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**DEPARTMENT OF AGRICULTURE**

**Food and Nutrition Service**

**7 CFR Part 246**

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:** Proposed Rule

**SUMMARY:** This proposed rule would revise regulations governing the WIC food packages to align the WIC food packages with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics, better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of food, provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences, and serve participants with certain qualifying conditions under one food package to facilitate efficient management of medically fragile participants. The revisions

largely reflect recommendations made by the Institute of Medicine of the National Academies in its Report “WIC Food Packages: Time for a Change,” with certain cost containment and administrative modifications found necessary by the Department to ensure cost neutrality. The proposed improvements to the WIC food packages can be made without increasing the projected costs. The proposed rule would revise the maximum monthly allowances and minimum requirements for certain supplemental foods; revise the substitution rates for certain supplemental foods and allow additional foods as alternatives; redesign WIC food packages to enhance breastfeeding promotion and support; revise age specifications for assignment to infant food packages; add fruits and vegetables for WIC participants 6 months of age and older and eliminate juice from infants food packages; add whole grains to food packages for children and women and infant food meat for fully breastfed infants 6 through 11 months of age; revise the purpose, content, and requirements for the Food Package for the Medically Fragile, and address general provisions that apply to all food packages.

**DATES:** To be assured of consideration, comments must be postmarked on or before (insert date 90 days after publication in the Federal Register).

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

- Mail: Send comments to Patricia N. Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302, (703) 305-2746.
- Web site: Go to <http://www.fns.usda.gov/wic>. Follow the online instructions for submitting comments through the link at the Supplemental Food Programs Division Web site.
- E-mail: Send comments to [WICHQ-SFPD@fns.usda.gov](mailto:WICHQ-SFPD@fns.usda.gov). Include “Docket ID Number 0584-AD77, WIC Food Packages Rule,” in the subject line of the message.
- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identities of the individuals or entities submitting the comments will be subject to public disclosure. All written submissions will be available for public inspection at the address above during regular business hours (8:30 a.m. to 5 p.m.) Monday through Friday. FNS may also make the comments publicly available by posting a copy of all comments on the FNS Web site at <http://www.fns.usda.gov/wic>.

A regulatory impact analysis has been prepared for this rule. It follows this regulation as an Appendix.

**FOR FURTHER INFORMATION CONTACT:** Debra Whitford, Chief,  
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305-2746, OR [Debbie.Whitford@fns.usda.gov](mailto:Debbie.Whitford@fns.usda.gov). A copy of the National  
Academies' Institute of Medicine report, "WIC Food Packages: Time for a  
Change," which provides the scientific backdrop for this proposed rule, is  
available on the FNS website at  
[http://www.fns.usda.gov/oane/menu/Published/WIC/FILES/Time4AChange\(main  
rpt\).pdf](http://www.fns.usda.gov/oane/menu/Published/WIC/FILES/Time4AChange(mainrpt).pdf).

**SUPPLEMENTARY INFORMATION:**

**I. Overview**

This proposed rule would implement the first comprehensive revisions to the WIC food packages since 1980. These revised food packages were developed to better reflect current nutrition science and dietary recommendations than do current food packages, within the parameters of current program costs. The proposal is based on the recommendations of the National Academies' Institute of Medicine (IOM), which was commissioned by FNS in September 2003, to independently review the WIC food packages. The IOM used current scientific information to assess

the nutrient adequacy of the diets of WIC participants; assess the supplemental nutrition needs of the population served by WIC; look at the nutrient contributions of the current packages; propose priority nutrients and general nutrition recommendations; and make recommendations for specific changes to the WIC food packages. The IOM used various data sources including the 2005 Dietary Guidelines for Americans, the Dietary Reference Intakes, WIC participant data, food consumption and intake data (Continuing Survey of Food Intakes by Individuals (CSFII); National Health and Nutrition Examination Survey (NHANES)) and examined nutrition-related health risks to identify nutrients and food groups to try to increase or decrease in the food packages with the goal of improving the nutrition of WIC participants. The review of the WIC food packages was further informed by extensive comments made in response to an Advanced Notice of Proposed Rulemaking on revisions to the WIC food packages and by comments received by the IOM in public forums during its review.

Compared to current WIC packages, the proposal:

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

Dietary Guidelines for Americans and WIC's role as a supplemental nutrition program.

- Supports improved nutrient intakes. The proposed additional foods and modified amounts of current foods support overall improvement in nutrient consumption and reduction in the prevalence of inadequate or excessive nutrient intakes. Compared with the current food packages, the revised packages are estimated to provide greater amounts of nearly all the nutrients of concern with regard to inadequate intake identified by the IOM such as iron, fiber, and vitamin E. The revised food packages for women and children also provide less saturated fat, cholesterol, total fat and sodium than the current packages.
- Provides greater consistency with established dietary recommendations for infants and children under 2, including encouragement and support for breastfeeding. The revised infant food packages improve overall nutrient density compared to current packages while keeping caloric content the same or slightly lower. The revised packages change age specification for assignment as well as establish three feeding categories to better address current dietary recommendations of the American Academy of Pediatrics (AAP) and promote breastfeeding. The packages for breastfeeding infant-mother pairs are revised to provide stronger incentives for continued breastfeeding, including providing less formula to partially breastfed infants

than current packages, and providing additional quantities/types of food for breastfeeding mothers. For older infants, the proposal delays the introduction of complementary foods, consistent with AAP, from four to six months of age and modifies formula amounts. Infant foods are added and juice eliminated in the packages for older infants in order to promote healthy dietary patterns.

- Addresses emerging public health nutrition-related issues. The prevalences of overweight and obesity in adults, adolescents, and children have increased dramatically, with direct implications for WIC participants. For example, childhood overweight has been linked to adverse health outcomes including elevated blood pressure, hyperinsulinemia, glucose intolerance, type 2 diabetes, dyslipidemia, and other early risks for chronic disease. The addition of fruits and vegetables and the emphasis on whole grains are consistent with recommendations for food patterns that may contribute to a health body weight. Compared to the current food packages, the revised food packages provide less saturated fat and cholesterol than the current packages for women and children. In addition, the revised food packages are designed to encourage breastfeeding and thus may contribute to a reduced risk of overweight in children.
- Reinforces the nutrition education messages provided to participants. The proposed food package more closely mirrors the 2005 Dietary Guidelines for

Americans and dietary recommendations for infants and children under two and is more consistent with the nutrition education provided to participants.

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

## **II. Background**

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



breastfeeding, non-breastfeeding postpartum women, infants and children up to five years of age who are at nutritional risk. In addition to WIC, the Department administers a variety of other complementary nutrition assistance programs that work together to provide a more complete diet to low-income persons. Low-income families can, and frequently do, receive benefits from more than one of these programs. The largest of these programs, the Food Stamp Program, provides general food assistance intended to increase the food buying power of low-income households.

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

Since the creation of the WIC Program in the 1970's, and the last major revision of the WIC food packages in the early 1980's, much has been learned about the nutritional needs of Americans, including WIC's target population of pregnant and postpartum women, infants, and preschool aged children. In recent years the ability of the WIC Program to address the supplemental nutritional needs of WIC

participants through its food packages and nutrition education has received growing attention. Significant interest in updating the food packages based on new information about the needs of low-income, culturally diverse women, infants, and children has been voiced by WIC Program administrators, the medical and scientific communities, advocacy groups, and Congress.

#### A. Advanced Notice of Proposed Rulemaking (ANPRM)

On September 15, 2003, FNS published an ANPRM at 68 FR 53903 seeking comments on revisions to the food packages offered through the WIC Program. FNS solicited public comments to determine if the WIC food packages should be revised to better improve the nutritional intake, health and development of participants and, if so, what specific changes should be made to the food packages. In response to this ANPRM, the Department received 195 letters. Respondents represented the general public, State and local WIC agencies, the National WIC Association (NWA), State WIC associations, industry, independent health professionals, vendors, WIC participants, and others. Comments received from NWA included two published position papers<sup>(1, 2)</sup> that provided recommendations based on that organization's analysis of the needs of WIC participants.

B. Review of the WIC Food Packages by the Institute of Medicine

In September 2003, FNS contracted with the National Academies' Institute of Medicine (IOM) to independently review the WIC Food Packages in a 22-month study. FNS charged the IOM with reviewing the nutritional needs of the WIC population, and recommending changes to the WIC food packages.

Recommendations were to be cost-neutral, efficient for nationwide distribution and vendor checkout, non-burdensome to administration, and culturally suitable. FNS asked IOM to consider the supplemental nature of the WIC Program, burdens/incentives for eligible families, the role of WIC food packages in reinforcing nutrition education, breastfeeding, and chronic disease prevention, and public comments received from FNS' ANPRM.

Under this contract, IOM selected a Committee of experts in nutrition, health, risk assessment and economics to conduct this study in two phases. During Phase I, the committee developed the following criteria to guide its work. It also used various data sources to identify nutrients and food groups to try to increase or decrease in the food packages (i.e., priority nutrients and priority food groups), with the goal of improving the nutrition of WIC participants.

<b>Criteria for a WIC Food Package</b>
<p>FROM: "WIC Food Packages; Time For A Change." The Institute of Medicine of the National Academies, The National Academies Press, 2005, page 37</p> <ol style="list-style-type: none"><li>1. The package reduces the prevalences of inadequate and excessive nutrient intakes in participants.</li><li>2. The package contributes to an overall dietary pattern that is consistent with the Dietary Guidelines for Americans, for individuals two years of age and older.</li><li>3. The package contributes to an overall diet that is consistent with established dietary recommendations for infants and children less than two years of age, including encouragement of and support for</li></ol>

breastfeeding.

4. Foods in the package are available in forms suitable for low-income persons who may have limited transportation, storage, and cooking facilities.
5. Foods in the package are readily acceptable, widely available, and commonly consumed; take into account cultural food preferences; and provide incentives for families to participate in the WIC program.
6. Foods will be proposed giving consideration to the impacts that changes in the package will have on vendors and WIC agencies.

In Phase II, the Committee used these criteria and its review of the nutritional needs of WIC participants to develop recommendations for changing the WIC food packages. The IOM published these recommendations in a report, “WIC Food Packages: Time for a Change” (IOM Report), which was released on April 27, 2005)<sup>(3)</sup>.

### C. Cost Neutrality

Since the WIC Program receives a finite amount of funding annually to serve as many participants as this funding allows, it is important that revisions to the WIC food packages be cost neutral to protect the program’s ability to serve the greatest number of eligible women, infants, and children.

The IOM conducted a cost analysis as part of its review and believes that its recommendations to revise the WIC food packages were relatively cost-neutral, given data available to the IOM at that time. However, based on updated data, the Department now estimates that implementing the IOM’s recommendations in full

would cost \$1.3 billion above the cost-neutral level over 5 years. Therefore, the Department has modified two of the IOM's recommendations to achieve a cost neutral proposal consistent with statutory requirements. The Department carefully considered which of the IOM recommendations to modify to achieve cost neutrality, basing the decision on 3 criteria--relative cost, nutritional impact, and overall context of the IOM recommendations. To achieve cost neutrality, the Department is proposing a cash-value fruit and vegetable voucher that is \$2 less per month than that recommended by the IOM, and is not proposing yogurt as an authorized alternative to milk.

The price of yogurt as compared to the price of milk would considerably increase the monthly cost of the food packages for children and women. Soy beverage and tofu also have higher per unit costs than milk; however, the estimated amount of tofu that would be purchased by WIC participants is substantially lower than that of yogurt. Soy beverage can serve as an alternative for all or part of the fluid milk for adult women, making it a more cost-effective substitute. For fruits and vegetables, the IOM's intent was to move WIC participants towards some amount of increased fruit and vegetable consumption and, at the same time, reinforce the role of the WIC food packages in nutrition education. The proposed \$2 reduction in the cash-value fruit and vegetable voucher fulfills this intent while ensuring cost neutrality.

The Department believes that this proposed rule largely sets forth the scope of the IOM recommendations notwithstanding these necessary modifications.

Commenters are encouraged to suggest alternative ways to achieve cost neutrality within the context of the overall IOM recommendations. State agencies will be responsible for determining how to fully implement the proposed provisions within their grants. Options available to State agencies include applying judicious use of currently authorized caseload management procedures, including the participant priority system in accordance with § 246.7(e)(4) of WIC regulations, or by implementing other cost containment measures. State agencies are also reminded that § 246.16a(g) authorizes State agencies to implement a cost containment system for any WIC food other than infant formula.

#### D. Stakeholder Comments

The comments FNS received from its ANPRM represented a wide range of perspectives. A majority of those who commented expressed general support for foods currently offered, but also proposed at least one change. Nearly three-fourths of those responding to FNS stated that fruits and vegetables should be added to the packages. Other comments addressed topics including priority nutrients, design and structure of the food package, amount of juice, amount of milk, choices of milk products, alternative sources of calcium, cereal and grain choices, physical forms of legumes (i.e., dried or canned beans or peas), peanut butter, eggs, tuna, alternative sources of protein, infant formula, medical foods regulations, cost, incentives to breastfeed, flexibility at the State agency level, and

more variety and choice at the participant level. Comments may be viewed at <http://www.fns.usda.gov/wic/lawsandregulations/revfoodpkg-anprm.htm#publiccomments>. Similar themes were addressed in over 70 written and 30 oral public comments submitted directly to the IOM committee during its 22-month review of the WIC food packages.

#### E. Legislative Requirements

Sections 17(a) and (b)(14) of the Child Nutrition Act of 1966, as amended, (CNA) (42 U.S.C. 1786(a) and (b)(14)) clearly established the WIC Program as "supplemental" in nature; that is, the WIC supplemental foods are not intended to provide a complete diet but are designed to provide nutrients determined by nutritional research to be lacking in the diets of the WIC population. The law also directs the Secretary in Section 17(f)(11) of the CNA (42 U.S.C. 1786(f)(11)) to assure that, to the degree possible, the fat, sugar, and salt content of supplemental foods is appropriate. Section 203(a)(2) of Public Law 108-265 amended Section 17(b)(14) of the CNA by revising the definition of supplemental foods to include foods that promote health as indicated by relevant nutrition science, public health concerns, and cultural eating patterns.

Early legislation for the WIC Program, Public Law 92-433 (1972) through Public Law 94-105 (1975), specifically identified protein, iron, calcium and vitamins A and C as nutrients of particular concern for WIC participants. Public Law 95-627,

enacted in November 1976, deleted reference to specific nutrients; however, the Department retained high-quality protein, iron, calcium, and vitamins A and C as the targeted nutrients in the WIC Program.

#### F. Current WIC Food Packages

WIC food package requirements appear in § 246.10 of the WIC Program regulations. The last major revision of the WIC Food Packages was in 1980 (45 FR 74854, November 12, 1980). The 1980 rule established six different monthly packages — Food Package I for infants 0-3 months; Food Package II for infants 4-12 months; Food Package III for children and women with special dietary needs; Food Package IV for children 1-5 years of age; Food Package V for pregnant and breastfeeding women; and Food Package VI for nonbreastfeeding postpartum women. The Department created an additional food package in 1992 (57 FR 56231, November 27, 1992). This enhanced food package, Food Package VII, was designed for breastfeeding women who elect not to receive infant formula through WIC for their infants.

Current WIC supplemental foods include iron-fortified infant formula, iron-fortified cereals, vitamin C-rich 100 percent fruit and/or vegetable juice, calcium/protein-rich milk and cheese, protein/iron-rich eggs, protein-rich peanut butter or dried beans/peas, and physician-prescribed formula/medical foods for participants with certain special dietary needs. The enhanced package for



breastfeeding women increases allowable amounts of juice, cheese, peanut butter and dry beans/peas, and also allows protein-rich tuna fish and carrots that provide beta-carotene (precursor to vitamin A) and dietary fiber.

#### G. New Nutrient Recommendations

Over the past decade, knowledge of nutrient requirements has increased substantially, resulting in a set of new dietary reference values called the Dietary Reference Intakes (DRIs).<sup>(4-9)</sup> The DRIs replace the 1989 Recommended Dietary Allowances (RDAs) as nutrient reference values for the United States population. Based on the DRIs, many of the recommendations for nutrient intakes for individuals (RDAs) have changed substantially since the WIC food packages were originally formulated. Although basic concepts of nutrition have not changed, there has been a substantial increase in knowledge of specific concepts such as bioavailability, nutrient-nutrient interactions, and the distribution of dietary intake of nutrients across subgroups of the population. In addition to recommended intakes, the DRIs include appropriate standards to use in determining whether diets are nutritionally adequate without being excessive. The DRIs encompass more aspects of nutrition than did the earlier RDAs, as follows:

- DRIs consider reduction in the risk of chronic disease, as well as the absence of signs of deficiency.
- For most nutrients, DRIs include both RDA and Estimated Average Requirement (EAR) values.

- For some nutrients, insufficient data were available to set EAR and RDA values. For these nutrients, Adequate Intake (AI) values were estimated.
- DRIs include Tolerable Upper Intake Levels (ULs), which are used in the evaluation of the risk of adverse effects from excess consumption.
- DRIs specify appropriate ranges of macronutrient densities, which are called Acceptable Macronutrient Distribution Ranges (AMDRs).
- When adequate data are available, DRIs provide reference values for food components other than nutrients.

Assessing nutrient adequacy involves determining the extent to which the diets of WIC-income-eligible subgroups meet nutrient requirements without being excessive. In its Report, the IOM conducted analyses applying the DRIs and the recommended methods to assess the nutrient adequacy of the diets of WIC participants.

### **III. Priority Nutrients, Nutrition-Related Health Priorities, and Priority Food Groups Cited by the IOM Report <sup>(3)</sup>**

The IOM Report cites fundamental changes that have occurred in the major health and nutrition risks faced by WIC's target population. The prevalences of

underweight and iron-deficiency anemia have decreased. Diets have improved in many respects, and nutrients for which intakes often appeared to be low in the 1970s (calcium and vitamins A and C) are less problematic, particularly for children. Despite improved access to health care and health services, the prevalences of overweight and obesity in adults, adolescents, and children have increased dramatically, regardless of WIC participation. In addition, marked demographic changes have occurred, with both a dramatic increase in the number of persons served by WIC and a substantial shift in the ethnic composition of the WIC population. Hispanics now make up the largest share of WIC participants. <sup>(10)</sup>

#### A. Priority Nutrients

IOM designated a nutrient as a priority nutrient if the prevalence of dietary inadequacy was non-trivial, or the mean intake is below the AI, or there is a recognized nutrition-related health priority (e.g., observable levels of iron deficiency anemia). The methodology used to identify nutrients at high risk of inadequacy is described by the IOM in “Dietary Reference Intakes: Applications

in Dietary Assessment.”<sup>(1)</sup> Based on detailed analyses<sup>1</sup>, the IOM Report cites the following nutrients as high priority for WIC participants.

- WIC infants under one year of age, non-breastfed: No nutrients were identified with a high risk of inadequacy. Priority nutrients related to risk of excessive intakes in non-breastfed infants are zinc, preformed vitamin A, and food energy (calories).
- Breastfed infants 6 through 11 months: Priority nutrients identified as lacking in the diets of breastfed infants six months and older are iron and zinc.
- WIC children 1 through 4 years of age: Priority nutrients identified as lacking in the diets of young children are vitamin E, fiber, and potassium, and iron. Nutrients that may be excessive in the diets of young children are zinc, preformed vitamin A, sodium, food energy (calories), and saturated fat.

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<sup>1</sup> The IOM analyzed nutrient intake using nationally representative data for WIC children and for non-breastfed WIC infants. However, the IOM found that for breastfed infants 6 through 11 months of age, and for the women’s groups, the nationally representative data did not provide adequate sample size of WIC participants for meaningful analysis. Consequently, the IOM used data for all infants 6 through 11 months and for all pregnant and lactating women. For non-breastfeeding postpartum women categorically eligible for WIC (up to six months postpartum), the IOM used data for all women within one year postpartum. The Department would have preferred to have adequate sample size to limit all of these analyses to the WIC actual groups, so that the recommendations could be completely tailored to the WIC population. Prior research using data from the Continuing Survey of Food Intakes by Individuals indicates that there are statistically significant differences in dietary intake between low income and higher income adults. For example, when controlling for a wide variety of independent factors, those adults with incomes below 130 percent of poverty have statistically lower usual mean intakes for food energy and almost all vitamins and minerals, and were less likely to meet either 70 percent or 100 percent of the RDA. (See Gleason P., A. Rangarajan and C. Olson. “Dietary Intake and Dietary Attitudes Among Food Stamp Participants and Other Low-Income Individuals,” United States Department of Agriculture, Food and Nutrition Service, Office of Analysis, Nutrition and Evaluation FSP-00-DI, Project Officer Sharron Cristofar, Alexandria, Virginia 2002.) However, the pattern of which nutrients more frequently have low intakes is very similar for the high- and low-income groups. For example, among the nine vitamins and five minerals studied, both the list and order of the six nutrients with the smallest portion of the population consuming 70% of the RDA is the same for the low- and high-income groups. Estimates based on too small a sample have an unacceptably high risk of inaccurately representing the true population mean and distribution. Therefore, for the purpose of comparing nutrient adequacy and excesses among a group of nutrients when the WIC sample is limited, use of the all-income sample is the best available alternative.

- Pregnant, lactating, and non-breastfeeding postpartum women: Priority nutrients identified as lacking are calcium, iron, magnesium, vitamin E, potassium, and fiber. Nutrients with moderate, but still high, levels of inadequacy are vitamins A, C, and B<sub>6</sub>, and folate. Nutrients with lower levels of inadequacy are iron, zinc, thiamin, niacin, and protein. Sodium intakes and saturated fat intakes as a percentage of food energy intakes are excessive in the diets of pregnant, lactating, and non-breastfeeding postpartum women.

## B. Nutrition-Related Health Priorities

In addition to analyses of nutrient adequacy, the IOM reviewed epidemiological evidence on body weight status, micronutrients of special concern during reproduction and early childhood, food allergies, and selected environmental risks to the health of women, infants, and children. Several concerns were identified by the IOM for all WIC subgroups—obesity, poor iron status, and contamination of food with dioxin and methylmercury. The IOM also determined that low folate intake is a concern for all women during their reproductive years because of its importance in preventing neural tube defects; insufficient calcium intake for pregnant and breastfeeding women may be associated with potential lead toxicity for the fetus and infant; low intake of vitamin D is a potential concern for women of reproductive age because of its importance in bone health; and inadequate zinc intake is a concern for breastfed infants 6 through 11 months of age because human milk does not provide recommended amounts of zinc for older infants.

