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Food and Nutrition Service

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Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

Food Package Policy and Guidance



Supersedes the following:

FNCS Instruction 804-1: Food Package Design: Administrative Adjustments and Nutrition Tailoring

Policy Memorandum #95-13 Determining Eligibility of WIC Foods Using the New Food Labels

Policy Memorandum #2001-6 Medicaid Primary Payor for Exempt Infant Formulas and Medicaid Foods

Policy Memorandum #95-4 Questions and Answers on the Enhanced Food Package for Breastfeeding Women (Food Package VII)

Unnumbered memo 9/8/1991: WIC Food Package Design

Unnumbered memo 7/15/2004: Private label or Store Branded Products as WIC Eligible Foods

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Chapter 1

Introduction

1.1 Purpose of Document

This document provides guidance related to implementing certain provisions of WIC food package regulations. The Food and Nutrition Service (FNS) Regional Offices and WIC State and local agencies should refer to the complete provisions and requirements for WIC foods at 7 CFR 246.10 and in WIC Policy Memorandum #2015-3¹.

Federal WIC regulations (7 CFR Part 246) are put forth to implement the legislative provisions contained in the Child Nutrition Act of 1966, as amended. FNS develops and issues policy memoranda (numbered and un-numbered) and other guidance documents to provide clarification and further interpretation of the Program regulations, as necessary or appropriate. Regulations, policy, and guidance are equally binding. Unless specifically identified as an option, State agencies (SAs) must adhere to requirements contained in regulation, policy, and guidance.

1.2 Basic Principles of WIC Food Packages

WIC food packages, together with nutrition education, are the primary means by which WIC affects the dietary quality and habits of participants. WIC food benefits are scientifically-based and intended to address the supplemental nutritional needs of WIC's pregnant, breastfeeding and postpartum women, infants and children. The WIC food packages are designed to provide WIC participants with a wide variety of food, and provide staff flexibility in prescribing food packages to meet an individual participant's nutrition and cultural needs.

By design, the food package quantities and types of foods are intended to (1) address the prevalence of inadequate and excessive nutrient intakes for each WIC participant category, (2) contribute to an overall dietary pattern consistent with the Dietary Guidelines for Americans and toddler and infant feeding practice guidelines, and (3) deliver priority nutrients to participants to meet their supplemental nutrition needs. To achieve the nutrition and health goals of the Program, the nutritional basis, or integrity, of the WIC food packages depends upon the provision of the maximum allowance of WIC foods, and the availability of adequate choice and variety of WIC foods for participants.

¹ All references to regulatory provisions and requirements in 7 CFR 246.10 in this document include, as appropriate, the provisions in WIC Policy Memorandum #2015-3 Eligibility of White Potatoes for Purchase with the Cash-Value Voucher.

Chapter 2Food Package Design

2.1 Overview

Federal WIC food package regulations at 7 CFR 246.10² set forth the food packages, quantities, substitutes, and minimum requirements of WIC foods. SAs are responsible for using these Federal regulations when determining the brands, types, and forms of foods authorized on the State food list. The process of food package design at the State level involves maximizing the nutritional value of WIC food packages while managing cost. Acceptability and availability of eligible foods to participants are also important considerations in designing SA food lists. Developing policies to ensure that food benefits issued to participants accommodate the nutritional and health goals of the Program is an important part of this process.

In designing food packages, nutrition integrity is the requirement to provide the full quantities of food in each food package as specified in WIC regulations at 7 CFR 246.10, including making available more than one food from each WIC food category (except for the categories of peanut butter and eggs). No limitations, other than those authorized by Federal regulations and policy, are authorized for fruits and vegetables purchased with the cash-value voucher.

2.2 Food Selection and Authorization

The SA is responsible for using appropriate criteria and methods for identifying, selecting and authorizing WIC foods in accordance with Federal regulations at 7 CFR 246.10. 7 CFR 246.10(b)(2)(i) requires SAs to 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 7 CFR 246.10. The WIC Nutrition Coordinator or other designated State dietitian/nutritionist, in collaboration with other State WIC staff (e.g., vendor, food delivery), should conduct food selection and authorization.

A. Criteria and methods for identifying, selecting and authorizing WIC foods.

- 1. Nutritional integrity and provision of maximum allowance of supplemental foods;
- 2. State-specific nutrition criteria, in addition to the minimum Federal requirements, such as "no artificial sweeteners" or "only low sodium canned vegetables" (7 CFR 246.10(b)(1)(i));
- 3. Variety and choice for participants, including cultural preferences;

² All references to regulatory provisions and requirements in 7 CFR 246.10 in this document include, as appropriate, the provisions in WIC Policy Memorandum #2015-3 Eligibility of White Potatoes for Purchase with the Cash-Value Voucher.

- 4. Special medical/nutritional needs of participants;
- 5. Religious considerations whenever possible, such as providing Kosher/Halal foods;
- 6. Availability, packaging, storage or preparation requirements, cost, participant acceptance, and convenience;
- 7. Infant formula rebate contract;
- 8. Feasibility of rebate contracts for foods other than infant formula;
- 9. Use of web-based tools such as the Infant Food Calculator³ and WIC Infant Formula Calculator⁴; and
- 10. Input from stakeholders, such as participants, health care providers, staff, vendors, and food manufacturers.

For further guidance, refer to Chapter 3: Determining Eligibility of WIC Foods

B. Provision of Maximum Allowances.

The WIC food packages are designed to ensure that food benefits issued to participants are consistent with the nutritional and health goals of the Program. Federal WIC regulations at 7 CFR 246.10(c) require the maximum monthly allowances of WIC foods be provided to WIC participants in full (except to the extent the packages are tailored to the needs of individual participants for reasons such as food allergies). The quantities of foods authorized are intended to be provided in full to deliver priority nutrients to participants to meet their supplemental nutrition needs. Reductions in these amounts cannot be made for cost-savings, administrative convenience, or to control vendor abuse. Quantities of WIC foods may only be reduced for individual participants and only for sound nutrition reasons based on nutrition risk condition, nutrition and dietary needs, personal food preferences or household conditions. (See Section 2.3 of this chapter Nutrition Tailoring.)

• To achieve the nutrition and health goals of the Program and ensure the nutritional integrity of the food benefits provided to participants, SAs must authorize WIC foods in package sizes that provide participants their full authorized food benefit. FNS recognizes that the Federal maximum monthly allowances for WIC foods affect which container sizes SAs may authorize for the Program. While not all manufacturers produce WIC foods in container sizes that provide the maximum allowance to participants, sufficient

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³ https://wicworks.fns.usda.gov/resources/wic-infant-foods-calculator

⁴ https://wicworks.fns.usda.gov/wic-infant-formula-calculator

numbers of most WIC foods in sizes and forms that meet the maximum exist in the marketplace. The SA is responsible for ensuring that container sizes of WIC foods do not shortchange the WIC food benefit for participants. Additionally, participants are authorized to pay the difference when the purchase of allowable fruits and vegetables exceeds the value of the Cash-Value-Voucher or Benefit.

For further guidance, refer to Appendix A: Container and Package Sizes

C. More than One Food from each WIC Food Category.

WIC regulations at 7 CFR 246.10(b)(2)(ii)(B) require SAs to make available to participants more than one food from each WIC food category, except for the categories of eggs and peanut butter. The purpose of this provision is to allow as much variety and choice from the authorized foods as is feasible considering cost constraints and availability. Providing more variety and choice accommodates the diverse needs of WIC participants, including different ethnic or cultural needs. This provision should not be interpreted to mean that SAs should limit the number of foods within a food category.

For further guidance, refer to Appendix B: Choice and Variety – "More Than One" Provision

D. Administrative Adjustment.

Administrative adjustment is the process by which a SA makes modifications to the packaging methods (pouch, can, jar), packaging size (single container, multi-pack, case), brands, types, and physical forms, but not quantities, of Federally allowable WIC foods and food packages. SAs have the authority to make adjustments to WIC foods for administrative convenience and to control costs.

Acceptable administrative adjustments attempt to decrease cost while maintaining nutrition integrity and include such decisions as eliminating expensive brands, convenient food forms or packaging, and higher-cost food items. Appropriate product selection can contain food costs and maximize food dollars while providing equivalent nutrition. SAs should build flexibility into administratively adjusted food packages to accommodate special needs by allowing alternative (allowable) foods for specific participants or nutrition risk criteria, such as providing peanut butter instead of beans for an underweight child.

In making administrative adjustments, SAs must ensure that the nutritional basis, or integrity, of the food packages is intact. Nutritional integrity depends upon the provision of the maximum allowance of WIC foods and the availability of adequate choice and variety of WIC foods for participants.

While SAs may make administrative adjustments to modify the types of foods issued through the WIC food instrument, SAs may not selectively choose which WIC-eligible fruits and vegetables are available to participants via the cash-value voucher. SAs must offer fresh fruits and vegetables, and at State option, may also allow WIC-eligible canned, frozen, and/or dried fruits and vegetables. If a SA chooses to offer canned, frozen and/or dried fruits and vegetables, it must authorize all WIC-eligible canned, frozen and/or dried fruits and vegetables and may not allow only a single variety. For example, if a SA authorizes dried fruits, it must authorize all WIC-eligible dried fruits and may not authorize only raisins. Similarly, if a SA authorizes canned vegetables, it must authorize all WIC-eligible canned vegetables, and may not authorize only canned peas.

