<sup>4</sup> The pilot study results cited participant acceptance and ease of implementation.

FNS agrees that yogurt is a desirable milk alternative for participants who might not otherwise drink sufficient amounts of fluid milk due to lactose intolerance or other reasons. Therefore, this final rule authorizes yogurt as a substitute for milk for children and women in Food Packages III–VII, at the State agency’s option.

#### (1) Maximum Monthly Allowance of Yogurt

At State agency option, 1 quart of yogurt may be substituted for 1 quart of milk for women and children in Food Packages III–VII. No more than 1 quart of yogurt is authorized per participant.

#### (2) Authorized Yogurts

As recommended by the IOM, yogurt must conform to the standard of identity for yogurt as listed in Table 4 of 7 CFR 246.10(e)(12) and may be plain or flavored with  $\leq 40$  grams of total sugar per 1 cup of yogurt. Only lowfat and nonfat yogurts are authorized for children over 2 years of age and women. Whole fat yogurt is authorized only for children less than two years of age. State agencies have the option to determine the container sizes of yogurt to authorize on their food lists.

#### h. Tofu

Under the interim rule, calcium-set tofu prepared only with calcium salts, (e.g., calcium sulfate), and without added fats, sugars, oils, or sodium, is authorized. A technical correction has been made in this final rule to clarify that tofu must be calcium-set, i.e., contain calcium salts, but may also contain other coagulants, i.e., magnesium chloride. This additional flexibility allows State agencies to meet the needs of WIC’s culturally diverse participants. Tofu with only calcium

<sup>4</sup> Fung, EB, et al. Randomized, controlled trial to examine the impact of providing yogurt to women enrolled in WIC. *J Nutr Educ Behav*. 2010 May–Jun;42(3 Suppl):S22–9.



sulfate may not be readily available in the marketplace. Major tofu manufacturers with national distribution make tofu with calcium sulfate alone or in addition to magnesium chloride as a coagulant. Magnesium chloride is not a flavoring or preservative, and should not be confused with sodium chloride, which is not permitted. The calcium content of various types of tofu, even those set only with calcium salts, varies. In choosing the brands and types of calcium-set tofu to include on food lists, State agencies should read the nutrition labels and choose tofu with the highest amount of calcium.

#### 5. Breastfeeding Provisions

Under the interim rule, food packages for infants and women are designed to strengthen WIC's breastfeeding promotion and support efforts and provide additional incentives to assist mothers in making the decisions to initiate and continue to breastfeed. The provisions disallow routine issuance of infant formula to partially breastfeeding infants in the first month after birth to help mothers establish milk production and the breastfeeding relationship. Overall, commenters expressed support for the breastfeeding provisions, with 7 State agencies stating they have already seen increases in breastfeeding rates attributable to the interim rule provisions. State agencies stressed that adequate training of WIC staff and the provision of appropriate counseling and support to mothers is critical to the success of the new food packages for the breastfeeding mothers and their infants.

##### a. Exclusive Breastfeeding

This final rule clarifies the intent of the WIC Program that all women be supported to exclusively breastfeed their infants and to choose the fully breastfeeding food package without infant formula at 7 CFR 246.10(e). Breastfeeding women who do not exclusively breastfeed are to be supported to continue breastfeeding to the maximum extent possible through minimum supplementation with infant formula.

##### b. Clarification of Partially Breastfeeding Terminology

Commenters asked FNS to address terminology used to describe the mother-infant pair who "partially" breastfeed (both breastfeed and formula feed). Confusion exists because partially breastfeeding is used to describe a combination of any amounts of breastfeeding and formula feeding. However, under the interim rule, for the purposes of food package issuance, the partially breastfeeding food package is

defined by a maximum quantity of formula that assumes the mother is substantially breastfeeding her infant. Confusion also exists because WIC's definition of a breastfeeding woman is the practice of feeding a mother's breast milk to her infant on the average of at least once a day. This definition determines the categorical eligibility of a participant as a breastfeeding woman, and did not change under the interim rule revising the WIC food packages. All women who meet this definition are counted as breastfeeding women for participation purposes, regardless of the food package they are issued or the amount of formula their infants receive.

Under the interim rule, three infant feeding variations are defined for the purposes of assigning food quantities and types in Food Packages I and II for infants: (1) Fully formula feeding, (2) fully breastfeeding (the infant does not receive formula from the WIC Program), and (3) partially breastfeeding (the infant is breastfed but also receives some infant formula from WIC up to the maximum allowance described for partially breastfed infants in Table 1 of 7 CFR 246.10(e)(9)). Breastfeeding assessment and the mother's plans for breastfeeding serve as the basis for determining food package issuance. Breastfed infants who are assessed to need more formula than is allowed under the food package for partially breastfed infants are assigned to the fully formula feeding package.

FNS agrees that terminology used to describe food packages for the mother-infant pair that both breastfeed and formula feed, regardless of amount from either source, needs clarification. Therefore, this final rule attempts to minimize confusion about food package issuance by parenthetically adding the descriptor "mostly" breastfeeding to the partially breastfeeding food package designation established under the interim rule.

##### c. Issuance of Formula to Breastfed Infants

There has been some confusion about the issuance of one can of powder infant formula in the first month to breastfed infants. For breastfeeding women who do not receive the fully breastfeeding package, WIC staff are expected to individually tailor the amount of infant formula based on the assessed needs of the breastfeeding infant and provide the minimal amount of formula that meets but does not exceed the infant's nutritional needs. This is consistent with long-standing FNS policy that dates back to the 1980s. State agencies should develop policies for handling breastfeeding mothers' formula requests

that encourage substantial and continued breastfeeding. This is true whether the infant receives the fully formula feeding package (although the infant may be minimally breastfeeding) or the partially (mostly) breastfeeding food package. The full nutrition benefit should not be used as the standard for issuance unless the mother is not breastfeeding the infant at all.

The interim rule strengthened the WIC food packages to better enhance breastfeeding promotion and support. Food packages for partially (mostly) breastfed infants and women were created that provide additional foods for mothers as incentives, to better meet nutritional needs, and to provide less infant formula to partially breastfed infants than to infants who receive the fully formula fed package.

The food packages for partially (mostly) breastfed mothers and infants are designed to provide for the supplemental nutrition needs of the breastfeeding pair, provide minimal formula supplementation to help mothers maintain milk production, and provide incentives for continued breastfeeding by way of a larger variety and quantity of food than the full formula/postpartum packages. FNS emphasizes that the benefits of the partially breastfed food packages are lost if the breastfeeding mother-infant pair is issued the full formula/postpartum packages. Appropriate support and counseling should be provided to mothers to minimize the number of breastfeeding infants receiving the full formula packages.

This final rule clarifies at 7 CFR 246.10(b)(2)(ii)(C) that food package quantities are to be issued based on assessment of each participant's individual breastfeeding and nutritional needs.

##### d. Issuance of Formula to Breastfed Infants in the First Month After Birth

This final rule clarifies that the issuance of any formula to breastfed infants in the first month after birth is a State agency option. If a State agency chooses this option, it may issue one can of powder infant formula in the container size that provides closest to 104 reconstituted fluid ounces to partially breastfed infants on a case-by-case basis. Breastfed infants who are provided this option are considered partially (mostly) breastfed. Breastfed infants should not receive more than the one can option in order to maintain the mother's milk production. State agencies should not create food packages that standardize issuance of formula to partially (mostly) breastfed infants in the first month after birth.

e. Food Package VII for Fully Breastfeeding Women

Under the interim rule, 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 (mostly) breastfeeding multiple infants. This final rule clarifies that Food Package VII is issued to partially (mostly) breastfeeding mothers who are breastfeeding multiples *from the same pregnancy*.

A total of 12 commenters (4 form letters) asked that partially breastfeeding women who are also pregnant be allowed to receive the more enhanced Food Package VII. FNS agrees with commenters that pregnant women who are also partially (mostly) breastfeeding singleton infants would benefit from the increased quantity and variety of foods in this food package. Therefore, this final rule authorizes pregnant women who are also partially (mostly) breastfeeding to receive Food Package VII.

Under the interim rule, women fully breastfeeding multiples receive 1.5 times the maximum allowance of foods authorized in Food Package VII to meet their nutritional needs. A total of 36 commenters (8 form letters) asked FNS to revise the food package quantities for women fully breastfeeding multiples to reflect a consistent amount each month and to specify amounts in quantities available in marketplace. In technical assistance provided to State agencies on the interim rule, FNS provided flexibility to allow States to choose how they will issue these quantities. Some States have elected to issue foods in this food package in amounts averaged over a 2-month timeframe to eliminate concern about providing quantities available in the marketplace. Others issue double the “regular” fully breastfeeding package one month and then issue the “regular” fully breastfeeding package the next month. FNS will allow State agencies to retain the flexibility to determine how best to issue food packages quantities for women fully breastfeeding multiples and therefore will not change the provision to specify a set amount that must be provided each month.

f. Human Milk Fortifier (HMF)

Fifteen commenters (4 form letters) asked that partially (mostly) breastfeeding women whose infants receive human milk fortifier (HMF) be considered fully breastfeeding.

Issuance of HMF as a WIC formula is allowed with medical documentation under the interim rule, as it was under previous WIC policy. A woman whose infant receives HMF is considered partially breastfeeding because her infant is receiving formula from WIC. HMF provides additional protein, minerals, and vitamins that, when added to breastmilk in the first postpartum month for premature infants, results in nutrient, mineral, and vitamin concentrations similar to those of the formulas developed for feeding preterm infants. HMF is given in the hospital, but most often is discontinued prior to discharge. There is a limit on how long HMF is necessary and the need and length of time an infant should remain on HMF should be determined and monitored by the health care provider.

Since HMF is to be used for only a very short time, the woman can be transitioned back to the fully breastfeeding package as soon as the infant is no longer receiving HMF from WIC. The final rule will retain the provision that Food Package VII is issued only to women whose infants do not receive formula from WIC, including HMF.

6. Whole Wheat Bread and Whole Grain Options

a. Authorized Breads

Under the interim rule, whole wheat breads, rolls and buns that meet the FDA standard of identity for whole wheat bread (21 CFR 136.180) are authorized. Some commenters asked FNS to allow baked products that do not meet the standard of identity for whole wheat bread, e.g., English muffins and bagels, if these products otherwise meet the whole wheat requirements. FNS has considered this request, but has determined that identifying the WIC-eligibility of whole wheat bread products that do not meet the standard of identity would be complex given the number of products in the marketplace. Therefore, the requirement that whole wheat breads meet the standard of identity for whole wheat bread is retained in this final rule in Table 4 of 7 CFR 246.10(e)(12).

b. Package Sizes of Whole Wheat/Whole Grain Bread

The interim rule established a maximum monthly allowance of two pounds of whole wheat bread or other whole grain options for children in Food Packages III and IV; and one pound of whole wheat bread or other whole grain options for women in Food Packages III, V and VII. Commenters

asked that FNS authorize bread in the more commonly available 20 ounce package size.

Although the availability of bread in package sizes to meet the WIC maximum monthly amount of bread authorized in WIC food packages was of initial concern as State agencies planned to implement the new food packages and supply in the marketplace may have been limited, bread manufacturers have increasingly produced WIC-eligible breads in 16 ounce package sizes to respond to the changes in the WIC Program. As such, all State agencies have breads in appropriate size packages on their WIC food lists. A greater number of WIC-eligible breads in 16 ounce package sizes continue to be introduced by manufacturers, which will further increase the bread options available to participants. Therefore, FNS believes that this situation has been addressed and the maximum allowance for whole wheat and whole grain bread is unchanged in this final rule.

c. Expansion of Whole Grain Options

Under the interim rule, whole grains (brown rice, bulgur, oats, and whole grain barley), as well as tortillas, are authorized as substitutions for whole wheat and whole grain bread. A total of 310 commenters (22 of these form letters) asked FNS to consider expanding the list of whole grain foods available to participants. Suggestions included whole grain pasta, whole wheat English Muffins, and whole wheat bagels.