### C. Priority Food Groups

To determine whether specific foods or types of food should receive priority in the re-design of WIC food packages, the IOM reviewed information about dietary guidance, amounts of foods consumed by groups that potentially are eligible for the WIC Program, and the amounts of foods in current WIC food packages. The IOM's assessment gave major consideration to the Dietary Guidelines for Americans (DGA), which form the basis of Federal food and nutrition programs (Public Law 101-445, U.S. Congress, 1990). To do this, the IOM used the DGA 2005 <sup>(12)</sup> as the source of dietary guidance for children ages two years and older and widely accepted dietary guidance from professional groups, such as the American Academy of Pediatrics, for children under two years of age. The IOM Report cites the following concerns:

1. Children ages 2 through 4 years and women in the childbearing years:
  - Overall: Intakes of whole grains, vegetable subgroups excluding potatoes and other starchy vegetables, fruits, milk and milk products, and meats are all lower than recommended on average;
  - Children ages 2 through 4: Intakes tend to be low in whole grains and in dark green leafy vegetables, deep yellow vegetables, cooked dry beans and peas rather than vegetables in general; and
  - Women: Intakes tend to be low in whole grains, dark green leafy vegetables, deep yellow vegetables, cooked dry beans and peas, and fruit and milk groups.

2. Infants and children younger than 2 years of age:

Dietary practices of most concern to the IOM include the short duration of breastfeeding, excessive consumption of fruit juice, early introduction of solid food and cow's milk, low consumption of fruits (other than juice) and vegetables, and infrequent exposure to new foods.

Exhibit A in this preamble, from the IOM Report <sup>(3)</sup>, summarizes nutrient and food group priorities that form the basis for the proposed revisions of the WIC food packages.

## Exhibit A Nutrient and Food Group Priorities for Proposed Revised WIC Food Packages

FROM "WIC Food Packages; Time For A Change." The Institute of Medicine of the National Academies, The National Academies Press, 2005, page 72.

Participant Category	Nutrients of Concern with Regard to Inadequate Intake	Priority Food Groups	Nutrients of Concern with Regard to Excessive Intake	Nutrients and Ingredients to Limit in the Diet
Infants, less than 1 y, non-breastfed	No need identified to increase particular nutrients; maintain iron intakes and continue to provide a balanced set of essential nutrients <sup>a</sup>	na	Decrease intakes of Zinc, Vitamin A, preformed, <sup>b</sup> and Food energy	
Infants, 6-11.9 mo, breastfed	Increase intakes of Iron and Zinc	na		
Children, 12-23.9 mo	Increase intakes of Iron, Potassium, Vitamin E, and Fiber	Increase intakes of a <i>variety of non-starchy vegetables</i> .	Decrease intakes of Zinc, Vitamin A, preformed, <sup>b</sup> and Food energy	
Children, 2-4.9 y	Increase intakes of Iron, Potassium, Vitamin E, and Fiber	Increase intakes of <i>whole grains</i> , and a <i>variety of non-starchy vegetables</i> .	Decrease intakes of Zinc, Sodium, Vitamin A, preformed, <sup>b</sup> and Food energy	Limit intakes of Saturated fat, Cholesterol, and Added sugars



## Exhibit A Nutrient and Food Group Priorities for Proposed Revised WIC Food Packages (continued)

FROM "WIC Food Packages; Time For A Change." The Institute of Medicine of the National Academies, The National Academies Press, 2005, page 72.

Participant Category	Nutrients of Concern with Regard to Inadequate Intake	Priority Food Groups	Nutrients of Concern with Regard to Excessive Intake	Nutrients and Ingredients to Limit in the Diet
Adolescent and adult women of reproductive age	<p>Give highest priority to increasing intakes of Calcium, Iron, Magnesium, Potassium, Vitamin E, and Fiber</p> <p><i>Also try to increase intakes of</i></p> <p>Vitamin A, Vitamin C, Vitamin D, Vitamin B<sub>6</sub>, and Folate</p>	Increase intakes of whole grains, a variety of non-starchy vegetables, fruit, and fat-reduced milk products.	Decrease intakes of Sodium, Food energy, and Total fat	

NOTE na = not applicable; UL = Tolerable Upper Intake Level.

<sup>a</sup>Iron intakes are apparently adequate for non-breastfed infants, probably due in part to provision of iron-fortified formula in the current WIC food packages.

<sup>b</sup>The UL applies only to preformed vitamin A (i.e., retinol) ingested from the combined sources of animal-derived foods, fortified foods, and dietary supplements. <sup>(13)</sup>

<sup>c</sup>*Trans* fatty acids have not specifically been identified as a hazard for infants and children, and thus are shown in the table as nutrients to limit only in the diets of adolescents and adults. <sup>(8)</sup> However, the dietary guidance to limit *trans* fatty acids from processed foods in the diet is presumed to apply to all individuals regardless of age.

## D. Identifying Foods to Reduce or Eliminate

Exhibit B in this preamble reflects the IOM’s recommendations and rationale regarding foods in the current WIC food packages to be deleted or reduced in the proposed revised food packages.

<b>Exhibit B Foods in the Current WIC Food Packages to be Deleted or Reduced in the Proposed Food Packages</b>		
FROM “WIC Food Packages; Time For A Change.” The Institute of Medicine of the National Academies, The National Academies Press, 2005, page 82.		
Food	Change	Rationale
Infant formula	Reduce maximum amounts for partially breastfed infants	The maximum amount provides approximately half the amount provided to fully formula fed infants to encourage the mother to breastfeed enough to provide at least half of the infant’s nutritional needs and to make possible other improvements in the WIC food packages.
Infant formula	Reduce maximum amounts for fully formula fed infants ages 6–11.9 mo of age	Since the food package for infants of this age provides greater amounts of nutrients through complementary foods, less formula is needed.
Juice	Delete juice for infants 4-11.9 mo of age; reduce amount of juice for children 1-4.9 y of age.	Meet AAP recommendations to delay introduction of juice for infants until after 6 mo of age; allow no more than 4-6 fl oz/day for infants above the age of 6 mo. <sup>(14)</sup> For infants age 6-11.9 mo, fruit juice has no nutritional benefit over whole fruit. <sup>(15)</sup>
Milk	Decrease maximum amounts allowed for children and adults	Amounts provided need not exceed amounts recommended by DGA 2005. <sup>(12)</sup>
Cheese	Reduce maximum amount allowed in women’s and children’s packages.	Meets recommendation from DGA 2005 <sup>(12)</sup> and recommendation from the IOM to reduce saturated fat and cholesterol intake. <sup>(8)</sup>
Eggs	Reduce maximum amount allowed	Protein is no longer a priority nutrient. Reduction in amount provided is consistent with DGA 2005 <sup>(12)</sup> and with recommendation from the IOM to reduce cholesterol intake. <sup>(8)</sup>
NOTE AAP = American Academy of Pediatrics; IOM = Institute of Medicine.		

The full context of IOM's recommendations, including analyses, can be found in its report "WIC Food Packages: Time for a Change" <sup>(3)</sup> available at <http://www.fns.usda.gov/oane/menu/Published/WIC/WIC.htm>.

#### E. The IOM's Recommendations in the Context of this Proposed Rule

The IOM Report considered current recommendations for nutrient intakes and dietary patterns, the major diet-related health problems and risks faced by WIC's target population, the characteristics of the WIC Program, and the diversity of its participants. IOM's recommendations are intended to make the WIC food packages better meet the supplemental nutrition needs of participants and be more consistent with national and professional dietary guidance and more consistent with nutrition education messages that promote healthful diets for the WIC population.

The IOM Report has provided FNS with a sound scientific basis for proposing a new set of food packages for the WIC Program. Except for certain cost containment and administrative modifications found necessary by the Department to ensure cost neutrality, FNS is largely setting forth IOM's recommendations in this proposed rule for public comment. However, FNS is aware that these proposed revisions represent substantial changes for the WIC Program, its participants, and authorized vendors. Implementation procedures, staff and vendor training, and the nature of the nutrition education provided are likely to

influence the effectiveness of the proposed revised food packages. Commenters are encouraged to provide input that would assist FNS in assessing the training and technical assistance needs of WIC State agencies and WIC-authorized vendors in implementing these proposed changes.

#### **IV. Re-design of WIC Food Packages to Enhance Breastfeeding Promotion and Support**

##### **A. Current Breastfeeding Promotion and Support in WIC**

WIC has historically promoted breastfeeding to all pregnant women as the optimal infant feeding choice, unless medically contraindicated. Current federal WIC regulations (§§ 246.7(e)(1)(iii), 246.7(g)(1)(iii), 246.10(c)(7), and 246.11(c)) contain provisions to encourage women to breastfeed and to provide appropriate nutritional support for breastfeeding participants, including:

- Information provided to WIC mothers choosing to breastfeed through counseling and breastfeeding educational materials;
- Follow-up support through peer counselors;
- Eligibility to participate in WIC longer than non-breastfeeding mothers;
- Enhanced food package for mothers who exclusively breastfeed their infants; and

- Breast pumps, breast shells or supplemental nursing systems to help support the initiation and continuation of breastfeeding.

In part as a result of strengthened WIC breastfeeding policy and program activities in the early 1990's, WIC breastfeeding rates have increased at a faster rate than in the non-WIC population in the United States in the last decade. Despite these gains, WIC participants lag behind the general population in progress toward meeting the breastfeeding objectives of Healthy People 2010. <sup>(16)</sup>

#### B. The IOM's Recommendations to Promote and Support Breastfeeding Via the WIC Food Packages

As described in the IOM Report, the proposed revised food packages for infants and women are designed to strengthen WIC's breastfeeding promotion efforts and provide additional incentives to assist mothers in making the decision to initiate and continue to breastfeed. Breastfeeding is the preferred method of infant feeding because of the nutritional value and health benefits of human milk. <sup>(15, 16, 17)</sup>

The IOM's three-pronged approach to better promote and support breastfeeding through the WIC food packages is proposed. The proposed approach focuses on the market value of the package for the mother/infant pair for the first year after birth, addresses differences in supplementary nutrition needs of breastfed and

formula fed infants, and considers how to minimize early supplementation with infant formula through continued or increased efforts to promote and support the breastfeeding dyad.

Proposed changes to help support breastfeeding address packages for the infant as well as the mother since both are eligible to receive a WIC food package.

According to the IOM, the perceived dollar value, from the mother's point of view, of the current food packages provided for formula-feeding infant-mother pairs is substantially larger than that of the packages for the fully breastfeeding pairs, especially during the first six months postpartum. The IOM believes that attractive packages for fully breastfeeding mother/infant pairs might act as an incentive for breastfeeding. The proposed revised food packages increase the value of the contents of the food packages for the fully breastfeeding mother/infant pairs while decreasing the relative value to mothers of the food packages for partially breastfeeding pairs and fully formula-feeding pairs.

As described by the IOM, the differences in the proposed packages for the mother-infant pairs are based on differences in nutritional needs. For example, fully breastfeeding women require additional calories per day during the first six months postpartum as well as higher levels of most vitamins and minerals. Thus, the package for fully breastfeeding women provides the most food energy and nutrients, and the package for fully formula-feeding women provides the least.

Similarly, starting at age six months, the proposed package for fully breastfed infants includes commercial infant food meats to add a source of iron and zinc.

Because early supplementation may contribute to the short duration of breastfeeding, only two infant feeding options were recommended initially after delivery—either full breastfeeding or full infant formula-feeding. The IOM recommended this approach because physiology provides a strong basis for avoiding supplemental formula. The amount of milk a breastfeeding woman produces depends directly on how often and how long she nurses. Providing supplemental formula to a new breastfeeding mother may interfere with her milk production and success at continued breastfeeding.

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

## **V. Proposed Revisions to the WIC Food Packages**

### **A. Use of Terms**

For the purposes of discussion, this proposed rule uses the following terms.

WIC food categories refers to WIC formula (infant formula, exempt infant formula and WIC-eligible medical foods); milk and milk alternatives; eggs; peanut butter; legumes (dried beans and peas); infant cereal; breakfast cereal; canned fish; whole wheat bread or other whole grains; infant fruits and vegetables; infant meat; cheese; juice; and fruits and vegetables.

Food type refers to specific foods within a category, e.g., skim milk and soy-based beverages are types of food in the milk and milk alternatives category.

Physical form refers to the way in which the food is manufactured and/or packaged, e.g., dried, frozen; fresh; powder; liquid concentrate; fluid; evaporated, canned.

## B. Revised Food Packages I and II for Infants

As recommended by the IOM, this rule proposes the following changes in Food Packages I and II for infants (currently §246.10(c)(1) and (c)(2)).

- Revise age specifications for assignment to infant food packages;
- Establish 3 feeding options within each infant food package — fully breastfed, partially breastfed, or fully formula fed;
- Revise maximum monthly infant formula allowances;
- Add infant food fruits and vegetables in Food Package II;



- Eliminate juice from both infant food packages;
- Disallow provision of infant formula for breastfed infants during the first month after birth;
- Disallow low iron infant formula;
- Allow commercial infant food meat for fully breastfed infants in Food Package II; and
- Reassign infants with a qualifying condition to proposed revised Food Package III—Participants With Qualifying Conditions—and authorize the issuance of exempt infant formulas only in Food Package III.

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

#### 1. Reassignment of infants with qualifying conditions to Food Package III

Medically fragile infants currently receive either Food Package I (§ 246.10(c)(1)) for infants 0-3 months of age or Food Package II (§ 246.10(c)(2)) for infants 4-12

months of age. The WIC formulas authorized for issuance to infants in Food Packages I and II include infant formula, exempt infant formula and WIC-eligible medical foods.

This rule proposes to revise § 246.10(c)(1) through (c)(3) of Program regulations for Food Packages I, II and III in order to develop a restructured Food Package III that would serve all categories of participants, including infants, who have certain diagnosed qualifying conditions. The revised title for this food package would be Food Package III—Participants with Qualifying Conditions. The rationale for including infants in Food Package III is to consolidate all medically fragile individuals with qualifying conditions into one package to facilitate efficient management and tracking of the benefits and costs of providing supplemental foods to these participants. Refer to section V.P. of this preamble, Revisions to Food Package III and their effect on Food Packages I and II, for further information.

## 2. Change in age specifications for assignment to Food Packages I and II

As recommended by the IOM, this proposed rule would revise Food Package I to serve infants from birth through age 5 months and revise Food Package II to serve infants ages 6 months through 11 months. Currently, the assignment to Food Package II occurs at age four months.

### 3. Establishment of infant feeding options

#### a. First Month After Birth

To support the successful establishment of breastfeeding, the proposed rule, as recommended by the IOM, would establish two infant feeding options for the first month after birth, either full breastfeeding or full formula-feeding. That is, formula would not be provided for fully or partially breastfeeding infants during the first month after birth. If a breastfeeding mother requests formula during the first month, the Department would advise WIC staff to continue to provide breastfeeding support for the mother, with special attention to the provision of peer counseling, breast pumps, consultation with lactation experts, and referrals to medical providers when appropriate. Anticipatory guidance for new mothers during the prenatal period would be important for the success of this approach. As is currently the case, the breastfeeding mother could ask to have the infant assigned to full formula feeding option at any time and WIC staff would reassign the infant's and the mother's food package accordingly.

#### b. Second Month After Birth Through Month Eleven

Beginning the second month after birth, a third infant feeding option is proposed—partial breastfeeding. As recommended by the IOM, this rule proposes that, for the purposes of assigning WIC food packages, a partially breastfed infant be defined as an infant who is breastfed but also receives formula from the WIC

Program in an amount not to exceed approximately half the amount of formula allowed for a fully formula fed infant. Currently, there is not a food package for partially breastfed infants. Instead, breastfeeding infants may receive up to the maximum amount of infant formula authorized in Food Packages I and II. State agencies are currently encouraged to tailor the amount of infant formula provided based on the assessed needs of the breastfeeding infant. Under this proposal, breastfeeding mothers who request more than the amount of formula allowed for partially breastfed infants could receive up to the maximum amount of formula for the fully formula fed infant. In such instances, the infant's feeding option would be changed from partially breastfed to fully formula fed and the mother's food package adjusted accordingly.

#### 4. Introduction of Complementary Foods at 6 Months of Age

As recommended by the IOM, the proposed Food Package I would provide only iron-fortified infant formula for partially breastfed and fully formula fed infants until an infant is six months old. As cited by the IOM, this change is consistent with recent position statements from the American Academy of Pediatrics emphasizing that the introduction of complementary feedings before six months of age only substitutes foods that lack the protective components of human milk and that exclusive breastfeeding should be used as the reference or normative model for feeding infants. Six months is the age at which most healthy infants are developmentally ready to handle complementary foods. Infants do not need

complementary foods for nutritional reasons at younger ages—either breastmilk or iron-fortified infant formula would entirely meet the nutritional needs of most infants. Providing complementary foods beginning at age six months is consistent with common guidelines for clinical practice in the field of pediatrics.

#### 5. Disallowance of Low-Iron Infant Formula in Food Packages I, II and III

It is well documented that iron-fortified infant formulas play an essential role in providing iron in the diets of non-breastfed infants. According to AAP, there are no known medical conditions warranting the use of a low-iron infant formula during infancy. In addition, the IOM recommends that the WIC Program continue to provide iron-fortified infant formula to prevent iron-deficiency anemia in infants. This proposed rule would revise WIC food package regulations to prohibit the issuance of all low-iron infant formulas to any infants.

#### 6. Proposed Revisions and Maximum Monthly Allowances in Food Package I – Infants Less Than 6 Months of Age

As recommended by the IOM, under this proposed rule, Food Package I would provide iron-fortified infant formula only. Infant formula would continue to be authorized in liquid concentrate, powder, and ready-to-feed (RTF) physical forms. However, powder infant formula would be recommended in Food Package I for partially breastfed infants ages one month through three months due to its longer shelf life, less waste and capability to mix the small amounts needed for the partially breastfed infant. Powder and RTF physical forms are substitutes or

alternatives to liquid concentrate and may be substituted at amounts that provide the approximate number of reconstituted fluid ounces as the liquid concentrate form of the same infant formula. Currently, in both Food Packages I and II, infant formula allowances are expressed in terms of fluid ounces of liquid concentrate, pounds of powder, and fluid ounces of RTF. WIC State agencies have suggested to FNS that maximum monthly formula allowances for liquid concentrate and powder physical forms be expressed in terms of reconstituted fluid ounces. The Infant Formula Act of 1980 and its amendments standardized the nutrient content of infant formulas ensuring that infant formulas distributed in the United States contain certain minimum levels of calories and nutrients per reconstituted fluid ounce. Therefore, the Department is proposing to express maximum monthly allowances of infant formula of liquid concentrate and powder physical forms in reconstituted fluid ounces according to the mixing directions on the container for preparation for consumption. RTF liquid will continue to be expressed in fluid ounces.

a. Liquid Concentrate Infant Formula

All liquid concentrate infant formula currently marketed is packaged in 13 fluid-ounce cans, is designed to be mixed with an equal quantity of water (i.e., has a 1:1 dilution ratio) and provides the standard dilution of 20 kilocalories per fluid ounce reconstituted. Thus, 403 fluid ounces of liquid concentrate formula reconstitutes to 806 fluid ounces. The proposed maximum monthly formula allowances are evenly divisible by the 13-fluid-ounce cans of liquid concentrate infant formula.

## b. Powder Infant Formula

The reconstituted yields for powder formulas vary according to types and brands of products. Powder milk-based infant formulas designed for healthy, full-term infants have among the highest yields when compared to soy-based infant formulas and exempt infant formulas. This proposed rule would revise the substitution rate for powder infant formula since the current substitution rate of 8 pounds powder per 403 fluid ounces liquid concentrate is no longer appropriate and could result in providing excess amounts of formula in some cases. The IOM recommended rounding to whole cans in order to reach recommended amounts of infant formula. Therefore, the proposed maximum monthly allowances of liquid concentrate and RTF are evenly divisible by the whole can sizes of infant formula currently available. However, none of the whole container sizes of powder infant formula commonly issued by State agencies would provide the same number of reconstituted fluid ounces as the liquid concentrate form of the same product in whole containers. The Department recognizes that powder is the most economical form for State agencies to issue. Therefore, in order to provide a nutritional benefit amount recommended by the IOM and to provide administrative flexibility for the issuance of infant formula, this proposal would authorize an amount of powder infant formula that would provide at least the maximum monthly allowance as the reconstituted liquid concentrate form of the same infant formula in the same food package and infant feeding option (fully formula fed or partially breastfed). State agencies would be required to provide at

least the number of fluid ounces as the same reconstituted liquid concentrate infant formula up to the maximum monthly allowance for reconstituted powder infant formula. This would ensure that participants receive comparable nutritional benefit no matter which physical form of infant formula they receive. The Department recognizes that participants issued powder infant formula may receive a slightly higher amount of reconstituted fluid ounces than the other forms due to the currently available container sizes and reconstitution rates.

c. RTF Infant Formula

Proposed § 246.10(e)(1)(iv) lists the reasons that RTF formula may be authorized as a substitute for liquid concentrate. The maximum monthly allowance of RTF formula provides about the same number of fluid ounces as the reconstituted liquid concentrate form of the same infant formula. The proposed maximum monthly allowances are evenly divisible by the 8 and 32-ounce whole containers of RTF infant formula.

d. Maximum Monthly Allowances of Infant Formula

As recommended by the IOM, the maximum monthly allowance of infant formula would depend on the feeding option, physical form of infant formula provided (concentrated, powder, or ready-to-use), and the age of the infant, as summarized in Exhibit C of this preamble.

- Fully formula fed infants would receive the equivalent of about 806 fluid ounces reconstituted infant formula per month from



birth through 3 months of age; thus, Food Package I is unchanged for fully formula fed infants from birth through 3 months of age. Fully formula fed infants 4 months through 5 months of age would receive the equivalent of about 884 fluid ounces of reconstituted infant formula per month;

- Juice and infant cereal would no longer be provided for infants ages 4 months through 5 months. Compared with the current package, the amount of infant formula is increased slightly for infants ages 4 months through 5 months to compensate in part for the decrease in nutrients and calories that results from the omission of juice and infant cereal;
- Partially breastfed infants ages 1 month through 3 months would receive the equivalent of about 364 fluid ounces reconstituted infant formula per month. Powder infant formula is recommended until the partially breastfed infants reaches four months of age due to its longer shelf life and to minimize waste; and
- Partially breastfed infants 4 months through 5 months of age would receive the equivalent of about 442 fluid ounces reconstituted infant formula per month.