SAs may invoke their administrative option at 7 CFR 246.10(b)(1)(i) to establish criteria in addition to the minimum Federal requirements in Table 4 of 7 CFR 246.10(e)(12), which could include restricting packaging (such as plastic containers) and package sizes (such as single serving) of processed fruits and vegetables available for purchase with the cash-value voucher, as well as establishing State-specific nutrition criteria (such as allowing only low-sodium canned vegetables). In addition, SAs may identify specific types of certain processed WIC-eligible fruits and vegetables (e.g., salsas, tomato sauces, stewed and diced tomatoes) on their food lists if they believe there is cause for significant vendor and participant confusion in identifying specific items within those categories that are WIC-eligible. SAs may not exclude the purchase of organic fresh fruits or vegetables.

For further guidance, refer to Appendix C: Administrative Adjustments to WIC Food Packages

2.3 Nutrition Tailoring

After making administrative adjustments and identifying allowable foods, SAs may establish individual tailoring policy based on State nutrition rationale and policy. Nutrition tailoring is a process of modifying food packages to better meet the supplemental nutrition needs of individual participants. The term "nutrition tailoring" is reserved solely for making food package accommodations, as authorized by WIC regulations in 7 CFR 246.10(c), to accommodate the needs of an individual participant based on the Competent Professional Authority's (CPA) assessment of the participant's nutritional risk condition, breastfeeding assessment, dietary needs, and personal food preferences. Nutrition tailoring entails making changes or substitutions to food types (e.g., dry beans vs. peanut butter) and physical food forms (e.g., dry milk vs. fluid milk). Nutrition tailoring may also involve eliminating foods due to allergy, medical or nutritional condition, or in situations where a participant cannot use or refuses the item.

For further guidance, refer to Chapter 4: Nutrition Tailoring

2.4 State Approved Food Lists

State agencies must receive approval prior to implementing food package design plans or changes. The SA must notify the FNS Regional Office via the State Plan, the State Plan amendment or other documentation of its food package design plans or changes. 7 CFR 246.10(b)(2)(i) requires SAs to provide to local agencies, and include in the State Plan, a list of all authorized foods and the maximum monthly allowances. The SA is responsible for maintaining a list of all WIC-eligible foods it authorizes. Such a list allows SAs to respond to questions about WIC-eligibility of a product, provide vendors and local agencies with a comprehensive list of WIC-authorized foods, and address recalls when necessary. State Plan documentation should also include SA-determined restrictions in allowable foods (beyond the Federal requirements) and nutrition tailoring policies.

For further guidance, refer to Appendix D: State Approved Food Lists

2.5 Proration of WIC Food Packages

While nutrition tailoring is based on individual nutrition needs and preferences, proration is apportioning the amount of supplemental food a participant is entitled to receive based on the remaining days/weeks in the month or issuance cycle. Program regulations allow an option of either issuing food instruments for the current month or the remaining portion of the month if a participant is late picking up benefits or to synchronize family/household members onto the same issuance schedule. For SAs that prorate food benefits, the system should reduce the food package based on the policy the SA adopts. Container sizes may influence the amount of foods provided in prorated packages.

The following foods may not be prorated:

- 1. Single item foods such as bread or other whole grain options in Food Packages V-VII (the exception to the single food item is eggs because of their availability in ½ dozen cartons). Because the maximum allowance of whole wheat/grain bread or other whole grain options in Food Package IV for children is 2 pounds, SAs may prorate to 1 pound for this food package.
- 2. Peanut butter or beans (dry or canned). Because both Food Package V (pregnant and partially breastfeeding women) and Food Package VII (fully breastfeeding women and other authorized participants) provide 1 pound of beans <u>and</u> 18 ounces of peanut butter, SAs may prorate these items by offering the participant the opportunity to choose either the beans or the peanut butter. The food instrument could read "18 ounces of peanut butter <u>or</u> 1 pound of beans."
- 3. Cash-value vouchers. The full monthly value of the cash-value voucher must be provided and may not be prorated.

2.6 Rounding Up of Infant Foods

A. Issuance of Container Sizes that Do Not Divide Evenly into Maximum Allowance.

WIC regulations at 7 CFR 246.10(h)(2) allow SAs to round up to the next whole container of infant food (infant cereal, fruits, vegetables and meat) when the maximum monthly allowance cannot be issued due to varying container sizes of authorized infant foods. SAs that use the rounding up option must issue infant foods in whole containers based on the methodology specified below. Infant food containers must be dispersed as evenly as possible over the food package timeframe (the number of months the participant will receive the food package). The methodology to round up infant food is as follows:

- 1. Multiply the maximum monthly allowance for the infant food by the timeframe (i.e., number of months) the participant will receive the food package to determine the total amount of food to be provided.
- 2. Divide the total amount of food provided by the container size the SA issues (e.g., ounces) to determine the total number of food containers to be issued during the timeframe that the food package is prescribed. If the number of containers issued does not result in a whole number of containers, the SA must round up to the next whole container in order to issue whole containers.

SAs may choose to authorize a variety of container sizes of infant foods, including those that divide evenly into the maximum (e.g., 4 ounce), those that when issued in combination (e.g., 4 ounce with 2-pack of 3.5 ounce) can reach the full food package benefit, and those that strictly require use of the rounding methodology (e.g., 2-pack of 3.5 ounce).

B. Food Cards and Participant Education When Offering a Variety of Container Sizes

When using the rounding methodology to issue authorized infant foods the food instrument must clearly indicate the correct number of containers the participant is authorized to receive each month. For example, if the participant is allowed a choice of the 2-pack of 3.5 ounce containers, the number of containers to be issued over a 6 month period using the rounding methodology is 18, 18, 18, 19, 19. The SA must ensure that the participant is aware that there is a variance in the amount they are authorized to receive each month over the 6-month period.

If the SA authorizes both the 4 ounce container and the 2-pack of 3.5 ounce containers, then the participant may receive a combination of these container sizes to reach their full food package benefit (e.g., 18 4-ounce containers and 8 2-packs of 3.5 ounce containers). Food cards and/or education materials should demonstrate to the parent and/or caretaker of the participant how to obtain the full food package benefit when combination package sizes that provide the maximum are authorized.

Additional guidance on issuing infant foods, including sample calculations and the WIC Infant Food Calculator, can be found at https://wicworks.fns.usda.gov/resources/wic-infant-foods-calculator.

2.7 State Plan Documentation Requirements

SAs must notify the FNS Regional Office in the State Plan, the State Plan amendment or other documentation of their food package design plans or changes for approval prior to implementation. The documentation should include allowable WIC foods, restrictions in allowable foods (beyond the Federal requirements), individual tailoring policies and the rationale and/or scientific basis behind those policies, e.g., offering cheese to participants as a partial substitute for milk. SAs also should document for approval situations where less than the maximum allowance is provided to participants. This includes providing rationale for authorizing package sizes that provides less than the maximum allowance.

Notifications to vendors and participants regarding any changes to WIC authorized foods should be timely.

2.8 Nutrition Education and Food Packages

In accordance with 7 CFR 246.11, nutrition education is a benefit of the Program and is to be thoroughly integrated into the delivery of supplemental foods. Nutrition education is provided to participants to help them understand that WIC foods are specifically chosen to meet the health and nutrition needs of pregnant, postpartum, and breastfeeding women, infants and children less than five years of age. Nutrition education is designed to help participants incorporate WIC supplemental foods into their overall diets and make healthy choices in all the foods they consume. Nutrition education should focus on the optimal use of WIC supplemental foods and other nutritious foods, e.g., shopping for value and nutrition, identifying authorized WIC foods, reading labels, preparing and cooking foods, and helping the participant achieve a positive change in overall dietary habits. Refer to WIC Nutrition Services Standards – Standard 7: Nutrition Education, for more information on providing quality nutrition education to WIC participants.

Chapter 3 Determining Eligibility of WIC Foods

3.1 Overview

WIC SAs are responsible for ensuring that the foods on State-approved WIC food lists meet minimum Federal WIC requirements. In accordance with Federal WIC regulations, 7 CFR 246.10, WIC SAs have the authority to determine the types, brands and physical forms of WIC-eligible foods to include on their State-approved WIC food lists. A number of factors may influence a SA's decision, such as other nutritional standards, packaging methods (pouch, can, jar), packaging sizes (single container, multi-pack, case), cost, State-wide availability, and participant acceptance gathered through surveys and other feedback. SAs have the flexibility to limit the foods authorized for use in their Programs, in accordance with WIC regulations at 7 CFR 246.10.

Although the routine responsibility of determining eligibility of WIC foods rests with the SA, FNS Regional Offices are available to provide guidance on the approval process to SAs if requested. Through Management Evaluations and review of State Plans, Regional Offices ensure that foods on a SA's food list meet Federal requirements.

3.2 Determining Eligibility

SAs should use the nutrition information the manufacturer provides with the eligibility request, or the nutrition information on a food product to determine whether or not the food meets minimum Federal WIC requirements. In cases where WIC food eligibility is difficult or impossible to determine from the information the manufacturer provides and/or the information on a food product's nutrition label is lacking such information, SAs should request additional documentation from the manufacturer that certifies the actual content of the nutrients/ingredients have met Federal WIC requirements (e.g., for vitamin C, iron, sodium, sugar, etc.).