To make available additional whole grain foods to participants, this final rule will add whole wheat pasta to the list of whole wheat/whole grain bread alternatives. Whole wheat macaroni (pasta) products that meet the FDA standard of identity (21 CFR 139.138) and have no added sugars, fats, oils, or salt (i.e., sodium) are WIC-eligible. Other shapes and sizes that otherwise meet the FDA standard of identity for whole wheat macaroni (pasta) products are also authorized (e.g. whole wheat rotini, whole wheat penne).

d. Technical Corrections

In technical assistance provided to State agencies on the interim rule, FNS clarified that State agencies must offer whole wheat and/or whole grain bread. State agencies have the option to also authorize the other whole grain options listed in Table 4 of 7 CFR 246.10(e)(12). This final rule clarifies this provision. Also, consistent with technical assistance provided to State agencies on the interim rule, FNS clarifies in Table 4 of 7 CFR 246.10(e)(12) of this final

rule that corn tortillas made from ground masa flour (corn flour) using traditional processing methods are WIC-eligible. FNS recognizes that a small loss of corn kernel occurs during the traditional processing of tortillas, and therefore, such tortillas are not considered whole grain. FNS encourages State agencies to authorize corn tortillas that have whole corn listed as their primary ingredient. However, if the market availability of such corn tortillas is limited, FNS will allow State agencies to authorize corn tortillas made from ground masa flour using traditional processing methods, due to the high participant acceptance of corn tortillas, especially among Hispanic cultures. A technical clarification has been made in Table 4 of 7 CFR 246.10(e)(12) to the minimum requirements and specifications for whole wheat tortillas to address the types of flour authorized. This final rule continues to require that whole grain breads and cereals meet FDA labeling requirements for making a health claim as a "whole grain food with moderate fat content." However, for simplicity and clarity, the final rule removes the specifics of the labeling requirements from Table 4 of 7 CFR 246.10(e)(12) and instead refers readers and manufacturers directly to the FDA health claim notification for further reference at <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073634.htm>.

A technical clarification has been made in Table 4 of 7 CFR 246.10(e)(12) to the minimum requirements and specification for whole wheat bread to address consistency with the standard of identity for whole wheat bread. For additional clarity and to aid State agencies and participants in identifying WIC-eligible whole grain bread products, a statement has been added to the requirements noting whole grain breads must conform to the FDA standard of identity for bread, buns and rolls.

#### 7. Breakfast Cereals

Under the interim rule, at least one half of all breakfast cereals on each State agency's authorized food list must meet the whole grain requirements as specified in Table 4 at 7 CFR 246.10(e)(12). This provision allows certain corn and rice-based cereals to be offered to participants who may have allergies to whole grain cereals. FNS is retaining this provision in this final rule, but encourages State agencies to issue whole grain cereals to participants to the maximum extent possible, reserving non-whole grain options for those participants with allergies or other

medical reasons where whole grains are contraindicated. Participants should receive nutrition education on the benefits of whole grain in the diets to reduce the risk of coronary heart disease and type-2 diabetes, help with body weight maintenance, and increase intake of dietary fiber.

A technical correction has been made in this final rule in Table 4 of 7 CFR 246.10(e)(12) to clarify that there is no FDA standard of identity listed for breakfast cereals.

#### 8. Infant Foods in Food Packages II and III

##### a. Fresh Bananas as Substitute for Jarred Infant Foods

Under the interim rule, State agencies have the option to offer fresh bananas as a substitute for up to 16 ounces of infant food fruit at a rate of one pound of bananas per eight ounces of infant food fruit via the regular WIC food instrument. To ensure participants receive the full food package benefit of this provision, and to simplify the transaction for vendors as well as participants, FNS will also allow State agencies the option to substitute fresh bananas at a rate of one banana per four ounces of jarred infant food fruit, up to a maximum of 16 ounces, in Food Packages II and III for infants 6 to 12 months of age. This is consistent with recommendations of the IOM.

##### b. Cash-Value Voucher in Lieu of Commercial Jarred Infant Foods

Under the interim rule, jarred infant foods (fruits, vegetables, and meat) are provided in Food Packages II and III for infants 6 months through 11 months of age. Although this provision overall has been well received, concerns initially made by commenters on the proposed rule persist regarding this provision. A total of 508 commenters on the interim rule asked FNS to include a State option to provide a cash-value voucher to older infants receiving Food Packages II and III in lieu of commercial jarred infant food fruits and vegetables. Commenters stated that foods for older infants should be developmentally appropriate as infants transition to toddler foods, and noted the lack of availability of jarred infant foods in appropriate textures for the older infant. Commenters also stated that the amount of jarred infant foods in the WIC food packages is excessive for some older infants who are progressing in their feeding skills and transitioning from infant foods to table foods consumed during family meals.

FNS remains committed to IOM's recommendation that commercial jarred infant foods be provided in the WIC

food packages to ensure that infants receive and consume fruits and vegetables in developmentally appropriate textures and in a variety of flavors. The IOM also intended that commercial jarred infant foods be provided to ensure that these items are consumed by infants and not other participants or family members. Food safety and nutrient content were also considerations. FNS recognizes these considerations and continues to provide commercial jarred infant foods in this final rule.

FNS acknowledges the preference for alternative options for infants and agrees that the lack of developmentally appropriate infant foods available in the marketplace may make it difficult for State agencies to provide a range of textures appropriate for infants at different stages of development. This void in the market is particularly noted among infant food products for older infants, and may compromise the appropriate progression of an infant's feeding skills. The FNS Infant Nutrition and Feeding Guide<sup>5</sup> indicates that at around nine months of age, most infants are developmentally ready to consume foods of increased texture and consistency. Such consistency should progress from pureed to ground to fork-mashed and eventually to diced.

Therefore, in light of these considerations, under this final rule, FNS will allow infants 9 months through 11 months of age to receive a cash-value voucher for the purchase of fresh fruits and vegetables in lieu of a portion of the infant food fruits and vegetables provided in Food Packages II and III. For partially breastfed infants and fully formula fed infants, participants may opt to receive a \$4 cash-value voucher plus 64 ounces of infant food fruits and vegetables; fully breastfed infants may receive an \$8 cash-value voucher plus 128 ounces of infant food fruit and vegetables. The decision to issue cash-value vouchers in lieu of infant food fruits and vegetables is a State agency option. If a State agency chooses this option, it may not categorically issue cash-value vouchers to all infants of this age group. Instead, the cash-value voucher is to be provided to the participant only after a thorough assessment by the CPA, as established by State agency policy, and is optional for the participant, i.e., the mother may choose to receive either the maximum allowance of jarred foods or the combination of jarred foods and a fruit

<sup>5</sup> Food and Nutrition Service 2009. Infant Nutrition and Feeding: A Guide for Use in the WIC and CSF Programs. Available at Internet site: <http://www.nal.usda.gov/wicworks/Topics/FG/CompleteIFG.pdf>.

and vegetable cash-value voucher for her infant. State agencies must ensure that appropriate nutrition education is provided to the caregiver addressing safe food preparation, storage techniques, and feeding practices to make certain participants are meeting their nutritional needs in a safe and effective manner.

States continue to have the option to offer, via the regular WIC food instrument, fresh bananas as a substitute for infant food fruit in Food Packages II and III for infants six to twelve months of age as described in section IV.C.8.a of this preamble.

This final rule clarifies that a fruit or vegetable must be listed as the primary (first) ingredient in WIC-eligible jarred infant foods. Further, this final rule clarifies that combinations of single ingredients of fruits and/or vegetables (e.g., peas and carrots, apples and squash) are allowed in Food Package II and III for infants 6 to 12 months of age.

#### c. White Potatoes in Jarred Infant Foods

White potatoes are excluded from purchase with the cash-value voucher in the WIC food packages. However, this final rule clarifies that jarred infant foods that meet the minimum requirements and specifications for an infant food product and include white potatoes as an ingredient, but not the primary ingredient, are allowed in Food Packages II and III for infants 6 to 12 months of age.

#### d. Infant Cereal

Under the interim rule, infant cereal is provided in Food Packages II and III for infants 6 months to 12 months of age. A total of 223 commenters (16 form letters) asked FNS to allow State agencies the option to offer “adult” breakfast cereals, as appropriate, to older infants to encourage developmental feeding skills and support the transition from infant foods to appropriate table and finger foods. Commenters stated that participants report not purchasing infant cereal because older infants prefer cereals they can eat with their fingers.

The IOM recommended the provision of iron-fortified infant cereal for infants 6 to 12 months of age as a quality source of iron and zinc, nutrients needed by infants for optimal growth and development. Providing infant cereal for infants 6 months through 11 months of age is consistent with pediatric nutrition guidelines. The FNS Infant Nutrition and Feeding Guide<sup>6</sup> states that ready-to-

eat, iron-fortified cereals designed for adults or older children are not recommended for infants because they: (1) often contain mixed grains; (2) tend to contain more sodium and sugar than infant cereals; and (3) typically contain less iron per infant-sized serving. Food safety is also of concern with the provision of adult cereals to infants as these products could cause choking if the infant is not developmentally ready to consume foods of this texture. For these reasons, the provision of iron-fortified infant cereal for infants 6 months of age through 12 months of age in Food Packages II and III remains unchanged in this final rule.

#### 9. Canned Fish

The IOM recommended that a variety of canned fish that do not pose a mercury hazard be offered in Food Package VII. In addition to canned light tuna, canned salmon, and canned sardines, the interim rule authorized canned mackerel in Food Package VII for fully breastfeeding women. However, the two species of mackerel specified in the interim rule—N. Atlantic and Chub (Pacific)—are not readily available in canned form in the United States. FNS received 21 comments asking that canned Jack mackerel also be authorized in Food Package VII, citing its lower levels of mercury and acceptance by WIC participants.

To allow more variety and choice among canned fish options, this final rule authorizes Jack mackerel as a canned fish option in Food Package VII. King mackerel is not authorized in any form. FNS encourages State agencies to offer all authorized canned fish options, i.e., tuna, salmon, sardines, and Jack mackerel, to ensure variety and choice for participants. This final rule also clarifies that canned fish with added sauces and flavorings, e.g., tomato sauce, mustard, lemon, are authorized at the State agency’s option.

#### 10. Food Package III for Children and Women With Qualifying Conditions

##### a. Infant Foods In Lieu of the Cash-Value Voucher

Under the interim rule, children and women with qualifying conditions who require the use of a WIC formula (i.e., infant formula, exempt infant formula or WIC-eligible nutritional (formerly WIC-eligible medical food)) receive Food Package III. Among the supplemental foods provided to participants in this food package is a cash-value voucher to purchase fruits and vegetables. A total

of 33 commenters requested the substitution of commercial jarred infant food fruit and vegetables in lieu of the cash-value voucher for participants over the age of one who have a qualifying medical condition, such as prematurity, developmental delays, and dysphasia (swallowing disorders). Commenters pointed out that these individuals would benefit from the use of this ready-to-feed form of pureed fruits and vegetables over the purchase of fresh fruits and vegetables.

Food Package III is reserved for medically fragile participants who have specific dietary needs that are dictated by their medical condition. FNS is committed to providing these individuals with WIC Formula (i.e., infant formula, exempt infant formula and WIC-eligible nutritional) and supplemental foods that best meet their special dietary needs. Thus, FNS finds merit in the argument that some participants with certain qualifying conditions may require a pureed form of fruits and vegetables to meet their nutritional needs, and would benefit from the convenience of purchasing jarred infant food fruits and vegetables. As such, this final rule allows State agencies the flexibility to provide children and women in Food Package III the option of receiving commercial jarred infant food fruits and vegetables in lieu of the cash-value voucher. The quantity of commercial jarred infant food fruits and vegetables is based on the substitution ratio of 128 ounces of infant food fruits and vegetables for the \$8 cash-value voucher for children and 160 ounces of infant food fruits and vegetables for the \$10 cash-value voucher for women. The need for commercial jarred infant food fruits and vegetables in lieu of the cash-value voucher will be determined by medical documentation that meets the criteria established in 7 CFR 246.10(d). Some participants may prefer to purchase fruits and vegetables via the cash-value voucher and process/puree the fruits and vegetables themselves; this remains an option and is encouraged for those who would benefit from this method of modifying the consistency and texture of foods to improve nutritional intake.