Since infant formula is supplemental to breast milk for partially breastfed infants, the maximum allowance of infant formula for partially breastfed infants is approximately 50 percent of the maximum allowance for fully formula fed infants. According to the IOM, this approach is designed to encourage mothers

who are using the combination feeding method (feeding both breast milk and infant formula) to aim for a greater contribution of breast milk to the infant’s intake.

By definition, fully breastfed infants would not receive infant formula from the WIC Program. Instead, they would receive the benefit of breast milk, which provides the nutrients they need and a wide array of protective and health-promoting components in a safe form.

**Exhibit C** Maximum Monthly Allowances for Proposed Food Package I for Infants Ages Birth to 6 months, by Feeding Option

WIC Food	Fully Breastfed Infants	Partially Breastfed Infants		Fully Formula fed Infants	
		1 through 3 months	4 through 5 months	0 through 3 months	4 through 5 months
Infant Formula	NA	364 fl oz reconstituted liquid concentrate*	442 fl oz reconstituted liquid concentrate	806 fl oz reconstituted liquid concentrate	884 fl oz reconstituted liquid concentrate

NA= not applicable

\*The maximum monthly allowance is specified in the liquid concentrate form; however, powder and RTF are allowable substitutes and the powder form is recommended for partially breastfed infants, ages 1 through 3 months of age.

7. Proposed Revisions and Maximum Monthly Allowances in Food Package II – Infants 6 through 11 Months of Age

As recommended by the IOM, this proposed rule would revise Food Package II to include the following changes:

- Food Package II would be provided to infants from 6 through 11 months of age. This package would differ substantially by infant feeding option, as shown in Exhibit D in this preamble. Infant formula would be decreased for fully formula fed infants to 624 fluid ounces of reconstituted liquid concentrate infant formula per month and for partially breastfed infants to 312 fluid ounces of reconstituted liquid concentrate infant formula per month;
- Infant foods would be added to the food package to encourage healthy dietary patterns; and
- Juice would be omitted to help make possible the addition of infant food fruits and vegetables.

The amount of infant cereal in the package would be unchanged. The proposed decrease in the maximum allowance of infant formula is consistent with meeting nutritional requirements. The amount of infant formula proposed for partially breastfed infants reflects and encourages a greater contribution of breast milk to the infant's diet. Decreasing the maximum amount of infant formula and omitting juice makes possible needed enhancements. For example, the addition of infant food fruits and vegetables in the second six months of infancy introduces infants to a variety of nutritious foods at an age when almost all infants are developmentally ready for semisolid foods. The infant food meat for fully breastfed infants provides needed iron and zinc in forms with high bioavailability,

and the larger quantities of infant food for fully breastfed infants may encourage some mothers to continue fully breastfeeding.

Long-standing WIC policy has not authorized infant cereals that included fruit or infant formula ingredients. However, this restriction was never incorporated into regulatory language. This proposed rule would clarify in WIC regulations that infant cereals with the added ingredients of infant formula, milk, fruit, or other non-cereal ingredients are not authorized based on recommendations of the AAP and cost concerns. The AAP recommends that single ingredient foods be introduced one at a time in an effort to isolate food sensitivities and possibly avert the development of food intolerances. Although cereal/fruit combinations may be appropriate once the risk of food sensitivity has diminished, these combination foods are more expensive than regular infant cereal. In reference to cereal/formula combinations, since infant formula is already provided in the food packages, it is not necessary to provide additional infant formula in combination with infant cereal. In addition, authorized infant cereals must continue to contain a minimum of 45 milligrams of iron per 100 grams of dry cereal.

a. Authorized Infant Foods

- Any variety of commercial infant food (fruit or vegetable) without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced; and

- Any variety, single ingredient, of commercial infant food meat with broth or with gravy. Texture may range from pureed through diced.

b. Maximum Monthly Allowance of Infant Foods (Fruits, Vegetables, and Meats) for Infant 6 through 11 months of age:

- For fully formula fed infants. 128 ounces of fruits and vegetables (e.g., 32 4-ounce jars);
- For partially breastfed infants. 128 ounces of fruits and vegetables (e.g., 32 4-ounce jars);
- For fully breastfed infants. 256 ounces of fruits and vegetables (e.g., 64 4-ounce jars); and
- For fully breastfed infants. 77.5 ounces of infant food meat (31 2.5-ounce jars).

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. Fresh bananas for infants in Food Package II would be issued via the standard food instrument system.

As cited by the IOM Report, the rationale for providing a greater quantity of infant food fruits and vegetables in the package for fully breastfed infants is to provide added nutritional value to improve the parity with other infant packages,

to provide sufficient fruits and vegetables to mix with infant food meats to increase the palatability of strained meats for older infants, and to encourage prolonged breastfeeding by adding to the convenience and monetary value of the food packages of the fully breastfeeding mother/infant pair.

**Exhibit D** Maximum Monthly Allowances for Proposed Food Package II for Infants Ages 6 Months to 1 Year, by Feeding Option

	<b>Fully Breastfed Infants</b>	<b>Partially Breastfed Infants</b>	<b>Fully Formula fed Infants</b>
<b>WIC Formula</b>			
<i>Infant Formula</i>		312 fluid ounces of reconstituted liquid concentrate formula	624 fluid ounces of reconstituted liquid concentrate formula
<b>WIC Food</b>			
<i>Infant food (Fruits and Vegetables)</i>	256 ounces of infant food fruits and vegetables	128 ounces of infant food fruits and vegetables	128 of ounces infant food fruits and vegetables
<i>Infant food (Cereal)</i>	24 ounces of iron-fortified infant cereal	24 ounces of iron-fortified infant cereal	24 ounces of iron-fortified infant cereal
<i>Infant food (Meat)</i>	77.5 ounces of infant food meat		

c. Rounding Up of Infant Foods

- Infant Formula

Public Law 108-265, the Child Nutrition and WIC Reauthorization Act of 2004, enacted on June 30, 2004, contains a provision that allows a State agency to round up to the next whole can of infant formula to allow all participants to receive the full-authorized nutritional benefit specified by regulation. This provision only applies to infant formula (not exempt infant formula or WIC-eligible medical foods) issued as a result from a solicitation bid on or after October 1, 2004. This proposal reflects this authority by calculating and dispersing the infant formula over the timeframe of the food package category and infant feeding option (fully formula fed or partially breastfed). This proposal would identify the full nutritional benefit (FNB) provided by infant formula as the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate for the food package category and infant feeding option. This proposal would require State agencies to issue at least the FNB but not more than the maximum monthly allowance for the food package category and infant feeding option. This proposal would require State agencies that use the rounding up option to issue infant formula in whole containers of the same size for administrative ease and to use the methodology described herein to calculate the number of cans of infant formula for issuance to participants.

This proposal would require calculating and dispersing the infant formula over the timeframe of the food package category and infant feeding option (fully formula



fed or partially breastfed). For example, a fully formula fed infant who participates in WIC from birth through eleven months of age would be issued infant formula in amounts provided by Food Package IA-FF from birth through 3 months of age, issued infant formula in amounts provided by Food Package IB-FF from four through five months of age, and issued infant formula in amounts provided by Food Package II- FF from 6 through eleven months of age. The timeframe or the total number of months that the participant will receive each food package is shown in Exhibit E.

**Exhibit E Food Package Timeframe**

<b>Food Package</b>	<b>Maximum Time Frame</b>
I A-FF	4 months
I B-FF	2 months
II-FF	6 months

Exhibit F describes the methodology that State agencies must use to calculate the amount of infant formula dispersed over the timeframe of the food package category and infant feeding option, when using the rounding up option.

**Exhibit F Rounding Up Infant Formula Methodology**

1	Multiply FNB by number of months in food package = Total amount of infant formula.
2	Determine yield (reconstituted fluid ounces) provided by the container issued by the State agency.
3	Divide total amount of infant formula by the container yield = total number of containers to issue.
4	Round up to the next whole same size container if the number of containers is not a whole number. (e.g. 4.3 containers would round up to 5 containers)
5	Distribute the total containers across the food package timeframe as evenly as possible (e.g. 2,1,2,1)

For example, a fully formula fed infant participant born January 1, 2006, would receive Food Package IA – FF issuance amount rounded over a 4-month timeframe multiplied by the FNB (806 fluid ounces reconstituted) to equal 3224 fluid ounces reconstituted total amount of infant formula for the 4-month timeframe. The total amount, 3224 fluid ounces reconstituted, would then be divided by the yield of fluid ounces reconstituted provided by the authorized container to determine the total number of containers needed to provide 3224 fluid ounces reconstituted. The reconstituted fluid ounce yield provided by container varies depending on container size and the reconstitution rate. Currently, Enfamil Lipil infant formula in a 12.9 ounce can reconstitutes to about 94 fluid ounces per container, Similac Advance infant formula in a 12.9 ounce can reconstitutes to about 96 fluid ounces per container, and Nestle Good Start Supreme infant formula in a 12.0 ounce can reconstitutes to about 87 fluid ounces per container. Therefore, the 3224 fluid ounces would be divided by either 94, 96 or 87 respectively, for a rounded up total of 35 12.9 ounce cans of Enfamil Lipil, or 34 12.9 ounce cans of Similac Advance, or 38 cans of 12 ounce cans Nestle Good Start Supreme. Using Enfamil Lipil as the example, the 35 cans would be dispersed over 4-months as evenly as possible, such as 9 cans the first month, 8 cans the second month, and 9 cans each for months 3 and 4.

Exhibit G shows the number of powder infant formula containers that would be issued to an infant participant born January 1, 2006, for the fully formula fed infant food packages, using the rounding up methodology, for Enfamil Lipil,

Similac Advance, or Nestle Good Start Supreme infant formulas for a 1-year certification timeframe.

**Exhibit G Number of Powder Infant Formula Containers Issued to an Infant Participant Born 01/01/2006, for Food Packages I & II Fully Formula Fed (FF) using Rounding Up**

Approximate Reconstitution amount per container		Mead Johnson 's Enfamil Lipil (number of 12.9 oz containers) 94 fl. oz.	Ross' Similac Advance (number of 12.9 oz containers) 96 fl. oz.	Nestle's Good Start Supreme (number of 12.0 oz containers) 87 fl. oz
<b>Food Package I-FF A (FNB = 806 fl. oz per month)</b>	January, age 0 months	9.0	9.0	10.0
	February, age 1 month	8.0	9.0	10.0
	March, age 2 months	9.0	8.0	9.0
	April, age 3 months	9.0	8.0	9.0
	Food Package I-FF A subtotal	35	34	38
<b>Food Package I-FF B (FNB = 884 fl oz per month)</b>	May, age 4 months	10.0	10.0	11.0
	June, age 5 months	9.0	9.0	10.0
	Food Package I-FF B subtotal	19	19	21
	July, age 6 months	7.0	7.0	8.0
	August, age 7 months	6.0	6.0	7.0
<b>Food Package II-FF (FNB=624 fl oz per month)</b>	September, age 8 months	7.0	7.0	7.0
	October, age 9 months	6.0	6.0	8.0
	November, age 10 months	7.0	7.0	7.0
	December, age 11 months	7.0	6.0	7.0
	Food Package II-FF subtotal	40	39	44
<b>Infant package total of formula issued</b>		<b>94</b>	<b>92</b>	<b>103</b>

- Infant Foods

This proposed rule would allow State agencies to round up and disperse whole containers of infant foods (infant cereal, infant fruit and vegetables, and infant

meat) over the timeframe of the food package category and infant feeding option (fully formula fed, fully breastfed or partially breastfed) to allow all participants to receive the maximum monthly allowance of infant foods as specified in regulations. This is consistent with the authority allowing State agencies to round up infant formula. Rounding up of infant foods provides administrative flexibility to State agencies since container sizes of infant foods vary and rounding ensures that infants would receive the full nutritional benefit recommended by the IOM.

This proposal would require State agencies that use the rounding up option for infant foods to use the same methodology proposed to calculate and disperse infant formula over the timeframe of the food package category and infant feeding option. Exhibit H describes the methodology that State agencies must use to calculate and disperse infant foods over the timeframe of the food package category and infant feeding option.

**Exhibit H** Rounding Up Infant Food Methodology

1	Multiply maximum monthly allowance by number of months in food package = Total amount of infant food in ounces.
2	Determine the container size (e.g., ounces) of infant food issued by the State agency.
3	Divide total amount of infant food by the container size = total number of containers to issue.
4	Round up to the next whole same size container if the number of containers is not a whole number. (e.g. 54.3 containers would round up to 55 containers)
5	Distribute the total containers across the food package timeframe as evenly as possible. (e.g. 10, 9, 9, 9, 9, 9)

For example, a fully formula fed infant participant born January 1, 2006, would receive Food Package II from July through December, for a 6-month total timeframe. The infant may receive 24 ounces infant cereal per month, multiplied by 6 months, to equal a total of 144 ounces infant cereal. Currently, authorized infant cereal is packaged in 8 and 16-ounce containers. Therefore, either 18 8-ounce containers or 9 16-ounce containers of infant cereal would be provided over the food package timeframe. The 18 8-ounce containers can be divided equally by the 6-month food package timeframe and results in 3 8-ounce containers of infant cereal issued each month. The 9 16-ounce containers must be dispersed across the food package timeframe as evenly as possible, for example, two containers per month issued for three months and one container per month issued for three months on alternating months (e.g. 2,1,2,1,2,1) to equal the 9 total containers.

The Department is seeking comments on the proposed methodology to round up and disperse infant formula and infant foods.

d. Department Soliciting Input on Changes to Infant Feeding Packages

The proposed infant feeding options represent a dramatic change in infant food package issuance procedures. The procedural changes affect not only assignment to one of three feeding options but impact the delivery of other nutrition services as well. We are aware that WIC State agencies will experience challenges in staff training, assessment of the mother-infant dyad, programming of management

information systems, and the provision of participant nutrition education.

Successful implementation of the infant feeding options may require enhanced nutrition education, peer counseling, and referral activities to support the successful establishment of breastfeeding.

The Department is soliciting input on the potential impacts of the proposed changes to Food Package I and II, and any comments or suggestions on alternative options for FNS to consider. Specifically, FNS would like comments regarding the following:

- The three infant feeding options;
- Impact of proposed changes on breastfeeding rates;
- Staff training and building support for proposed changes among WIC staff;
- The expression of monthly maximum amounts of infant formula in reconstituted fluid ounces;
- The methodology used to round up infant formula and infant foods;
- Participant nutrition education; and
- Administrative feasibility.

#### C. Overview of Revised Food Package IV for Children

Currently there is one package for children without special dietary needs, Food Package IV for children ages 1 to 5 years (currently § 246.10(c)(4)). This proposed rule would continue to provide Food Package IV to children ages 1 through 4 years. However, as recommended by the IOM, only whole milk would be authorized for children age one year (12 through 23 months), and only milk with a fat content not to exceed two percent would be authorized for children 2 years of age and older. Compared with the current package, the revised food package, as recommended by the IOM, would include smaller amounts of milk and juice but would add fruits, vegetables, and whole grains. Cheese would continue to be allowed as a partial substitute for milk; however, the maximum cheese substitution would be reduced from current WIC regulations. As recommended by the IOM, with proper medical documentation, soy-based beverage and tofu would be authorized as substitutes for milk. As cited by the IOM Report, these changes would make the entire food package for children more consistent with the DGA 2005 <sup>(12)</sup> and help ensure a more balanced nutrient intake for WIC participants.

#### D. Overview of Revised Food Packages V, VI, and VII for Women

Currently, there are three food packages for women without special dietary needs. These are Food Package V for pregnant and breastfeeding women; Food Package VI for nonbreastfeeding postpartum women; and Food Package VII for breastfeeding women who do not receive infant formula for their infants from the

WIC Program (currently § 246.10(c)(5) through (c)(7)). As recommended by the IOM, this proposed rule would retain these food packages, but as discussed in section V.B. of this preamble, would add for the purposes of assigning a food package, a definition of partially breastfeeding. Currently, a woman is certified to be eligible for the Program as a breastfeeding woman if she is breastfeeding on the average of at least once a day and meets other WIC eligibility criteria. Under this proposed rule, a woman would continue to be certified eligible as a breastfeeding woman if she is breastfeeding on the average of at least once a day. However, whether or not she receives a food package and which food package she is assigned would be based on the amount of infant formula she requests and receives from WIC for her infant and the age of the infant.

Under this proposed rule, Food Package V would be provided for pregnant and partially breastfeeding woman (up to 1 year postpartum) whose infants participate in the WIC Program and receive infant formula in amounts that do not exceed the maximum allowances for the partially-breastfed infant food packages, as appropriate for the age of the infant.

Food Package VI would continue to be provided for non-breastfeeding postpartum women (up to 6 months). Food Package VI would also be provided to partially breastfeeding postpartum women (up to 6 months) whose infants are receiving more than the maximum allowances for the partially breastfed infant food package, as appropriate for the age of the infant. In terms of the variety of



foods and amounts offered, Food Package V for partially breastfeeding women is more desirable than Food Package VI. Food Package V provides whole wheat bread or other whole grains, peanut butter in addition to legumes, and more milk and juice than Food Package VI. Food Package VI does not provide whole wheat bread or other whole grains, and provides the option of peanut butter or legumes, but not both. The incentive value of Food Package V may encourage a higher level of breastfeeding among mothers who both breastfeed and formula-feed their infants.

Food Package VII would continue to be provided to fully breastfeeding women whose infants do not receive infant formula from the WIC Program. In addition, based on estimates of increased nutrient and energy needs of women pregnant with more than one fetus, these women, as recommended by the IOM, would now receive Food package VII rather than Food Package V. Women who are fully breastfeeding multiple infants would be prescribed 1.5 times the maximum amounts of Food Package VII to cover their higher needs for energy and nutrients. Women partially breastfeeding multiple infants would receive also Food Package VII. Further, all breastfeeding women would be prescribed Food Package VII during the first month postpartum because their infants would not be receiving any infant formula from the WIC Program.

As recommended by the IOM, under this proposed rule Food Package VII, for fully breastfeeding women, would provide the greatest variety and quantity of

food; and Food Package VI for postpartum women, would provide the least. Compared with the current food packages, all 3 revised food packages for women would provide smaller amounts of milk products, eggs, and juice; the same amount of iron-fortified cereal; add a requirement that cereals be whole grain; and would add fruits and vegetables. Whole grain bread or other whole grains would be added to Food Packages V and VII. The food packages for women would no longer authorize whole milk, and would allow several alternatives to cow's milk to address calcium needs. Canned light tuna would continue to be allowed in Food Package VII; canned salmon and sardines would be authorized as substitutes for light tuna.

Women greater than 6 months postpartum whose infants do not meet the definition of a partially breastfed infant

The IOM recommends that a partially breastfeeding woman who requests, after the sixth month postpartum, more than the maximum amount of formula for a partially breastfed infant, no longer be certified for the WIC Program. However, FNS has determined that this approach is incongruous with the definition of breastfeeding in WIC regulations at § 246.2—the practice of feeding a mother's breastmilk to her infant(s) on the average of at least once per day. In WIC, this definition is used to determine Program eligibility, and allows all breastfeeding women, regardless of feeding pattern, to participate in the WIC Program, be counted as a breastfeeding woman, and receive supplemental foods, breastfeeding

promotion and support, and referrals to health care. The definition recognizes that any breastfeeding, even if only on an average of once a day, provides some immunological and nutritional benefits that would otherwise not be provided to an infant.

As such, rather than adopt IOM's recommendation in its entirety, FNS proposes to revise the definition for WIC "participation" at § 246.2. The definition would now include the number of breastfeeding women who receive no supplemental foods or food instruments but whose breastfed infant(s) receives supplemental food or food instruments. Counting these women, although they are not receiving a food package, is consistent with the current practice of counting the infants of exclusively breastfeeding women. Therefore, a partially breastfeeding woman who requests, after the sixth month postpartum, more than the maximum amount of formula for a partially breastfed infant would no longer receive a food package but would continue to count as a WIC participant and receive other Program benefits (nutrition education, including breastfeeding promotion and support, and referrals to health and social services). This would serve to meet the intent of IOM's recommendations within the context of WIC regulations.

#### E. Inclusion of Fruits and Vegetables in Food Packages III through VII

As recommended by the IOM, this proposed rule would add a variety of fruits and vegetables to Food Packages III, IV, V, VI, and VII (currently § 246.10(c)(3))

through (c)(7)). The IOM Report states that the addition of fruits and vegetables to WIC food packages is consistent with a major recommendation of the DGA 2005 <sup>(12)</sup>— namely, to increase daily intake of fruits and vegetables. The IOM’s basis for recommending the addition of fruits and vegetables was the substantial body of literature that supports the association of fruit and vegetable consumption with reduced risk of chronic disease including stroke and perhaps other cardiovascular diseases, some cancers, and type 2 diabetes. Evidence also suggests that increased fruit and vegetable consumption may be useful in programs to promote and sustain loss of body weight in overweight individuals. The IOM and FNS received many public comments from health professionals, consumers, WIC Program staff, WIC participants, and others, advocating for the inclusion of fruits and vegetables in the WIC food packages.

#### 1. Authorized Fruits and Vegetables

As recommended by the IOM, this proposed rule would include fresh and processed (canned, frozen, and dried) fruits and vegetables. Fresh, canned, and frozen fruits and vegetables would be authorized for children and women in Food Packages III through VII. Dried fruits and dried vegetables would be authorized for women in Food Packages III and V through VII. As recommended by the IOM, dried fruit and dried vegetables would not be authorized for children in Food Packages III or IV to reduce the risk of choking.

As recommended by the IOM, to improve the consumption of fresh fruits and vegetables and the appeal of this option, especially for people of different cultural backgrounds, this proposed rule would place minimal restrictions on participant choice of fresh produce. Because a fresh produce option might not be practical in some situations, a processed option and a combined fresh and processed option for fruits and vegetables are also proposed.

As recommended by the IOM, for children and adults in Food Packages III-VII, different physical forms of fruit and vegetable offerings are proposed, as follows.

a. Fresh fruits and vegetables

- Any variety of fresh whole or cut fruit without added sugars; and
- Any variety of fresh whole or cut vegetable, except white potatoes, without added sugars, fats, or oils.

b. Processed fruits and vegetables (canned, frozen, and dried):

- Any variety of canned fruits, including applesauce; juice pack or water pack without added sugars, fats, oils, or salt (i.e., sodium);
- Any variety of frozen fruits without added sugars;
- Any dried fruit or vegetable without added sugars, fats, oils, or salt (i.e., sodium); and
- Any variety of canned or frozen vegetables, except white potatoes (orange yams and sweet potatoes are allowed), without added sugars, fats, oils.

