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NATIONAL DAIRY COUNCIL®

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December 15, 2003

Patricia Daniels
Director, Supplemental Food Programs Division
Food and Nutrition Service
USDA
3101 Park Center Drive, Room 520
Alexandria, Virginia 22302

RE: Revisions to the WIC Food Packages
68 Federal Register 53903, Vol. 68, No. 178

Dear Ms. Daniels:

The NATIONAL DAIRY COUNCIL ® (NDC) submits the following comments on the docket referenced above.

NDC is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The NATIONAL DAIRY COUNCIL ® has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NATIONAL DAIRY COUNCIL ® is recognized throughout the nation as a leader in nutrition research and education.

NDC appreciates the opportunity to provide comments on the Advanced Notice of Proposed Rulemaking regarding the U.S. Department of Agriculture Food and Nutrition Service's Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions to the WIC Food Packages.

The WIC program has been successful at improving nutrient intake and health outcomes in millions of at risk, low-income pregnant, breastfeeding and postpartum women, infants and children up to five years old. In light of the high prevalence of obesity and low level of physical activity in the US, including among WIC's target population, it is of critical importance to provide WIC participants with a food package that promotes positive dietary patterns, while meeting the unique nutrient needs for this group.

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NDC commends the department for its decision to enlist independent technical experts via the Institute of Medicine to provide scientific evidence based guidance to any revisions in the target nutrients and/or food package. NDC commends the department for continuing its steadfastness in evaluating the science as it evolves and taking action when appropriate.

Thank you for the opportunity to comment on these very important issues.

Sincerely,

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Director
Nutrition and Scientific Affairs

Gregory D. Miller, PhD, FACN
Senior Vice President
Nutrition and Scientific Affairs

Introduction

WIC provides more than 7.5 million at risk, low-income pregnant, breastfeeding and postpartum women, infants and children up to five years old with supplemental food, nutrition education and referrals to health and social services. The WIC program has been successful at improving nutrient intake and health outcomes in this group. This accomplishment should be applauded, and it is obvious why the continuation and improvement of the WIC program should remain a top priority.

Making changes to the WIC food package will influence the diet and health status of millions of people who are currently in unstable conditions, and thus recommendations to change the packages should be made keeping the welfare of WIC participants top of mind. Such a responsibility requires that any changes to the WIC food package be based on scientific evidence and consumer research; assumed benefits should not be grounds for change. An adequate base of scientific evidence should include: documentation of the nutrient needs and food preferences of WIC participants; data on the best way to use supplemental foods to improve nutritional status, which would require an understanding of overall dietary patterns of WIC participants; and an understanding of the *consequences* of the proposed changes in terms of nutrition, cost and incentives for participation.

Using the Dietary Guidelines and Food Guide Pyramid to adjust food packages for this population do not meet the goals of the WIC program to provide supplemental foods containing target nutrients likely to be missing in the diets of the targeted at-risk population. In addition, planning supplementary food packages for WIC participants is not an appropriate use for the Dietary Guidelines, in part because Dietary Guidelines were designed to serve healthy populations of people older than two years. The recommendations are not intended for the physiological needs of pregnant women and new mothers, and infants and 1 year old children are not included. The goal of changes is the improvement of the nutritional status of the WIC population. Using the national guidelines to plan WIC packages implies that the nutrient needs for this group are the same as for the rest of the population, but this has not been demonstrated.

There is abundant evidence to show that the vast majority of the population does not meet calcium recommendations. Naturally nutrient-rich dairy foods are the best source of calcium, they supply more than eight other essential nutrients and they are versatile, convenient and reasonably-priced. Nutrients in dairy foods are critical for healthy bone and teeth development in children, for peak bone mass in adolescents, and for prevention of osteoporosis in adult women; for helping prevent hypertension during pregnancy and throughout life, including in children and adolescents; and dairy foods may exert a measure of control over energy metabolism and body composition, providing a valuable tool in the fight against obesity. Ample scientific evidence, and common sense, support a USDA decision to keep dairy foods in the WIC package at current levels.