Some commenters asked FNS to allow children in Food Package IV the option to receive commercial jarred infant foods in lieu of the cash-value voucher. However, FNS believes it appropriate that caregivers of children who do not have qualifying conditions making them eligible for Food Package III, and who need modifications in food consistency, receive nutrition education on choosing and preparing foods that meet the child’s needs, e.g., pureeing fruits and

<sup>6</sup>Food and Nutrition Service 2009. Infant Nutrition and Feeding: A Guide for Use in the WIC and CSF Programs. Available at Internet site:

<http://www.nal.usda.gov/wicworks/Topics/FG/CompleteIFG.pdf>

vegetables and/or choosing those with soft texture/consistency.

**b. Allowance of Infant Formula in Food Package III for Infants**

Food package III is reserved for participants who have one or more qualifying conditions that require an exempt infant formula or WIC-eligible nutritional (formerly WIC-eligible medical food) to supplement their nutrition needs, as determined by the participant's health care professional. Infants who have a qualifying condition and are successfully managed with an infant formula are issued Food Package I or II, as deemed appropriate for their age and feeding method.

Under the interim rule, infants who require a combination of infant formula and a WIC-eligible nutritional or exempt infant formula are not able to receive both products through a WIC food package. In addition, these infants at 6 months of age may not be developmentally ready to consume solid foods due to their medical condition and would benefit from an increased amount of formula in place of infant foods at that timeframe. FNS received 74 comments requesting that infants who are not developmentally ready to consume solid foods be allowed increased infant formula amounts in lieu of infant foods in Food Package II.

FNS agrees that there are a small percentage of infants who have a qualifying condition, such as prematurity, whose nutritional needs may be successfully managed with infant formula alone or a combination of infant formula and WIC-eligible nutritional. These infants are considered medically fragile and would benefit from the close medical supervision provided under Food Package III. These infants may not be ready to consume infant foods at 6 months of age, as would otherwise generally healthy term infants, and they may benefit from receiving additional formula in lieu of infant foods at that time. Therefore, this final rule expands the type of formula authorized to infants with qualifying conditions in Food Package III to include infant formula. The issuance of infant formula in Food Package III would be strictly reserved for those infants who are medically fragile. Infants who do not have a qualifying condition and are otherwise generally healthy infants will continue to receive Food Packages I and II, as appropriate. In Food Package III, infants greater than 6 months of age may receive additional infant formula, exempt infant formula or WIC-eligible nutritional (formerly WIC-eligible medical food) in lieu of infant foods at

the same maximum monthly allowance as infants ages 4 through 5 months of age of the same feeding option. As with exempt infant formula and WIC-eligible nutritional, infants receiving infant formula in Food Package III will need medical documentation that meets the criteria established in 7 CFR 246.10(d).

**11. Liquid Concentrate Infant Formula Amounts and Full Nutrition Benefit**

Table 1 in 7 CFR 246.10(e)(9) of the interim rule established the full nutrition benefit and the maximum monthly allowances of each physical form of infant formula, for each food package category and infant feeding variation. The interim rule also described the full nutrition benefit as the reconstituted fluid ounce amounts for liquid concentrate infant formula (based on a 13 ounce can) which formed the basis of substitution rates for other physical forms of infant formula (i.e., powder and ready-to-feed infant formula). Providing the full nutrition benefit amounts ensure that participants receive a comparable nutritional benefit no matter which physical form of infant formula they receive.

For decades, infant formula manufacturers consistently provided liquid concentrate and ready-to-feed infant formula in container sizes or packaging that evenly divide into the maximum monthly allowance, while powder infant formulas traditionally vary in package size across manufacturers. FNS has become aware of a shift in the marketplace, such that liquid concentrate and ready-to-feed infant formula container sizes (i.e., 13 and 32-fluid ounces) are no longer standard for all major infant formula manufacturers. Because the maximum monthly allowance amounts of liquid infant formula under the interim rule are evenly divisible by a 13 ounce standard for liquid concentrate (reconstituted) and a 32 ounce standard of ready-to-feed infant formula, there is little flexibility to accommodate changes in the package size while still providing the full nutrition benefit and not exceeding the maximum monthly allowance amount.

This final rule provides the technical correction of revised maximum monthly allowance amounts for liquid concentrate and ready-to-feed infant formula. The revision of maximum monthly allowance amounts for liquid infant formula (i.e., liquid concentrate and ready-to-feed) is consistent with the legislative authority granted to the Secretary of Agriculture in Section 733 of Public Law 111–80 and reiterated in Section 712 of Public Law 112–55, the Consolidated and Further Continuing

Appropriations Act, 2012 that authorizes State Agencies to exceed the current maximum amount of liquid infant formula to ensure the full nutrition benefit be provided to participants. This will maintain competition in the infant formula market and address recent changes in package size availability of liquid concentrate and ready-to-feed infant formula.

Liquid concentrate infant formula will now have a separate maximum monthly allowance amount different from the full nutrition benefit to accommodate market changes in packaging. This provision does not change the full nutrition benefit amounts as established in the interim rule. The full nutrition benefit will now be defined as the minimum amount of reconstituted liquid concentrate infant formula as specified in Table 1 of 7 CFR 246.10(e)(9) of this rule for each food package category and infant feeding option (e.g., Food Package IA fully formula fed, IA–FF).

Infant formula issuance, whether using monthly issuance or rounding methodology, should be based on providing the amount of infant formula that most closely provides the full nutrition benefit to all infant participants as deemed appropriate based on breastfeeding assessment and infant food package and feeding method. At a minimum, State agencies must provide the full nutrition benefit to all non-breastfed infants. For breastfed infants, even those receiving the fully formula fed package, infant formula amounts should be tailored based on the assessed needs of the breastfed infant and provide the minimal amounts of formula that meets but does not exceed the infant's nutritional needs. This final rule adds the definition of full nutrition benefit at 7 CFR 246.2.

**12. Infant Formula Requirements Technical Correction**

A technical correction has been made to infant formula requirements in 7 CFR 246.246.10(e)(1)(iii) to clarify the qualifying conditions for the types of supplemental foods (i.e., noncontract brand infant formula and any contract brand infant formula that does not meet the requirements in Table 4 of 7 CFR 246.10(e)(12)) that may be issued in this food package only with medical documentation.

**Procedural Matters**

*Executive Order 12866 and Executive Order 13563*

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

This final rule has been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

*Regulatory Impact Analysis Summary*

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 final rule. The RIA for this rule was published as part of docket number FNS–2006–0037 on [www.regulations.gov](http://www.regulations.gov). A summary of the analysis follows:

*Need for Action.* This final rule considers public comments submitted

in response to the interim rule revising the WIC food packages published in December 2007 (72 FR 68966). The interim rule implemented the first comprehensive revisions to the WIC food packages since 1980. The interim rule revised regulations governing the WIC food packages to align them more closely with updated nutrition science and the infant feeding practice guidelines of the American Academy of Pediatrics, promote and support more effectively 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.

This final rule addresses public comments received on the interim rule and makes adjustments that improve clarity of the provisions set forth in the interim rule.

*Benefits.* The revised food packages were developed to better reflect current nutrition science and dietary recommendations, promote and support more effectively the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of food than do current food packages, and provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural

food preferences. The final rule makes additional administrative and food package changes that will allow local WIC agencies to better meet the nutritional needs and dietary preferences of program participants.

*Costs.* FNS estimates that the cost of all mandatory and optional provisions in this final rule will total \$1.17 billion over 5 years assuming State implementation beginning May 1, 2014 (for all provisions except the split tender and soy-based beverage for children provisions, which have effective dates of October 1, 2014) and yogurt for women and children with an effective date of April 1, 2015. If the optional provisions are adopted by fewer than all State agencies, then the cost of the rule will be lower. The cost of the mandatory provisions across all State agencies, plus the cost of the optional provisions by State agencies that serve half of WIC participants, is estimated to be \$999 million over 5 years.

*Accounting statement.* The following accounting statement gives the estimated discounted, annualized costs of the rule assuming full State agency implementation of the rule’s mandatory and optional provisions. The figures are computed from the nominal 5-year estimates developed in the full RIA. The accounting statement contains figures computed with 7 percent and 3 percent discount rates.

	Estimate	Year dollar	Discount rate (percent)	Period covered
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**Benefits**

*Qualitative:* The final rule modifies several provisions of the interim rule based on comments from State and local agencies, interest groups, participants, and others. These modifications better fulfill the intent of the interim rule and the IOM recommendations that are the basis for the WIC food package changes. The rule would increase the quantity of fruits and vegetables contained in the food packages for children to the level recommended by the IOM. The rule also gives States and local agencies more flexibility to meet the medical needs and cultural preferences of WIC participants. Recent research on WIC participants indicates that changes in the WIC food package have resulted in increases in consumption of healthful foods recommended by IOM (see RIA text). The effect of the rule, therefore is a benefit to participants and not simply a transfer of Federal funds replacing costs that WIC participants would have incurred in the absence of this rule. Because we do not quantify the value of the benefits in the impact analysis, and therefore cannot separate them from the estimated Federal transfer to WIC participants, we show our entire dollar impact under transfers. No longer requiring medical documentation for children to receive soy-based beverage and tofu as milk substitutes will save participants some time, although we believe the overall impact on that their time will be minimal and the savings will be nominal. There may also be a benefit in that some WIC participants may not have been taking the soy-based beverage and tofu substitution because getting medical documentation was presenting a barrier. Providing a mechanism to access soy-based beverage and tofu by working with a WIC Competent Professional Authority will help to remove that barrier and may result in nutrition benefits for this group of participants.

**Transfers**

Annualized Monetized .....	\$225.2	2014	7	FY2014–2018
(\$millions/year) .....	230.5	2014	3	

*Quantified:* The rule contains a mix of mandatory provisions and State options. For purposes of this impact analysis we estimate the value of both the mandatory and optional provisions assuming full implementation by all WIC State Agencies. The figures shown here are estimates of the value of full implementation of mandatory and optional provisions assuming no offsetting savings. The figures shown here which are limited to the food benefit, are transfers from the Federal government to WIC participants.

**Costs**

	Estimate	Year dollar	Discount rate (percent)	Period covered
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*Qualitative:* Local and State WIC agencies will incur some administrative costs, other than reporting and recordkeeping, to implement the final rule. However, we are unable to quantify the potential increases in administrative burden due to the final provisions. These include the costs of training WIC clinic and administrative staff and the periodic review and updating of WIC-approved food lists. The State option to authorize farmers' markets to accept WIC cash-value vouchers may introduce administrative costs, however in general, we anticipate that State Agencies and local WIC providers will be able to absorb the burden associated with implementing this rule with 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, as well as adapt to certain ongoing administrative requirements associated with the final rule. FNS will continue to provide technical assistance to State and local agencies to assist them in implementing the new provisions of the final rule.

### *Regulatory Flexibility Act*

This final rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612). Pursuant to that review, FNS Administrator Audrey Rowe certified that this rule would not have a significant 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 RFA, FNS prepared a Regulatory Flexibility Analysis describing the impact of this interim rule on small entities that reflects comments that were received on the Regulatory Flexibility Analysis that was included in the WIC Food Package interim rule published at 72 FR 68982, December 6, 2007.

### *Need for and Objectives of the Final Rule*

The interim rule, published in the **Federal Register** on December 6, 2007 (72 FR 68966), revised the WIC food packages. The revisions align the WIC food packages with the Dietary Guidelines for Americans and infant feeding practice guidelines of the American Academy of Pediatrics. The interim rule revisions largely reflect recommendations made by the Institute of Medicine (IOM) of the National Academies in its report, "WIC Food Packages: Time for a Change," with certain cost containment and administrative modifications found necessary by the Department to ensure cost neutrality. The interim rule allowed FNS to obtain feedback on the major changes as recommended by IOM, as well as the implementation of procedures, while allowing implementation to move forward. State agencies, including Indian Tribal Organizations, were required to implement the changes by October 1, 2009, and new food packages are now being provided to WIC participants in all States. The interim rule comment period ended February 1, 2010. Public

comments received on the interim rule are reflected in the final rule.