If a SA establishes additional nutrition standards for WIC foods that exceed the minimum Federal WIC requirements, it should also request that the manufacturer supply the relevant information needed in the format most convenient to the SA for evaluating the food. A SA that establishes additional restrictions on sodium or artificial color/flavor for WIC foods, for example, would need to request and/or review these nutrient values/ingredient lists.

It is relatively straightforward to determine if a food is WIC-eligible when nutrient values are expressed in the metric measurements specified in Federal WIC regulations at 7 CFR 246.10. However, food product labels and information manufacturers provide may not report all values in metric measurements. The SA must either request this information from the manufacturer or perform its own calculations/conversions to determine eligibility.

Use of % Daily Value (DV) and the Nutrition Facts Panel.

Use of %DV on the Nutrition Facts panel to calculate the amounts of vitamins or minerals in a food can result in values that are inconsistent with those that manufacturers provide to SAs. The Food and Drug Administration (FDA) permits manufacturers to apply rounding in calculating %DVs for vitamins and minerals listed on the Nutrition Facts panel. For example, nutrients that fall within 10-50% of the DV can be expressed to the nearest 5% of the %DV. Due to the rounding that may be applied to the %DV, it is not possible to get an accurate and specific calculation of the amount of iron in a cereal, for example, using information from the Nutrition Facts panel. This could result in the misidentification of products that meet WIC-eligibility criteria. Additionally, nutrients may be reported in serving sizes and associated weights for these serving sizes that differ from those specified in Federal WIC regulations. Furthermore, the same serving size of the same product type can have different weights. Cereals, juices and whole grains present the most challenge in using the information provided on the food label to determine WIC eligibility.

Example: Federal WIC regulations specify that dry cereal must contain \leq 21.2 g sucrose and other sugars per 100 g dry cereal. One cup of Cereal A weighs 30 g and contains 6 g sugar per cup, while one cup of Cereal B weighs 55 g and contains 8 g sugar per cup. Thus a SA must perform calculations to determine the amount of sugar in g/100g cereal for both Cereal A (20 g sugar/100 g dry cereal) and B (14.5 g sugar/100 g dry cereal).

Instead of using the %DV to perform such calculations, SAs are encouraged to request information from the manufacturer specifying the nutrient content expressed in the metric measurements specified in Federal WIC regulations. Using the above example, SAs should request nutrient information (sugar, iron, etc.) per 100 grams of dry cereal when reviewing cereals for WIC-eligibility. SAs may wish to request other product information concerning types and sizes of package containers, suggested or average retail cost, State-wide availability, etc., to assist in making decisions about the food products to authorize on State food lists.

3.3 WIC Formula

A. Review of infant formula and exempt infant formula for WIC-eligibility.

In review of infant formula and exempt infant formula products for WIC-eligibility, SAs should include the following information:

1. WIC-eligible category (infant formula, exempt infant formula). To be classified as an exempt infant formula or infant formula, the product must meet the definition of an exempt infant formula or infant formula in section 412 (h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 350a(h)) or section 201(z) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(z)).

- 2. Whether the product is a new formula or a reformulation of an existing product. Information about the Food and Drug Administration's (FDA) notification process can be found at
- https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/infantformula/default.htm. (Please note: any reformulation that would meet the definition of a "major change" to the formula per section 412(c)(2)(B) of the Federal Food and Drug Cosmetic Act at 21 CFR 106.30(c)(2), such as the addition of a new ingredient or a significant change in the amount of protein, fat or carbohydrate should be re-evaluated for WIC-eligibility.)
- 3. The product has been introduced into interstate commerce (via a point of sale either online and/or retail), which means that the product meets 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 FDA regulations at 21 CFR parts 106 and 107. The product is intended for enteral digestion and it can be used as an oral and/or tube feeding.
- 4. The product is nutritionally complete, not requiring the addition of any ingredients other than water before being served in a liquid state.
- 5. Product type (standard milk-based, soy-based, hydrolyzed milk-protein, amino acid-based, etc.)
- 6. Identification of the different product container sizes, unit type (e.g., can, bottle, etc.), and packaging (e.g., single units versus multiple-packs or cases).
- 7. Physical form of product (i.e., liquid concentrate, powder, ready-to-feed).
- 8. Electronic product labels for each physical form which should include nutrient level and an ingredient listing.
- 9. Nutrient composition of each physical form including caloric content. (This should include iron content in terms of milligrams per liter or milligrams per kilocalories of formula and the calorie content in terms of kilocalories per reconstituted fluid ounce of formula, such as 20 kcal/oz.).

How to Determine the Calories per Fluid Ounce for Infant Formula

	Steps and Examples
Step 1.	Review the infant formula's product label for nutrient level specified for each 100 calories. The label shall bear a statement of the number of fluid ounces supplying 100 kilocalories.
Step 2.	Divide 100 calories by the amount of fluid ounces (oz.) supplying 100 kilocalories, prepared as directed.
Examples	Nutrients per 100 Calories (5 fl oz., prepared as directed) 100 Calories ÷ 5 fluid oz. = 20 calories per fluid oz. Nutrients per 100 Calories (5.3 fl oz., prepared as directed) 100 Calories ÷ 5.3 fluid oz. = 18.9 calories per fluid oz. (round to 19 cal/oz.)

- 10. Reconstituted yield (e.g., total fluid ounces), as consumed, per container and/or package size of product.*
- 11. Other product information: the product's special characteristics; how the product should be prepared/served.
- 12. Indication for product use in WIC (e.g., prematurity, inborn errors of metabolism, malabsorption syndromes, etc.).
- 13. Recommended age of use.
- 14. Availability of additional flavors.
- 15. Product availability (e.g., from pharmacies, grocery stores, directly from the manufacturer, etc.).
- 16. Universal Product Code (UPC)
- 17. Price list.

B. Review of WIC- eligible nutritionals

In review of WIC-eligible nutritionals, SAs should include the following information:

- 1. The product is intended for enteral digestion and it can be used as an oral and/or tube feeding.
- 2. The WIC-eligible nutritional serves the purpose of a food, meal or diet (may be nutritionally complete or incomplete) and provides a source of calories and one or more nutrients; may be nutritionally complete or incomplete.
- 3. WIC-eligibility category (WIC-eligible nutritional); medical documentation required for issuance.
- 4. Product type (amino acid-based, inborn errors of metabolism, etc.)
- 5. Identification of the different product container sizes, unit type (e.g., can, bottle, sachet, etc.), and packaging (e.g., single units versus multiple-packs or cases).
- 6. The product's physical form (i.e., liquid concentrate, powder, ready-to-feed or ready-to-feed.
- 7. Electronic product labels for each physical form, which should include nutrient level and ingredient listing
- 8. Nutrient composition of each physical form including caloric content (the calorie content in terms of kilocalories per reconstituted fluid ounce of formula (such as 20 kcal/oz.)).
- 9. Product reconstituted yield, as consumed, per container and/or package size of product or per standard preparation guidelines/common dosage recipe.*
- 10. The product's intended uses, including identification of the types of medical conditions for which the product was designed (e.g., inborn errors of metabolism, malabsorption syndromes, severe food allergies, etc.).
- 11. Recommended age of use.
- 12. If the product comes in additional flavors.
- 13. Other product information: the product's special characteristics: how the product should be prepared/ served.
- 14. Product availability (e.g., from pharmacies, grocery stores, directly from manufacturers, etc.).

C. Products Not Allowed.

^{*} The package size/reconstitution yield of the container of the product will likely contribute to a SA's determination of an appropriate issuance methodology.

WIC regulations in Table 4 of 7 CFR 246.10(e)(12) disallow the following products:

- 1. 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).
- 2. Medicines or drugs
- 3. Hyperalimentation feedings (nourishment administered through a vein)
- 4. Enzymes, herbs, or botanicals
- 5. Conventional foods
- 6. Oral rehydration fluids or electrolyte solutions
- 7. Flavoring or thickening agents
- 8. Feeding utensils or devices (e.g., feeding tubes, bags, pumps) designed to administer a WIC-eligible formula
- 9. Sports or breakfast drinks

Chapter 4 Nutrition Tailoring of WIC Food Packages

4.1 Overview

Nutrition tailoring is the process of modifying food packages to better meet the supplemental nutrition needs of *individual* participants. WIC regulations authorize individual nutrition tailoring based on the CPA's assessment of the participant's supplemental nutrition needs, including breastfeeding needs. Nutrition tailoring entails making changes or substitutions to food types (e.g., dry beans vs. peanut butter) and physical food forms (e.g., dry milk vs. fluid milk). Nutrition tailoring may also involve eliminating foods due to allergy, medical or nutritional condition, or in situations where a participant cannot use or refuses the item.