1. **Please indicate what elements of the WIC food packages you would keep the same and why.**

Since 1978, the Women, Infants and Children (WIC) Supplemental Food Program has served low-income, at risk pregnant, breastfeeding and postpartum women, infants and children up to five years old. It has grown significantly so that it now serves more than 7.5 million participants. As outlined in the Advanced Notice of Proposed Rulemaking, the WIC package has been successful at increasing target nutrient intakes, improving pregnancy outcomes, decreasing iron deficiency anemia and reducing healthcare costs among the population it serves. The mandate of the WIC program is to provide foods which contain target nutrients likely to be insufficient in diets of low-income women, infants and children which, since the inception of the program, have been protein, vitamins A and C, and iron and calcium. Despite WIC's many successes, recommendations have been made for program reforms.

Because the WIC package must remain cost-neutral, any changes in package components may introduce trade-offs regarding nutrition, health benefits and incentives for participation. Because WIC has been so successful at increasing nutrient intakes and improving health incomes, it is alarming that changes to the WIC package have been suggested without strong evidence that nutrient needs of the population served by the program have changed. Furthermore, there is little evidence that the suggested changes will lead to benefits comparable to the current package. The USDA has a responsibility to the many individuals served by the WIC program to limit unintended, negative consequences resulting from changes to the WIC package. Any changes made should be evidence based.

The nutrient most likely to be in short supply in a typical American diet is calcium [1]. The federal interagency task forces on U.S. health goals that produced the plans "Healthy People 2000" and "Healthy People 2010," identified calcium deficiency as a problem of sufficient magnitude to warrant a national effort. CSFII data clearly shows that, of nutrients evaluated for percent of individuals who do not meet the RDA, calcium shows the highest percentage at more than 70%. Milk and other dairy foods are the major source of calcium in the U.S., providing 72% of the calcium available in the food supply [2]. Few other foods provide dairy's concentrated natural source of calcium along with more than eight other essential nutrients including potassium, phosphorus, protein, vitamins A, D, B12, riboflavin and niacin. In an analysis of food sources of calcium, naturally nutrient-rich milk and milk products provided 83% of the calcium in the diets of young children, 77% of the calcium in adolescent females' diets, and between 65% and 72% of the calcium in adults' diets [3]. Without consuming dairy products, it is difficult to meet dietary calcium recommendations [4, 5].

Calcium and other dairy nutrients are critical for adequate growth and development in children. For women, they support fetal growth, maternal nutrition and post-partum lactation and recovery, as well as preventing pregnancy-associated hypertension. Dairy products are convenient, nutrient-dense and low-cost, and inclusion of dairy foods improves the overall nutritional quality of the diet. Food packages which contain foods naturally rich in nutrients also support effective nutrition education. This rationale is based on ample evidence outlined in these comments and elsewhere, and provides support for the continuation of calcium as a target nutrient for the WIC population, and dairy foods in the WIC package at current levels.

Infant packages for 0-3 month olds contain infant formula alone, and for 4-12 month olds, formula plus juice and cereal, but do not contain dairy foods Therefore, the following comments will focus on the WIC food packages which contain dairy foods, those for children 1-5 years old and pregnant, breastfeeding and postpartum women.

Calcium Intakes in the U.S.

Most people in the U.S., especially women, do not meet calcium requirements, which are listed below in Table 1. Data from the Continuing Survey of Food Intakes by Individuals 1994-1996 (CSFII 1994-1996) and the National Health and Nutrition Examination Survey III (NHANES III) show similar findings [1, 6]. Overall, nine out of 10 women fail to meet their calcium needs. Among women in the most common age ranges in WIC, only 16% of women 20-29 meet requirements, and only 14% of women 30-39 consume adequate calcium. Among pre-school children, on average, only 70% of children 5 years and under are meeting current recommendations. Decreases in calcium intake can be observed starting at very early ages: 81% of children 1 to 2 years meet recommendations, but only 56% of 3-5 year olds consume adequate calcium. This trend becomes especially alarming during the teen years (12-19 years old), when only 12% of females and 32% of males consume adequate calcium.