The interim rule required substantial changes by State and local agencies. Overall, implementation proceeded smoothly and all States have successfully implemented the changes. This final rule makes a much more limited number of modifications than those contained in the interim rule and requires less significant changes in response to the public comments received. Therefore, the expected effects are minimal for FNS and other Federal Agencies. FNS will continue to provide technical assistance to State and local agencies to assist them in fully implementing the changes. This rule will require State and local agencies to make further modifications to their procedures that are far less substantial than the changes required under the Interim rule. Foreign countries will not be affected.

### *Description and Estimate of Number of Small Entities to Which the Final Rule Would Apply*

This final 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. 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 final rule, small vendors will be impacted differently in each State depending upon how that State chooses to meet the new requirements. 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 final rule.

A 2011 evaluation conducted by Altarum Institute<sup>7</sup> sought to understand

the impact that the WIC food package changes had on small stores. The study demonstrated that most small WIC stores were able to maintain their authorization with the WIC Program during the period the food package changes were implemented. Small stores appear to have added healthy foods to their inventory in response to the WIC food package changes. The report concludes that adequate vendor preparation likely factored into the overall success of implementation, and cites the need for ongoing engagement of these and other WIC stakeholders.

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

Modifications included in the final rule to eliminate certain medical documentation requirements imposed by the interim rule will decrease the Information Collection Burden associated with this rule.

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

FNS considered significant alternatives in developing the interim rule including those that may reduce the indirect impact on small business. These considerations included (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 the 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

<sup>7</sup> Altarum Institute 2011. Impact of the Revised WIC Food Package on Small WIC Vendors: Insight from a Four State Evaluation.

children up to age 5 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. Therefore, this final rule retains those requirements.

FNS did, however, modify the new food provisions in an effort to mitigate the impact on small entities. As in the past, 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. The interim rule added 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 interim rule allowed canned, frozen and dried fruits and vegetables to be substituted for fresh produce. These provisions are all retained in this final rule.

The interim rule authorized State agencies the option to allow participants to pay the difference if the fruit and vegetable purchase exceeds the value of the cash-value voucher, a transaction known as "split tender." In response to public comments received on the interim rule, this final rule requires State agencies to allow split tender transactions with the cash-value voucher.

#### *Unfunded Mandates Reform Act*

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

alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

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

#### *Executive Order 12372*

The WIC Program is listed in the Catalog of Federal Domestic Assistance Programs under 10.557. For the reasons set forth in the final rule in 7 CFR part 3015, subpart V, and related Notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

#### *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 13121.

#### *Prior Consultation With State Officials*

Since publication of the interim rule revising the WIC food packages, FNS has obtained input from WIC State and local agency staff about the provisions and implementation of the changes. Examples of the different forums and methods FNS has used to solicit WIC State and local agency staff input on the WIC food packages include the following:

- Hosting annual meetings 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 WIC, including aspects related to the authorized foods and food packages;
- Consulting and collaborating with the National WIC Association (NWA) on a wide variety of WIC issues, including those related to the WIC food packages. NWA is a non-profit organization that was founded in 1983 by State and local agencies that administer the WIC Program. NWA's paid membership includes 72 of the 90 WIC State agencies, 813 local agencies, 7 State WIC Associations, and 27 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; and

- Regular meetings and consultation with State health officials and other WIC stakeholders, including the medical community, advocacy groups, and retailers.

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

This final rule considers public comments submitted in response to the interim rule revising the WIC food packages published in December 2007 (72 FR 68966). The interim rule implemented the first comprehensive revisions to the WIC food packages since 1980. This final rule addresses public comments received on the interim rule and makes adjustments that improve clarity of the provisions set forth in the interim rule.

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

FNS has considered the impact of final 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.

#### *Executive Order 12988*

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is not 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 and timely implementation. This rule is not intended to have retroactive effect unless so specified in the DATES section of the final rule. Prior to any judicial challenge to the provisions of the final rule, all applicable administrative procedures must be exhausted.

#### *Civil Rights Impact Analysis*

The intent of this final rulemaking is not to limit participation or to have an adverse effect on current participants. FNS does not expect any protected populations to be adversely affected by the implementation of the requirements in this rule. State agencies must ensure participant access to supplemental foods. The foods available to WIC participants as a result of this final rule are intended to broaden the appeal of the WIC food packages for all groups



and encourage participation in WIC. This final rule revises certain provisions to better address the needs of participants with certain medical conditions, and provides State agencies increased flexibility in prescribing culturally appropriate packages for diverse groups. FNS does not anticipate this rulemaking will result in any adverse civil rights impacts.

#### *Executive Order 13175*

Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. In late 2010 and early 2011, USDA engaged in a series of consultative sessions to obtain input by Tribal officials or their designees concerning the impact of this rule on the tribe or Indian Tribal governments, or whether this rule may preempt Tribal law. USDA did not receive any input during these sessions that this rule preempts any Tribal law. Input received relative to this rule included overall satisfaction with the new WIC foods, especially the fruits and vegetables and whole grains, and changes related to supporting breastfeeding mothers. Some tribes reported that WIC participants who were enrolled in WIC during the transition from the previous food packages to the revised food packages expressed displeasure with issuance of lower fat milks and less cheese. The input from Indian tribes during these sessions was consistent with the general comments received for the interim rule, and have been addressed in this final rule. Reports from these consultations will be made part of the USDA annual reporting on Tribal Consultation and Collaboration. USDA will respond in a timely and meaningful manner to all Tribal government requests for consultation concerning this rule and will provide additional venues, such as webinars and teleconferences, to periodically host collaborative conversations with Tribal officials or their designees concerning ways to improve this rule in Indian country.

#### *Paperwork Reduction Act of 1995*

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR 1320) requires that the Office of Management

and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This final rule changes the information collection burden previously approved under OMB 0584–0545. Implementation of the data collection requirements resulting from this final rule is contingent upon OMB approval under the Paperwork Reduction Act of 1995.

The proposed food package rule was published in the **Federal Register** [71 FR 44784] with a 60-day notice on August 7, 2006, which provided the public an opportunity to submit comments on the information collection burden resulting from the proposed rule. 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.

The interim food package rule was published in the **Federal Register** [72 FR 68966] on December 6, 2007, and included an estimated annual information collection burden of 14,919 burden hours, which was approved as OMB Number 0584–0545. These information collection burden hours were merged into the information collection, WIC Program Reporting and Recordkeeping Requirements, OMB Number 0584–0043, changing the total approved burden hours for OMB Number 0584–0043 from 3,595,075 to 3,609,994. Information collection OMB Number 0584–0545 was then discontinued. Information collection OMB Number 0584–0043 was renewed as of December 27, 2012, changing the total approved burden hours from 3,609,994 to 4,024,697.

In this final rule, FNS will no longer require a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS will no longer require documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance. As a result of this final rulemaking, the overall information collection burden associated with OMB Number 0584–0043 is estimated to have decreased by 4,200 burden hours annually due to program changes in this rulemaking. The total estimated burden hours for

OMB Number 0584–0043 will decrease from 4,024,697 to 4,020,497.

The breakdown of the changes is described below:

OMB Number 0584–0043;  
WIC Program Reporting and Recordkeeping Requirements;  
expiration date December 31, 2015.

*Type of Request:* Revision of a currently approved collection.

*Abstract:* Federal regulations at 7 CFR 246.10(d)(1)(vi) and (viii) require medical documentation for the issuance of soy-based beverage and tofu for children, and tofu above the maximum substitution amount for women. Federal regulations at 7 CFR 246.10(d)(1)(v) require medical documentation for the issuance of supplemental foods to participants who receive Food Package III (for participants with qualifying conditions).

Under the interim rule, medical documentation by a health care professional licensed to write medical prescriptions is required for the issuance of certain milk alternatives for children and women. A total of 180 comment letters (53 of these form letters) opposed this requirement, primarily the documentation for children to receive soy-based beverage. Commenters stated that the provision is unnecessary, costly and burdensome for participants and physicians, creates barriers to services, and undermines FNS' efforts to provide foods that meet the cultural needs of participants. The NWA and the American Dietetic Association (now known as the Academy of Nutrition and Dietetics) stressed that WIC dietitians and nutritionists are health professionals trained and capable of doing a complete nutrition assessment, selecting WIC foods, and providing appropriate education to participants and caregivers, in consultation with the health care provider when warranted.

Based on the experiences cited by WIC State and local agencies related to medical documentation throughout implementation of the new food packages, FNS will no longer require a health care professional licensed to write medical prescriptions to provide documentation for children to receive soy-based beverage and tofu as milk substitutes. Also, FNS will no longer require documentation from a health care professional licensed to write medical prescriptions for women to receive tofu in excess of the maximum substitution allowance.

#### *Estimate of Burden*

This final rule amends the supplemental foods that require medical documentation as described in 7 CFR

246.10(d)(1) However, medical documentation continues to be required for issuance of supplemental foods in Food Package III. After revising to reflect the changes made by this final rule, the total annual reporting and recordkeeping burden estimated for medical documentation is decreased by 4,200 hours.

FNS estimates that approximately 1 percent of participants (89,606) will be issued supplemental foods under Food Package III. FNS estimates that it will take three minutes (0.05 hours) for the documentation required to issue the authorized foods, thus resulting in an estimated reporting burden for participants of 8,961 hours (89,606 total participants × 0.05 person hours × 2 certification periods per year). This results in a decrease in the approved reporting burden under OMB 0584-0043 for participants providing medical documentation for supplemental foods from 13,160 burden hours to 8,961 burden hours (a decrease of 4,200 burden hours).

FNS will submit an Information Collection Request clearance package to OMB based on the provisions of this final rule. These amended 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** announcing OMB approval.

*E-Government Act Compliance*

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

**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 7 CFR part 246 continues to read as follows:

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

■ 2. In § 246.2:

- a. Add a definition for “Farmers’ market” in alphabetical order;
- b. Add a definition for “Full nutrition benefit” in alphabetical order;
- c. Remove the definition heading “WIC-eligible medical foods” and add in its place “WIC-eligible nutritional conditions (hereafter referred to as “WIC-eligible nutritional”); and
- d. Remove the term “WIC-eligible medical foods” and add in its place the term “WIC-eligible nutritional” wherever it appears.

■ The revisions and additions read as follows:

**§ 246.2 Definitions.**

\* \* \* \* \*

*Farmers’ market* means an association of local farmers who assemble at a defined location for the purpose of selling their produce directly to consumers.

\* \* \* \* \*

*Full nutrition benefit* means the minimum amount of reconstituted fluid ounces of liquid concentrate infant formula as specified in Table 1 of § 246.10(e)(9) for each food package category and infant feeding variation (e.g., Food Package IA fully formula fed, IA-FF).

\* \* \* \* \*

- 3. In § 246.4:
  - a. Amend paragraph (a)(11)(iii) by removing “§ 246.10(b)(1)” and adding in its place “§ 246.10(b)(2)(i)”.
  - b. Revise paragraph (a)(14)(iii);
  - c. Redesignate paragraphs (a)(14)(v) through (xvii) as paragraphs (vi) through (xviii) and add a new paragraph (a)(14)(v);
  - d. Amend newly designated paragraph (a)(14)(vi) by removing “§ 246.12(k)(1)(i)” and adding in its place “§ 246.12(l)(1)(i)”;
  - e. Revise newly designated paragraph (a)(14)(xii); and
  - f. Amend paragraph (a)(18) by removing the words “and food vendors” and adding in their place the phrase “, food vendors, farmers and farmers’ markets”.