For further guidance, refer to Appendix E: Issuance of Fat-reduced Milks/Yogurt to One Year Olds

A. Provision of full maximum monthly allowance. WIC regulations at 7 CFR 246.10(c) (Nutrition Tailoring) require that the full maximum monthly allowances of all supplemental foods in all food packages must be made available to participants if medically or nutritionally warranted. By design, the food package quantities and types of foods are intended to (1) address the prevalence of inadequate and excessive nutrient intakes for each WIC participant category, (2) contribute to an overall dietary pattern consistent with the Dietary Guidelines for Americans and toddler and infant feeding practice guidelines, and (3) deliver priority nutrients to participants to meet their supplemental nutrition needs. Reductions in quantities of WIC foods cannot be made for cost-savings, administrative convenience, or to control vendor abuse. In addition, quantities may not be reduced for categories, groups or subgroups of WIC participants, i.e., categorical tailoring.

B. Provision of less than the maximum monthly allowance to individual WIC participants.

Provision of less than the maximum monthly allowances of supplemental foods to an individual WIC participant in all food packages is appropriate only under the following 3 circumstances (7 CFR 246.10(c)):

1. When medically or nutritionally warranted (e.g., to eliminate a food due to a food allergy or medical condition or tailor formula amounts for breastfeeding infants). Medically or nutritionally warranted reasons to eliminate or reduce the quantity of foods for individual WIC participants include, but are not limited to, such situations and conditions as exclusive tube feeding, vegan diets (eliminating dairy and infant meat), a

food allergy, an inborn error of metabolism, and prematurity.

Overweight and obesity are <u>not</u> medically or nutritionally warranted reasons to provide less than the maximum monthly allowance of foods authorized for participants. The quantities of foods in the WIC food packages are supplemental and, by design, intended to deliver priority nutrients to WIC participants and address the prevalence of inadequate and excessive nutrient intakes for each WIC participant category. Although obesity is not a medically or nutritionally warranted reason to reduce quantities of foods, a food package may be tailored, based on a nutrition assessment of the participant, to lower the fat and calorie content by such means as substituting beans for peanut butter.

2. A participant refuses or cannot use the maximum monthly allowances. The maximum food benefit must be offered to participants (except for infant formula for breastfed infants). Only in situations when there is a food allergy or if a participant cannot use the quantities provided by WIC for reasons such as having limited household storage, going out of town, or similar circumstances may quantities be reduced or eliminated on an asneeded basis. For example, if a participant raises chickens and has a plentiful supply of eggs, a WIC food package without eggs may be issued. The reason for tailoring an individual's food package prescription should be documented in the participant's record.

While such situations indicate justifiable reasons to reduce or eliminate foods from a participant's food package, it is incumbent upon local agency staff to convey to participants that WIC foods and quantities are chosen to deliver priority nutrients and meet the supplemental health and nutrition needs of pregnant, postpartum, and breastfeeding women, infants and children less than five years of age. Nutrition education should focus on the optimal use of WIC foods, e.g., shopping for value and nutrition, and preparing and cooking WIC foods to assist participants in full use of their WIC food benefits.

3. The quantities necessary to supplement another programs' contribution to fill a medical prescription would be less than the maximum monthly allowances (see Section 6.2 of Chapter 6 Infant Formula and WIC-Eligible Nutritionals).

Chapter 5 Homeless and Other Emergency Accommodations

5.1 Overview

Section 246.10(b)(1)(ii) of WIC regulations allows SAs to make food package adjustments to better accommodate participants who are homeless and may not have the capability to make the best use of many standard WIC foods. This includes those participants in situations where access to water, cooking, refrigeration or storage of WIC foods are limited, e.g., emergency evacuees. Food package adjustments for these participants must be conducted on an individual basis in keeping with nutrition tailoring regulations at 7 CFR 246.10(c). Categorically tailoring a food package for groups of participants in such situations is not authorized.

Refer also to WIC Disaster Response at https://www.fns.usda.gov/wic/guidance

5.2 Authorized Accommodations

During the assessment, the CPA should gather and document information about the participant's living conditions such as refrigeration and storage capabilities, restricted water supply and the ability to use WIC foods. This information must be considered when assigning a food package. SAs should develop guidelines for its local agencies that describe modifications available for tailoring a food package for an individual WIC participant whose circumstances find them without running water, cooking facilities, and/or adequate refrigeration.

A. Examples of allowable modifications to WIC food packages.

- 1. Individual serving-size containers to accommodate lack of food storage or preparation facilities:
- 2. Canned beans for dry beans;
- 3. Ready-to-feed infant formula for liquid concentrate or powdered formula (in accordance with 7 CFR 246.10(e)(1)(iv));
- 4. Shelf stable containers of fluid milk or juice;
- 5. Hard boiled eggs (where readily available for purchase in small quantities);
- 6. UHT, dry or evaporated milk

SAs that do not routinely authorize canned or dried fruits and vegetables must make accommodations for participants in emergency situations who do not have ability to properly store fresh or frozen produce.

B. Ready-to-Feed Formula.

SAs should consider policies for issuing ready-to-feed formula in emergency situations where a participant's household has an unsanitary or restricted water supply or poor refrigeration. In accordance with WIC regulations Section 246.10(e)(1)(iv), ready-to-feed (RTF) WIC formulas may be authorized when the CPA determines and documents that one or more of the following criteria are met:

- 1. The participant's household has an unsanitary or restricted water supply or poor refrigeration;
- 2. The person caring for the participant may have difficulty correctly diluting concentrated liquid or powder forms; or
- 3. The WIC infant formula is only available in RTF.

For participants that receive Food Package III-Participants with qualifying condition-there are two additional criteria which may be used to issue RTF: 1) if a RTF form better accommodates the participant's condition; and 2) if RTF improves the participant's compliance in consuming the prescribed WIC formula.

C. Substitution of eggs.

SAs are authorized to issue 64 ounces of canned beans or 18 ounces of peanut butter or 15 ounces of canned fish as a substitute for one dozen eggs for homeless participants who lack refrigeration. Combinations of peanut butter, canned beans and canned fish may be issued. Providing additional legumes, peanut butter and/or canned fish as a substitute for eggs may significantly increase the amount of these foods participants receive. In issuing additional quantities of beans, peanut butter or canned fish, SAs should assess the amount of these food items participants would reasonably consume in a month's time.

D. Cheese in Food Package VII.

Food Package VII provides 1 pound of cheese as a separate food category, i.e., *in addition to* the 24 quart maximum allowance of milk. Except for homeless participants, no substitutions for the extra pound of cheese in Food Package VII are authorized. For homeless participants where refrigeration is limited or not available, 3 quarts of UHT or dry or evaporated milk may be provided in lieu of the one pound of cheese in Food Package VII.

5.3 Participant Education

Local agencies should counsel participants on food preparation and safety concerns due to conditions such as loss of refrigeration or unsafe drinking water. Participants should also be advised that in emergency situations grocery stores may not have sufficient stock to provide the full food package or may not be open to accept WIC food instruments. In these situations, or in the event of a disaster that results in discontinuation of WIC services, clinics should refer participants to other programs such as food banks, congregate feeding sites, Red Cross and other disaster relief agencies. Additionally, it is critical for local agency staff to provide breastfeeding education and support, when appropriate, during a disaster situation. Not only is human milk a safe source of food for the infant that provides nourishment and protection from diseases, but breastfeeding also promotes the health of the mother during a disaster by reducing stress and providing comfort.

Chapter 6WIC Formula

6.1 Overview

WIC State and local agencies are responsible for ensuring that WIC Formula (i.e., infant formula, exempt infant formula and WIC-eligible nutritionals) is issued in amounts consistent with WIC regulations. Table 1 of 7 CFR 246.10 establishes the maximum monthly allowances of reconstituted fluid ounces of liquid concentrate, ready-to-feed and powder infant formula for each infant food package (I, II, and III) and infant feeding option (i.e., partially breastfed and fully formula fed).

A. Full Nutrition Benefit.

The amounts listed as reconstituted fluid ounces of liquid concentrate infant formula are referred to in regulations as the full nutrition benefit (FNB). Thus, the FNB serves as a common denominator that ensures all participants receive a similar amount of formula regardless of the physical form issued to them. While the FNB serves as the minimum amount of formula that must be provided to WIC participants (excluding individual nutrition tailoring based on a participant's breastfeeding assessment), the maximum monthly allowance amounts represent the upper limit of issuance for each of the physical forms of infant formula. If powder or ready-to-feed is substituted for liquid concentrate, SAs must provide the FNB of the same product in the same food package up to the maximum monthly amount for the respective physical form (i.e., powder or ready-to-feed).

This includes infant formula and exempt infant formula (contract as well as non-contract). SAs must issue these formulas per the method (i.e., monthly issuance or use of rounding up methodology) that provides the FNB without exceeding the maximum amounts for the physical form. It is the responsibility of the SA to determine which method (i.e., monthly issuance or use of rounding up methodology) it will use to provide the FNB without exceeding the maximum monthly allowance for the WIC formulas authorized on the State food list.

However, WIC staff are expected to individually tailor the amount of infant formula based on the assessed needs of the breastfeeding infant and provide the minimal amount of formula that meets but does not exceed the infant's nutritional needs (this amount will be less than the FNB).

B. Monthly Issuance.

To issue formula on a monthly basis, SAs divide the FNB amount of the infant's food package and feeding option (i.e., partially breastfed or fully formula) by the reconstitution yield of the product container. SAs then round up to the next whole container amount (e.g., 8.57 rounds up to 9 containers) and multiply this number of containers once again by the reconstitution yield of the container to ensure the amount issued does not exceed the maximum monthly allowance for the infant's food package and feeding option.