## 2. Restrictions on Authorized Fruits and Vegetables

This proposed rule would not authorize:

- White potatoes (orange yams and sweet potatoes are allowed);
- Catsup or other condiments;
- Pickled vegetables and olives; or
- Soups.

IOM's recommended restriction on white potatoes is based on the amounts suggested in DGA 2005 <sup>(12)</sup> for consumption of starchy vegetables; food intake data indicating that consumption of starchy vegetables meets or exceeds these suggested amounts; and food intake data showing that white potatoes are the most widely used vegetable.

Although not addressed by IOM, the Department is proposing further restrictions on fruits and vegetables; and therefore this proposal would also not authorize:

- Herbs or spices;
- Edible blossoms and flowers, e.g., squash blossoms (broccoli, cauliflower and artichokes are allowed);
- Creamed or sauced vegetables;
- Vegetable-grain (pasta or rice) mixtures;
- Fruit-nut mixtures;
- Breaded vegetables;

- Fruits and vegetables for purchase on salad bars;
- 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;
- Fruit leathers and fruit roll-ups;
- Peanuts;
- Juices (juices are provided as a separate WIC food category);
- Canned and dried mature legumes (these legumes are provided as a separate WIC food category); and
- Items such as blueberry muffins and other baked goods.

### 3. Maximum Monthly Allowances

The IOM recommended that fruits and vegetables be provided at levels of \$10 per month for women and \$8 per month for children. However, as discussed earlier in this preamble, to achieve cost neutrality, the Department has reduced this recommendation by \$2 for both women and children. Therefore, this proposed rule establishes the value of fruit and vegetable vouchers at levels of \$8 per month for women and \$6 per month for children. The Department welcomes comments or suggestions from State agencies regarding cost-neutral options for providing vouchers at the IOM-recommended levels.

#### a. Fresh produce option

Because few fresh fruits and vegetables are sold in uniform weight units with uniform bar codes, and their prices vary considerably across seasons, regions, and stores, they cannot be prescribed in quantity terms and still control the overall cost of the WIC food packages. Therefore, this proposal would include cash-value food instruments at the level of \$8 per month for women and \$6 per month for children for fresh fruits and vegetables.

Cash-value food instruments will be set at \$6 for children and \$8 for women in the year in which the proposed food package revisions take effect. FNS will adjust the maximum value of the vouchers in whole dollar increments to reflect the sum of annual, un-rounded increases in inflation using the Bureau of Labor Statistics' Consumer Price Index for Fresh Fruits and Vegetables. In the fiscal year in which the whole dollar increment accrues, the Department would have the option to increase the value of the fruit and vegetable vouchers by the whole dollar increment. If the Department elects this option, it would request the funding necessary for the additional program costs.

The recommendation to use cash-value food instruments for fresh fruits and vegetables is based on input IOM received from vendors in public meetings. The IOM also cited two recent pilot studies in which cash-value vouchers for fresh fruits and vegetables were provided to WIC participants.<sup>(18, 19)</sup> The experience from both pilot studies, albeit unpublished at the present time, suggests that providing fresh produce to WIC participants using cash-value vouchers increased



the intakes of fruits and vegetables, added variety to the diets of WIC participants, and was highly acceptable to WIC participants of various ethnic/cultural backgrounds.

Because of greater participant choice, lower cost in many States, and potentially greater nutrient contribution from fresh produce, State agencies are encouraged to offer fresh produce to the extent possible.

b. Processed fruit and vegetables option

As recommended by the IOM, this proposal would allow processed (canned, frozen, and dried) fruits and vegetables to be substituted when fresh produce is limited and to accommodate participant preference. The Department proposes to also provide the processed options via the \$8 or \$6 cash-value food instrument. State agencies would be authorized to allow the cash-value food instrument to be used to obtain any combination of fresh produce and processed fruits and vegetables, thereby providing maximum flexibility for the participant. In addition, the ability to combine all fruit and vegetable options on one type of cash-value food instrument should reduce the administrative complexity for State agencies and vendors.

State agencies are encouraged to allow participants the wide variety of choices within the authorized fresh and processed options. To ensure participant choice among the fresh and processed fruit and vegetables authorized by the State agency, § 246.12(g)(3)(i) would be revised to require that vendors authorized by

the State agency carry a minimum of two varieties each of fruits and vegetables, in any combination of fresh and processed. However, it is the Department's expectation that more than two varieties each of fruits and vegetables be authorized by State agencies. The Department welcomes comments or suggestions on ways to provide the widest variety of choice without introducing undue program complexity or administrative burden.

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

Under this proposed rule, State agencies would be encouraged to issue small denomination, such as \$2, cash-value fruit/vegetable food instruments. In consideration of the perishable nature of fresh fruits and vegetables, small denominations are needed so the participant can obtain small amounts of fresh product at various times during the month, lessening the chance of food spoilage and waste. Any combination of authorized fresh or processed fruit or vegetable would be allowed in quantities with a value up to the amount of the cash-value food instrument(s). The Department welcomes comments or suggestions on implementation of fresh fruit and vegetable options.

##### a. Operational requirements for cash-value fruits and vegetables food instruments

Under this proposed rule, cash-value food instruments for fruits and vegetables, as with any WIC food instrument, would be subject to the requirements in § 246.12

—Food Delivery Systems. Section 246.12 sets forth design and operational requirements for food delivery systems, including vendor authorization, accountability, redemption and disposition of food instruments.

b. Benefit Delivery

While most of the proposed food package changes could be administered via existing State benefit delivery systems, the cash-value food instruments for the purchase of fruits and vegetables differs from other WIC benefits which provide specified quantities of approved food items. The fruit and vegetable benefit would require changes to WIC benefit delivery systems to accommodate a more open-ended benefit determined by a cash value rather than a fixed quantity of a specific food item. States and vendors would have to modify operations and procedures to issue, transact, and process the redemption of a cash value benefit. The implementation of a cash value paper voucher or check may prove administratively burdensome and prohibitively expensive given additional processing costs that may be applied to each transaction, depending on a State's benefit processing arrangement. The cost and implications of these changes in the existing WIC benefit delivery system is an area that must be carefully considered.

The fruit and vegetable benefit may lend itself to electronic benefit delivery in line with current trends in commercial retail transaction processing and consistent with the FNS 5-Year Plan for Electronic Benefit Transfer (EBT). While the majority of State WIC agencies deliver benefits via paper checks or vouchers, 5

States are testing the feasibility of EBT and an additional State has adopted EBT statewide. These pilots are testing and evaluating the feasibility of smartcard and online technologies. By 2008, FNS hopes to identify national model(s) that are technically and financially viable for retail transaction processing for WIC EBT.

Although it will take a number of years to implement WIC EBT fully in all States, the fruit and vegetable benefit may provide opportunities for alternative forms of benefit delivery and allow some States to move toward limited electronic benefit processing prior to the implementation of EBT for all WIC purchases. These solutions could provide participants with greater flexibility in redeeming benefits by allowing them to spread their purchases out across the month, although some solutions will likely prove prohibitively costly in relation to the cash value of the proposed benefit. FNS will explore the range of possibilities for using existing commercial infrastructure to administer the fruit and vegetable benefit including WIC EBT smartcard and online solutions as well as commercial debit cards and other technologies.

FNS will assess the administrative burden, technical feasibility, advantages and costs of alternative approaches to delivering the cash value benefit for fruits and vegetables. We recognize that this benefit will pose challenges and added costs for the existing paper voucher and check system and that various technical approaches may also be costly and complicated to develop, implement, and operate. Since the implications of alternative solutions are likely to vary across

State WIC agencies depending on their current participating vendor characteristics and benefit delivery systems, several different options may be needed to deliver the cash value benefit throughout the Program. FNS seeks to minimize the complexity and cost associated with administering this benefit and invites comments and suggestions on alternative approaches and considerations.

c. Farmers' Markets

The Department proposes to allow the State agency to authorize farmers at farmers' markets to accept the WIC cash-value food instrument for fruits and vegetables. Such markets would have to meet vendor selection criteria specified at § 246.12(g)(3) and would be subject to the vendor agreement requirements outlined in § 246.12(h)(3).

F. Addition of Peanut Butter in Food Package V

As recommended by the IOM, this proposed rule would add 18 ounces of peanut butter in Food Package V (currently § 246.10(c)(5)) to improve the intake of several nutrients, including iron, folate, Vitamin E, and fiber, in the diets of pregnant and breastfeeding women. At present, Food Package V allows peanut butter only as an alternative to dry beans and peas.

G. Addition of Legumes in Food Package VI

As recommended by the IOM, this proposed rule would add 1 pound of dried beans or peas or, as an alternative, 18 ounces of peanut butter, to Food Package VI for postpartum women (currently § 246.10(c)(6)). Currently Food Package VI does not provide legumes of any kind. This addition would improve the intake of several nutrients, including iron, folate, Vitamin E, and fiber, in the diets of these participants.

#### H. Addition of Canned Mature Legumes as an Optional Substitute for Dry Legumes in Food Packages III-VII

As recommended by the IOM, this proposed rule would allow the substitution of canned mature beans/peas for dry mature beans/peas in Food Packages III, IV, V, VI and VII (currently § 246.10(c)(3) through (c)(7)). This substitution, currently authorized for homeless persons, would be allowed under this proposed rule to increase flexibility and variety in food choices for participants receiving Food Packages III-VII.

##### 1. Authorized Types of Canned Beans

This proposed rule would allow any type of mature dry beans in canned form. Examples include but are not limited to black beans (“turtle beans”), blackeye peas (cowpeas of the blackeye variety, “cow beans”), garbanzo beans (chickpeas), great northern beans, kidney beans, lima beans (“butter beans”), pinto beans, navy

beans, soybeans, split peas, and lentils. Baked beans may be provided for participants with limited cooking facilities, at the State agency's discretion.

## 2. Restrictions on Authorized Types of Canned Beans

This proposed rule would not authorize the following forms of canned beans:

- Soups;
- With the exception of baked beans, those containing added sugars, fats, meat or oils as purchased;
- Immature varieties of legumes, such as those used in canned green peas, green beans, snap beans, orange beans, and wax beans; or
- Baked beans with meat, e.g., beans and franks.

## 3. Maximum Monthly Substitution Rate

As recommended by the IOM, this proposed rule would allow the substitution of 64 ounces (e.g., four 16-ounce cans) of canned mature beans/peas for 1 pound of dry mature legumes in Food Packages III-VII.

Although not addressed by IOM, the Department proposes to allow the following additional substitutions in Food Package V and VII:

- 1 pound dry and 64 ounces of canned beans/peas (and no peanut butter)

Or

- 2 pounds dry or 128 ounces of canned beans/peas (and no peanut butter)

Or

- 36 ounces of peanut butter (and no beans).

I. Addition of Whole Wheat Bread or other Whole Grains to Food Packages III, IV, V, VII

As recommended by the IOM, this proposal would add whole wheat bread or other whole grains for children and pregnant and breastfeeding women in Food Packages III, IV, V and VII (currently § 246.10(c)(3) through (c)(5), and (c)(7)). This addition responds to recommendations of the DGA 2005 <sup>(12)</sup> to consume at least 3 servings per day of whole grains to reduce the risk of coronary heart disease and type 2 diabetes, to help with body weight maintenance, and to increase intake of dietary fiber.

#### 1. Authorized Whole Grains

This proposed rule would include any bread that conforms to the Food and Drug Administration (FDA) standard of identity for whole grain bread as defined by 21 CFR 136.180 or that meets labeling requirements for making a health claim as a “whole grain food with moderate fat content” as defined by FDA in its December 9, 2003, Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/~dms/flgrain2.html> (e.g., must contain a minimum of 51% whole grains). Proposed allowable substitutions for whole grain bread would include brown rice, bulgur, oatmeal, and whole-grain barley



without added sugars, fats, oils, or salt (i.e., sodium). Under this proposed rule, soft corn or whole wheat tortillas without added fats or oils would be allowed at the State agency's option. Using the minimum requirements and specifications in proposed § 246.10(e)(12), State agencies would determine which types and brands of whole grain products to allow on State food lists.

## 2. Maximum Monthly Allowance

As recommended by the IOM, this proposed rule would allow 2 pounds of whole grain bread or other whole grain options for children in Food Packages III and IV; and 1 pound of whole grain bread or other whole grain options for women in Food Packages III, V and VII.

## J. Milk and Milk Alternatives

As recommended by the IOM, this proposed rule would continue to provide milk in food packages for children and women (currently § 246.10(c)(4) through (c)(7)) as an important and concentrated source of vitamin D and calcium. This proposed rule would also authorize State agencies to provide alternatives for milk for individuals with lactose maldigestion and for those who avoid milk for cultural, religious, or other reasons. To maintain the nutritional content and cost neutrality of the food packages, some alternatives for milk (i.e., calcium-set tofu and cheese) would be allowed in limited amounts.

## 1. Nomenclature

This proposed rule uses terminology for fat-reduced milk products as required by FDA on labeling for milk and milk products (21 CFR 101.62), i.e., “reduced fat” has two percent milk fat, “low fat” has one percent milk fat, and “nonfat” is skim or fat-free. The term “fat-reduced” is used in this proposal to refer to all varieties with two percent or less milk fat.

## 2. Authorized milks

As long as a milk conforms to the FDA standard of identity for milk as defined by 21 CFR Part 131 and meets WIC Federal requirements, it is an authorized milk in Food Packages IV, V, VI, and VII (currently § 246.10(c)(4) through (c)(7)). WIC regulations also require that all authorized milks must be pasteurized and contain at least 400 International Units of vitamin D per quart (100 IU per cup) and 2000 International Units of vitamin A per quart (500 IU per cup).

As recommended by the IOM, under this proposed rule, only whole milk (not less than 3.25% milk fat) is authorized for children less than 2 years of age in Food Package IV (currently § 246.10(c)(4)). For children two years of age and older and women (adolescent and adult) in Food Packages IV, V, VI, and VII (currently § 246.10(c)(4) through (c)(7)), this proposed rule would authorize only milk with no more than 2% milk fat.

### 3. Maximum Monthly Milk Allowances

The current maximum monthly allowances provide about 3.2 cups of milk a day for children and postpartum women and about 3.7 cups a day for pregnant and all breastfeeding women. As recommended by the IOM, this proposed rule would decrease the maximum monthly allowances for milk in all food packages.

Reducing the amount of milk provided through WIC is consistent with recommended limits on saturated fat, total fat, and cholesterol consumption put forth in the DGA 2005 <sup>(12)</sup>. According to the IOM, amounts of milk provided by the WIC food packages need not exceed amounts recommended by DGA 2005 <sup>(12)</sup>. Therefore, this proposed rule would reduce the maximum monthly milk allowances for children 1 through 5 years and postpartum women from 24 quarts to 16 quarts, which would provide 2.1 cups per day. This proposed rule would reduce the maximum monthly milk allowances for pregnant and partially breastfeeding women from 28 to 22 quarts of milk (2.9 cups per day); and would reduce the maximum monthly milk allowances for fully breastfeeding women from 28 quarts to 24 quarts of milk (3.2 cups per day).

#### a. Substitution rates of evaporated milk.

This proposed rule would change the substitution rate of evaporated milk for fluid milk in Food Packages IV, V, VI, and VII (currently § 246.10(c)(4) through (c)(7)). The current substitution rate is 13 fluid ounces of evaporated milk (or 26 fl. oz. reconstituted evaporated milk) per quart (or 32 fl. oz.) of fluid milk. This proposal would increase the substitution rate to 16 fluid ounces of evaporated

milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. This is based on a dilution rate of equal parts evaporated milk and water (i.e., 12 oz. can evaporated milk + 12 oz. water = 24 oz. reconstituted milk) and would ensure that participants issued evaporated milk would receive the same maximum monthly allowance of milk (reconstituted) as those issued fluid milk . The substitution rate is the same for both evaporated whole and evaporated fat reduced milks. When a combination of different milk physical forms (e.g., fluid plus evaporated) is provided, State agencies would have to ensure that the full maximum monthly allowances for milk are issued in Food Packages IV through VII.

b. Substitution rates of dry milks.

This proposed rule would change how the substitution rates of dry milks for fluid milk issued in Food Packages IV, V, VI, and VII (§ 246.10(c)(4) through (c)(7)) are expressed. Currently the rates are stated as:

- 1 pound of nonfat or lowfat dry milk per 5 quarts of fluid whole milk; or
- 1 pound of dry whole milk per 3 quarts of fluid whole milk.

The Department proposes to express the new substitution rates in terms of reconstituted fluid ounce yields of dry milk to make it easier for State agencies to calculate the amount of dry milk to substitute for fluid milk. Although the container sizes commonly available for dry milks vary in weight, the reconstituted yields are consistent with the substitution ratios of dry milk to fluid milk stated

above. For example, a 25.6 oz. box of nonfat dry milk reconstitutes to 8 quarts of fluid milk. This yield is consistent with the 1 pound of nonfat dry milk per 5 quarts of fluid whole milk WIC substitution ratio.

The proposed change will better accommodate the wide range of container sizes for dry milks now on the market and those that may be added in the future. When a combination of different milk physical forms (e.g., fluid plus nonfat dry) is provided, State agencies would have to ensure that the full maximum monthly milk allowances are issued in Food Packages IV-VII.

#### 4. Authorized substitutions for milk (cheese, tofu, soy-based beverage)

As recommended by the IOM to provide more flexibility for WIC State agencies and more variety and choice for WIC participants, this proposed rule would allow cheese to be substituted for milk for children at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 pound of cheese may be substituted for milk. State agencies could authorize, with medical documentation, amounts of cheese that exceed this substitution maximum for children in Food Package IV, up to the maximum allowance for fluid milk, in cases of lactose intolerance or other qualifying conditions.

For women, this proposed rule would allow cheese or calcium-set tofu to be substituted at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this

manner in Food Packages V and VI; however, no more than 1 pound of cheese may be substituted for milk. A maximum of 6 quarts of milk can be substituted in this manner in Food Package VII; therefore, a maximum of two pounds of cheese may be substituted for milk in Food Package VII. State agencies could authorize, with medical documentation, amounts of cheese or calcium-set tofu that exceed these substitution maximums, up to the maximum allowance for fluid milk, in cases of lactose intolerance or other qualifying conditions.

This proposed rule would authorize soy-based beverage to be substituted for milk for women in Food Packages V, VI and VII at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum allowance of milk. Under this proposed rule, soy-based beverage and tofu are not allowed as substitutes for milk for children in Food Package IV without medical documentation. The qualifying conditions may include, but are not limited to, milk allergy, severe lactose maldigestion, and vegan diets. Requiring medical documentation ensures that a child's medical provider is aware that the child may be at nutritional risk when milk is replaced by other foods. State agencies could authorize, with medical documentation, soy-based beverages to be substituted for milk for children in Food Package IV on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted, with medical documentation, for milk for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.

a. Authorized Cheese

This proposed rule would clarify that a cheese that is a blend of authorized WIC cheeses (any combination of domestically produced, made with 100% pasteurized milk, Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, part-skim or whole Mozzarella, pasteurized American processed) is a WIC-eligible food. This proposed rule would clarify that cheeses that are labeled low, free, reduced, less, or light in the nutrients sodium, fat, or cholesterol are WIC-eligible.

b. Authorized Tofu

To be authorized, the tofu must be calcium-set (prepared with only calcium salts, e.g., calcium sulfate), and may not contain added fats, sugars, oils or sodium. Under this proposed rule, tofu is not allowed as a substitute for milk for children in Food Package IV without medical documentation.

c. Authorized Soy-Based Beverages

Section 102 of the Child Nutrition and WIC Reauthorization Act of 2004 (Public Law 108-265) requires that nondairy beverages offered as an alternative to fluid milk in the National School Lunch Program and School Breakfast Program must be nutritionally equivalent to fluid milk and meet nutritional standards set by the

Secretary of Agriculture. FNS believes that it is imperative for WIC and the school nutrition programs to use the same standards for defining allowable soy-based beverages as alternatives to fluid milk. In setting minimum nutritional standards for soy-based beverages, FNS considered the IOM recommendations and Food and Drug Administration (FDA) standards, and examined the nutrient levels found in various types of milk using the Nutrient Database for Dietary Studies.<sup>(20)</sup> IOM recommended allowing as milk alternatives only soy-based beverages that are fortified to contain nutrients in amounts similar to cow's milk. The IOM also recommended minimum levels per cup of 300 mg calcium and 120 International Units (IU) vitamin D. FDA, at 21 CFR Part 131, specifies that if added, milk should provide not less than 2000 IU vitamin A per quart (500 IU per cup) and 400 IU vitamin D per quart (100 mg per cup.) Among the varieties of fluid milk, whole milk (3.25% milkfat) typically provides the lowest levels of several nutrients. Since soy beverage may be allowed as a substitute for milk over a variety of fat content levels, a single, broadly applicable standard is needed. Further, FNS believes that the statutory requirement of Public Law 108-265 for nutritional equivalency takes precedence over the IOM recommendations for WIC. Therefore, whole milk was used as a benchmark for all nutrients except vitamins A and D, which already have Federally-established standards for fortification of fluid milk. The chosen levels of vitamins A and D derive from the milk fortification levels required by the FDA. Based on the above, this rule proposes that authorized soy-based beverages provide, at a minimum, the following nutrients:



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

K. Cereal (for women and children)

1. Nomenclature

This proposed rule would adopt the term “breakfast cereal” as a substitute for the terms “cereal (hot or cold)” and “adult cereal (hot or cold)” currently used in § 246.10(c). FDA regulations (21 CFR 170.3(n)(4)) define breakfast cereals as those including ready-to-eat and instant and regular hot cereals. This term is consistent with USDA’s long-standing interpretation of WIC cereals (hot or cold) as meaning breakfast cereals that are either ready-to-eat or those cereals (e.g., oatmeal, grits, cream of wheat) that require the addition of a liquid (e.g., water or milk) and heating or cooking before being served.