The revisions and additions read as follows:

**§ 246.4 State plan.**

- (a) \* \* \*
- (14) \* \* \*
- (iii) *A sample vendor, farmer and/or farmers’ market, if applicable, agreement.* The sample vendor agreement must include the sanction schedule, the process for notification of violations in accordance with § 246.12(l)(3), and the State agency’s policies and procedures on incentive items in accordance with

§ 246.12(g)(3)(iv), which may be incorporated as attachments or, if the sanction schedule, the process for notification of violations, or policies on incentive items are in the State agency’s regulations, through citations to the regulations. State agencies that intend to delegate signing of vendor, farmer and/or farmers’ market agreements to local agencies must describe the State agency supervision and instruction that will be provided to ensure the uniformity and quality of local agency activities;

\* \* \* \* \*

(v) *Farmer monitoring.* The system for monitoring farmers and/or farmers’ markets within its jurisdiction, if applicable, for compliance with program requirements;

\* \* \* \* \*

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

\* \* \* \* \*

- 4. In § 246.10:
  - a. Remove the term “WIC-eligible medical food” and add in its place the term “WIC-eligible nutritional” wherever it appears; and remove the term “WIC-eligible medical foods” and replace it with “WIC-eligible nutritional” wherever it appears;
  - b. Revise paragraph (b)(1)(i);
  - c. Amend paragraph (b)(2)(ii)(C) by removing the words “age and” before “nutritional” and adding the words “and breastfeeding” after “nutritional”;
  - d. Amend paragraph (d)(1)(ii) by removing the phrase “a child” and adding in its place the phrase “an infant, child,”;
  - e. Remove paragraphs (d)(1)(vi) through (d)(1)(viii);
  - f. Redesignate paragraph (d)(1)(ix) as (d)(1)(vi);
  - g. Revise the heading of paragraph (d)(2);
  - h. Amend paragraph (d)(2)(ii) by adding a space between “formula” and “and”;
  - i. Revise paragraph (d)(3)(i);
  - j. Revise paragraph (d)(4)(ii)(D);
  - k. Revise paragraphs (e) introductory text through (e)(1)(iii);
  - l. Revise paragraph (e)(1)(v);
  - m. Revise paragraph (e)(2)(ii);
  - n. Revise paragraph (e)(2)(iv);
  - o. Revise paragraph (e)(3)(v);

- p. Revise paragraphs (e)(4)(ii) through (e)(7)(ii); and
- q. Revise paragraphs (e)(9) through (e)(12).

The revisions and additions read as follows:

#### § 246.10 Supplemental foods.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section for the supplemental foods in their States, except that the State agency may not selectively choose which eligible fruits and vegetables are available to participants. These State agency criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal. For eligible fruits and vegetables, State agencies may restrict packaging, e.g., plastic containers, and package sizes, such as single serving, of processed fruits and vegetables available for purchase with the cash-value voucher. In addition, State agencies may identify certain processed WIC-eligible fruits and vegetables on food lists where the potential exists for vendor or participant confusion in determining authorized WIC-eligible items.

\* \* \* \* \*

(d) \* \* \*

(2) *Medical documentation for other supplemental foods.* \* \* \*

(3) \* \* \*

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

\* \* \* \* \*

(4) \* \* \*

(ii) \* \* \*

(D) The qualifying condition(s) for issuance of the authorized supplemental food(s) requiring medical documentation, as described in paragraphs (e)(1) through (e)(7) of this section; and

\* \* \* \* \*

(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 participants. Breastfeeding assessment and the mother's plans for breastfeeding serve as the basis for determining food package issuance for all breastfeeding

women. The intent of the WIC Program is that all breastfeeding women be supported to exclusively breastfeed their infants and to choose the fully breastfeeding food package without infant formula. Breastfeeding mothers whose infants receive formula from WIC are to be supported to breastfeed to the maximum extent possible with minimal supplementation with infant formula. Formula amounts issued to breastfed infants are to be tailored to meet but not exceed the infant's nutritional needs. The seven 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. The following infant feeding variations are defined for the purposes of assigning food quantities and types in Food Packages I: Fully breastfeeding (the infant doesn't receive formula from the WIC Program); partially (mostly) breastfeeding (the infant is breastfed but also receives infant formula from WIC up to the maximum allowance described for partially (mostly) breastfed infants in Table 1 of paragraph (e)(9) of this section; and fully formula fed (the infant is not breastfed or is breastfed minimally (the infant receives infant formula from WIC in quantities that exceed those allowed for partially (mostly) breastfed infants).

(ii) *Infant feeding age categories.*—(A) *Birth to one month.* Two infant food packages are available during the first month after birth—fully breastfeeding and fully formula-feeding. State agencies also have the option to make available a third food package containing not more than one can of powder infant formula in the container size that provides closest to 104 reconstituted fluid ounces to breastfed infants on a case-by-case basis. The infant receiving this food package is considered partially breastfeeding. State agencies choosing to make available a partially breastfeeding package in the first month may not standardize issuance of this food package. Infant formula may not be routinely provided during the first month after birth to breastfed infants in order to support the successful establishment of breastfeeding.

(B) *One through 5 months.* Three infant food packages are available from 1 months through 5 months—fully breastfeeding, partially (mostly) breastfeeding, or fully formula-fed.

(iii) *Infant formula requirements.* This food package provides iron-fortified infant formula that is not an exempt

infant formula and that meets the requirements in Table 4 of paragraph (e)(12) of this section. The issuance of any contract brand or noncontract brand infant formula that contains less than 10 milligrams of iron per liter (at least 1.5 milligrams iron per 100 kilocalories) at standard dilution is prohibited. Except as specified in paragraph (d) of this section, local agencies must issue as the first choice of issuance the primary contract infant formula, as defined in § 246.2, with all other infant formulas issued as an alternative to the primary contract infant formula. Noncontract brand infant formula and any contract brand infant formula that does not meet the requirements in Table 4 of paragraph (e)(12) of this section may be issued in this food package only with medical documentation of the qualifying condition. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that indicates the need for the infant formula. For situations that do not require the use of an exempt infant formula, such determinations include, but are not limited to, documented formula intolerance, food allergy or inappropriate growth pattern. Medical documentation must meet the requirements described in paragraph (d) of this section.

\* \* \* \* \*

(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 nutritionals are authorized only in Food Package III. The maximum monthly allowances, allowed options and substitution rates of supplemental foods for infants in Food Packages I are stated in Table 1 of paragraph (e)(9) of this section.

(2) \* \* \*

(ii) *Infant food packages.* Three food packages for infants 6 through 11 months are available — fully breastfeeding, partially (mostly) breastfeeding, or fully formula fed.

\* \* \* \* \*

(iv) *Authorized categories of supplemental foods.* Infant formula, infant cereal, and infant foods are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options and substitution rates of supplemental foods for infants in Food Packages II are stated in Table 1 of paragraph (e)(9) of this section.

\* \* \* \* \*

(3) \* \* \*

(v) *Authorized categories of supplemental foods.* The supplemental foods authorized in this food package require medical documentation for issuance and include WIC formula (infant formula, exempt infant formula, and WIC-eligible nutritionals), infant cereal, infant foods, milk, cheese, eggs, canned fish, fresh fruits and vegetables, breakfast cereal, whole wheat/whole grain bread, juice, legumes and/or peanut butter. The maximum monthly allowances, allowed options and substitution rates of supplemental foods for infants in Food Package III are stated in Table 1 of paragraph (e)(9) of this section. The maximum monthly allowances, allowed options, and substitution rates of supplemental foods for children and women in Food Package III are stated in Table 3 of paragraph (e)(11) of this section.

\* \* \* \* \*

(4) \* \* \*

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fresh fruits and vegetables, whole wheat/whole grain bread, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options and substitution rates of supplemental foods for children in Food Package IV are stated in Table 2 of paragraph (e)(10) of this section.

(5) *Food Package V—Pregnant and partially (mostly) 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 partially (mostly) breastfeeding women participants, up to 1 year postpartum, who do not have a condition qualifying

them to receive Food Package III and whose partially (mostly) 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 partially (mostly) breastfeeding more than one infant from the same pregnancy, pregnant women fully or partially breastfeeding singleton infants, and women participants pregnant with two or more fetuses, 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, fresh fruits and vegetables, whole wheat/whole grain bread, eggs, legumes and peanut butter are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options and substitution rates of supplemental foods for women in Food Package V are stated in Table 2 of paragraph (e)(10) 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 (mostly) breastfed infants as described in Table 1 of paragraph (e)(9) of this section, and who do not have a condition qualifying them to receive Food Package III.

(ii) *Authorized categories of supplemental foods.* Milk, breakfast cereal, juice, fresh fruits and vegetables, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed

options and substitution rates of supplemental foods for women in Food Package VI are stated in Table 2 of paragraph (e)(10) 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 exclusively breastfeeding their infants), and who do not have a condition qualifying them to receive Food Package III. This food package is also designed for issuance to women participants pregnant with two or more fetuses, women participants partially (mostly) breastfeeding multiple infants from the same pregnancy, and pregnant women who are also partially (mostly) breastfeeding singleton infants, and who do not have a condition qualifying them to receive Food Package III. Women participants fully breastfeeding multiple infants from the same pregnancy receive 1.5 times the supplemental foods provided in Food Package VII.

(ii) *Authorized categories of supplemental foods.* Milk, cheese, breakfast cereal, juice, fresh fruits and vegetables, whole wheat/whole grain bread, eggs, legumes, peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. The maximum monthly allowances, allowed options and substitution rates of supplemental foods for women in Food Package VII are stated in Table 2 of paragraph (e)(10) of this section.

\* \* \* \* \*

(9) Full nutrition benefit and 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—FULL NUTRITION BENEFIT (FNB) AND MAXIMUM MONTHLY ALLOWANCES (MMA) OF SUPPLEMENTAL FOODS FOR INFANTS IN FOOD PACKAGES I, II AND III

Foods <sup>1</sup>	Fully formula fed (FF)		Partially (mostly) 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>2,3</sup> B: 1 through 3 months C: 4 through 5 months	Food Packages II—BF/FF & III BF/FF 6 through 11 months	Food Package I—BF 0 through 5 months	Food Package II—BF 6 through 11 months
WIC Formula <sup>4,5,6,7,8</sup>	A: FNB=806 fl oz, MMA=823 fl oz, reconstituted liquid concentrate or 832 fl. oz. RTF or 870 fl oz reconstituted powder.	FNB=624 fl oz, MMA=630 fl oz, reconstituted liquid concentrate. or 643 fl. oz RTF or 696 fl oz reconstituted powder.	A: 104 fl oz reconstituted powder. B: FNB=364 fl oz, MMA=388 fl oz, reconstituted liquid concentrate or 384 fl oz RTF or 435 fl oz reconstituted powder.	FNB=312 fl oz, MMA=315 fl oz, reconstituted liquid concentrate or 338 fl oz RTF or 384 fl oz reconstituted powder.		

TABLE 1—FULL NUTRITION BENEFIT (FNB) AND MAXIMUM MONTHLY ALLOWANCES (MMA) OF SUPPLEMENTAL FOODS FOR INFANTS IN FOOD PACKAGES I, II AND III—Continued

Foods <sup>1</sup>	Fully formula fed (FF)		Partially (mostly) 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>2,3</sup> ) B: 1 through 3 months C: 4 through 5 months	Food Packages II–BF/FF & III BF/FF 6 through 11 months	Food Package I–BF 0 through 5 months	Food Package II–BF 6 through 11 months
	B: FNB=884 fl oz, MMA=896 fl oz, reconstituted liq- uid concentrate or 913 fl oz RTF or 960 fl oz reconsti- tuted powder.		C: FNB=442 fl oz, MMA=460 fl oz, reconstituted liq- uid concentrate or 474 fl oz RTF or 522 fl oz reconsti- tuted powder.			
Infant Cereal <sup>9 11</sup> .....	24 oz .....	24 oz .....	24 oz .....	24 oz .....	24 oz .....	24 oz.
Infant food fruits and vegetables <sup>9 10 11 12 13</sup>	128 oz .....	128 oz .....	128 oz .....	128 oz .....	128 oz .....	256 oz.
Infant food meat <sup>9</sup> ....						77.5 oz.