C. Rounding Up Methodology.

If the reconstitution yield of an infant formula container is such that the FNB cannot be provided without exceeding the maximum monthly allowance, SAs must use the rounding up methodology for issuing that product. The rounding up methodology more closely provides the FNB of formula to participants, as the FNB is determined over the timeframe (number of months the participant receives the food package). In any given month of the timeframe, the monthly issuance of reconstituted fluid ounces of infant formula may exceed the maximum monthly allowance or fall below the FNB; however, the cumulative average over the timeframe may not fall below the FNB. SAs may choose to select one or more infant food package (i.e. 0-3 months, 4-5 months, 6-11 months) for rounding up issuance.

To issue formula using the rounding up methodology as described in WIC regulations at 7 CFR 246.10(h), SAs must:

- 1. Multiply the FNB by the number of months in food package to obtain the total amount of infant formula to be issued.
- 2. Determine the yield (in reconstituted fluid ounces) provided by the container of formula issued by the SA.
- 3. Divide the total amount of formula by the container yield to obtain the total number of containers to issue during timeframe (e.g. 6 months).
- 4. Round up to the next whole same size container if the number of containers is not a whole number (e.g., 33.3 containers would round up to 34 containers).
- 5. Distribute the total containers across the food package timeframe (number of months) as evenly as possible, with the most benefit provided to participants in the beginning months of the food package timeframe (e.g., 9, 9, 8, 8).

SA management information systems (MIS) must support the option to use either method (i.e., monthly issuance or rounding up methodology) for the 3 timeframes (0-3 months, 4-5 months, 6-11 months). The SA MIS must be flexible in order to: 1) provide the FNB without exceeding the maximum monthly allowance for the WIC formulas authorized; 2) to support the ability for infant formula to be individually tailored according to the breastfed infant's needs as determined by the breastfeeding assessment; and 3) adapt to any changes in issuance methodology, such as reconstituted yield.

D. WIC Infant Formula Calculator.

As a courtesy to WIC SAs, the FNS National Office developed the WIC Infant formula calculator, a web-based tool to assist WIC SAs with determining infant formula issuance amounts consistent with WIC regulations. The WIC infant formula calculator can be used to determine issuance of one infant formula product at a time. It can display issuance results via the

rounding up method as well as issuance of infant formula on a monthly basis, and can be accessed via the following link: https://wicworks.fns.usda.gov/wic-infant-formula-calculator.

E. Individual Tailoring of Infant Formula.

The food packages for partially breastfeeding mothers and infants are designed to provide for the supplemental nutrition needs of the breastfeeding dyad, provide minimal formula supplementation to help mothers maintain milk supply, and provide incentives for continued breastfeeding. The benefits of these food packages are lost if the dyad is issued the fully formula food packages.

For partially breastfed infants, WIC staff are expected to tailor the amount of infant formula based on the assessed needs of the breastfeeding infant and provide the minimal amount of formula that meets but does not exceed the infant's nutritional needs (this amount will be less than the FNB). SA MIS should support the ability for infant formula to be tailored according to the infant's needs as determined by the breastfeeding assessment.

Additionally, SAs should develop policies for handling formula requests from breastfeeding mothers that encourage substantial and continued breastfeeding. This is true whether the infant receives the partially (mostly) breastfeeding food package or the fully formula fed food package. When a breastfeeding mother requests infant formula, staff should assess and listen to the mother to determine her reason(s) for requesting formula and ensure the mother receives support from WIC staff with breastfeeding training, a peer counselor, WIC Designated Breastfeeding Expert, or other healthcare professional who can adequately address the mother's concerns and help her continue to breastfeed.

F. Individual Tailoring of WIC Formula in Food Package III for Children and Women.

Women and children who receive Food Package III have qualifying medical conditions that require the use of a WIC formula. The amount of WIC formula issued to these medically fragile participants is based on medical documentation of their assessed nutritional needs. Table 3 of 7 CFR 246.10(3)(11) establishes the maximum monthly allowance for WIC Formula (i.e., infant formula, exempt infant formula and WIC-eligible nutritionals) in Food Package III for children and women. Unlike Food Package III for infants, Food Package III for children and women does not contain an FNB amount, meaning that issuance of WIC Formula is "up to" the maximum monthly allowance. SAs may not exceed the maximum monthly allowance established for WIC formula in Food Package III for children and women. WIC staff are expected to tailor the amount of the WIC Formula based on the assessed needs of the individual. The State must have the capability to issue the WIC Formula up to the maximum monthly allowance as needed.

G. Unused and Returned WIC Formula

While SAs should have policies and procedures to ensure that nutrition tailoring of WIC formula occurs, as there may be a number of reasons why participants may have unused WIC formula. FNS does not recommend reissuing or donating unused/returned WIC formula, including donating formula to an animal shelter or farm. This approach ensures safety, meets the Federal

regulatory requirement at 7 CFR 246.4 (a)(14)(xviii) that participants only obtain WIC infant formulas from facilities that are registered with FDA, and satisfies the Public Health Security and Bioterrorism Preparedness and Response Act as well as the Food Safety Modernization Act. Returned unused WIC formula may have been inappropriately stored (e.g., exposed to extremely high temperatures), may be past its use-by-date, or subjected to tampering (e.g., labels or use-by-dates changed). Such conditions can cause products to lose nutrients, which could impact the product's safety as well as potentially threaten the health of nutritionally at risk participants.

Additionally, SA policies and procedures should take measures to prevent and avoid fraud by including provisions such as, but not limited to:

- Documenting assessed nutritional needs for the amount of formula issued and rationale for food package tailoring, as appropriate.
- Educating participants on how to redeem and utilize WIC food instruments to prevent having unused formula, how to handle unused formula (i.e., proper disposal), and that attempting to sell, trade, or gift WIC food benefits qualifies as a participant violation.
- Ensuring accurate issuance and rebate billing that does not exceed the maximum monthly allowances.

If a SA chooses to accept unused WIC formula from participants and dispose of it, then the SA would need to develop policies and procedures for their local agencies. SAs are strongly encouraged to consult with their health department and, as needed, with legal counsel for issues related to State-procured rebate contracts, local and State health laws, and clinic documentation recommendations when developing such policies and procedures.

6.2 Coordination with Medical Payers and Other Programs that Provide or Reimburse for Formulas

WIC regulations at 7 CFR 246.10(e)(3)(vi) require WIC SAs to 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 nutritionals benefits to mutual participants. Food Package III provides exempt infant formulas and WIC-eligible nutritionals to participants who have a diagnosed medical condition that precludes or restricts the use of conventional foods. The provision of these exempt formulas and WIC-eligible nutritionals helps to prevent expensive health care costs, resulting in savings to health insurance providers, such as Medicaid⁵. Medical documentation, written by a healthcare professional licensed to write medical prescriptions under state law, is required to issue exempt infant formulas and WIC-eligible medical foods.

Medicaid as primary payer. The Medicaid Program is the primary payer for exempt infant formulas and medical foods issued to WIC participants who are also Medicaid beneficiaries. Annually, WIC State agencies are expected to coordinate with their State Medicaid counterpart to ensure that the nutritional needs of mutual participants are met. For additional guidance, refer

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⁵ WIC-eligible nutritionals may or may not meet the criteria for medical foods per Medicaid guidelines.

to WIC Policy Memorandum #2015-07 Medicaid Primary Payer for Exempt Infant Formulas and Medical Foods.

Chapter 7Vendor Management

7.1 Overview

WIC State agency nutrition and vendor management staff should work collaboratively when establishing minimum stocking requirements, choosing a list of authorized WIC food items and developing vendor training to ensure that the goals of the WIC Program are achieved. It is the responsibility of both nutrition and vendor management staff to develop and monitor for compliance of State agency policies to ensure that participants receive the quantities and types of WIC foods intended to deliver priority nutrients to participants. WIC authorized vendors are critical partners in the successful delivery of WIC benefits. It is only when WIC food instruments are redeemed in full for the specified foods that the desired nutrition benefit for participants can be achieved.

7.2 Vendor Stocking of Authorized Foods

WIC regulations at 7 CFR 246.10(b)(2)(i) require SAs to identify the authorized brands of foods and package sizes that are acceptable for use in the Program in accordance with the requirements of 7 CFR 246.10. WIC regulations at 7 CFR 246.12(g)(3)(i) require SAs to establish minimum requirements for the variety and quantity of supplemental foods that vendor applicants must continually stock to become an authorized vendor. These requirements include that the vendor stock at least two different fruits, two different vegetables, and at least one whole grain cereal authorized by the State agency. WIC regulations at 7 CFR 246.12(h)(3)(ii) require that vendors provide to participants only the authorized supplemental foods listed on the food instrument or cash-value voucher. The vendor may not provide unauthorized food items or substitute an unauthorized food item for a similar authorized food item. For example vendors may not substitute whole milk for low-fat milk, or a 22-ounce package of bread for the 16-ounce package on the food instrument. These transactions would not be in compliance with Federal regulations and would be considered a violation and subject to Federal mandatory vendor sanctions. WIC regulations at 7 CFR 246.12(l)(iv)(A) indicate that a SA must disqualify a vendor for one year from participating in the WIC Program for a pattern of providing unauthorized food items in exchange for food instruments or cash-value voucher. WIC regulations at 246.12(i) require SAs to provide training to vendors on topics such as the purpose of the Program, the supplemental foods authorized by the SA, and the minimum varieties and quantities of authorized supplemental foods that vendors must stock, along with other requirements to participate as an authorized WIC vendor.