## 2. Authorized Cereals

As recommended by the IOM, this proposal would add new minimum requirements for WIC breakfast cereals in Food Packages III, IV, V, VI, and VII (currently § 246.10(c)(3) through (c)(7)). To address current dietary guidance to increase whole grains and lower saturated fat and cholesterol, proposed authorized WIC breakfast cereals must meet labeling requirements for making a health claim as a “whole grain food with moderate fat content” as defined by FDA in its December 9, 2003, “Health Claim Notification for Whole Grain Foods with Moderate Fat Content” at <http://www.cfsan.fda.gov/~dms/flgrain2.html> (e.g., must contain a minimum of 51% whole grains). In addition, all authorized WIC breakfast cereals must continue to contain a minimum of 28 mg per iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of dry cereal (6 grams per dry ounce). In Food Package III, infant cereal may be substituted for breakfast cereal for children and women.

### L. Eggs

This proposed rule would change the maximum monthly allowance for fresh shell eggs from the current 2 or 2 ½ to 1 dozen fresh shell eggs for children and women in Food Packages IV, V, and VI. This recommendation is consistent with recommendations of the IOM<sup>(8)</sup> and the DGA 2005<sup>(12)</sup> to reduce cholesterol. In

addition, the IOM determined that protein is no longer a priority nutrient for the WIC population. For fully breastfeeding women in Food Package VII, the maximum monthly allowance would be 2 dozen eggs. The quantity of eggs provided by the revised packages is comparable with the average amount of eggs consumed by children who are participating in the WIC Program. <sup>(21)</sup>

This proposed rule would allow the substitution of pasteurized liquid whole eggs, or dried egg mix for fresh shell eggs in these same food packages on an equivalent yield ready to eat versus weight or volume basis to accommodate differences among brands of these egg products. The proposed rule would authorize hard boiled eggs, where readily available for purchase in small quantities, for homeless participants.

#### M. Canned Fish

As recommended by the IOM, this proposed rule would authorize 30 ounces of a variety of canned fish that do not pose a mercury hazard, as identified by federal advisories of the Food and Drug Administration and the U.S. Environmental Protection Agency, <sup>(22)</sup> in Food Package VII for fully breastfeeding women (currently § 246.10(c)(7)). For ease of administration by State agencies, to accommodate participant preferences, and to minimize intake of mercury, this proposed rule would authorize the following varieties of canned fish—light tuna, salmon, and sardines. The Department seeks comments on additional canned fish

to offer in Food Package VII. This proposed rule would clarify that fish packaged in foil bags (“pouches”) are WIC-eligible.

#### N. Juice

This proposed rule would clarify that authorized juices must be 100 percent unsweetened fruit/vegetable juice or blends of these juices, and contain a minimum of 30 milligrams of vitamin C per 100 milliliters of juice. This proposed rule would clarify that juices that are fortified with other nutrients may be allowed at the State agency’s option. This proposed rule would also require that juices be pasteurized.

The Department acknowledges that 100 percent citrus juices (i.e., orange, grapefruit, tangerine and blends of these juices) should naturally contain at least 30 milligrams of vitamin C per 100 milliliters of juice. To ease the administrative burden on State agencies in approving juices, this proposed rule would not require the verification of vitamin C content for 100 percent citrus juices. However, verification of vitamin C content for non-citrus juices would be a requirement.

As recommended by the IOM, this proposed rule would change the maximum monthly allowance of juice for women and children in Food Packages IV, V, VI, and VII (currently § 246.10(c)(4) through (c)(7)). For children in Food Packages III and IV, the proposed maximum monthly allowance of juice is 128 fluid ounces

of single strength juice (4.3 fluid ounces per day). For pregnant and partially breastfeeding women in Food Package V and fully breastfeeding women in Food Package VII, the proposed maximum monthly allowance of juice is 144 fluid ounces (4.8 fluid ounces per day). For postpartum women in Food Package VI, the proposed maximum monthly allowance of juice is 96 fluid ounces (3.2 fluid ounces per day).

In its Report, the IOM states that deleting or reducing the quantity of juice in the WIC food packages helps allow for the inclusion of whole fruits and vegetables while containing food costs. The reduction in the amount of juice provided for children to about 4 ounces per day is consistent with the AAP recommendation for that age group.<sup>(14)</sup> The AAP also notes that juice does not provide any additional nutritional benefit beyond that of whole fruit. The reduced amount of juice for women is consistent with the recommendation of the DGA 2005<sup>(12)</sup> that whole fruits be used for a majority of the total daily amount of fruit.

In Food Packages III, IV, V, VI and VII, this proposed rule would allow the substitution of shelf-stable and frozen concentrated juices for single strength juice. The proposed rule would allow combinations of single strength and concentrated juices provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.

O. Peanut Butter

This proposed rule clarifies that reduced fat peanut butter is an optional alternative for regular peanut butter in Food Packages III, IV, V, VI and VII (currently § 246.10(c)(3) through (c)(7)) provided that it meets the FDA standard of identity for peanut butter as defined by 21 CFR 164.150. That is, it must contain 90 percent peanuts by weight, contain no more than 10 percent by weight of seasonings and stabilizing ingredients, and contain no more than 55 percent of fat by weight.

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

Food Package III (currently § 246.10(c)(3)) was initially designed for women and children with special dietary needs. The IOM recommended that this unique aspect of Food Package III be retained; however, it recommended that infants with qualifying conditions be assigned to this food package to facilitate efficient management and tracking of the benefits and costs of providing supplemental foods to these participants. The IOM also recommended that the foods contained in Food Package III be restrictive only to the extent dictated by the participant's health condition. This rule proposes these recommendations and, in addition, certain technical adjustments found necessary by the Department.

This rule proposes the following changes in Food Package III:

- Adds medically fragile infants to the population served;
- Revises the maximum monthly allowances for WIC formulas;
- Clarifies the purpose and the qualifying conditions that it serves;
- Includes other WIC food(s), when not medically contraindicated, up to the same maximum monthly allowance authorized for Food Packages II, and IV through VII; and
- Clarifies the physical forms of authorized WIC-eligible medical foods.

Over the years the Department has received numerous requests from WIC State agencies, advocates and participants to revise this food package to better meet the needs of the medically fragile. The Department recognizes that this nutritionally vulnerable segment of the nation's population has very special needs and WIC can assist in helping to address many of those nutritional needs. Some participants issued this food package may require a type of formula for which there is no substitute and their health would be seriously jeopardized if they did not receive this food package.

The Department is proposing to revise Food Package III to serve all medically fragile WIC participants under the same food package and to include other supplemental foods when not medically contraindicated. The Department estimates that the current subgroup of participants who have medical conditions to receive Food Package III is only about 1-2 percent of the total WIC caseload. The inclusion of other supplemental foods in this food package would provide

flexibility in accommodating the wide range of different nutritional needs of the participants served by this food package.

#### 1. Categories of Participants Served by Food Package III

Food Package III (currently § 246.10(c)(3)) serves only women and children who have a diagnosed medical condition when the use of conventional foods is precluded, restricted or inadequate to meet their nutritional needs. These medical conditions include, but are not limited to, metabolic disorders, inborn errors of amino acid metabolism, gastrointestinal disorders, malabsorption syndromes and food allergies.

Infants with qualifying medical conditions currently receive either Food Package I, which serves infants 0-3 months of age, or Food Package II for infants 4-12 months of age. These infants have the same diagnosed medical condition(s) cited for women and children who currently receive Food Package III.

The Department is proposing to revise § 246.10(c)(1) through (c)(3) of Program regulations for Food Packages I, II and III in order to serve all medically fragile participants with qualifying conditions, including infants, with Food Package III. The revised title for this food package would be “Food Package III—Participants With Qualifying Conditions”. Under revised Food Package III, infants would receive exempt infant formula and appropriate supplemental foods for the age and feeding option of the infant, when not medically contraindicated; children and



adults would receive WIC formula (WIC-eligible infant formula, exempt infant formula, or WIC-eligible medical food) and appropriate supplemental foods, when not medically contraindicated.

Infants who do not have a qualifying condition to receive exempt infant formula in Food Package III would continue to be served either under Food Package I or II, as deemed appropriate for their age and feeding option. Both Food Packages I and II would continue to authorize a variety of WIC-eligible infant formulas, consistent with Federal WIC regulations, State agency policies and authorization, and infant formula rebate contract agreements with manufacturers.

## 2. Qualifying Conditions under Food Package III

The Department is aware that in the past some State agencies have experienced difficulty in determining which medical conditions qualify under Food Package III. For these reasons, this proposed rule would clarify the types of conditions that would qualify participants as medically fragile participants eligible to receive Food Package III. Food Package III would be reserved for participants who have one or more qualifying conditions and, as a result of the qualifying condition, require a WIC formula (infant formula, exempt infant formula or WIC-eligible medical food) to supplement their nutrition needs as determined by the participant's health care professional who is licensed to write medical prescriptions under State law. The WIC formulas prescribed in this food package provide nutritional support for specific conditions that are clinically serious or

life-threatening and are generally required for long periods of time. The qualifying conditions include but are not limited to premature birth, low birth weight, failure to thrive, inborn errors of metabolism and metabolic disorders, gastrointestinal disorders, malabsorption syndromes, immune system disorders, severe food allergies that require an elemental formula, and life threatening disorders, diseases and medical conditions that impair ingestion, digestion, absorption or the utilization of nutrients that could adversely affect the participant's nutrition status.

### 3. Restricted Uses of Food Package III

Under this proposed rule, Food Package III would not be authorized for infants whose only condition is:

- A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein, or soy protein that does not require the use of an exempt infant formula; or
- A non-specific formula or food intolerance.

Infants with these infant formula intolerances or food allergies would not receive revised Food Package III but instead would receive either revised Food Package I or II based on age and feeding option, as described in section V.B. of this preamble. Food Package I and II have collectively provided infant formulas that are soy-based, lactose-free, or sucrose-free to accommodate most food

intolerances or food allergies. While commercially available infant formulas in the United States may vary by containing different ingredients to address such intolerances and allergies, these infant formulas are still considered to be infant formulas (as opposed to exempt infant formulas) as long as the definition and requirements of § 246.2 are met. Therefore, Food Packages I and II would continue to authorize a variety of infant formulas, consistent with State agency policies and infant formula rebate contract agreements with manufacturers for infants with food intolerances and/or food allergies who do not have qualifying conditions in order to receive exempt infant formulas.

Proposed Food Package III would not be authorized for a child or woman with a non-qualifying condition, such as a food dislike, or food intolerance (i.e. lactose intolerance) or a suspected but unconfirmed allergy (i.e. milk protein allergy). Currently other supplemental foods, such as cheese and lactose-free milk, are available and encouraged to address lactose intolerance. Proposed food packages IV-VII, described in sections V.C. and V.D. of this preamble, include new foods as substitutes or alternatives to milk, such as soy-based beverage and calcium-set tofu, that may provide more flexibility to the State and the participant, may be easier to obtain in retail establishments, and may be more appropriate to meet the nutritional needs of the participants who do not have a qualifying condition. The use of conventional foods when appropriate is important due to the additional nutrients, fiber and other benefits that conventional foods provide. WIC nutrition education supports the importance of obtaining nutrients from foods when

appropriate and that a balanced diet remains the preferred overall source of nutrients.

#### 4. Authorized Foods in Food Package III

Section 246.10(c)(3) of current regulations lists the authorized foods for children and women receiving Food Package III as WIC formula (infant formula, exempt infant formula and WIC-eligible medical foods), cereal and juice. As recommended by the IOM, this proposed rule would expand the WIC food categories offered in Food Package III of WIC formula, cereal and juice by adding milk and milk alternatives, fruits and vegetables, eggs, whole wheat bread, legumes and/or peanut butter, cheese, fish and infant foods, as medically appropriate and prescribed. Exempt infant formula would be the only WIC formula authorized for infants in revised Food Package III. Infant formula, exempt infant formula and WIC-eligible medical foods would be authorized for children and women in revised Food Package III.

#### 5. Authorized WIC Formulas

Current authorized WIC formulas (infant formulas, exempt infant formulas, and WIC-eligible medical foods) are defined in § 246.2 of WIC regulations.

WIC formulas are generally described as follows:

- Infant formulas are food substitutes for human milk for generally healthy, full-term infants;

- Exempt infant formulas are food substitutes for human milk for both pre-term or full-term infants who have a nutritionally-related medical problem; and
- WIC-eligible medical foods are specifically formulated to provide nutritional support for participants with a diagnosed medical condition.

The Department proposes to revise the existing definition for “WIC-eligible medical foods” in § 246.2 to clarify that medical foods are designed for children (12 months and older) and adults. Infants served under Food Package III cannot receive WIC-eligible medical foods.

#### 6. Products Not Authorized as WIC Formulas

Products not authorized as WIC formulas or foods in Food Package III or any other food package include, but are not limited to:

- Medicines or drugs, as defined and regulated under the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), as amended;
- Parenteral or intravenous nutrition products;
- Enzymes;
- Flavoring and thickening agents;
- Oral rehydration fluids or electrolyte solutions;
- Sports or breakfast drinks; and

- Over-the-counter weight control/loss products.

In addition, all apparatus or devices (e.g., feeding tubes, bags and pumps) designed to administer WIC formulas are not WIC-allowable costs.

## 7. Physical Forms of WIC Formulas.

### a. Current Physical Forms

WIC regulations for Food Packages I, II and III (§ 246.10(c)(1) through (c)(3)) identify the three physical forms of WIC formulas as concentrated liquid, powder and ready-to-feed (RTF) in liquid form.

### b. Ready to Feed in Other Than Liquid Forms

New formulas and medical foods have been developed due to advancements in technology and these products do not strictly conform to the current physical form descriptions. While different forms of infant formula and exempt infant formula could be developed, it is anticipated that the largest variety of physical forms will be within the WIC-eligible medical foods category. The forms of WIC-eligible medical foods currently available include, but are not limited to, ready-to-feed bars, ready-to-eat puddings, and gels and capsules specifically designed for inborn errors of metabolism. The Department has determined that some of these products meet the minimum Federal WIC requirements for a WIC-eligible medical food, however the technical guidance regarding how to determine

maximum monthly allowances is being considered in light of the IOM report recommendations that powder and ready-to-feed forms may be substituted for liquid concentrate on an equivalent nutritional basis. Inclusion of these additional forms of WIC-eligible medical foods into Federal WIC regulations and their appropriate maximum monthly allowances would increase flexibility for State agencies to help meet the nutritional needs of the medically fragile participant. FNS is seeking comments on the appropriate equivalent standard to be used (e.g., protein equivalent, kilocalorie equivalent, volumetric or weight equivalent, number of serving equivalents, and/or other type of equivalent) to determine maximum monthly allowances for WIC-eligible medical foods in these new physical forms (e.g., bars, gels, and capsules) for those medically fragile participants served by Food Package III. Comments are also requested regarding how to determine maximum monthly allowances for WIC-eligible medical foods prescribed to children and women that are only available in ready-to-feed forms such as capsules or gels and therefore the liquid concentrate equivalent does not exist.

c. Restrictions for Issuing RTF Forms of WIC Formulas

Current regulations (§ 246.10(c)(1)(ii)) governing Food Packages I and II restrict the issuance of WIC formulas in RTF liquid form to only the following conditions:

- The participant's household has an unsanitary or restricted water supply or poor refrigeration.
- The participant or person caring for the participant may have difficulty in correctly diluting concentrated forms or reconstituting powder forms, or the WIC formula is only available in RTF form.

This proposed rule would continue to include these same restrictions for issuing a WIC formula in a RTF form issued under revised Food Package III. However, recognizing the needs of participants with qualifying conditions, this proposed rule would expand upon these restrictions to also authorize a RTF form in Food Package III when the product:

- Better accommodates the participant's medical condition (e.g., RTF semi-solids for swallowing disorders and RTF forms to reduce the possibility of food contamination and risk of infection in cases of immune system disorders); or
- Improves the participant's compliance in consuming the prescribed formula (e.g., improved taste of RTF solid bars versus RTF liquid forms of WIC-eligible medical foods).

This proposed rule would continue to authorize the WIC local agency competent professional authority, in consultation with the participant's attending health care provider when appropriate, to determine and document if a WIC formula in a RTF form is required.



## 8. Maximum Monthly Allowances for Food Package III

As recommended by the IOM, this proposed rule would revise Food Package III to serve medically fragile women, infants and children with qualifying conditions. These participants would receive up to the same maximum monthly amounts of supplemental foods unless medically contraindicated, as those same participant categories (infants, children, pregnant or partially breastfeeding women, non-breastfeeding postpartum women, and fully breastfeeding women) who do not have a qualifying condition.

### a. Infants, ages birth through 11 months

Infants with a qualifying condition would receive exempt infant formula and infant foods in up to the same maximum monthly allowances as infants of the same age and feeding option with no qualifying condition who are issued Food Packages I or II unless medically contraindicated.

### b. Children, ages 1 year through 4 years

A child with a qualifying condition would receive up to 455 fluid ounces in liquid concentrate form of WIC Formula (infant formula, exempt infant formula, or WIC-eligible medical food). Formulas in other forms, such as powder or RTF could be substituted by providing nutritional equivalent amounts. Unless medically contraindicated, the participant may receive any or all of the following

supplemental foods in up to the maximum monthly amounts with medical documentation—milk and milk alternatives, juice, breakfast cereal (hot or cold), eggs, fruits and vegetables, whole wheat bread or other whole grains, legumes, or peanut butter.

c. Pregnant or Partially Breastfeeding

A pregnant, or partially breastfeeding woman, whose participating infant receives formula in amounts that do not exceed the maximum allowances provided by Food Packages I or II for partially breastfeeding infants, as appropriate for the age of the infant, and who has a documented qualifying condition would receive up to 455 fluid ounces in liquid concentrate form of WIC Formula (infant formula, exempt infant formula, or WIC-eligible medical food). Formulas in other forms, such as powder or RTF could be substituted by providing nutritional equivalent amounts. Unless medically contraindicated, the participant may receive any or all of the following supplemental foods up to the maximum monthly amounts with medical documentation—milk and milk alternatives, juice, breakfast cereal (hot or cold), eggs, fruits and vegetables, whole wheat bread or other whole grains, legumes, and peanut butter.

d. Postpartum

A non-breastfeeding postpartum woman (up to 6 months postpartum) or a breastfeeding postpartum woman (up to 6 months postpartum) whose partially breastfed infant receives formula in amounts that exceed the maximum

allowances provided by Food Packages I or II for partially breastfeeding infants, as appropriate for the age of the infant, and who has a documented qualifying condition would receive up to 455 fluid ounces in liquid concentrate form of WIC Formula (infant formula, exempt infant formula or WIC-eligible medical food). Formulas in other forms, such as powder or RTF, could be substituted by providing nutritional equivalent amounts. Unless medically contraindicated, the participant may receive any or all of the following supplemental foods up to the maximum monthly amounts with medical documentation—milk and milk alternatives, juice, breakfast cereal (hot or cold), eggs, fruits and vegetables, legumes, or peanut butter.

e. Fully Breastfeeding

A fully breastfeeding woman (up to 1 year postpartum) whose infant does not receive formula from WIC; all breastfeeding women during the first month postpartum; women pregnant with two or more fetuses; and women partially breastfeeding multiple infants (up to 1 year postpartum) with a qualifying condition would receive up to 455 fluid ounces in liquid concentrate form of WIC Formula (infant formula, exempt infant formula, or WIC-eligible medical food). Formulas in other forms, such as powder or RTF, could be substituted by providing nutritional equivalent amounts. Unless medically contraindicated, the participant may receive any or all of the following supplemental foods up to the maximum monthly amounts with medical documentation—milk and milk alternatives, juice, breakfast cereal (hot or cold), cheese, eggs, fruits and

vegetables, whole wheat bread or other whole grains, fish (canned), legumes, and peanut butter. Women fully breastfeeding multiple infants (up to 1 year postpartum) with a qualifying condition would be prescribed 1.5 times the maximum amounts of supplemental foods provided by Food Package III with medical documentation.

The Department recognizes that the types of qualifying conditions warranting Food Package III are varied and can impose different dietary restrictions on participants. For example, the presence of an inborn error of amino acid metabolism, such as phenylketonuria, known as PKU, would severely limit the types of traditional foods a participant could have, especially those high in protein. For these participants, the maximum monthly allowances of a WIC formula may be warranted to meet their special protein needs, but some of the food categories of the other allowable supplemental foods (e.g., eggs, legumes and fish) may be medically prohibited.

The combination of WIC food options made available under revised Food Package III would provide flexibility in accommodating the wide range of different nutritional needs of the participants served by this food package.

#### 9. Coordination with Other Programs That Provide or Reimburse for Formulas

This proposal would require WIC State agencies to coordinate with other Federal, State, or local government agencies or with private agencies that operate programs that also provide or reimburse, or could provide or reimburse, for

exempt infant formula and WIC-eligible medical food benefits that may be authorized by WIC State agencies.

Such coordination recognizes that WIC participants could fully participate in and benefit from other assistance programs. At a minimum, WIC State agencies would be required to coordinate with the Medicaid Program regarding the provision of exempt infant formulas and WIC-eligible medical foods prescribed for WIC participants who are also Medicaid recipients. The WIC State agency would be responsible for providing up to the maximum amount of exempt infant formulas and WIC-eligible medical foods under Food Package III in situations where reimbursement is not provided by another entity.

In coordinating with programs on the provision of WIC-authorized exempt infant formulas and WIC-eligible medical foods, the Department strongly encourages WIC State agencies to:

- Become knowledgeable of the participant eligibility criteria for receiving exempt infant formula and WIC-eligible medical foods benefits from other programs;
- Implement a formula agreement or memorandum of understanding with these other programs to share the responsibility of meeting the exempt infant formula and WIC-eligible medical foods need of mutual participants;

- Establish policies and procedures for issuing exempt infant formulas and WIC-eligible medical foods to WIC participants who are able to meet any portion of their exempt infant formula and WIC-eligible medical foods needs through these other programs; and
- Assist WIC participants in quickly obtaining from the other programs any exempt infant formula and WIC-eligible medical foods needs beyond the maximum monthly allowances that may be needed to meet the amount prescribed.

#### 10. Infant Cereal in Food Package III

Longstanding policy has allowed infant cereal to be substituted for hot or cold cereal intended for children and adults in Food Packages III whenever infant cereal was needed to better meet participants' nutritional needs due to qualifying conditions. However, this provision was never incorporated into regulatory language for these food packages.

The iron content of infant cereal is higher and in a form that is better absorbed than the iron in adult cereal. In addition, infant cereal has a finer texture than adult cereal for easier swallowing. Therefore, women and children who have increased iron requirements, developmental delays, or swallowing disorders may benefit from receiving infant cereal in lieu of adult cereal.