**Table 1 footnotes:** (Abbreviations in order of appearance in table): FF = fully formula fed; BF/FF = partially (mostly) breastfed; BF = fully breastfed; RTF = Ready-to-feed; 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. The competent professional authority (CPA) is authorized to determine nutritional risk and prescribe supplemental foods as established by State agency policy in Food Packages I and II. In Food Package III, the CPA, as established by State agency policy, is authorized to determine nutritional risk and prescribe supplemental foods per medical documentation.

<sup>2</sup> State agencies have the option to issue not more than one can of powder infant formula in the container size that provides closest to 104 reconstituted fluid ounces to breastfed infants on a case-by-case basis.

<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 nutritionals. Infant formula may be issued for infants in Food Packages I, II and III. Medical documentation is required for issuance of infant formula, exempt infant formula, WIC-eligible nutritionals, and other supplemental foods in Food Package III. Only infant formula may be issued for infants in Food Packages I and II.

<sup>5</sup> The full nutrition benefit is defined as the minimum amount of reconstituted fluid ounces of liquid concentrate infant formula as specified for each infant food package category and feeding variation (e.g., Food Package IA—fully formula fed).

<sup>6</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>7</sup> State agencies must provide at least the full nutrition benefit authorized to non-breastfed infants up to the maximum monthly allowance for the physical form of the product specified for each food package category. State agencies must issue whole containers that are all the same size of the same physical form. Infant formula amounts for breastfed infants, even those in the fully formula fed category should be individually tailored to the amounts that meet their nutritional needs.

<sup>8</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 nutrition benefit. State agencies must use the methodology described in accordance with paragraph (h)(1) of this section.

<sup>9</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>10</sup> At State agency option, for infants 6–12 months of age, 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. State agencies may also substitute fresh bananas at a rate of 1 banana per 4 ounces of jarred infant food fruit, up to a maximum of 16 ounces.

<sup>11</sup> In lieu of infant foods (cereal, fruit and vegetables), infants greater than 6 months of age in Food Package III may receive infant formula, exempt infant formula or WIC-eligible nutritionals at the same maximum monthly allowance as infants ages 4 through 5 months of age of the same feeding option.

<sup>12</sup> At State agency option, infants 9 months through 11 months in Food Packages II and III may receive a cash-value voucher to purchase fresh (only) fruits and vegetables in lieu of a portion of the infant food fruits and vegetables. Partially (mostly) breastfed infants and fully formula fed infants may receive a \$4 cash-value voucher plus 64 ounces of infant food fruits and vegetables; fully breastfeeding infants may receive a \$8 cash-value voucher plus 128 ounces of infant food fruit and vegetables.

<sup>13</sup> State agencies may not categorically issue cash-value vouchers for infants 9 months through 11 months. The cash-value voucher is to be provided to the participant only after an individual nutrition assessment, as established by State agency policy, and is optional for the participant, i.e., the mother may choose to receive either the maximum allowance of jarred foods or a combination of jarred foods and a fruit and vegetable cash-value voucher for her infant. State agencies must ensure that appropriate nutrition education is provided to the caregiver addressing safe food preparation, storage techniques, and feeding practices to make certain participants are meeting their nutritional needs in a safe and effective manner.

(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 (Mostly) 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 11</sup> .....	22 qt <sup>7 8 9 10 12</sup> .....	16 qt <sup>7 8 9 10 12</sup> .....	24 qt <sup>7 8 9 10 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.
Fresh fruits and vegetables <sup>14 15</sup>	\$8.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.
Whole wheat or whole grain bread <sup>16</sup> .	2 lb .....	1 lb .....	N/A .....	1 lb.
Fish (canned) .....	N/A .....	N/A .....	N/A .....	30 oz.
Legumes, dry <sup>17</sup> and/or Peanut butter.	1 lb or 18 oz .....	1 lb and 18 oz .....	1 lb or 18 oz .....	1 lb 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. The competent professional authority (CPA) is authorized to determine nutritional risk and prescribe supplemental foods as established by State agency policy.

<sup>2</sup> Food Package V is issued to two categories of WIC participants: Women participants with singleton pregnancies; breastfeeding women whose partially (mostly) breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances, 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 infants receive more than the maximum infant formula allowances, 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 four categories of WIC participants: Fully breastfeeding women whose infants do not receive formula from the WIC Program; women pregnant with two or more fetuses; women partially (mostly) breastfeeding multiple infants from the same pregnancy; and pregnant women who are also fully or partially (mostly) breastfeeding singleton infants.

<sup>5</sup> Women fully breastfeeding multiple infants from the same pregnancy 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 is the standard milk for issuance to 1-year-old children (12 through 23 months). At State agency option, fat-reduced milks may be issued to 1-year-old children for whom overweight or obesity is a concern. The need for fat-reduced milks for 1-year-old children must be based on an individual nutritional assessment and consultation with the child's health care provider if necessary, as established by State agency policy. Lowfat (1%) or nonfat milks are the standard milk for issuance to children ≥ 24 months of age and women. Reduced fat (2%) milk is authorized only for participants with certain conditions, including but not limited to, underweight and maternal weight loss during pregnancy. The need for reduced fat (2%) milk for children ≥ 24 months of age (Food Package IV) and women (Food Packages V–VII) must be based on an individual nutritional assessment as established by State agency policy.

<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.

<sup>9</sup> For children and women, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. For children and women in Food Packages IV–VI, no more than 1 pound of cheese may be substituted. For fully breastfeeding women in Food Package VII, no more than 2 pounds of cheese may be substituted for milk. State agencies do not have the option to issue additional amounts of cheese beyond these maximums even with medical documentation. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for children and women in Food Packages IV–VI. No more than a total of 6 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in Food Package VII.)

<sup>10</sup> For children and women, yogurt may be substituted for fluid milk at the rate of 1 quart of yogurt per 1 quart of milk; a maximum of 1 quart of milk can be substituted. Additional amounts of yogurt are not authorized. Whole yogurt is the standard yogurt for issuance to 1-year-old children (12 through 23 months). At State agency option, lowfat or nonfat yogurt may be issued to 1-year-old children for whom overweight and obesity is a concern. The need for lowfat or nonfat yogurt for 1-year-old children must be based on an individual nutritional assessment and consultation with the child's health care provider if necessary, as established by State agency policy. Lowfat or nonfat yogurts are the only types of yogurt authorized for children ≥ 24 months of age and women. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for children and women in Food Packages IV–VI. No more than a total of 6 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in Food Package VII.)

<sup>11</sup> For children, issuance of tofu and soy-based beverage as substitutes for milk must be based on an individual nutritional assessment and consultation with the participant's health care provider if necessary, as established by State agency policy. Such determination can be made for situations that include, but are not limited to, milk allergy, lactose intolerance, and vegan diets. Soy-based beverage may be substituted for milk for children on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk for children at the rate of 1 pound of tofu per 1 quart of milk. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for children in Food Package IV.) Additional amounts of tofu may be substituted, up to the maximum allowance for fluid milk for lactose intolerance or other reasons, as established by State agency policy.

<sup>12</sup> For women, soy-based beverage may be substituted for milk on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk at the rate of 1 pound of tofu per 1 quart of milk. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in Food Packages V and VI. No more than a total of 6 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in Food Package VII.) Additional amounts of tofu may be substituted, up to the maximum allowances for fluid milk, for lactose intolerance or other reasons, as established by State agency policy.

<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> Both fresh fruits and fresh vegetables must be authorized by State agencies. Processed fruits and vegetables, i.e., canned (shelf-stable), frozen, and/or dried fruits and vegetables may also be authorized to offer a wider variety and choice for participants. State agencies may choose to authorize one or more of the following processed fruits and vegetables: canned fruit, canned vegetables, frozen fruit, frozen vegetables, dried fruit, and/or dried vegetables. The cash-value voucher may be redeemed for any eligible fruit and vegetable (refer to Table 4 of paragraph (e)(12) of this section and its footnotes). Except as authorized in paragraph (b)(1)(i) of this section, State agencies may not selectively choose which fruits and vegetables are available to participants. For example, if a State agency chooses to offer dried fruits, it must authorize all WIC-eligible dried fruits.

<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> Whole wheat and/or whole grain bread must be authorized. State agencies have the option to also authorize brown rice, bulgur, oatmeal, whole-grain barley, whole wheat macaroni products, or soft corn or whole wheat tortillas on an equal weight basis.

<sup>17</sup> Canned legumes may be substituted for dry legumes at the rate of 64 oz. (e.g., four 16-oz cans) of canned beans for 1 pound dry beans. In Food Packages V and VII, both beans and peanut butter must be provided. However, when individually tailoring Food Packages V or VII for nutritional reasons (e.g., food allergy, underweight, participant preference), State agencies have the option to authorize the following substitutions: 1 pound dry and 64 oz. canned beans/peas (and no peanut butter); or 2 pounds 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 (MMA) OF SUPPLEMENTAL FOODS FOR CHILDREN AND WOMEN WITH QUALIFYING CONDITIONS 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>9,10,11,12,13</sup> .....	22 qt <sup>9,10,11,12,14</sup> .....	16 qt <sup>9,10,11,12,14</sup> .....	24 qt <sup>9,10,11,12,14</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.
Fruits and vegetables <sup>17,18,19</sup> .....	\$8.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.	\$10.00 in cash-value vouchers.
Whole wheat or whole grain bread <sup>20</sup> .	2 lb .....	1 lb .....	N/A .....	1 lb.
Fish (canned) .....	N/A .....	N/A .....	N/A .....	30 oz.
Legumes, dry <sup>21</sup> and/or Peanut butter.	1 lb .....	1 lb .....	1 lb .....	1 lb.
	Or .....	And .....	Or .....	And.
	18 oz .....	18 oz .....	18 oz .....	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. The competent professional authority (CPA), as established by State agency policy, is authorized to determine nutritional risk and prescribe supplemental foods per medical documentation.

<sup>2</sup> This food package is issued to two categories of WIC participants: Women participants with singleton pregnancies and breastfeeding women whose partially (mostly) breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

<sup>3</sup> This food package is issued to two categories of WIC participants: Non-breastfeeding postpartum women and breastfeeding postpartum women whose breastfed infants receive more than the maximum infant formula allowances as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.

<sup>4</sup> This food package is issued to four categories of WIC participants: Fully breastfeeding women whose infants do not receive formula from the WIC Program; women pregnant with two or more fetuses; women partially (mostly) breastfeeding multiple infants from the same pregnancy, and pregnant women who are also partially (mostly) breastfeeding singleton infants.

<sup>5</sup> Women fully breastfeeding multiple infants from the same pregnancy 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 nutritionals.

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

<sup>9</sup> Whole milk is the standard milk for issuance to 1-year-old children (12 through 23 months). Fat-reduced milks may be issued to 1-year old children as determined appropriate by the health care provider per medical documentation. Lowfat (1%) or nonfat milks are the standard milks for issuance for children ≥ 24 months of age and women. Whole milk or reduced fat (2%) milk may be substituted for lowfat (1%) or nonfat milk for children ≥ 24 months of age and women as determined appropriate by the health care provider per medical documentation.

<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.

<sup>11</sup> For children and women, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. For children and women in the pregnant, partially breastfeeding and postpartum food packages, no more than 1 pound of cheese may be substituted. For women in the fully breastfeeding food package, no more than 2 pounds of cheese may be substituted for milk. State agencies do not have the option to issue additional amounts of cheese beyond these maximums even with medical documentation. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for children and women in the pregnant, partially breastfeeding and postpartum food packages. No more than a total of 6 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in the fully breastfeeding food package.)