WIC regulations at 7 CFR 246.12(h)(1) require SAs to enter into written agreements with all authorized vendors. WIC regulations at 7 CFR 246.12(h)(3)(xxii) require vendors to comply with the vendor agreement and Federal and State statutes, regulations, policies, and procedures governing the Program. In addition, the vendor agreement requires the vendor to comply with

the minimum variety and quantity of supplemental foods selection criterion throughout the agreement period. Vendors that frequently do not have sufficient stock of supplemental foods inconvenience participants and potentially undermine both the integrity and the nutritional goals of the Program. When the SA becomes aware of such situations, the SA should send a warning notification to the vendor that failure to meet the minimum stock requirements may result in termination of the vendor agreement. The SA should follow up such warnings with a reassessment of the vendor, which may include a site visit to the vendor to evaluate their stock levels. Upon completion of an assessment, if the vendor fails to meet the minimum variety and quantity selection criteria, the SA should terminate the vendor's agreement.

SAs should review their procedures for ensuring that WIC vendors consistently stock authorized supplemental foods and work with vendors and/or distributors to ensure that WIC-authorized food items are readily available for WIC participants to purchase.

Appendix A

Container and Package Sizes

A. Authorization of appropriate package sizes. To achieve the nutrition and health goals of the Program and ensure the nutritional integrity of the food benefits provided to participants, SAs must authorize WIC foods in package sizes that provide participants their full authorized food benefit. (This does not apply to infant foods or infant formula since rounding up is authorized in order to provide the full nutritional benefit for infants.) See Section 2.6 of Chapter 2 Food Package Design.

Package size specifications should be consistent with safe food practices and consider a household's storage capabilities and the amount of the food suggested for daily consumption. Careful consideration of package sizes helps to ensure that the foods are eaten only by the participant and that food spoilage is minimized.

FNS recognizes that the Federal maximum monthly allowances for WIC foods affect which container sizes SAs may authorize for the Program. While not all manufacturers produce WIC foods in container sizes that allow SAs to provide the maximum allowance to participants, sufficient numbers of most WIC foods in sizes and forms that meet the full maximum allowance exist in the marketplace. The SA is responsible for ensuring that container sizes of WIC foods do not shortchange participants of their food benefits.

B. Limited Availability. Limited availability refers to situations where package sizes that provide the maximum allowance are unavailable or limited, resulting in reduced choice and variety for participants. While this is not an issue for most WIC foods, FNS will allow SAs the option to authorize package sizes that provide less than the maximum allowance for certain food items when there is limited availability as long as the nutritional integrity of the food package is not compromised. FNS grants approvals for package size flexibilities on a case by case review. Thus, with FNS approval, SAs may authorize containers of these foods in sizes that most closely meet container sizes that allow the maximum allowance for those foods as long as container sizes (or combination of container sizes) that provide the maximum allowance are also authorized. For example, a 15-ounce can of beans may be authorized as long as the SA also authorizes a 16-ounce can that provides the maximum allowance. However, a 59-ounce container of juice for a child or woman as an option for the 64-ounce container of juice may not be authorized because (1) the nutritional integrity of the package would be compromised and (2) there are sufficient numbers of WIC-eligible juices available in package sizes that provide the maximum allowance.

Such authorization of package sizes must be done on a State-wide basis; SAs may not authorize a variance in package sizes in different areas of the State. Where choice and variety of WIC foods are adequate in package sizes that meet the maximum, it is not appropriate to authorize other package sizes. At least one package size (*or combination of sizes*) must add up to the full maximum monthly allowance that participants are authorized to receive. The choice to achieve the full maximum allowance must be made available to participants, and local agencies must

provide appropriate education to participants about how to obtain their full food package benefit.

Vendor minimum stock and training materials should ensure that participants are able to obtain their full benefit. If a range of package sizes is authorized, e.g., 16-18 ounces of peanut butter, the vendor agreement should specify that the vendor must stock at least one brand of peanut butter in an 18-ounce container.

C. Food Instruments and Participant Education. The paper food instrument must specify the container size (e.g., 2- 64-ounce containers of juice or 3- 11.5 or 12 ounce containers juice concentrate that reconstitute to 48 ounces each). If a SA chooses to authorize a range of package sizes based on limited availability, it must specify the range on the food instrument, e.g., 15-16 ounces canned beans. To ensure participants choose authorized container sizes, SAs may not use terms such as "16 ounces or less" "up to 16 ounces." Food cards and/or education materials should demonstrate to participants how to obtain their full food package benefit when combination package sizes that do not provide the maximum are authorized.

When SAs authorize package sizes that work for only one food package category (e.g., 24-ounce packages of bread for women fully breastfeeding multiples who receive 1.5 times the maximum allowance, or 32 ounce packages of bread for children (2 pounds)), they must restrict purchase of those sizes by other participant categories by using appropriate wording on the food card such as "allowed only when listed on WIC food instrument" or indicating the authorized amount on the participant's food instrument.

D. Aggregation of WIC benefits for WIC families. SAs may aggregate WIC supplemental food amounts for families. This may be useful when benefits are issued via electronic-benefit transfer. However, SAs may not authorize container sizes that exceed the monthly maximum allowance for an individual participant. Foods on State authorized food lists must meet the needs of the individual food package prescription. Federal regulations at 7 CFR 246.10(b)(2)(ii)(D) require that local agencies advise participants or their caretakers that the supplemental foods are only for the participant's personal use. This information is an important component of nutrition education for agencies that aggregate food benefits.

Appendix B

Choice and Variety—"More than One" Provision

A. Overview. WIC regulations at 7 CFR 246.10(b)(2)(ii)(B) require SAs to make available to participants more than one food from each WIC food category. This provision should not be interpreted to mean that SAs should limit the number of foods within a category.

The only exceptions are the categories of peanut butter and eggs (at least one type of peanut butter, e.g., creamy, and one type of eggs, e.g., medium white, must be made available). No limitations, other than those authorized by Federal regulations and policy, are authorized for fruits and vegetables purchased with the cash-value voucher. The purpose of these provisions is to allow as much variety and choice from the authorized foods as is feasible considering cost constraints and availability. Providing more variety and choice will accommodate the diverse needs of WIC participants, including different ethnic or cultural needs.

B. Implementing the "More than One" Provision. The following describes the WIC food package categories and how to implement the "more than one" provision. Note that offering different *brands* of a product, e.g., Safeway brand 100% whole wheat bread and Albertsons brand 100% whole wheat bread, do not meet the intent of the "more than one" provision.

Refer to Table 4 of 7 CFR 246.10(e)(12) for a list of authorized WIC foods and their minimum specifications.

1. Milk Category

WIC-eligible milks include milk (cow and goat) that is whole, reduced fat, low-fat, or non-fat milks, flavored milks, fluid, shelf-stable, evaporated or dried, or cultured, lactose-free milk, lactose-reduced milk, kefir. At a minimum, unflavored fluid cow's milk and at least one other of these milks, e.g., lactose free, must made available.

For Food Packages III-VII, cheese may be provided as an alternative (substitute) to milk and, as such, it is not required that more than one cheese type be offered, although it is encouraged for variety and choice. (Food Package VII has a separate cheese requirement.) The same is true for yogurt, tofu and soy-based beverages.

2. <u>Cheese Category</u> (cheese is a separate food category for Food Package VII only)

WIC-eligible cheeses include Monterey Jack, Colby, natural Cheddar, Swiss, Brick, Muenster, Provolone, part-skim or whole Mozzarella, and pasteurized processed American. At a minimum, more than one of these cheeses must be made available, e.g., Monterey Jack and natural Cheddar.

3. <u>Dried Bean Category</u>

WIC-eligible dried beans include, but are not limited to, black beans, black-eyed peas, garbanzo beans, great northern beans, kidney beans, lima beans, navy beans, pinto beans, soybeans, split peas, and lentils. At a minimum, more than one of these dried beans must be made available, e.g., black beans and kidney beans.

Canned beans are a substitute for dry beans. Therefore, it is not a requirement that more than one variety of canned beans be made available, although it is encouraged for variety and choice.

4. Breakfast Cereal Category

WIC-eligible cereals include those made from whole wheat, oat, corn, and rice and other grains. At a minimum, more than one of these cereal grains must be made available; however, SAs are encouraged to offer a wide variety of grains. SAs should first determine how many types of grains will be offered on their food lists—at least half must be whole grain.

5. Whole Wheat Bread Category

WIC-eligible breads include whole wheat bread (includes whole wheat buns and rolls) and whole grain bread (includes whole grain buns and rolls). At a minimum, more than one of these breads must be made available, for example, whole wheat bread and whole grain bread, or whole wheat bread and 100% whole wheat rolls. Other WIC-eligible whole grains such as tortillas, brown rice, whole grain pasta, etc. are optional additions in this category. Therefore, it is not required that more than one of these whole grain options be made available, although it is encouraged for variety and choice.