This rule proposes to authorize only in Food Package III the substitution of 32 dry ounces of infant cereal for 36 dry ounces of adult cereal for children and women when the WIC competent professional authority or the supporting medical prescription documents that this provision is necessary. The Department believes that the vast majority of children and women who would require this cereal substitution would be served in Food Package III rather than the other food packages.

#### Q. Medical Documentation and Supervision Requirements for Food Packages I through VII

##### 1. Current Requirements

Federal WIC regulations at § 246.10(c)(1)(iii)(A) through (c)(1)(iii)(D) require medical documentation for the issuance of any contract brand infant formula that does not meet the requirements of an iron fortified infant formula; any non-contract brand infant formula; any exempt infant formula; or any WIC-eligible medical food. The medical documentation is intended to verify that the participant has a medical condition that dictates the use of a WIC formula (infant formula, exempt infant formula or WIC-eligible medical food). The current medical documentation technical requirements (§ 246.10(c)(1)(v)(B)) are:

- The brand name of the WIC formula prescribed;
- Medical diagnosis warranting the WIC formula;

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

Medical documentation may be provided as an original written document, electronically, by facsimile or by telephone to the competent professional authority who must promptly document the information. However, the receipt of medical documentation by telephone may only be used when absolutely necessary on an individual participant basis to prevent undue hardship to a participant or to prevent a delay in the provision of infant formula that would place the participant at increased nutritional risk. Section 246.10(c)(1)(v)(B) of current WIC regulations requires that this information be documented in writing and kept on file at the WIC local clinic. Therefore, receipt of medical documentation via the telephone must be followed by written documentation.

## 2. Proposed Requirements

This proposed rule would continue to require medical documentation for any contract brand infant formula that does not meet the requirements of an infant formula as specified in Table 4 of § 246.10(e)(12) of the proposed rule, any non-contract brand infant formula, any exempt infant formula, or any WIC-eligible medical food. In addition, medical documentation would be required for certain milk alternatives for children and women as described in section V.J. of this



preamble and for any supplemental foods authorized in proposed Food Package III for participant's with certain qualifying conditions as described in section V.P. of this preamble. In addition to retaining all of the current medical documentation requirements, this proposed rule would add the following requirements to medical documentation:

- Contact information for the participant's healthcare provider who makes the medical determination;
- Date of medical determination;
- Name of specific supplemental food(s) to be prescribed;
- Amount prescribed per day;
- Medical determination of a qualifying condition which warrants the issuance of the specific supplemental food(s); and
- Length of time the specific supplemental food(s) is medically required.

All required medical documentation necessary for the issuance of supplemental foods including WIC formulas would continue to be received as an original written document, an electronic document, or received by facsimile or telephone and kept on file. This proposed rule would broaden the file requirement to allow electronic medical documentation files.

Medical documentation requirements for specific supplemental foods that do not usually require a prescription in order to obtain the food(s) are established to ensure that the participant's healthcare professional, licensed in the State to write

prescriptions, has determined that the supplemental foods are not medically contraindicated by the participant's condition.

### 3. Roles of the State-licensed Health Care Provider and WIC Competent Professional

Due to the nature of the health conditions of participants who would receive Food Package III, close medical supervision is essential for each participant's overall dietary management. The Department considers it appropriate that the responsibility for this close medical supervision remain with the participant's health care provider. This proposed rule would consider it the responsibility of the WIC competent professional authority to ensure that only the amounts of WIC formula and supplemental foods up to the regulatory maximum amounts prescribed by the participant's health care provider are issued in the participant's food package.

### 4. State Agency Guidance to Local Agencies

The Department encourages State agencies to develop guidance for their local agencies and clinic sites, including but not limited to guidance in the State's procedure manual, to use in assisting the participant to obtain the required medical documentation for receiving Food Package III or the milk alternatives for children and women in Food Packages IV-VII and for health care professionals in local communities. Such guidance should assist local agencies in identifying and understanding:

- Qualifying conditions;
- Maximum monthly allowances of WIC formula (meaning infant formula, exempt infant formula and WIC-eligible medical foods) and specific supplemental food(s) authorized; and
- Related State agency policies and procedures for issuing WIC formulas and specific supplemental foods(s) that require medical documentation.

State agencies are encouraged to develop a standardized form for health care professionals to use in prescribing Food Package III to help ensure that the WIC local clinics obtain the required medical documentation.

#### R. Flexibility and Variety

As recommended by the IOM, WIC State agencies are encouraged to allow as much variety and choice from the proposed authorized foods as is feasible considering cost constraints and availability. Providing more variety and choice will facilitate the tailoring of food packages to specific situations, especially for different ethnic or cultural groups.

This rule proposes that State agencies make available to participants at least two fruits and two vegetables from the category of fruits and vegetables (fresh or processed) in each authorized food package. However, it is the Department's expectation that more than two varieties each of fruits and vegetables be authorized by State agencies and encourages States to offer participants the

widest variety of fruit and vegetable options practicable. This rule also proposes that State agencies make available to participants more than one food type from each WIC food category in each authorized food package, except for the categories of peanut butter and eggs.

#### S. Cultural Food Package Proposals

The IOM was charged with considering the cultural needs of WIC participants and its recommendations for revisions to the WIC food packages reflect those considerations. The IOM's recommendations, as put forth in this proposed rule, include allowing participants a broad selection of fruits and vegetables, tofu and soy-based beverages as substitutes for milk, participant choice for whole grains (including tortillas), and salmon and sardines as substitutions for tuna.

IOM's recommendations, as largely put forth in this proposed rule, include those foods that State agencies and participants have requested over the years to accommodate cultural needs of participants. In addition, the IOM recommendations reflect those put forth in NWA's Position Paper — "NWA WIC Culturally Sensitive Food Prescription Recommendations." <sup>(2)</sup> Developing, reviewing, and analyzing cultural food package proposals is a time consuming process for WIC State agencies and the Department. Because the increased variety and choice in the supplemental foods proposed in this rule will provide State agencies increased flexibility in prescribing culturally appropriate packages

for diverse groups, the Department proposes to no longer consider WIC State agency proposals for cultural accommodations. While we acknowledge that the future demographics of WIC participants may change, WIC is a supplemental program, and is not intended to provide all of the foods that may meet cultural food preferences. Future reviews of the WIC food packages by the Department will be used to determine the need for additional cultural accommodations.

## T. General Provisions that Affect All WIC Food Packages

### 1. State Authority to Determine Brands

This rule would clarify that State agencies have the authority to establish additional criteria for WIC-authorized foods that exceed Federal requirements.

These State criteria could address, but not be limited to:

- Other nutritional standards;
- Competitive cost;
- State-wide availability; and
- Participant appeal.

### 2. Nutrition Tailoring

Nutrition tailoring is a process of modifying the standard food package to better meet the supplemental nutrition needs of participants. Nutrition tailoring entails making changes or substitutions to food types (e.g., dry beans vs. peanut butter), physical food forms (e.g. dry milk vs. fluid milk), and to quantities of foods.

Current FNS policy allows both categorical and individual nutrition tailoring of WIC food packages. Individual nutrition tailoring is based on the Competent Professional Authority's assessment of the participant's supplemental nutrition needs. Categorical nutrition tailoring for participant groups or subgroups with similar supplemental nutrition needs is based on scientific nutrition rationale and State established policies.

According to the IOM, the proposed revised food packages have the potential to address current nutrient inadequacies and excesses; discrepancies between dietary intake and dietary guidance; and current and future health-related problems in WIC's target population. The IOM recommends that the revised food packages be provided to each participant in full, except to the extent that the packages are tailored to the needs of individual WIC participants. Therefore, this proposed rule would prohibit categorical nutrition tailoring, but continue to allow individual nutrition tailoring based on the Competent Professional Authority's assessment of a participant's supplemental nutrition needs.

Provisions of less than the maximum monthly allowances of supplemental foods to an individual WIC participant would be appropriate when:

- Medically or nutritionally warranted (e.g., to eliminate a food due to a food allergy);
- A participant refuses or cannot use the supplemental foods; or

- The quantities necessary to supplement another program's contribution to fill a medical prescription would be less than the maximum monthly allowances.

Consistent with current FNS policy, reductions in amounts of supplemental foods could not be made for cost-savings, administrative convenience, caseload management, or to control vendor abuse. However, State agencies could continue to make administrative adjustments for economic purposes. Acceptable administrative adjustments decrease cost while maintaining the nutrition integrity of the food packages and include such decisions as eliminating expensive brands, packaging or physical forms of WIC supplemental foods.

### 3. Homeless Participants

This proposal clarifies that State agencies would continue to have the authority to make food package adjustments to better accommodate homeless participants.

### 4. Individual Use by Participants

The WIC food packages are individual food prescriptions that, in order to have the full effect on improving a participant's nutritional status, are intended to be consumed only by the participant and not by other family members.

## 5. Settings for Participant use of Supplemental Foods

Under this proposal, State or local agencies would have to advise participants that the supplemental foods issued are only for their personal use. Supplemental foods would not be authorized for participant use while hospitalized on an in-patient basis. In addition, consistent with § 246.7(n)(1)(i)(B), supplemental foods would not be authorized for use in the preparation of meals served in a communal food service. This restriction would not preclude the provision or use of supplemental foods for an individual participant in a:

- Non-residential setting (e.g., child care facility, family day care home, school, or other educational program);
- Homeless facility; or
- At the State agency's discretion, a residential institution (e.g., home for pregnant teens, prison, or residential drug treatment center) that meets the requirements currently set forth in § 246.7(n)(1) and (n)(2).

## U. Implementation of Revised Food Packages

The proposed revisions to the WIC food packages will result in substantial changes to all aspects of program operations including management information systems, nutrition education and counseling, vendor authorization, training and management, and, breastfeeding promotion and support. The Department seeks



comments from State agencies on the type and scope of administrative burden that may be associated with implementing the provisions in this proposed rule.

In its report, the IOM identified certain proposed changes that were so significant that it recommended pilot testing or limited application of the changes before full-scale implementation by all State agencies. As such, the Department seeks comments on the following proposed implementation plan that is designed to address the IOM recommendation for testing of certain provisions while allowing State agencies sufficient time and broad flexibility to implement the majority of the food packages.

1. Pregnant Women – The most significant changes to the food package for pregnant women include the addition of the \$8.00 cash value voucher for fresh fruits and vegetables and whole wheat bread (or other whole grain options). Also, pregnant women may receive soy-based beverage or tofu in addition to cheese as a substitute for milk. The Department is proposing a one-year implementation timeframe for these changes.

2. Postpartum Women - The primary changes to the food package for postpartum women include the addition of the \$8.00 cash value voucher for fresh fruits and vegetables and the option to receive soy-based beverage or tofu in addition to cheese as a substitute for milk. The Department is proposing a one-year implementation timeframe for these changes.

3. Breastfeeding Women – The proposed food package changes subdivide breastfeeding women as either fully breastfeeding or partially breastfeeding. For fully and partially breastfeeding women, the most substantial food package changes include the addition of the \$8.00 cash value voucher for fresh fruits and vegetables and whole wheat bread (or other whole grain options). Also, fully and partially breastfeeding women may receive soy-based beverage or tofu in addition to cheese as a substitute for milk. Recognizing that the “fully breastfeeding woman” is likely to be the same individual who under the current food package system receives Food Package VII, the enhanced breastfeeding package, the Department believes that a one-year implementation timeframe for these changes is appropriate.

For partially breastfeeding women, the IOM recommends changes that strengthen and support breastfeeding as the optimal infant feeding choice and that support WIC’s breastfeeding promotion efforts. However, the IOM was concerned about the impact of the food package changes that support and promote breastfeeding on the mother/infant dyad, particularly not allowing partially breastfeeding status during the infant’s first month of life. While there is empirical evidence that shows early supplementation with infant formula is associated with shorter duration of breastfeeding, particularly exclusive breastfeeding, some mothers who might otherwise try breastfeeding may choose formula feeding to be sure they can obtain formula from WIC if they run into

breastfeeding difficulties. Recognizing the potential impacts associated with proposed changes to the partially breastfeeding woman's package, the Department is proposing to analyze and assess the proposed changes before proceeding to full implementation. The Department believes that an experimental design with random assignment of mother-infant dyads is impractical. Therefore, the Department proposes to limit to not more than 4 sites within up to eight State agencies (32 total local sites) the ability to implement the partially breastfeeding food package changes. After the Department has had an opportunity to examine the effects of the revised changes on the initiation and duration of breastfeeding (based on a comparison of the experiences in the test sites to comparison sites in the selected State agencies), the Department will determine when all State agencies can implement the revised partially breastfeeding women's food package. The State agencies will be selected based on willingness and ability to cooperate with evaluation data collection and design protocols (including identification of appropriate comparison sites for the 4 test sites within the State), past breastfeeding rates in the State (the Department proposes to seek a range of high, medium and low past breastfeeding rates), adequacy of the infrastructure in place to provide the necessary support to breastfeeding mothers (the Department proposes to seek both "best case" and "average case" levels of infrastructure), ability of the management information system to provide requested data on the impact of the food package changes, and diversity of the population to receive the new food package.

4. Infants - The proposed food package changes subdivide infants as fully formula fed, fully breastfed or partially breastfed. In addition, the food packages for fully formula fed infants are designated as birth through 3 months; 4 through 5 months; and 6 through 11 months. The food packages for partially breastfed infants are designated as 1 through 3 months, 4 through 5 months, and 6 through 11 months. The infant food packages for fully breastfed infants are designated as birth through 5 months, and 6 through 11 months.

For the fully formula fed infant, the amount of infant formula has been reduced for the 6 through 11 month old. This reduction has been offset by the addition of infant food fruits and vegetables. However, the amount of infant formula has been increased for the 4 through 5 month old. Also, juice has been eliminated. The Department proposes a six-month timeframe to implement the elimination of juice and a one-year timeframe to implement the remaining changes in the fully formula fed package.

For the partially breastfed infant category, the most significant change is the inability to receive any WIC infant formula during the first month following birth. In the first month after birth there are only two feeding options — fully formula fed or fully breastfed. The other changes include a reduction of the amount of infant formula that can be received from WIC, elimination of juice and the addition of infant food fruits and vegetables. As noted above, the IOM was concerned about the impact of the recommended food package changes on

the breastfeeding mother/infant dyad. Therefore, the Department proposes to limit the ability to implement the partially breastfed infant food packages changes to not more than 32 sites within up to eight State agencies selected to implement the partially breastfeeding woman's food package. After the Department has had an opportunity to examine the effects of the revised changes on the initiation and duration of breastfeeding (based on a comparison of the experiences in the test sites to comparison sites in the eight State agencies), the Department will determine when all State agencies can implement the revised partially breastfed infant food package. The State agencies will be selected based on willingness and ability to cooperate with evaluation data collection and design protocols (including identification of appropriate comparison sites for the test sites), past breastfeeding rates in the State (the Department proposes to seek a range of high, medium and low past breastfeeding rates), adequacy of the infrastructure in place to provide the necessary support to breastfeeding mothers (the Department proposes to seek both "best case" and "average case" levels of infrastructure), ability of the management information system to provide requested data on the impact of the food package changes, and diversity of the population to receive the new food package.

For the fully breastfed infant, the most significant change is the addition of infant fruits and vegetables, and infant meats. The Department believes that a one-year implementation timeframe for these changes is appropriate.

5. Children – The most significant changes to the child’s food package include the addition of the \$6.00 cash value voucher for fresh fruits and vegetables and whole wheat bread (or other whole grain options), and the reductions in the amounts of milk and juice. Also, children 2 years of age and older may no longer receive whole milk. Cheese remains a substitute for milk. The Department is proposing a one-year implementation timeframe for these changes.

6. Participants with Qualifying Conditions – The most significant changes to the food package that address the dietary needs of participants’ with certain qualifying conditions is the addition of other supplemental food(s), when not medically contraindicated, and serving all medically fragile participants under one food package (Food Package III). Women, infants and children with qualifying conditions would receive the same maximum monthly amounts of supplemental foods, with medical documentation, as those same participant categories that do not have a qualifying condition. The Department is proposing a one-year implementation timeframe for these changes.

The following chart summarizes the proposed implementation timeframes on which the Department is seeking comments. As noted, in most instances State agencies will have one year to implement the new food packages. During the one-year phase-in period, State agencies would be required to issue food benefits based on either the new food packages or current food packages but could not combine the two. For example, a State agency could not add whole wheat bread

and fresh fruits and vegetables to the current foods and quantities available under the children’s food package. The State agency may, however, phase-in the new food packages on a participant category basis. To minimize participant and vendor confusion, the Department proposes that once the State agency begins issuing the new food packages, it must be done on a Statewide basis.

**Proposed Timelines for Implementation of Food Package Changes**

Food Package Category	Who May Implement	Timeframe for Implementation
Pregnant Women	All State Agencies	One Year from Publication of Interim Rule
Postpartum Women	All State Agencies	One Year from Publication of Interim Rule
Fully Breastfeeding Women	All State Agencies	One Year from Publication of Interim Rule
Partially Breastfeeding Women	Not More Than 32 sites (4 sites within each of up to 8 State agencies)	One Year from Publication of Interim Rule (The selected sites will have authority to issue the revised packages for no more than 3 years.)
Fully Formula fed Infants	All State Agencies	One Year from Publication of Interim Rule
Partially Breastfed Infants	The sites selected for the Partially Breastfeeding Women’s Package	One Year from Publication of Interim Rule (The selected sites will have authority to issue the revised packages for no more than 3 years.)
Fully Breastfed Infants	All State Agencies	One Year from Publication of Interim Rule
Juice Elimination from Infant Food Packages	All State Agencies	Six months from Publication of Interim Rule
Children	All State Agencies	One Year from Publication of Interim Rule
Participants with Certain Medical Conditions (Women, Infants and Children)	All State Agencies	One Year from Publication of Interim Rule

## VI. Endnotes

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(3) Institute of Medicine, National Academy of Sciences. "WIC Food Packages: Time for a Change," 2005. Available at Internet site:

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(6) Institute of Medicine, National Academy of Sciences, 2000. Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids. Washington, DC: National Academy Press.

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(11) Institute of Medicine, National Academy of Sciences, 2000. "Dietary Reference Intakes: Applications in Dietary Assessment." National Academy Press.

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

(13) Institute of Medicine, National Academy of Sciences, 2001. "Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc." National Academy Press.

(14) American Academy of Pediatrics, Committee on Nutrition. "The use and misuse of fruit juice in pediatrics." "Pediatrics" 107(5):1210-1213, May 2001. Available at Internet site: <http://www.aap.org/policy/re0047.html>.

(15) American Academy of Pediatrics, Committee on Nutrition, 2004. "Pediatric Nutrition Handbook." 5<sup>th</sup> edition.

- (16) U. S. Department of Health and Human Services, “Healthy People 2010: Understanding and Improving Health, 2<sup>nd</sup> edition.” U.S. Government Printing Office. Available at Internet site: <http://www.healthypeople.gov/document>
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<http://aappolicy.aappublications.org/cgi/content/full/pediatrics;115/2/496>.
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## **VII. Procedural Matters**

### **Executive Order 12866**

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

### **Regulatory Impact Analysis**

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

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

Benefits. Benefits of this rule include bringing the WIC food packages in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics, better promoting and supporting the establishment of successful long-term breastfeeding, providing WIC participants with a wider variety of food, providing WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences, and serving all participants with certain medical conditions under one food package to facilitate efficient management of medically fragile participants.

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

### **Regulatory Flexibility Act**

This proposed rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C 601-612). Pursuant to that review, Eric M. Bost, Under Secretary, Food, Nutrition and Consumer Services, has

determined that this rule will not have a significant economic impact on a substantial number of small entities. State and local agencies and WIC recipients will be most affected by the rule and WIC authorized vendors and the food industry may be indirectly affected. The proposed rule would provide State and local agencies with increased flexibility in meeting food package requirements for the Program. Vendors and the food industry would realize increased sales of some foods and decreases in other foods, with an overall neutral effect on sales nationally.

Although not required by the Regulatory Flexibility Act, FNS has prepared an Initial Regulatory Flexibility Analysis (IRFA) describing the impact of this proposed rule on small entities. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadline for comments as provided in the Dates section. Additional analysis of the regulatory flexibility considerations of this proposed rule may be found in the Regulatory Impact Analysis section of this preamble and the cited RIA itself.

#### Need for, and objectives of, the proposed rule

This proposed rule would revise regulations governing the WIC food packages to change the maximum monthly allowances and minimum requirements for certain supplemental foods, and add new foods such as fruits, vegetables and whole

grains. The revisions largely reflect recommendations made by the Institute of Medicine of the National Academies in its Report “WIC Food Packages: Time for a Change”. These revisions would bring the WIC food packages in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics, better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of food, and provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences.

Description and Estimate of Number of Small Entities to Which the Proposed Rule Would Apply

This proposed rule would have a direct application only to WIC State agencies with respect to their selection of foods to be included on their food lists. As a result, vendors and the food industry would realize increased sales of some foods and decreases in other foods, with an overall neutral effect on sales nationally.

The rule may have an indirect economic affect on certain small businesses because they may have to carry a larger variety of certain foods to be eligible for authorization as a WIC vendor. Currently, approximately 45,000 stores are authorized to accept WIC food instruments, some of which are small businesses. With the high degree of State flexibility allowable under this proposed rule, small vendors will be impacted differently in each State depending upon how that State

chooses to meet the proposed requirements. It is therefore not feasible to accurately estimate the rule's impact on small vendors. Since neither FNS nor the State agencies regulate food producers under the WIC program, it is not known how many small entities within that industry may be indirectly affected by the proposed rule. However, such entities are encouraged to comment on this IRFA and the proposed rule and their comments will be considered in the development of the final rule.

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

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

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



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

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

FNS has, however, modified the new food provision in an effort to mitigate the impact on small entities. Currently, State agencies must establish minimum requirements for the variety and quantity of foods that a vendor must stock in order to receive WIC Program authorization. This proposal would add 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 would 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 proposal allows canned, frozen and dried fruits and vegetables to be substituted for fresh produce.

#### Federal Rules that may Duplicate, Overlap, or Conflict with the Proposed Rule

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

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

Title II of the UMRA establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, 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 to State, local, or tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and

consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

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

#### **Executive Order 12372**

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) is listed in the Catalog of Federal Domestic Assistance under No. 10.557. For reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related Notice (48 FR 29114, June 24, 1983), this Program is included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

#### **Federalism Summary Impact Statement**

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for

inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2) (B) of Executive Order 13132.