<sup>12</sup> For children and women, yogurt may be substituted for fluid milk at the rate of 1 quart of yogurt per 1 quart of milk; a maximum of 1 quart of milk can be substituted. Additional amounts of yogurt are not authorized. Whole yogurt is the standard yogurt for issuance to 1-year-old children (12 through 23 months). Lowfat or nonfat yogurt may be issued to 1-year-old children (12 months to 23 months) as determined appropriate by the health care provider per medical documentation. Lowfat or nonfat yogurts are the standard yogurt for issuance to children ≥ 24 months of age and women. Whole yogurt may be substituted for lowfat or nonfat yogurt for children ≥ 24 months of age and women as determined appropriate by the health care provider per medical documentation. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for children and women in the pregnant, partially breastfeeding and postpartum food packages. No more than a total of 6 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in the fully breastfeeding food package.)

<sup>13</sup> For children, soy-based beverage and tofu may be substituted for milk as determined appropriate by the health care provider per medical documentation. Soy-based beverage may be substituted for milk on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk for children at the rate of 1 pound of tofu per 1 quart of milk. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for children.) Additional amounts of tofu may be substituted, up to the maximum allowance for fluid milk for children, as determined appropriate by the health care provider per medical documentation.

<sup>14</sup> For women, soy-based beverage may be substituted for milk on a quart for quart basis up to the total maximum monthly allowance of milk. Tofu may be substituted for milk at the rate of 1 pound of tofu per 1 quart of milk. (No more than a total of 4 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in the pregnant, partially breastfeeding and postpartum food packages. No more than a total of 6 quarts of milk may be substituted for a combination of cheese, yogurt or tofu for women in the fully breastfeeding food package.) Additional amounts of tofu may be substituted, up to the maximum allowances for fluid milk, as determined appropriate by the health care provider per medical documentation.

<sup>15</sup> 32 dry ounces of infant cereal may be substituted for 36 ounces of breakfast cereal as determined appropriate by the health care provider per medical documentation.

<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> Both fresh fruits and fresh vegetables must be authorized by State agencies. Processed fruits and vegetables, i.e., canned (shelf-stable), frozen, and/or dried fruits and vegetables may also be authorized to offer a wider variety and choice for participants. State agencies may choose to authorize one or more of the following processed fruits and vegetables: canned fruit, canned vegetables, frozen fruit, frozen vegetables, dried fruit, and/or dried vegetables. The cash-value voucher may be redeemed for any eligible fruit and vegetable (refer to Table 4 of paragraph (e)(12) of this section and its footnotes). Except as authorized in paragraph (b)(1)(i) of this section, State agencies may not selectively choose which fruits and vegetables are available to participants. For example, if a State agency chooses to offer dried fruits, it must authorize all WIC-eligible dried fruits.

<sup>18</sup> Children and women whose special dietary needs require the use of pureed foods may receive commercial jarred infant food fruits and vegetables in lieu of the cash-value voucher. Children may receive 128 oz of commercial jarred infant food fruits and vegetables and women may receive 160 oz of commercial jarred infant food fruits and vegetables in lieu of the cash-value voucher. Infant food fruits and vegetables may be substituted for the cash-value voucher as determined appropriate by the health care provider per medical documentation.

<sup>19</sup> The monthly value of the fruit/vegetable cash-value vouchers will be adjusted annually for inflation as described in §246.16(j).

<sup>20</sup> Whole wheat and/or whole grain bread must be authorized. State agencies have the option to also authorize brown rice, bulgur, oatmeal, whole-grain barley, whole wheat macaroni products, or soft corn or whole wheat tortillas on an equal weight basis.

<sup>21</sup> Canned legumes may be substituted for dry legumes at the rate of 64 oz. (e.g., four 16-oz cans) of canned beans for 1 pound dry beans. In Food Packages V and VII, both beans and peanut butter must be provided. However, when individually tailoring Food Packages V or VII for nutritional reasons (e.g., food allergy, underweight, participant preference), State agencies have the option to authorize the following substitutions: 1 pound dry and 64 oz. canned beans/peas (and no peanut butter); or 2 pounds 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; (2) Be designed for enteral digestion via an oral or tube feeding; (3) Provide at least 10 mg iron per liter (at least 1.5 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.
Exempt infant formula ...	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.
WIC-eligible nutritionals. <sup>1</sup>	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 nutritionals 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.
MILK AND MILK ALTERNATIVES:	



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

Categories/foods	Minimum requirements and specifications
Cow's milk <sup>2</sup> .....	<p>Must conform to FDA standard of identity for whole, reduced fat, lowfat, or nonfat milks (21 CFR 131.110). Must be pasteurized. May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dry. Dry whole milk must conform to FDA standard of identity (21 CFR 131.147). Nonfat dry milk must conform to FDA standard of identity (21 CFR 131.127).</p> <p>Cultured milks must conform to FDA standard of identity for cultured milk, e.g. cultured buttermilk, kefir cultured milk, acidophilus cultured milk (21 CFR 131.112).</p> <p>Acidified milk must conform to FDA standard of identity for acidified milk, e.g., acidified kefir milk, acidified acidophilus milk or acidified buttermilk (21 CFR 131.111).</p> <p>All reduced fat, lowfat, and nonfat cow's milk types and varieties must 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).</p>
Goat's milk .....	<p>Must be pasteurized. May be flavored or unflavored. May be fluid, shelf-stable, evaporated or dry (i.e., powdered).</p> <p>All reduced fat, lowfat, and nonfat goat's milk must 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).</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 process American, or blends of any of these cheeses are authorized.</p> <p>Cheeses that are labeled low, free, reduced, less or light in sodium, fat or cholesterol are WIC eligible.</p>
Yogurt (cow's milk) .....	<p>Yogurt must be pasteurized and conform to FDA standard of identity for whole fat (21 CFR 131.200), lowfat (21 CFR 131.203), or nonfat (21 CFR 131.206); plain or flavored with ≤40 g of total sugars per 1 cup yogurt. Yogurts that are fortified with vitamin A and D and other nutrients may be allowed at the State agency's option. Yogurts sold with accompanying mix-in ingredients such as granola, candy pieces, honey, nuts and similar ingredients are not authorized. Drinkable yogurts are not authorized.</p>
Tofu .....	<p>Calcium-set tofu prepared with calcium salts (e.g., calcium sulfate). May not contain added fats, sugars, oils, or sodium. Tofu must be calcium-set, i.e., contain calcium salts, but may also contain other coagulants, i.e., magnesium chloride.</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. May be flavored or unflavored.</p>
JUICE .....	<p>Must be pasteurized 100% unsweetened fruit juice. Must contain at least 30 mg of vitamin C per 100 mL of juice. Must conform to FDA standard of identity as appropriate (21 CFR part 146) or vegetable juice must conform to FDA standard of identity as appropriate (21 CFR part 156). With the exception of 100% 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. Blends of authorized juices are allowed.</p> <p>Vegetable juice may be regular or lower in sodium.</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).</p> <p>Hard boiled eggs, where readily available for purchase in small quantities, may be provided for homeless participants.</p>
BREAKFAST CEREAL (READY-TO-EAT AND INSTANT AND REGULAR HOT CEREALS).	<p>Must contain a minimum of 28 mg iron per 100 g dry cereal.</p> <p>Must contain ≤21.2 g sucrose and other sugars per 100 g dry cereal (≤6 g per dry oz).</p> <p>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>3</sup></p>
FRUITS AND VEGETABLES (FRESH AND PROCESSED) <sup>4 5 6 8 9</sup> .	<p>Any variety of fresh (as defined by 21 CFR 101.95) whole or cut fruit without added sugars.</p> <p>Any variety of fresh (as defined by 21 CFR 101.95) whole or cut vegetable, except white potatoes, without added sugars, fats, or oils (orange yams and sweet potatoes are allowed).</p> <p>Any variety of canned fruits (must conform to FDA standard of identity as appropriate (21 CFR part 145)); including applesauce, juice pack or water pack without added sugars, fats, oils, or salt (i.e., sodium). The fruit must be listed as the first ingredient.</p> <p>Any variety of frozen fruits without added sugars, fats, oils, or salt (i.e., sodium).</p> <p>Any variety of canned or frozen vegetables, except white potatoes (orange yams and sweet potatoes are allowed); without added sugars, fats, or oils. Vegetable must be listed as the first ingredient. May be regular or lower in sodium. Must conform to FDA standard of identity as appropriate (21 CFR part 155).</p> <p>Any type of dried fruits or dried vegetable, except white potatoes (orange yams and sweet potatoes are allowed); without added sugars, fats, oils, or salt (i.e., sodium).</p> <p>Any type of immature beans, peas, or lentils, fresh or in canned<sup>5</sup> forms.</p> <p>Any type of frozen beans (immature or mature). Beans purchased with the CVV may contain added vegetables and fruits, but may not contain added sugars, fats, oils, or meat as purchased. Canned beans, peas, or lentils may be regular or lower in sodium content.</p> <p>State agencies must allow organic forms of WIC-eligible fruits and vegetables.</p>
WHOLE WHEAT BREAD, WHOLE GRAIN BREAD, AND WHOLE GRAIN OPTIONS: Bread .....	<p><i>Whole wheat bread</i> must conform to FDA standard of identity (21 CFR 136.180). (Includes whole wheat buns and rolls.) "Whole wheat flour" and/or "bromated whole wheat flour" must be the only flours listed in the ingredient list.</p>

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

Categories/foods	Minimum requirements and specifications
Whole Grain Options ....	OR Whole grain bread must conform to FDA standard of identity (21 CFR 136.110) (includes whole grain buns and rolls). AND Whole grain must be the primary ingredient by weight in all whole grain bread products. AND Must meet FDA labeling requirements for making a health claim as a “whole grain food with moderate fat content”. <sup>3</sup>
FISH (CANNED) <sup>5</sup> .....	Brown rice, bulgur, oats, 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. Soft corn tortillas made from ground masa flour (corn flour) using traditional processing methods are WIC-eligible, e.g., whole corn, corn (masa), whole ground corn, corn masa flour, masa harina, and white corn flour. For whole wheat tortillas, “whole wheat flour” must be the only flour listed in the ingredient list. Whole wheat macaroni products. Must conform to FDA standard of identity (21 CFR 139.138) and have no added sugars, fats, oils, or salt (i.e., sodium). “Whole wheat flour” and/or “whole durum wheat flour” must be the only flours listed in the ingredient list. Other shapes and sizes that otherwise meet the FDA standard of identity for whole wheat macaroni (pasta) products (139.138), and have no added sugars, fats, oils, or salt (i.e., sodium), are also authorized (e.g., whole wheat rotini, and whole wheat penne). Canned only: Light tuna (must conform to FDA standard of identity (21 CFR 161.190)); Salmon (Pacific salmon must conform to FDA standard of identity (21 CFR 161.170)); Sardines; and Mackerel (N. Atlantic <i>Scomber scombrus</i> ; Chub Pacific <i>Scomber japonicas</i> ; Jack Mackerel) <sup>10</sup> May be packed in water or oil. Pack may include bones or skin. Added sauces and flavorings, e.g., tomato sauce, mustard, lemon, are authorized at the State agency’s option. May be regular or lower in sodium content.
MATURE LEGUMES (DRY BEANS AND PEAS) <sup>7</sup> .	Any type of mature dry beans, peas, or lentils in dry-packaged or canned <sup>5</sup> forms. Examples include but are not limited to black beans, black-eyed peas, garbanzo beans (chickpeas), great northern beans, white beans (navy and pea beans), kidney beans, mature lima (“butter beans”), fava and mung beans, pinto beans, soybeans/edamame, split peas, lentils, and refried beans. All categories exclude soups. May not contain added sugars, fats, oils, vegetables, fruits or meat as purchased. Canned legumes may be regular or lower in sodium content. <sup>11</sup> Baked beans may only be provided for participants with limited cooking facilities. <sup>11</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 forms are allowed. Peanut butters with added marshmallows, honey, jelly, chocolate or similar ingredients are not authorized.
INFANT FOODS:	
Infant Cereal .....	Infant cereal must contain a minimum of 45 mg of iron per 100 g of dry cereal. <sup>12</sup>
Infant Fruits .....	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. The fruit must be listed as the first ingredient. <sup>13</sup>
Infant Vegetables .....	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. The vegetable must be listed as the first ingredient. <sup>14</sup>
Infant Meat .....	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>15</sup>

**Table 4 Footnotes:** FDA = Food and Drug Administration of the U.S. Department of Health and Human Services.

<sup>1</sup> The following are not considered a WIC-eligible nutritional: 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 conform to FDA standards of identity for milks as defined by 21 CFR part 131 and meet WIC’s requirements for vitamin fortification as specified in Table 4 of paragraph (e)(12) of this section. Additional authorized milks include, but are not limited to: calcium-fortified, lactose-reduced and lactose-free, organic 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> FDA Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm073634.htm>

<sup>4</sup> Processed refers to frozen, canned,<sup>5</sup> or dried.