6. Juice Category

WIC-eligible juices include fruit and vegetable juices such as orange, apple, pineapple, grape, tomato and others. At a minimum, more than one WIC-eligible juice must be made available, e.g., orange and pineapple.

7. Canned Fish Category

WIC-eligible fish include light tuna, salmon, mackerel, and sardines. At a minimum, more than one canned fish must be made available, e.g., light tuna and salmon.

8. <u>Infant Cereal Category</u>

WIC-eligible infant cereals include those made from rice, barley, oat, multi-grain, barley and whole wheat. At a minimum, more than one of these cereal grains must be made available.

9. Infant Food Fruits and Vegetables Category

WIC-eligible infant food fruits and vegetables include different varieties (e.g., applesauce, peaches, pears, carrot, peas, sweet potatoes, spinach). At a minimum, more than one variety must be made available. A combination variety, e.g., carrots/peas, is considered one variety.

10. Fruits and Vegetables via Cash-Value Voucher or Cash-Value Benefit

The "more than one provision" does not apply to the cash-value voucher. SAs may not selectively choose which WIC-eligible fruits and vegetables are available to participants via the cash-value voucher. See Section 2.2.D. in Chapter 2 Food Package Design.

Appendix C

Administrative Adjustments to WIC Food Packages

A. Administrative Adjustment Overview. Administrative adjustment is the process by which a SA makes modifications to the packaging methods, container sizes, brands, types, and physical forms, but not quantities, of Federally-allowable WIC foods and food packages. SAs have the authority to make adjustments to WIC foods for administrative convenience and to control costs (See Section 2.2.D. in Chapter 2 Food Package Design). For additional guidance, refer to WIC Policy Memorandum #2015-6: Promising Practices in WIC Food Cost Containment

Acceptable administrative adjustments attempt to decrease cost while maintaining nutrition integrity and include such decisions as eliminating expensive brands, convenient food forms or packaging, and higher-cost food items. Appropriate product selection can contain food costs and maximize food dollars while providing equivalent nutrition. SAs should build flexibility into administratively-adjusted food packages to accommodate special needs by allowing alternative WIC-eligible foods for specific participants or nutrition risk criteria, such as providing peanut butter instead of beans for an underweight child.

- **B. Nutrition Integrity.** In making administrative adjustments, SAs must ensure that the nutritional basis, or integrity, of the food packages is intact. Nutritional integrity depends upon providing the maximum allowance of WIC foods, and the availability of adequate choice and variety of WIC foods for participants. Participant food preferences, based on taste and cultural influences, are equally important considerations. FNS urges WIC SAs to work towards a reasonable balance between cost reduction and participant acceptance.
- C. **Cost-Savings Strategies.** Rebates on WIC foods other than infant formula can be an effective cost-savings strategy. Other ways to maximize food costs include but are not limited to:
 - a. appropriate vendor selection, monitoring and sanctioning;
 - b. use of private label or store branded products that are nutritionally equivalent to national brands;
 - c. encouraging participants to shop in a cost-conscious manner.

D. Administrative food package adjustments available to SAs:

- 1. General adjustments that affect all foods
 - Allow only store brands or generic brands, where available, unless name brands are less expensive.
 - Reduce number of flavors or forms/types authorized. Certain brands, flavors, and forms/types of eligible supplemental foods have lower costs than others, thus savings can be achieved when participants are given fewer options in a given food category.

• Limit organic products and "natural" food items unless they are less expensive. SAs may not, however, restrict the purchase of organic fruits and vegetables with the cash-value voucher.

2. Milk and Milk Alternatives

- Limit milk selections by packaging size, and allow only the more economical packaging when possible.
- Allow only larger boxes of dry milk, when practical. Some vendors may only stock particular box sizes. Permit smaller boxes only when they are needed to provide the amount of milk prescribed. For reference, examples of different box sizes of nonfat dry milk and their reconstituted yields are listed below:

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64-ounce (4 lb.) box = 20 quarts milk (4.4 lb.) = 22 quarts milk (4.4 lb.) = 22 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk (4.4 lb.) = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk = 20 quarts milk <math>(4.4 lb.) = 20 quarts milk = 20 quart
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*NOTE: The reconstituted yield information above is provided as a convenience to WIC agencies. Boxes marked with an asterisk contain individual envelopes of nonfat dry milk, each weighing 3.2-ounce and yielding 1 quart of reconstituted milk. The 32-ounce box contains 10 envelopes, the 9.6-ounce box contains 3 envelopes, and the 16-ounce box contains 5 envelopes. Because this type of packaging is more convenient, it may also be more expensive than other boxes that provide nonfat dry milk in bulk.

- Limit the substitution of cheese for milk unless an individual's household conditions or nutritional/medical needs warrant cheese.
 - SAs must provide the maximum allowance from the milk category to participants
 if cheese is substituted for milk in order for participants to obtain their full milk
 benefit.
 - When substituting cheese for milk, the "dangling quart" may not be eliminated as a cost containment measure. However, States may issue half gallon containers every other month to contain costs.
 - In Food Package VII for fully breastfeeding women, one pound of cheese is made available as a separate food category. The one pound of cheese may <u>not</u> be eliminated as a cost containment measure in Food Package VII.
- Issue cheese, lactose-reduced, or lactose-free milk to participants only when there is a true medical or nutritional need such as lactose intolerance. The CPA should probe further to validate the self-reported diagnosis and offer dietary guidance as outlined in Risk Factor #355 (e.g., consuming smaller amounts of dairy at a time) and provide nutrition education on dietary sources of calcium other than dairy.

- Limit cheese to less expensive types, brands and packaging (e.g., store/private label brands; no shredded or individually wrapped cheese slices).
- Limit yogurt to quart size containers if smaller sizes that add up to 32 ounces are more expensive
- Limit substitution of tofu and soy beverage for milk unless an individual's nutritional/medical/cultural needs warrant.

3. Eggs

- Limit the types and brands to those lower in cost. Disallow "specialty" brands or types of eggs (e.g., organic or altered fat/cholesterol eggs).
- Limit the selection of eggs to small or medium size white eggs.

4. Cereal

• Limit types, flavors, brands and box sizes to those lower in cost (e.g., store/private label and larger box sizes).

5. Juice

- Limit types, flavors and brands of juice to those lower in cost.
- Limit selections by type of packaging and size of container (e.g., 12-ounce frozen concentrate for women).

6. Canned Fish

• Limit the purchase of canned fish to lower-priced packaging, brands and varieties (e.g., disallow packaging in pouches; authorize pink salmon instead of red).

7. Whole Wheat and Whole Grain Bread

• Limit to store brands where possible and limit varieties to least expensive.

8. Dry Beans/Peas/Peanut Butter

- Authorize dry beans instead of canned beans. Provide nutrition education to ensure participants know how to cook dry beans and the importance of dry beans in the diet.
- Limit the substitution of peanut butter for dried beans/peas or lentils to those participants who have medical conditions warranting extra calories (e.g., underweight), who have limited cooking skills/facilities, or who dislike cooked dried beans/peas or lentils.

- Issue peanut butter and dried beans/peas or lentils on alternating months where appropriate.
- Authorize beans instead of peanut butter to contain costs, but only in those food packages where either peanut butter or beans are authorized, i.e., Food Packages IV and VI. This is not allowed in Food Packages V and VII, where peanut butter and beans must be made available. WIC regulations at 7 CFR 246.10(e)(10) (Table 2, Footnote 17) gives various substitution rates for peanut butter/beans. In Food Packages V and VII the substitution rates for beans for peanut butter only applies when tailoring a food package for an individual participant.

9. Fruits and Vegetables

- The value of the cash-value voucher may not be reduced for cost-containment purposes.
- For administrative convenience, SAs may invoke the option at 7 CFR 246.10(b)(1)(i) to establish criteria in addition to the minimum Federal requirements in Table 4 of 7 CFR 246.10(e)(12), which could include restricting packaging (such as plastic containers) and package sizes (such as single serving) of processed fruits and vegetables available for purchase with the cash-value voucher. In addition, SAs may identify specific types of certain processed WIC-eligible fruits and vegetables (e.g., salsas, tomato sauces, stewed and diced tomatoes) on their food lists if they believe there is cause for significant vendor and participant confusion in identifying specific items within those categories that are WIC-eligible. SAs may not exclude the purchase of organic fresh fruits or vegetables. (See Section 2.2.D in Chapter 2 Food Package Design.)

Appendix D

State Approved Food Lists and Participant Food Cards/Pamphlets

A. State Food Lists. WIC regulations at 7 CFR 246.10(b)(2)(i) require SAs to provide to local agencies, and include in the State Plan, a list of all authorized foods and the maximum monthly allowances. The SA is responsible for maintaining a list of all WIC-eligible foods the SA authorizes. Such a list allows SAs to respond to questions about WIC-eligibility of a product, provide vendors and local agencies with a comprehensive list of WIC-authorized foods, and address recalls when necessary.

SAs must ensure that WIC foods participants purchase are eligible and authorized. Product labeling is not consistent and is often confusing. Making the participant or vendor responsible for these determinations will likely lead to frustration on the part of participants and vendors, and may lead to the purchase of foods that are not WIC-eligible.