#### Prior Consultation with WIC State and Local Agency Officials

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

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

- Publishing an advanced notice of public rulemaking (ANPRM) in 2003 to solicit comments to determine if the WIC food packages should be revised to better improve the nutritional intake, health and development of participants;

and, if so, what specific changes should be made to the food packages. In response to the ANPRM, FNS received 195 total comments;

- Commissioning the National Academies' Institute of Medicine (IOM) to independently review the WIC Food Packages. IOM solicited public comment on revisions to the WIC food packages, via 3 public hearings, letters and e-mail, throughout its 22-month study period. IOM considered these comments, as well as comments the Department received in response to the ANPRM, in developing recommendations to revise the WIC food packages. IOM published its reports of these recommendations on April 27, 2005: "WIC Food Packages: Time for a Change."<sup>(3)</sup> This proposed rule incorporates IOM's recommendations;
- Holding nine public outreach sessions across the nation as part of FNS' development of its 2004 reauthorization proposals. Interested parties, including WIC State and local staff, offered oral testimony and written statements on the WIC food packages as well as on a variety of other WIC issues;
- Hosting annual meetings (1977-present) of the National Advisory Council on Maternal, Infant and Fetal Nutrition that includes WIC staff as members of the Council; the Council develops recommendations for FNS on how to improve

operations of the WIC and Commodity Supplemental Food Programs, including aspects related to the authorized foods and food packages; and

- Consulting and collaborating with NWA on a wide variety of WIC issues, including those related to the WIC food packages (1983-present). NWA is a non-profit organization that was founded in 1983 by State and local agencies that administer the WIC Program. As of June 1, 2005, its paid membership included 73 of the 89 WIC State agencies, 675 local agencies, 4 State WIC Associations, and 18 sustaining members (i.e., for-profit and non-profit businesses or organizations). Functioning as a coalition of WIC agencies, NWA is dedicated to maximizing WIC resources through effective management practices. NWA also serves in a leadership role for WIC agencies by developing position papers on issues of concern to the WIC community.

#### Nature of Concerns and the Need to Issue this Rule

- Congress has requested a WIC food package rule that includes fruits and vegetables and allows for cultural food accommodations. Starting in fiscal year 2001, Congress has directed the Department, in language accompanying WIC appropriations bills, to move expeditiously to publish a proposed food package rule for public comment;
- The National Advisory Council on Maternal, Infant, and Fetal Nutrition, in its 1992, 1996 and 2002 Reports to Congress, recommended better

accommodation of the nutritional and cultural needs of WIC participants through the WIC food packages; and

- In 1999, NWA (then the National Association of WIC Directors (NAWD)) published a position paper entitled “NAWD WIC Food Prescription Recommendations” <sup>(1)</sup> and in 2003, NWA published a position paper entitled “NWA WIC Culturally Sensitive Food Prescription Recommendations.” <sup>(2)</sup> NWA’s major recommendations in these two reports were to reframe the WIC food packages to be consistent with the Dietary Guidelines for Americans and allow State agencies flexibility to accommodate cultural eating patterns.

Based upon the need to address the nutritional needs of the WIC population given current scientific information and consumption patterns as exemplified by the concerns and recommendations of NWA, and others, FNS was aware of the need to revise the WIC food packages.

#### Extent to Which We Meet those Concerns

FNS has considered the impact of the proposed rule on State and local agencies. FNS believes that the recommendations in the IOM Report, which are largely laid out in this proposed rule, are responsive to the expressed concerns and requests of commenters representing State and local concerns.

#### **Executive Order 12988**

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

### **Civil Rights Impact Analysis**

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



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

This rule merely addresses revisions to the WIC food packages to bring them into line with the DGA 2005 <sup>(12)</sup> and current infant feeding recommendations from the American Academy of Pediatrics. Several provisions are specifically designed to better accommodate WIC's highly diverse population. This proposed rule provides WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural food preferences, including allowing participants a broad selection of fruits and vegetables; tofu and soy-based beverages as substitutes for milk; participant choice for whole grains (including tortillas); and salmon and sardines as substitutions for tuna. This proposed rule also makes provisions to better accommodate the special dietary needs of high-risk participants served in Food Package III, helping to protect the health and well-being of this nutritionally vulnerable subset of WIC participants.

#### **Paperwork Reduction Act (60-day Notice)**

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35; see 5 CFR part 1320) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This proposed rule contains information collections that are

subject to review and approval by OMB; therefore, FNS has submitted an information collection which contains the changes in burden from adoption of the proposals in the rule, for OMB's review and approval.

Comments on the information collection in this proposed rule must be received by [Insert date that is 60 days from publication in the Federal Register].

Send comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for FNS, Washington, DC, 20503. Please also send a copy of your comments to Patricia N. Daniels, Director, Supplemental Food Programs Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 528, Alexandria, Virginia 22302. For further information, or for copies of the information collection requirements, please contact Debra Whitford at the address indicated above.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the Agency's functions, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the proposed information collection burden, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and, (d) ways to minimize the burden of the collection of information on those who are to respond,

including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this request for comments will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Title: WIC Food Packages.

OMB Number: Not Assigned

Expiration Date: Not Yet Determined

Type of Request: New

Abstract: This rule proposes revisions to the food packages to bring them in line with the 2005 Dietary Guidelines for Americans and current infant feeding practice guidelines of the American Academy of Pediatrics. The revisions would also: better promote and support the establishment of successful long-term breastfeeding, provide WIC participants with a wider variety of foods, provide WIC State agencies with greater flexibility in prescribing food packages to accommodate participants with cultural preferences, and serve participants with certain qualifying conditions under one food package to facilitate efficient management of medically fragile participants.

The average burden per response and the annual burden hours are explained below and summarized in the chart which follows.

Respondents for this Rule: Individuals or households and State, Local or Tribal Governments.

Estimated Number of Respondents: 152,783

Estimated Number of Responses per Respondent: 2

Estimate Average Hours per Response: 0.05

Estimated Total Annual Burden on Respondents: 14,598 Hours

<b>ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN</b>				
Section of Regulations	Annual Number of Respondents	No. Responses Per Respondent	Average Burden per Response	Annual Burden Hours
Reporting Burden				
§ 246.10(d)	142,783	2	0.05	14,728
Recordkeeping Burden				
§ 246.10(d)	10,000	2	0.016	320
Total Reporting and Recordkeeping Burden in the Proposed Rule:	152,783	2	0.05	14,598

**1. Reporting:**

Sections 246.10(d) would require medical documentation for the issuance of any supplemental foods issued to participants who receive Food Package III; any authorized soy-based beverage or tofu issued to children who receive Food Package IV; and, any additional authorized tofu and cheese issued to women who receive Food Packages V and VII that exceeds the maximum substitution rate.

In addition, the content of the medical documentation would be expanded to include: 1) contact information for the participant's healthcare provider making the medical determination; 2) date of medical determination; 3) the specific supplemental foods to be prescribed; 4) amount prescribed per day; 5) the medical determination of the qualifying conditions which warrants the supplemental foods; and 6) the length of time the supplemental foods is medically required.

FNS estimates that approximately 1 percent of participants (86,375) will be issued supplemental foods under food package III; 1 percent of children (42,408) will be authorized soy-based beverage or tofu under Food Package IV; and, 1 percent of women (14,000) will be authorized tofu and cheese in excess of the maximum substitution rate under Food Packages V and VII. Further, FNS estimates that it will take three minutes (0.05 person hours) for the documentation required to issue the authorized foods. Thus, the estimated reporting burden is 14,278 (142,783 total participants x 0.05 person hours x 2 certification periods per year).

## **2. Recordkeeping:**

FNS estimates that it will take one minute (0.016 per record) for each clinic (10,000 clinics) to file the required medical documentation provided by participants, for an estimated burden of 320 hours (10,000 clinics x 0.016 hours per record x 2 times per year).

### **E-Government Act Compliance**

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

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

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

For reasons set forth in the preamble, 7 CFR Part 246 is proposed to be amended as follows:

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

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

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

2. In §246.2:

- a. Revise the definition of “Participation”; and
- b. Amend the definition of “WIC-eligible medical foods” by removing the words “for individuals with a diagnosed medical condition” and adding in their place the words “for women or children with a qualifying condition”, and by revising the second sentence.

The revisions read as follows:

**§ 246.2 Definitions.**

\*\*\*\*\*

Participation means the sum of: (a) the number of persons who received supplemental foods or food instruments during the reporting period; (b) the number of infants who did not receive supplemental foods or food instruments but whose breastfeeding mother received supplemental foods or food instruments during the report period; and (c) the number of breastfeeding women who did not

receive supplemental foods or food instruments but whose infant received supplemental foods or food instruments during the report period.

\* \* \* \* \*

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

3. Revise § 246.10 to read as follows:

**§246.10 Supplemental foods.**

(a) General. This section prescribes the requirements for providing supplemental foods to participants. The State agency must ensure that local agencies comply with this section.

(b) State agency responsibilities.

(1) State agencies may:

(i) Establish criteria in addition to the minimum Federal requirements in Table 4 of paragraph (e)(12) of this section for the supplemental foods in their States.

These State criteria could address, but not be limited to, other nutritional standards, competitive cost, State-wide availability, and participant appeal; and



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

(2) State agencies must:

(i) Identify the brands of foods and package sizes that are acceptable for use in the Program in their States in accordance with the requirements of this section. State agencies must also provide to local agencies a list of acceptable foods and their maximum monthly allowances as specified in Tables 1 through 3 of paragraphs (e)(9) through (e)(11) of this section; and

(ii) Ensure that local agencies:

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

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

(C) Authorize only a competent professional authority to prescribe the categories of authorized supplemental foods in quantities that do not exceed the regulatory

maximum and are appropriate for the participant, taking into consideration the participant's age and nutritional needs; and

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

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

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

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

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

(d) Medical documentation.

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

(i) Any non-contract brand infant formula;

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

(iii) Any exempt infant formula;

(iv) Any WIC-eligible medical food;

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

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

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

(viii) Any additional authorized tofu and cheese issued to women who receive Food Packages V and VII that exceeds the maximum substitution rate; and

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

(2) Supplemental foods not requiring medical documentation.

(i) State agencies may authorize local agencies to issue a non-contract brand infant formula that meets the requirements in Table 4 of paragraph (e)(12) of this section without medical documentation in order to meet religious eating patterns; and

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

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

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

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

(4) Technical Requirements.

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

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

- (A) The name of the authorized WIC formula (infant formula, exempt infant formula, WIC-eligible medical food) prescribed, including amount needed per day;
- (B) The authorized supplemental food(s) appropriate for the qualifying condition(s) and their prescribed amounts;
- (C) Length of time the prescribed WIC formula and/or supplemental food is required by the participant;
- (D) The qualifying condition(s) for issuance of the authorized supplemental food(s) requiring medical documentation, as described in paragraphs (e)(3) through (e)(7) of this section; and
- (E) Signature, date and contact information (or name, date and contact information), if the initial medical documentation was received by telephone and the signed document is forthcoming, of the health care professional licensed by the State to write prescriptions in accordance with State laws.

(iii) Written confirmation.

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

(B) Medical documentation provided by telephone. Medical documentation may be provided by telephone to a competent professional authority who must promptly document the information. The collection of the required information by telephone for medical documentation purposes may only be used until written confirmation is received from a health care professional licensed to write medical

prescriptions and used only when absolutely necessary on an individual participant basis. The local clinic must obtain written confirmation of the medical documentation within a reasonable amount of time (i.e., one or two week's time) after accepting the initial medical documentation by telephone.

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

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

(1) Food Package I – Infants birth through 5 months.

(i) Participant category served. This food package is designed for issuance to infant participants from birth through age 5 months who do not have a condition qualifying them to receive Food Package III.

(ii) Infant feeding categories.

(A) Birth through one month. Two infant feeding options are available during the first month after birth — fully breastfeeding, i.e., the infant receives no infant formula from the WIC Program, or fully formula-feeding. Infant formula is not provided during the first month after birth to fully breastfed infants to support the successful establishment of breastfeeding.

(B) Two through 5 months. Three infant feeding options are available from 2 months through 5 months — fully breastfeeding, fully formula-feeding, or partially breastfeeding, i.e., the infant is breastfed but also receives infant formula from the WIC Program in an amount not to exceed approximately half the amount of infant formula allowed for a fully formula fed infant.

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

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

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

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

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

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

(2) Food Package II—Infants 6 through 11 months.

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

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

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

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

(3) Food Package III—Participants with qualifying conditions.



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

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

(A) Infants whose only condition is:

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

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

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

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

(iii) Restrictions on the issuance of WIC formulas in ready-to-feed (RTF) forms.

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

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

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

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

(v) Authorized categories of supplemental foods. The supplemental foods authorized in this food package require medical documentation for issuance and include infant formula (for children or women), exempt infant formula, WIC-eligible medical foods (for children and women), infant cereal, infant food fruits and vegetables, milk and milk alternatives, cheese, eggs, canned fish, fruits and

vegetables, breakfast cereal, whole wheat bread or other whole grains, juice, legumes and/or peanut butter.

(vi) Coordination with medical payors and other programs that provide or reimburse for formulas. WIC State agencies must coordinate with other Federal, State or local government agencies or with private agencies that operate programs that also provide or could reimburse for exempt infant formulas and WIC-eligible medical foods benefits to mutual participants. At a minimum, a WIC State agency must coordinate with the State Medicaid Program for the provision of exempt infant formulas and WIC-eligible medical foods that are authorized or could be authorized under the State Medicaid Program for reimbursement and that are prescribed for WIC participants who are also Medicaid recipients. The WIC State agency is responsible for providing up to the maximum amount of exempt infant formulas and WIC-eligible medical foods under Food Package III in situations where reimbursement is not provided by another entity.

(4) Food Package IV—Children 1 through 4 years.

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

(ii) Authorized categories of supplemental foods. Milk, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. Cheese may be substituted for milk in amounts described in

Table 2 of paragraph (e)(10) of this section. Substitutions exceeding the maximum substitution allowance of cheese, up to the maximum allowance for fluid milk, may be allowed with medical documentation of the qualifying condition. Soy-based beverages and tofu can be substituted for milk only with medical documentation in this food package, in amounts described in Table 2 of paragraph (e)(10) of this section. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a child cannot drink milk and requires soy-based beverage, tofu, or additional cheese as a substitute for milk. Such determination can be made for situations that include, but are not limited to, milk allergy, severe lactose maldigestion, and vegan diets. Medical documentation must meet the requirements described in paragraph (d) of this section.

(5) Food Package V—Pregnant and partially breastfeeding women.

(i) Participant category served. This food package is designed for issuance to women participants with singleton pregnancies who do not have a condition qualifying them to receive Food Package III. This food package is also designed for issuance to breastfeeding women participants, up to 1 year postpartum, who do not have a condition qualifying them to receive Food Package III and whose partially breastfed infants receive formula from the WIC program in amounts that do not exceed the maximum allowances described in Table 1 of paragraph (e)(9) of this section. Women participants breastfeeding more than one infant, and women participants pregnant with more than one fetus, are eligible to receive Food Package VII as described in paragraph (e)(7) of this section.

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

(6) Food Package VI—Postpartum women.

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

(ii) Authorized categories of supplemental foods. Milk, breakfast cereal, juice, fruits and vegetables, eggs, and legumes or peanut butter are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu

may be substituted for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

(7) Food Package VII—Fully breastfeeding (enhanced).

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

(ii) Authorized categories of supplemental foods. Milk, cheese, breakfast cereal, juice, fruits and vegetables, whole wheat bread or other whole grains, eggs, legumes, peanut butter, and canned fish are the categories of supplemental foods authorized in this food package. Cheese or calcium-set tofu may be substituted

for milk in amounts described in Table 2 of paragraph (e)(10) of this section. Amounts of cheese or calcium-set tofu exceeding the maximum substitution allowances may be allowed with medical documentation of the qualifying condition, up to the maximum allowance for fluid milk. A health care professional licensed by the State to write prescriptions must make a medical determination and provide medical documentation that a woman cannot drink milk and requires additional cheese or calcium-set tofu. Such determination can be made for situations that include, but are not limited to, milk allergy or severe lactose maldigestion. Medical documentation must meet the requirements described in paragraph (d) of this section.

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

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

**TABLE 1 Maximum Monthly Allowances of Supplemental Foods For Infants In Food Packages I, II and III**

Foods <sup>1</sup>	Fully Formula fed (FF)		Partially Breastfed (BF/FF)		Fully Breastfed (BF)	
	Food Packages I-FF & III-FF A: 0 through 3 months B: 4 through 5 months	Food Packages II-FF & III-FF 6 through 11 months	Food Packages I-BF/FF & III BF/FF A: 1 through 3 months <sup>2</sup> B: 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 & III BF 6 through 11 months
Infant formula <sup>3,4,5,6</sup> and Exempt Infant formula	A: 806 fl oz reconstituted liquid concentrate or 800 fl. oz. RTF or 870 fl oz reconstituted powder  B: 884 fl oz reconstituted liquid concentrate or 896 fl. oz. RTF or 960 fl oz reconstituted powder	624 fl. oz. reconstituted liquid concentrate or 640 fl. oz. RTF or 696 fl oz reconstituted powder	A: 364 fl oz reconstituted liquid concentrate or 364 fl oz RTF or 435 fl oz reconstituted powder  B: 442 fl. oz. reconstituted liquid concentrate or 448 fl. oz. RTF or 522 fl oz reconstituted powder	312 fl. oz. reconstituted liquid concentrate or 320 fl. oz. RTF or 384 fl oz reconstituted powder		
Infant cereal <sup>7</sup>		24 oz		24 oz		24 oz
Infant food <sup>7,8</sup> fruits and vegetables Infant food meat		128 oz		128 oz		256 oz  77.5 oz





**TABLE 1 FOOTNOTES:** (abbreviations in order of appearance in table): FF = fully formula fed; BF/FF = partially breastfed (i.e., the infant is breastfed but also receives formula from the WIC Program in an amount not to exceed approximately half the amount of formula allowed for a fully formula fed infant); BF = fully breastfed (i.e., the infant receives no formula through the WIC program).

- 1** Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.
- 2** The powder form is the form recommended for partially breastfed infants, ages 1 through 3 months in Food Package I.
- 3** The maximum monthly allowance is specified in reconstituted fluid ounces for liquid concentrate, ready-to-feed (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.
- 4** Only infant formula may be issued for infants in Food Packages I and II. Exempt infant formula may only be issued for infants in Food Package III.
- 5** If powder infant formula is provided, State agencies must provide at least the number of reconstituted fluid ounces as the maximum allowance for the liquid concentrate form of the same product in the same Food Package up to the maximum monthly allowance for powder. State agencies must issue whole containers that are all the same size.
- 6** State agencies may round up and disperse whole containers of infant formula over the food package timeframe to allow participants to receive the full authorized nutritional benefit (FNB). State agencies must use the methodology described in accordance with paragraph (h)(1) of this section.
- 7** 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.
- 8** Fresh banana may replace up to 16 ounces of baby food fruit at a rate of 1 pound of bananas per 8 ounces of baby food fruit.

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

**TABLE 2 Maximum Monthly Allowances of Supplemental Foods for Children and Women in Food Packages IV, V, VI and VII**

Foods <sup>1</sup>	Children	Women		
	Food Package IV 1 through 4 years	Food Package V: Pregnant and Partially Breastfeeding (up to 1 year postpartum) <sup>2</sup>	Food Package VI: Postpartum (up to 6 months postpartum) <sup>3</sup>	Food Package VII: Fully Breastfeeding (Enhanced), (up to 1 year post- partum) <sup>4, 5</sup>
Juice, single strength <sup>6</sup>	128 fl oz	144 fl oz	96 fl oz	144 fl oz
Milk, fluid	16 qt <sup>7, 8, 9, 10</sup>	22 qt <sup>7, 8, 11, 12</sup>	16 qt <sup>7, 8, 11, 12</sup>	24 qt <sup>7, 8, 11, 12</sup>
Breakfast cereal	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>13, 14</sup>	\$6.00 in cash value vouchers	\$8.00 in cash value vouchers	\$8.00 in cash value vouchers	\$8.00 in cash value vouchers
Whole wheat bread or other whole grains <sup>15</sup>	2 lb	1 lb	N/A	1 lb
Fish (canned)	N/A	N/A	N/A	30 oz
Legumes, dry <sup>16</sup>	1 lb	1 lb	1 lb	1 lb
<i>and/or</i>	<i>Or</i>	<i>And</i>	<i>Or</i>	<i>And</i>
Peanut butter	18 oz	18 oz	18 oz	18 oz

**TABLE 2 FOOTNOTES:** N/A= the supplemental food is not authorized in the corresponding food package

- <sup>1</sup> Table 4 of paragraph (e)(12) of this section describes the minimum requirements and specifications for the supplemental foods.
- <sup>2</sup> Food Package V is issued to two categories of WIC participants: women participants with singleton pregnancies and breastfeeding women whose partially breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances for Food Packages I-BF/FF-A, I-BF/FF-B, or II-BF/FF, as appropriate for the age of the infant.
- <sup>3</sup> Food Package VI is issued to two categories of WIC participants: non-breastfeeding postpartum women and breastfeeding postpartum women whose partially breastfed infants receive more than the maximum infant formula allowances for Food Packages I-BF/FF-A, I-BF/FF-B, or II-BF/FF, as appropriate for the age of the infant.
- <sup>4</sup> Food Package VII is issued to 4 categories of WIC participants: fully breastfeeding women whose infants do not receive formula from the WIC Program; all breastfeeding women during the first month postpartum; women pregnant with two or more fetuses; and women fully or partially breastfeeding multiple infants.
- <sup>5</sup> Women fully breastfeeding multiple infants are prescribed 1.5 times the maximum allowances.
- <sup>6</sup> Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.
- <sup>7</sup> Whole milk, as specified in FDA standards, is the only type of milk allowed for 1-year-old children (12 through 23 months). Reduced fat milks, as specified in FDA standards, i.e., 2% milk fat, are the only types of milk allowed for children  $\geq$  24 months of age and women.
- <sup>8</sup> Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. Dry milk may be substituted at an equal reconstituted rate to fluid milk. When a combination of different milk forms is provided, the full maximum monthly fluid milk allowance must be provided.
- <sup>9</sup> For children, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 lb. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese may be substituted in cases of lactose intolerance or other qualifying conditions, up to the maximum allowance for fluid milk.
- <sup>10</sup> For children, soy-based beverage and calcium-set tofu may be substituted for milk only with medical documentation for qualifying conditions. Soy-based beverages may be substituted for milk, with medical documentation, for children in Food Package IV on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.
- <sup>11</sup> For women, cheese or calcium-set tofu may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this manner in Food Packages V and VI; however, no more than 1 pound of cheese may be substituted for milk. A maximum of 6 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 2 lbs. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese or tofu may be substituted, up to the maximum allowances for fluid milk, in cases of lactose intolerance or other qualifying conditions.
- <sup>12</sup> For women, soy-based beverage may be substituted for milk at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum monthly allowance of milk.
- <sup>13</sup> Processed (canned, frozen, dried) fruits and vegetables may be substituted for fresh fruits and vegetables. Dried fruit and dried vegetables are not authorized for children in Food Package IV.
- <sup>14</sup> The maximum value of the vouchers may be adjusted in whole dollar increments to reflect accrued annual, un-rounded inflationary increases.
- <sup>15</sup> Brown rice, bulgur, oatmeal, whole-grain barley, soft corn or whole wheat tortillas may be substituted for whole wheat bread on an equal weight basis.
- <sup>16</sup> Canned legumes may be substituted for dried legumes at the rate of 64 oz of canned beans for 1 lb dried beans. Under Food Packages V and VII, two additional combinations of dry or canned beans/peas are authorized: 1 lb. Dry and 64 oz. Canned beans/peas (and no peanut butter); or 2 lb. Dry or 128 oz. Canned beans/peas (and no peanut butter) or 36 oz. peanut butter (and no beans).