Table 1: Calcium DRIs

Age	Calcium (mg)
Children 1-3	500 mg.
Children 4-8	800 mg.
Children 9-18	1,300 mg.
Pregnant or Breastfeeding <=18	1,300 mg
Adults 19-50	1,000 mg.
Pregnant or Breastfeeding 19-50	1,000 mg.
Adults 50+	1,200 mg.

In CSFII 1994-1996, lower income is associated with lower calcium intakes. Percentages of individuals with diets containing less than 100% of the 1989 Recommended Daily Allowance (RDA) was highest in people earning less than 131% of the poverty level and lowest in those earning more than 350% of the poverty level [9].

Dairy products are clearly the best and easiest way to meet calcium recommendations. As pointed out in Healthy People 2010, "With current food selection practices, use of dairy products may constitute the difference between getting enough calcium in one's diet or not" [7]. In a study to evaluate how best to meet calcium Daily Reference Intakes (DRIs) through foods, researchers found that dairy foods were the most practical way to fill calcium requirements [8]. In this report, USDA researchers report that, "...increasing servings of food groups other than milk to meet calcium and magnesium DRIs is less likely to be practical, at least in the near term." Fluid milk provides more calcium in the diet than any other food, and comes in a nutrient-dense package that is inexpensive and easily available.

Health Benefits of Dairy Nutrients

Data presented below illustrate that an adequate intake of dairy foods, with their broad complement of essential nutrients, is a critical factor in the reduction of the disease burden and healthcare costs of several medical conditions.

Bone

Dietary calcium has been unequivocally demonstrated to enhance bone health at every stage of life, with high routine intakes being associated with formation of greater bone mass in childhood and adolescence and with reduced bone loss and fracture risk in the elderly. In addition to calcium, milk provides several nutrients important to bone growth, including phosphorus, protein and vitamin D. Inadequate calcium and dairy food intake in youth sets the stage for skeletal fragility in later life, resulting in a higher risk for osteoporosis and osteoporotic fractures, which can be debilitating and life-threatening.

Children require adequate calcium, vitamin D, protein and other dairy nutrients for proper bone growth, development and maintenance. Children and adolescents' low calcium intake is of great concern because the teenage years are a period of rapid skeletal growth during which there is a critical "window of opportunity" to maximize peak bone mass and protect the skeleton against future risk of osteoporosis [9-11]. Bone mass later in life is determined primarily by peak bone mass, of which more than 90% is attained by 20 years of age. Dietary calcium intake early in life is positively associated with bone mass [12, 13]. After adolescence, the period for optimizing peak bone mass by calcium rapidly declines. In pregnant women, sufficient maternal intake of calcium and other nutrients is necessary to support bone and teeth development of the. Teeth and bones begin to form during the first few months of pregnancy, and mineralization continues into adolescence [14].

Osteoporosis is now recognized as a "pediatric disease with geriatric consequences" [15]. Osteoporosis is characterized by low bone mass and bone tissue deterioration, leading to skeletal fragility. According to the National Osteoporosis Foundation, 10 million Americans are estimated to have osteoporosis, and 34 million are at increased risk for the disease due to low bone mass, making the disease a major public health threat to 44 million Americans. In an analysis of papers published since 1975 on the relationship between calcium intake and bone health, Heaney found that of 52 investigator-controlled calcium intervention studies, 50 demonstrated better bone balance at high intakes, greater bone gain during growth, reduced bone loss in the elderly or reduced fracture risk [16]. Of the 86 observational studies, 64 showed a positive association between calcium and bone, confirming that the causal relationship observed in the intervention studies also exists in free-living populations. Six of the intervention studies used dairy foods as calcium sources and all reported a positive link between dairy/calcium intake and bone health. All dairy interventions showed significantly positive effects that were as strong as, or stronger than, the effects of calcium supplements. These results are not surprising because it is well-known that milk and milk products are good sources of the nutrients needed for bone development and maintenance.