SAs are also responsible for determining WIC eligibility of WIC foods in accordance with Table 4 of 7 CFR 246.10(e)(12) and its footnotes--Minimum Requirements and Specifications for Supplemental Foods.

B. State Food Cards/Pamphlets. FNS realizes that food cards for participants have space limitations that may preclude listing all possible authorized foods. At a minimum, the following WIC-eligible foods must be identified by brand, type and size on the food cards/materials for participants and vendors:

- Whole Grain Bread
- Tortillas (soft corn and whole wheat)
- Whole Wheat Macaroni (Pasta)
- Cereal
- Non-citrus juices
- Soy-based beverage
- Tofu
- Infant foods (infant cereal, fruits, vegetables, meat)
- Yogurt

1. Whole Wheat Bread

To save space on food cards SAs have the option to list the words "100% whole wheat bread" instead of specifying the brands and names of all authorized whole wheat breads. These breads are easy to identify by front of package labeling and have a standard of identity. The appropriate package size of 100% whole wheat bread must also be listed on the food card. Choosing this option does not eliminate the requirement that SAs maintain a list of all its authorized WIC foods, including brands, names, and package sizes of its authorized whole wheat bread, in accordance with 7 CFR 246.10(b)(2)(i).

Education must be provided to participants to ensure they understand that the front of the package must say "100% whole wheat bread," "100% whole wheat roll," or "100% whole wheat bun" and not just "whole wheat" or "wheat" or other wording that does not accurately describe a bread, bun or roll made up of 100% whole wheat. Participants should receive education on label reading advising them to also look for "whole wheat" as the first ingredient as a means to ensure they have made the correct choice.

SAs must continue to specify authorized whole wheat tortillas and whole grain breads on the food card to ensure participants choose the authorized food. Unlike whole wheat bread, whole wheat tortillas and whole grain breads do not have a standard of identity.

2. Cereal

Unlike whole wheat bread, there is no standard of identity for cereals. A great deal of variance in ingredients exists in cereal types and brands. SAs must specify names and brands of authorized cereals on its food card to ensure participants can easily choose authorized cereals that meet WIC eligibility requirements, specifically those for iron and sugar.

"Any Store Brand" is not an acceptable way to list cereals on food cards. SAs must list store brands by identifying the specific store, e.g., "Bran Flakes: Hannaford, IGA, Stop & Shop." To save space on food cards, SAs may list specific stores and specific brands above a list of cereal types. The SA must ensure that all cereals underneath a general statement have been evaluated for each store and brand listed.

Appendix E

necessary, and as established by SA policy.

Issuance of Fat-reduced Milks and/or Fat-reduced Yogurt to One Year Old Children in Food Package IV

A. Option to issue fat-reduced milks and/or fat-reduced yogurt to 1 year old children. WIC regulations at 7 CFR 246.10(e)(10) (Table 2, Footnotes 7 and 10) authorize SAs the option to issue fat-reduced milks and/or fat-reduced yogurt to 1 year old children (12 months through 23 months of age) for whom overweight or obesity is a concern. The CPA may make a determination for the need for fat-reduced milks and/or fat-reduced yogurt based on an individual nutrition assessment and consultation with the child's health care provider, if

Whole milk and whole fat yogurt are the standard issuance to 1 year old children. The regulatory provision granting WIC State agencies the option to issue fat-reduced milks acknowledges the American Academy of Pediatrics (AAP) 2008 clinical report titled, "Lipid Screening and Cardiovascular Health in Childhood." The AAP statement identifies parental history of obesity, lipidemia and cardiovascular disease as determinants of a child for whom overweight or obesity is a concern.

B. Developing SA policy defining assessment criteria. SAs that choose to authorize fat-reduced milks and/or fat-reduced yogurt for the 1 year old child must develop policy that defines the assessment criteria the CPA will use to make the determination of whether the child is in need of fat-reduced milks and/or yogurt. FNS strongly recommends that such a policy be developed in consultation with the health care community.

For example, a SA may choose to use existing WIC nutrition risk 114: Overweight or At-risk of Overweight (Infants and Children) to identify children 1 year of age for whom overweight or obesity is a concern. Nutrition risk 114 requires the collection of the biological mother and/or father's BMI at certification with a BMI score of \geq 30 placing the child at risk. Additionally, State agencies may consider using WIC nutrition risk 115: High Weight for Length, which requires the CPA to plot the child's length and weight using CDC growth charts, with \geq 97.7th percentile placing the child at risk.

Given the potential burden and inaccuracies associated with the collection of self-reported familial medical histories, SAs may decide to not use the determinants of familial history of lipidemia and cardiovascular disease as part of the WIC nutrition assessment to identify children 1 year of age for whom overweight or obesity is a concern.

C. Specifying types of milk authorized. In addition to defining the assessment criteria, the SA policy should also specify which types of fat-reduced milk (i.e., reduced fat (2%), low-fat (1%) and non-fat milk) and which types of yogurt (i.e., low-fat and non-fat) are authorized for the 1 year old child for whom overweight or obesity is a concern. If more than one type of fat-reduced

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⁶ American Academy of Pediatrics, Committee on Nutrition. Lipid Screening and Cardiovascular Health in Childhood. Pediatrics. April 2008.

milk and/or yogurt is authorized, then the policy should also direct the CPA on the appropriate steps to follow for issuance of the specific type of fat-reduced milk and/or yogurt. For example, a SA may develop policy that would require the CPA to consult with the participant's health care provider prior to the issuance of milk or yogurt with 1% or less milk fat to the participant. Additionally, a SA may determine when issuing 1% or less milk fat is inappropriate, such as for a 1 year old child, with obese parents, but whose growth is plotted at less than the 5th percentile on the growth chart.

AAP recommends exclusive breastfeeding for the first 6 months of life, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by the mother and child. While the fat content of human milk increases with breastfeeding duration, human milk should not be discontinued for concerns about being overweight.

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American Academy of Pediatrics, Section on Breastfeeding. Breastfeeding and the Use of Human Milk. Pediatrics. February 2012.

Glossary & Acronyms

Administrative Adjustment – the process by which a State agency (SA) modifies the packaging methods (pouch, can, jar), packaging size (single container, multi-pack, case), brands, types, and physical forms, but not quantities, of Federally-allowable WIC foods and food packages. SAs have the authority to make adjustments to WIC foods for administrative convenience and to control costs.

Breastfeeding Dyad – Mother-infant breastfeeding pair.

Cash-Value Voucher – a fixed-dollar amount check, voucher, electronic benefit transfer (EBT) card or other document which a WIC participant uses to obtain authorized fruits and vegetables.

Competent Professional Authority (CPA) – an individual on the local agency staff authorized to determine nutritional risk and prescribe supplemental foods. The following persons are the only persons the SA may authorize to serve as a competent professional authority: Physicians, nutritionists (bachelor's or master's degree in Nutritional Sciences, Community Nutrition, Clinical Nutrition, Dietetics, Public Health Nutrition or Home Economics with emphasis in Nutrition), dietitians, registered nurses, physician's assistants (certified by the National Committee on Certification of Physician's Assistants or certified by the State medical certifying authority), or State or local medically trained health officials. This definition also applies to an individual who is not on the local agency staff but who is qualified to provide data upon which nutritional risk determinations are made by a competent professional authority.

Electronic Benefits Transfer (EBT) – an electronic system that replaces paper food checks or vouchers with a card for food benefit issuance and redemption at authorized WIC grocery stores.

Food Instrument – a voucher, check, electronic benefits transfer card (EBT), coupon or other document which is used by a participant to obtain supplemental foods.

Food and Nutrition Service (FNS) – the Food and Nutrition Service of the U.S. Department of Agriculture.

Full Nutrition Benefit (FNB) – the minimum amount of reconstituted fluid ounces of liquid concentrate infant formula as specified in Table 1 of 7 CFR 246.10(e)(9) for each food package category and infant feeding variation (e.g., Food Package IA fully formula fed, IA–FF).

Nutrition Tailoring – a process of modifying food packages to better meet the supplemental nutrition needs of individual participants. The term "nutrition tailoring" is reserved solely for making food package accommodations, as authorized by WIC regulations in 7 CFR 246.10(c), to accommodate the needs of an *individual* participant based on the Competent Professional Authority's (CPA) assessment of the participant's nutritional risk condition, breastfeeding assessment, dietary needs, and personal food preferences. Nutrition tailoring entails making changes or substitutions to food types (e.g., dry beans vs. peanut butter) and physical food forms (e.g., dry milk vs. fluid milk). Nutrition tailoring may also involve eliminating foods due to allergy, medical or nutritional condition, or in situations where a participant cannot use or refuses

the item.

State agency (**SA**) – the health department or comparable agency of each State; an Indian tribe, band or group recognized by the Department of the Interior; an intertribal council or group which is an authorized representative of Indian tribes, bands or groups recognized by the Department of the Interior and which has an ongoing relationship with such tribes, bands or groups for other purposes and has contracted with them to administer the Program; or the appropriate area office of the IHS.

State Plan – a Program operation and administration plan that describes the manner in which the State agency intends to implement and operate all aspects of Program administration within its jurisdiction in accordance with 7 CFR 246.4.

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