<sup>5</sup> “Canned” refers to processed food items in cans or other shelf-stable containers, e.g., jars, pouches.

<sup>6</sup> The following are not authorized: herbs and spices; creamed vegetables or vegetables with added sauces; mixed vegetables containing noodles, nuts or sauce packets, vegetable-grain (pasta or rice) mixtures; fruit-nut mixtures; breaded vegetables; fruits and vegetables for purchase on salad bars; peanuts or other nuts; 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; decorative blossoms and flowers, and foods containing fruits such as blueberry muffins and other baked goods. Home-canned and home-preserved fruits and vegetables are not authorized.

<sup>7</sup> Mature legumes in dry-packed or canned forms may be purchased with the WIC food instrument only. Immature varieties of fresh or canned beans and frozen beans of any type (immature or mature) may be purchased with the cash-value voucher only. Juices are provided as separate food WIC categories and are not authorized under the fruit and vegetable category.

<sup>8</sup> Excludes white potatoes, mixed vegetables containing white potatoes, dried white potatoes; catsup or other condiments; pickled vegetables; olives; soups; juices; and fruit leathers and fruit roll-ups. Canned tomato sauce, tomato paste, salsa and spaghetti sauce without added sugar, fats, or oils are authorized.

<sup>9</sup> State agencies have the option to allow only lower sodium canned vegetables for purchase with the cash-value voucher.

<sup>10</sup> FDA defines jack mackerel as any of the following six species: *Trachurus declivis*, *trachurus japonicas*, *trachurus symmetricus*, *trachurus murphyi*, *trachurus novaezelandiae*, and *trachurus lathamii* in The Seafood List at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm113260.htm>. King mackerel is not authorized.

<sup>11</sup> The following are not authorized in the mature legume category: soups; immature varieties of legumes, such as those used in canned green peas, green beans, snap beans, yellow 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, oils, meats, fruits or vegetables.

<sup>12</sup> Infant cereals containing infant formula, milk, fruit, or other non-cereal ingredients are not allowed.

<sup>13</sup> Mixtures with cereal or infant food desserts (e.g., peach cobbler) are not authorized; however, combinations of single ingredients (e.g., apple-banana) and combinations of single ingredients of fruits and/or vegetables (e.g., apples and squash) are allowed.

<sup>14</sup> Combinations of single ingredients (e.g., peas and carrots) and combinations of single ingredients of fruits and/or vegetables (e.g., apples and squash) are allowed. Mixed vegetables with white potato as an ingredient (e.g., mixed vegetables) are authorized. Infant foods containing white potatoes as the primary ingredient are not authorized.

<sup>15</sup> No infant food combinations (e.g., meat and vegetables) or dinners (e.g., spaghetti and meatballs) are allowed.

■ 5. In § 246.12:

■ a. Remove the phrase “WIC-eligible medical foods” and add in its place “WIC-eligible nutritionals” wherever it appears;

■ b. Amend paragraph (a)(1) by removing the words “and farmers” after “vendors” in the second sentence and adding in their place the phrase “, farmers and farmers’ markets,”;

■ c. Amend paragraphs (f)(2)(ii) and (f)(2)(iv) by removing the word “voucher may” and adding in its place the words “voucher may” whenever it appears in these paragraphs;

■ d. Add a new paragraph (f)(4);

■ e. Amend paragraph (g)(3)(i) by removing the words “varieties of” in both places that it appears in the second sentence and adding in their place the word “different”;

■ f. Amend paragraph (h)(3)(i) by removing the word “voucher only” and adding in its place the words “vouchers only”;

■ g. Amend paragraph (h)(3)(vii) by adding the words “, or cash-value vouchers” after the word “instruments”;

■ h. Revise the heading and the first two sentences of paragraph (h)(3)(viii);

■ i. Amend paragraph (h)(3)(x) by removing the last sentence of the paragraph;

■ j. Redesignate paragraphs (h)(3)(xi) through (h)(3)(xxv) as paragraphs (h)(3)(xii) through (h)(3)(xxvi) and add a new paragraph (h)(3)(xi);

■ k. Amend paragraph (l)(1)(ii)(A) by adding the words “, or cash-value vouchers,” after the word “instruments”;

■ l. Revise paragraph (o);

■ m. Amend paragraphs (r)(3) and (t) by adding the phrase “, farmers’ markets,” after the word “farmer”;

■ n. Amend paragraph (u)(5) by adding the words “, farmers, farmers’ markets,” after the word “contractors”;

■ o. Revise the heading and introductory text of paragraph (v);

■ p. Amend paragraph (v)(1) by adding the words “or farmers’ market” after the word “farmer”;

■ q. Revise paragraph (v)(1)(iv);

■ r. Amend paragraphs (v)(2) through (v)(6) by adding the words “or farmers’ market” after the word “farmer” wherever it occurs;

■ s. Revise paragraph (v)(3);

■ t. Redesignate paragraphs (v)(4) through (v)(6) as paragraphs (v)(5) through (v)(7), and add a new paragraph (v)(4); and

■ u. Add a new paragraph (v)(8).

The revisions and additions read as follows:

**§ 246.12 Food delivery systems.**

\* \* \* \* \*

(f) \* \* \*

(4) *Split tender transactions.* The State agency must implement procedures that allow the participant, authorized representative or proxy to pay the difference when a fruit and vegetable purchase exceeds the value of the cash-value vouchers.

\* \* \* \* \*

(h) \* \* \*

(3) \* \* \*

(viii) *Food instrument and cash-value voucher redemption.* The vendor must submit food instruments and cash-value vouchers for redemption in accordance with the redemption procedures described in the vendor agreement. The vendor may redeem a food instrument or cash-value voucher only within the specified time period. \* \* \*

(xi) *Split tender for cash-value vouchers.* The vendor must allow the participant, authorized representative or proxy to pay the difference when a fruit and vegetable purchase exceeds the value of the cash-value vouchers (also known as a split tender transaction).

\* \* \* \* \*

(o) *Participant parent/caretaker, proxy, vendor, farmer, farmers’ market, 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, farmers’ markets, home food delivery contractors, and direct distribution contractors. Complaints of civil rights discrimination must be handled in accordance with § 246.8(b).

\* \* \* \* \*

(v) *Farmers and farmers’ markets.* The State agency may authorize farmers, farmers’ markets, and/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 and/or farmers’ markets. The agreement must be signed by a representative who has legal authority to obligate the farmer or farmers’ market and a representative of the State agency. The agreement must be for a period not to exceed 3 years. Only farmers or farmers’ markets authorized by the State agency may redeem the fruit and vegetable cash-value voucher. The State agency must require farmers or farmers’ markets to reapply at the expiration of their agreements and must provide farmers or farmers markets with not less than 15 days advance written notice of the expiration of the agreement.

\* \* \* \* \*

(1) \* \* \*

(iv) Redeem the cash-value voucher in accordance with a procedure established by the State agency. Such procedure must include a requirement for the farmer or farmers’ market to allow the participant, authorized representative or proxy to pay the difference when the purchase of fruits and vegetables exceeds the value of the cash-value vouchers (also known as a split tender transaction);

\* \* \* \* \*

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

(4) *Farmer agreements for State agencies that do not authorize farmers.* Those State agencies which authorize farmers’ markets but not individual farmers’ markets shall require authorized farmers’ markets to enter into a written agreement with each farmer within the market that is authorized to accept cash-value vouchers. The State agency shall set forth the required terms for the written agreement as defined in § 246.12(v)(1) and (v)(2), and provide a sample agreement for use by the farmers’ market.

\* \* \* \* \*

(8) *Monitoring farmers and farmers’ markets.*—(i) The State agency must design and implement a system for monitoring its authorized farmers and farmers’ markets for compliance with

program requirements. The State agency must document, at a minimum, the following information for all monitoring visits: name(s) of the farmer, farmers market, or roadside stand; name(s) and signature(s) of the reviewer(s); date of review; and nature of problem(s) detected.

(ii) *Compliance buys.* For compliance buys, the State agency must also document:

(A) The date of the buy;

(B) A description of the farmer (and farmers' market, as appropriate) involved in each transaction;

(C) The types and quantities of items purchased, current retail prices or prices charged other customers, and price charged for each item purchased, if available. Price information may be obtained prior to, during, or subsequent to the compliance buy; and

(D) The final disposition of all items as destroyed, donated, provided to other authorities, or kept as evidence.

■ 6. In § 246.16, revise paragraph (j)(2) to read as follows:

§ 246.16 Distribution of funds.

\* \* \* \* \*

(j) \* \* \*

(2) *Base value of the fruit and vegetable voucher.* The base year for calculation of the value of the fruit and vegetable voucher is fiscal year 2008. The base value to be used equals:

(i) \$8 for children; and

(ii) \$10 for women.

\* \* \* \* \*

■ 7. In § 246.18:

■ a. Revise paragraph (a)(4);

■ b. Amend paragraphs (b), (d), (e), and (f) by adding the phrase "or farmers' market" after the word "farmer" whenever it appears;

■ c. Revise the first sentence in paragraph (b)(9);

■ d. Amend paragraph (c) introductory text by adding the phrase ", farmer, or farmers' market" after the word "vendor" in the last sentence; and

■ e. Revise paragraph (c)(2);

The revisions and additions read as follows:

§ 246.18 Administrative review of State agency actions.

(a) \* \* \*

(4) *Farmer or farmers' market appeals.*—(i) *Adverse actions.* The State agency shall provide a hearing procedure whereby farmers or farmers' markets adversely affected by certain actions of the State agency may appeal those actions. A farmer or farmers' market 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 or farmers' markets.* 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. The State agency must make all other adverse actions effective no earlier than 15 days after the date of the notice of 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 an administrative review, no later than the date the farmer or farmers' market receives the review decision.

(b) \* \* \*

(9) Written notification of the review decision, including the basis for the decision, within 90 days from the date of receipt of the request for an administrative review from a vendor, farmer, or farmer's market, and within

60 days from the date of receipt of a local agency's request for an administrative review. \* \* \*

(c) \* \* \*

(2) A decision-maker who is someone other than the person who rendered the initial decision on the action and whose determination is based solely on whether the State agency has correctly applied Federal and State statutes, regulations, policies, and procedures governing the Program, according to the information provided to the vendor, farmer, or farmers' market concerning the cause(s) for the adverse action and the response from the vendor, farmer, or farmers' market.

\* \* \* \* \*

■ 8. In § 246.23:

■ a. Amend paragraph (a)(1) by removing the words "or food instruments" and by adding in its place the phrase "food instruments, or cash-value vouchers"; and

■ b. Revise paragraph (a)(2).

The revisions read as follows:

§ 246.23 Claims and penalties.

(a) \* \* \*

(2) If FNS determines that any part of the Program funds received by a State agency; or supplemental foods, either purchased or donated commodities; or food instruments or cash-value vouchers, were lost as a result of thefts, embezzlements, or unexplained causes, the State agency shall, on demand by FNS, pay to FNS a sum equal to the amount of the money or the value of the supplemental foods, food instruments, or cash-value vouchers so lost.

\* \* \* \* \*

Dated: February 20, 2014.

Janey Thornton,

Acting Under Secretary, Food, Nutrition, and Consumer Services.

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