At least four randomized clinical trials (RCT) have reported significant fracture reduction with increased calcium intake [12, 13, 15, 16]. For example, Chapuy et al. observed an approximately 40% reduction in hip and other extremity fractures within 18 months employing a combination of calcium, phosphorus, and vitamin D [17]. Dawson-Hughes et al. [18] reported that supplementation with calcium and vitamin D reduced non-vertebral fractures by 55% within 3 years. These studies also highlight the importance of the multiple nutrients contained in dairy foods. In an osteoporosis prevention study in which women received 1000 mg/day calcium via either a supplement or milk, the latter group concurrently and significantly improved the intake of 11 other key dietary nutrients. Analysis by Barger-Lux and Heaney [19] of the diets of premenopausal women revealed that women consuming <60% of recommended levels of calcium also were consuming low levels of at least four other key nutrients that are delivered by dairy foods.

Calcium and vitamin D work in concert to promote bone health, and milk is the main source of vitamin D in the U.S. diet. Vitamin D is necessary for proper bone growth from infancy through puberty, and for bone maintenance in adulthood. Vitamin D increases intestinal absorption of calcium to help maintain calcium levels in the blood, and it stimulates bone cells that build the matrix of bone. With adequate calcium intake, but insufficient vitamin D, calcium uptake and utilization can be compromised, and bone matrix is not mineralized properly. In children, this deficiency leads to rickets, a disease which occurs before epiphyseal plates fuse, and in adults, to osteomalacia.

Rickets, with typical bowing of the leg and slowed growth, was commonly seen in children in the U.S. up until the 1930's, when milk began to be routinely fortified with vitamin D. There are few dietary sources of vitamin D other than fortified milk. Fortification of milk, the major dietary source of calcium in the U.S., was a natural choice because of the physiological synergy among calcium, vitamin D and other dairy nutrients. Recently, cases of rickets, or vitamin D deficiency, have appeared in the U.S. Three main issues have led to an increase in rickets: long-term breast feeding without vitamin D supplements, decreased exposure to sunlight and high prevalence of rickets in groups emigrating from less developed countries [20]. Vitamin D can be obtained through sunlight exposure, but increased use of sunscreens, limited time spent in outside activities, and reduced sun exposure – especially for those living in northern latitudes – can limit vitamin D production. The topic of vitamin D was recently reviewed at an NIH conference entitled "Vitamin D and Health in the 21st Century: Bone and Beyond." A report form the conference is in preparation. The conference highlighted the increased appearance of deficiencies, especially in dark-skinned populations, infants and pregnant women.

Pregnant women with inadequate vitamin D status can give birth to infants with vitamin D deficiency and poor calcium status. Rickets is often seen in children of women who exclusively breast feed, but do not supplement with vitamin D. Infants weaned onto low dairy diets are also susceptible. In adults, frank vitamin D deficiency is rarely observed in the U.S., but marginal vitamin D deficiencies over many years can exacerbate the development of the long-latency bone disease osteoporosis [21] or osteomalacia [22]. Some experts believe that higher vitamin D requirements are warranted in some populations, including pregnant women [20]. Because women have lower bone density than men, adequate calcium and vitamin D status is especially important for their lifelong bone health.

Hypertension

Substantial scientific evidence indicates that calcium or calcium-rich dairy foods have a beneficial effect on blood pressure regulation [23-31]. A 1984 analysis of the first National Health and Nutrition Examination Survey (NHANES I), comprising dietary data from more than 10,000 American adults identified an inverse association between dietary calcium and blood pressure levels; dietary calcium intake >1000 mg was associated with a 40-50% reduction in hypertension prevalence [32]. Of the 17 nutrients assessed in that study, including sodium and potassium, calcium was the only nutrient that differed significantly in intake between persons with and without hypertension. The relationship between higher calcium intake and lower blood pressure has now been reported in numerous population surveys [reviewed in 29-31].