(11) Maximum monthly allowances of supplemental foods for children and women with qualifying conditions in Food Package III.

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

**TABLE 3 Maximum Monthly Allowances of Supplemental Foods for Children and Women in Food Package III**

Foods <sup>1</sup>	Children	Women		
	1 through 4 years	Pregnant and Partially Breastfeeding (up to 1 year postpartum) <sup>2</sup>	Postpartum (up to 6 months postpartum) <sup>3</sup>	Fully Breastfeeding (Enhanced), (up to 1 year postpartum) <sup>4, 5</sup>
Juice, single strength <sup>6</sup>	128 fl oz	144 fl oz	96 fl oz	144 fl oz
WIC Formula <sup>7, 8</sup>	455 fl oz liquid concentrate	455 fl oz liquid concentrate	455 fl oz liquid concentrate	455 fl oz liquid concentrate
Milk	16 qt <sup>9, 10, 11, 12</sup>	22 qt <sup>9, 10, 13, 14</sup>	16 qt <sup>9, 10, 13, 14</sup>	24 qt <sup>9, 10, 13, 14</sup>
Breakfast cereal <sup>15</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>16, 17</sup>	\$6.00 in cash value voucher	\$8.00 in cash value vouchers	\$8.00 in cash value vouchers	\$8.00 in cash value vouchers
Whole wheat bread <sup>18</sup>	2 lb	1 lb	N/A	1 lb
Fish (canned)	N/A	N/A	N/A	30 oz
Legumes, dry <sup>19</sup>	1 lb	1 lb	1 lb	1 lb
<i>and/or</i>	<i>Or</i>	<i>And</i>	<i>or</i>	<i>And</i>
Peanut butter	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.
- <sup>2</sup> Issued to two categories of WIC participants — women participants with singleton pregnancies and breastfeeding women whose partially breastfed infants receive formula from the WIC Program in amounts that do not exceed the maximum formula allowances for Food Packages I-BF/FF-A, I-BF/FF-B, or II-BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.
- <sup>3</sup> Issued to two categories of WIC participants — non-breastfeeding postpartum women and breastfeeding postpartum women whose partially breastfed infants receive more than the maximum formula allowances for Food Packages I-BF/FF-A, I-BF/FF-B, or II-BF/FF, as appropriate for the age of the infant as described in Table 1 of paragraph (e)(9) of this section.
- <sup>4</sup> Issued to 4 categories of WIC participants — fully breastfeeding women whose infants do not receive formula from the WIC Program; all breastfeeding women during the first month postpartum; women pregnant with two or more fetuses; and women fully or partially breastfeeding multiple infants.
- <sup>5</sup> Women fully breastfeeding multiple infants are prescribed 1.5 times the maximum allowances.
- <sup>6</sup> Combinations of single-strength and concentrated juices may be issued provided that the total volume does not exceed the maximum monthly allowance for single-strength juice.
- <sup>7</sup> WIC formula means infant formula, exempt infant formula, or WIC-eligible medical food.
- <sup>8</sup> Powder and Ready-to-Feed may be substituted at rates that provide comparable nutritive value.
- <sup>9</sup> Whole milk (not less than 3.25% milk fat) is the only type of milk allowed for 1-year-old children (12 through 23 months). Reduced fat milks (up to 2% milk fat) are the only types of milk allowed for children  $\geq$  24 months of age and women.
- <sup>10</sup> Evaporated milk may be substituted at the rate of 16 fluid ounces of evaporated milk per 32 fluid ounces of fluid milk or a 1:2 fluid ounce substitution ratio. Dry milk may be substituted at an equal reconstituted rate to fluid milk. When a combination of different milk forms is provided, the full maximum monthly fluid milk allowance must be provided.
- <sup>11</sup> For children, cheese may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk. No more than 1 lb. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese may be substituted in cases of lactose intolerance or other qualifying conditions, up to the maximum allowance for fluid milk.
- <sup>12</sup> For children, soy-based beverage and tofu may substituted for milk only with medical documentation for qualifying conditions. Soy-based beverages may be substituted for milk, with medical documentation, for children in Food Package IV on a quart for quart basis up to the total maximum allowance of milk. Tofu may be substituted for milk, with medical documentation, for children in Food Package IV at the rate of 1 pound of tofu per 1 quart of milk up to the total maximum allowance of milk.
- <sup>13</sup> For women, cheese or calcium-set tofu may be substituted for milk at the rate of 1 pound of cheese per 3 quarts of milk or 1 pound of tofu per 1 quart of milk. A maximum of 4 quarts of milk can be substituted in this manner in Food Packages V and VI; however, no more than 1 pound of cheese may be substituted for milk. A maximum of 6 quarts of milk can be substituted in this manner in Food Package VII; therefore, no more than 2 lbs. of cheese may be substituted for milk. With medical documentation, additional amounts of cheese or tofu may be substituted, up to the maximum allowances for fluid milk, in cases of lactose intolerance or other qualifying conditions.
- <sup>14</sup> For women, soy-based beverage may be substituted for milk at the rate of 1 quart of soy-based beverage for 1 quart of milk up to the total maximum monthly allowance of milk.
- <sup>15</sup> 32 dry ounces of infant cereal may be substituted for 36 ounces of breakfast cereal.
- <sup>16</sup> Processed (canned, frozen, dried) fruits and vegetables may be substituted for fresh fruits and vegetables. Dried fruit and dried vegetables are not authorized for children.
- <sup>17</sup> The maximum value of the vouchers may be adjusted in whole dollar increments to reflect accrued annual, un-rounded inflationary increases.
- <sup>18</sup> Brown rice, bulgur, oatmeal, whole-grain barley, soft corn or whole wheat tortillas may be substituted for whole wheat bread on an equal weight basis.
- <sup>19</sup> Canned legumes may be substituted for dried legumes at the rate of 64 oz of canned beans for 1 lb dried beans. Issuance of two additional combinations of dry or canned beans/peas is authorized for the Pregnant and Partially Breastfeeding (up to 1 year postpartum) category and Fully Breastfeeding (Enhanced) (up to 1 year postpartum) category: 1 lb. Dry and 64 oz. Canned beans/peas (and no peanut butter); or 2 lb. Dry or 128 oz. Canned beans/peas (and no peanut butter) or 36 oz. Peanut butter (and no beans).

(12) Minimum requirements and specifications for supplemental foods. Table 4 describes the minimum requirements and specifications for supplemental foods in all food packages:

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements and Specifications</b>
<b>WIC formula</b>	
Infant formula	<p>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;</p> <p>(2) be designed for enteral digestion via an oral or tube feeding;</p> <p>(3) provide at least 10 mg iron per liter (at least 1.8 mg iron/ 100 kilocalories) at standard dilution;</p> <p>(4) provide at least 67 kilocalories per 100 milliliters (approximately 20 kilocalories per fluid ounce) at standard dilution.</p> <p>(5) not require the addition of any ingredients other than water prior to being served in a liquid state.</p>
Exempt infant formula	<p>All authorized exempt infant formula must (1) meet the definition and requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 350a(h)) and the regulations at 21 CFR parts 106 and 107; and</p>

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements and Specifications</b>
<p><b>WIC Formula</b> (continued)</p> <p>Exempt infant formula (continued)</p> <p>WIC-eligible medical foods <sup>1</sup></p>	<p>2) be designed for enteral digestion via an oral or tube feeding.</p> <p>Certain enteral products that (1) are specifically formulated to provide nutritional support for woman or children with a qualifying condition when the use of conventional food is precluded, restricted or inadequate;</p> <p>(2) 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;</p> <p>(3) must be designed for enteral digestion via an oral or tube feeding;</p> <p>(4) may not be a conventional food, drug, flavoring or enzyme; and</p> <p>(5) include many but not all products that meet the definition of medical foods in Section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)).</p>
<p><b>Milk and milk alternatives</b></p> <p>Cow's milk</p>	<p>Must conform to FDA standard of identity for whole, reduced fat, low-fat, or non-fat milks (21 CFR 131.110). Must be pasteurized and contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2000 IU of vitamin A per quart (500 IU per cup).</p>



<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Milk and milk alternatives</b> (continued)	
Cow's milk (continued)	<p>May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dried (i.e., powder) (21 CFR 131.147). <sup>2</sup></p> <p>Cultured Milks. Must conform to FDA standard of identity for cultured milk (21 CFR 131.112—cultured buttermilk, kefir cultured milk, acidophilus cultured milk).</p>
Goat milk	<p>Must conform to FDA standard of identity for whole, reduced fat, low-fat, or non-fat milks (21 CFR 131.110). Must be pasteurized and contain at least 400 IU of vitamin D per quart (100 IU per cup) and 2000 IU of vitamin A per quart (500 IU per cup) following FDA fortification standards (21 CFR 131). May be flavored or unflavored. May be fluid, shelf-stable, evaporated (21 CFR 131.130), or dried (i.e., powdered) (21 CFR 131.147). <sup>2</sup></p>
Cheese	<p>Domestic cheese made from 100 percent pasteurized milk. Must conform to FDA standard of identity (21 CFR 133); Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, part-skim or whole Mozzarella, pasteurized processed American, or blends of any of these cheeses are authorized.</p> <p>Cheeses that are labeled low, free, reduced, less or light in the nutrients of sodium, fat or cholesterol are WIC-eligible. <sup>3</sup></p>

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Milk and milk alternatives</b> (continued)	
Tofu	Calcium-set tofu prepared with only calcium salts (e.g., calcium sulfate). May not contain added fats, sugars, oils, or sodium.
Soy-based beverage	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 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.
<b>Juice</b>	<p>Must be pasteurized 100% unsweetened fruit juice. Must conform to FDA standard of identity (21 CFR Part 146) or vegetable juice must conform to FDA standard of identity (21 CFR Part 156) and contain at least 30 mg of vitamin C per 100 mL of juice. With the exception of 100 percent citrus juices, State agencies must verify the vitamin C content of all State-approved juices. Juices that are fortified with other nutrients may be allowed at the State agency's option. Juice may be fresh, from concentrate, frozen, canned, or shelf-stable.</p> <p>Vegetable juice may be regular or lower in sodium.<sup>3</sup></p>

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Breakfast cereal</b>	<p>Breakfast cereals as defined by FDA in 21 CFR 170.3(n)(4) for ready-to-eat and instant and regular hot cereals.</p> <p>Meet labeling requirements for making a health claim as a “whole grain food with moderate fat content”:<sup>4</sup></p> <p>(1) contain a minimum of 51% whole grains (using dietary fiber as the indicator);</p> <p>(2) meet the regulatory definitions for “low saturated fat” at 21 CFR 101.62 (<math>\leq 1</math> g saturated fat per RACC) and “low cholesterol” (<math>\leq 20</math> mg cholesterol per RACC);</p> <p>(3) bear quantitative <i>trans</i> fat labeling; and</p> <p>(4) contain <math>\leq 6.5</math> g total fat per RACC and <math>\leq 0.5</math> g <i>trans</i> fat per RACC.</p> <p>Contain a minimum of 28 mg iron per 100 g dry cereal.</p> <p>Contain <math>\leq 21.2</math> g sucrose and other sugars per 100 g dry cereal (<math>\leq 6</math> g per dry oz).</p>
<b>Eggs</b>	<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>

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Fruits and Vegetables</b> (fresh and processed)	<p>Any variety of fresh whole or cut fruit without added sugars. <sup>5</sup></p> <p>Any variety of fresh whole or cut vegetable, except white potatoes, without added sugars, fats, or oils (orange yams and sweet potatoes are allowed). <sup>5</sup></p> <p>Any variety of canned <sup>6</sup> fruits (must conform to FDA standard of identity (21 CFR 145); including applesauce; juice pack or water pack without added sugars, fats, oils, or salt (i.e. sodium). Any variety of frozen fruits without added sugars. <sup>7</sup></p> <p>Any variety of canned <sup>6</sup> or frozen vegetables (must conform to FDA standard of identity (21 CFR Part 155)) except white potatoes (orange yams and sweet potatoes are allowed); without added sugars, fats, or oils. May be regular or lower in sodium. <sup>3, 7</sup></p> <p>Any type of dried fruits or dried vegetable without added sugars, fats, oils, or salt (i.e., sodium). <sup>5</sup></p>
<b>Whole wheat bread or other whole grains</b>	Whole wheat bread (must conform to FDA standard of identity (21 CFR 136.180))

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Whole wheat bread or other whole grains</b> (continued)	<p><b>OR</b></p> <p>Meet labeling requirements for making a health claim as a “whole grain food with moderate fat content”: <sup>4</sup></p> <p>(1) contain a minimum of 51% whole grains (using dietary fiber as the indicator);</p> <p>(2) meet the regulatory definitions for “low saturated fat” at 21 CFR 101.62 (<math>\leq 1</math> g saturated fat per RACC) and “low cholesterol” (<math>\leq 20</math> mg cholesterol per RACC);</p> <p>(3) bear quantitative <i>trans</i> fat labeling; and</p> <p>(4) contain <math>\leq 6.5</math> g total fat per RACC and <math>\leq 0.5</math> g <i>trans</i> fat per RACC.</p> <p>Brown rice, bulgur, oatmeal, whole-grain barley without added sugars, fats, oils, or salt (i.e., sodium). May be instant-, quick-, or regular-cooking.</p> <p>Soft corn or whole wheat tortillas without added fats or oils may be allowed at the State agency’s option.</p>
<b>Canned fish</b> <sup>6</sup>	<p>Canned only:</p> <p>light tuna (must conform to FDA standard of identity (21 CFR 161.190));</p>

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Canned fish</b> (continued)	<p>salmon (must conform to FDA standard of identity (21 CFR 161.170));</p> <p>Sardines.</p> <p>May be packed in water or oil. Pack may include bones or skin. May be regular or lower in sodium content.<sup>3</sup></p>
<b>Mature legumes</b> (dry beans and peas)	<p>Any type of mature dry beans, peas, or lentils in dry-packaged or canned<sup>6</sup> forms. Examples include but are not limited to black beans (“turtle beans”), blackeye peas (cowpeas of the blackeye variety, “cow beans”), garbanzo beans (chickpeas), great northern beans, kidney beans, lima beans (“butter beans”), navy beans, pinto beans, soybeans, split peas, and lentils. All categories exclude soups. May not contain added sugars, fats, oils or meat as purchased. Canned legumes may be regular or lower in sodium content.<sup>3, 9</sup></p> <p>Baked beans may be provided for participants with limited cooking facilities.<sup>9</sup></p>

<b>Table 4: Minimum Requirements and Specifications for Supplemental Foods (cont.)</b>	
<b>Categories/Foods</b>	<b>Minimum Requirements</b>
<b>Peanut butter</b>	Peanut butter and reduced fat peanut butter (must conform to FDA Standard of Identity (21 CFR 164.150)); creamy or chunky, regular or reduced fat, salted or unsalted <sup>3</sup> forms are allowed.
<b>Infant Foods: Infant cereal</b>	Infant cereal, must contain a minimum of 45 mg of iron per 100 g of dry cereal. <sup>10</sup>
<b>Infant fruits</b>	Any variety of single ingredient commercial infant food fruit without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced. <sup>11</sup>
<b>Infant vegetables</b>	Any variety of single ingredient commercial infant food vegetables without added sugars, starches, or salt (i.e., sodium). Texture may range from strained through diced. <sup>12</sup>
<b>Infant meat</b>	Any variety of single ingredient commercial infant food meat without added sugars, starches, vegetables or salt (i.e., sodium). Broth (unsalted, i.e., without added sodium) may be an ingredient. Texture may range from pureed through diced. <sup>13</sup>

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

- 1** The following are not considered a WIC eligible medical food: Formulas used solely for the purpose of enhancing nutrient intake, managing body weight, addressing picky eaters or used for a condition other than a qualifying condition (e.g., vitamin pills, weight control products, etc.); medicines or drugs, as defined by the Food, Drug and Cosmetic Act (21 U.S.C. 350a) as amended; enzymes, herbs, or botanicals; oral rehydration fluids or electrolyte solutions; flavoring or thickening agents; and feeding utensils or devices (e.g., feeding tubes, bags, pumps) designed to administer a WIC-eligible formula.
- 2** All authorized milks must confirm to FDA, DHHS standards of identity for milks as defined by 21 CFR Part 131 and meet WIC's requirements for vitamin fortification as stated above. Additional authorized milks include, but are not limited to: calcium-fortified, lactose-reduced and lactose-free, acidified, and UHT pasteurized milks. Other milks are permitted at the State agency's discretion provided that the State agency determines that the milk meets the minimum requirements for an authorized milk.
- 3** Any of the following lower sodium forms are allowable:  
Sodium-free—less than 5 mg sodium per serving;  
Very low sodium—35 mg sodium or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 35 mg sodium or less per 50 g of the food;  
Low-sodium—140 mg sodium or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 140 mg sodium or less per 50 g of the food;  
Light in sodium—at least 50 percent less sodium per serving than average reference amount for same food with no sodium reduction;  
Lightly salted—at least 50 percent less sodium per serving than reference amount (If the food is not “low in sodium,” the statement “not a low-sodium food” must appear on the same panel as the Nutrition Facts panel.); and  
Reduced or less sodium—at least 25 percent less sodium per serving than reference food.
- 4** Food and Drug Administration (FDA), Health Claim Notification for Whole Grain Foods with Moderate Fat Content at <http://www.cfsan.fda.gov/~dms/flgrain2.html>
- 5** Herbs or spices; edible blossoms and flowers, e.g., squash blossoms (broccoli, cauliflower and artichokes are allowed); creamed or sauced vegetables; vegetable-grain (pasta or rice) mixtures; fruit-nut mixtures; breaded vegetables; fruits and vegetables for purchase on salad bars; peanuts; ornamental and decorative fruits and vegetables such as chili peppers on a string; garlic on a string; gourds; painted pumpkins; fruit baskets and party vegetable tray; and items such as blueberry muffins and other baked goods are not authorized. Mature legumes (dry beans and peas) and juices are provided as separate food WIC categories and are not authorized under the fruit and vegetable category.
- 6** “Canned” refers to processed food items in cans or other shelf-stable containers, e.g., jars, pouches.
- 7** Excludes white potatoes; catsup or other condiments; pickled vegetables, olives; soups; juices; and fruit leathers and fruit roll-ups.
- 8** The following canned mature legumes are not authorized: soups; immature varieties of legumes, such as those used in canned green peas, green beans, snap beans, orange beans, and wax beans; baked beans with meat; e.g., beans and franks; and beans containing added sugars (with the exception of baked beans), fats, meat, or oils.
- 9** Infant cereals containing infant formula, milk, fruit, or other non-cereal ingredients are not allowed.
- 10** Mixtures with cereal or infant food desserts (e.g., peach cobbler) are not authorized; however, combinations of single ingredients (e.g., apple-banana) are allowed.
- 11** Combinations of single ingredients (e.g., peas and carrots) are allowed.
- 12** No infant food combinations (e.g., meat and vegetables) or dinners (e.g., spaghetti and meatballs) are allowed.



(f) USDA purchase of commodity foods.

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

(2) The State agency must:

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

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

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

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

(1) Infant Formula. (i) State agencies must use the maximum monthly allowance of reconstituted fluid ounces of liquid concentrate infant formula as specified in Table 1 of paragraph (e)(9) of this section as the full nutritional benefit (FNB) provided by infant formula for each food package category and infant feeding option (e.g., Food Package I A fully formula fed, IA-FF). When using the rounding up option for infant formula, State agencies must issue whole containers that provide at least the FNB but not more than the maximum monthly allowances as specified in Table 1 of paragraph (e)(9) of this section.

(i) State agencies that use rounding up of infant formula must:

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

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

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

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

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

(B) Divide the total amount of infant formula provided by the yield of the container (in reconstituted fluid ounces) issued by the State agency to determine

the total number of containers to be issued during the timeframe that the food package is prescribed.

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

(2) Infant foods. (i) State agencies may use the rounding up option to the next whole container of infant food (infant cereal, fruits, vegetables and meats) when the maximum monthly allowance cannot be issued due to varying container sizes of authorized infant foods.

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

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

(B) Issue infant foods in whole containers; and

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

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

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

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

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

In §246.12, paragraph (g)(3)(i) is revised to read as follows:

**§246.12 Food delivery systems.**

\* \* \* \* \*

(g)\* \* \*

(3)\* \* \*

(i) Minimum variety and quantity of supplemental foods. The State agency must establish minimum requirements for the variety and quantity of supplemental foods that a vendor applicant must stock to be authorized. These requirements must include that the vendor stock at least two varieties of fruits and vegetables

authorized by the State agency. The State agency may not authorize a vendor applicant unless it determines that the vendor applicant meets these minimums. The State agency may establish different minimums for different vendor peer groups.

\* \* \* \* \*

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Eric M. Bost

Under Secretary for

Food, Nutrition and Consumer Services

\_\_\_\_\_

Date