RCTs that have assessed the effects of calcium or dairy products on blood pressure suggest a blood pressure-lowering effect of adequate calcium consumption from foods and from supplements [23-25, 28]. Although blood pressure responses to modifications in nutrient intake typically vary among individuals, the beneficial blood pressure effect tends to be more consistent when foods rather than calcium supplements are used as the mineral source [23, 24, 33]. This finding indicates that calcium may serve as a marker for dairy foods, and that observed blood pressure benefits are not derived solely from calcium, but from the full nutritional profile of dairy foods, which include multiple minerals, vitamins, protein and essential fatty acids.

In the Coronary Artery Risk Development in Young Adults (CARDIA) Trial, a multicenter population-based prospective observational study, a consistent reduction was observed in the incidence of hypertension with higher consumption of dairy foods (p for trend

<0.001) in initially overweight individuals (≥25 kg/m^2) [34]. Other factors related to the insulin resistance syndrome were also lower with higher dairy intake, including obesity, abnormal glucose tolerance, and dyslipidemia. The 10-year cumulative incidence of hypertension with the lowest dairy consumption (<10 times/week or <1.5 eating occasions/day) was 22.9% compared to 8.7% in those with the highest dairy intake (≥35 times/week or ≥5 eating occasions/day). The odds of elevated blood pressure were considerably lower with both low-fat (OR 0.79, 95% CI 0.64-0.98) and full-fat dairy (OR 0.84, 95% CI 0.71-0.99). The odds of elevated blood pressure were lower by nearly 20% for each daily eating occasion of dairy products.

In the landmark controlled-feeding intervention trial *Dietary Approaches to Stop Hypertension* (DASH) [23], persons with high-normal blood pressure consumed one of three diets for 8 weeks. A control, or "typical American," diet was compared to a diet rich in fruits and vegetables (8-10 servings/day) and to a third diet containing fruits and vegetables plus 3 servings of dairy products/day and was lower in total fat, saturated fat and high in fiber. The latter, the "DASH diet," resulted in impressive reductions in both systolic blood pressure (SBP) (5.5 mm Hg) and diastolic blood pressure (DBP) (3 mm Hg) compared to the typical American, diet. The fruits-and-vegetables diet (without the dairy component) produced blood pressure reductions of roughly half that magnitude (SBP 2.7 mm Hg; DBP 1.9 mm Hg). In persons with established hypertension (SBP ≥140 mm Hg or DBP ≥ 90 mm Hg), the DASH diet with dairy foods, resulted in decreases of 11.4 mm Hg SBP and 5.5 mm Hg DBP. As noted by the investigators, these blood pressure improvements rival those attainable with antihypertensive medications [23].

Compared with whites, hypertension in African Americans develops earlier in life and average blood pressures are much higher. African Americans have higher rates of death from stroke and heart disease, and a dramatically higher rate of hypertension related renal disease than those in the general population [35, 36]. High blood pressure occurs even in African American children and adolescents. Researchers from the Bogalusa Heart Study found that African American children had significantly higher blood pressure than while children starting as early as age 10 years [37].

Subgroup analysis of the DASH trial revealed a profound effect of the DASH diet among African-Americans. In this group, the DASH diet resulted in blood pressure reductions of 6.9 mm Hg SBP and 3.7 mm Hg DBP compared to the control diet [38]. These reductions were approximately double those achieved with the fruits-and-vegetables diet without dairy foods. Particularly noteworthy in this cohort, in which lactose maldigestion is presumed to occur more commonly than in other racial groups, was the lack of adverse gastrointestinal effects that might be expected with the addition of 3 dairy servings to the daily diet [23]. There were no dropouts of African American participants due to an inability to tolerate the diet.

U.S. calcium requirements are currently linked to prevention of bone disease, or osteoporosis. The evidence available in Blacks, both African and American, indicates that Blacks have lower calcium requirements for supporting bone health [39]. Their bone density is higher, and they retain more calcium from the diet, thus the calcium intake necessary to maintain optimal skeletal mass is lower in blacks than other racial groups.

However, as mentioned, the incidence of hypertension and related diseases is much higher in blacks than other races, possibly due to the same physiological mechanisms that are protective against skeletal losses. It has been suggested that hypertension should be the "index disease" for determining calcium requirements for blacks, instead of bone [39]. Using this criterion, calcium requirements are similar for African Americans and other racial groups. The National Medical Association (NMA), the organization which represents physicians of African descent and has identified the elimination of health disparities among African Americans as a priority goal, recently held a Consensus Conference and developed a Report and Recommendations which is pending publication. It supports the need for adequate calcium intake in African American populations, based on the unique health and nutrition needs of African Americans, including prevention of hypertension. The NMA recommends at least three servings (i.e., 3-4/day) of dairy a day in the diets of African Americans.

Calcium also provides benefits for pregnant women. Sufficient calcium during pregnancy helps prevent pregnancy-related hypertension or preeclampsia, a condition with potentially grave consequences for mother and fetus [40, 41]. Supplementation with calcium can also improve blood pressure in offspring of supplemented women. In an extension of a study that examined the effect of calcium on preeclampsia, children born to women supplemented with 2 g of calcium beginning between weeks 13 and 21 of gestation until delivery had systolic blood pressure that was significantly lower than the placebo group at three months and two years [42]. In the mothers, blood pressure was associated with circulating levels of $1,25(OH)_2D3$, but did not differ between calcium supplemented and placebo groups.

Blood Lipids

In one study, daily calcium intake, in which dairy products provided 60% of the total calcium, was negatively correlated with plasma LDL cholesterol (LDL-C), total cholesterol and the ratio of total/HDL cholesterol [43]. In a cross-sectional analysis of NHANES III, dairy product consumption ranging from <1 to >5 servings per day was associated with a modest increase in total and saturated fat intake. However, dairy consumption was not related to plasma LDL-C, TC or triglycerides [44]. In the CARDIA study, no association between dairy intake and the incidence of high LDL-C was observed [34].

Body Weight and Composition

Studies outlining the relationship between dairy foods and body weight are outlined in detail under Question #5. To summarize here, the available data provide strong support for a beneficial effect of increased dairy foods on body weight and fat loss. Animal studies have demonstrated an important role of increased dairy on decreasing body weight and body fat during over-consumption and during energy restriction. Most observational data and clinical trial results indicate a statistically significant inverse relationship between dairy intake/calcium intake and body weight and body fat loss. Recent clinical studies also have demonstrated that increased body weight/body fat loss, when adequate calcium is provided by supplements, is further augmented by dairy foods, indicating that additional nutrients from dairy foods are playing a role. As recently stated in the proceedings of a symposium on dairy products and weight regulation, if emerging data can be confirmed, "increasing the low dairy product and calcium intakes in the United States may greatly contribute to reducing the growing epidemic of obesity and IRS" [45].

Additional Benefits of Dairy

In addition to the nutrient package delivered by dairy foods, they are safe, reasonably-priced, readily available products that are processed and distributed within a well-established market network. These characteristics of dairy foods assure program administrators and participants that fresh dairy foods will be available in essentially all locations and areas of the country, they will deliver a known amount of nutrients, and can be used easily by participants. Consistent products ease the administrative burden at the state level and the shopping process at the individual level. Dairy foods deliver a consistent nutrient package due to the standard of identity established by the Food and Drug Administration. Products that attempt to imitate dairy do not have standards of identity, and their processing methods and nutrient contents can vary widely.

Nutrition Education

WIC has been at the forefront of providing food and developing good eating habits in low-income populations through healthful supplemental foods and nutrition education. By including dairy foods in the WIC package, WIC supports nutrition education using whole, natural foods as described in the food guide pyramid and helps develop good eating habits for life.

2. What changes, if any, are needed to the *types* of foods currently authorized in the WIC food packages? Additions or deletions? Discuss recommended quantities and cost implications.

Current WIC packages have improved the nutrient intake of low-income women, infants and children. Because the WIC package must remain cost-neutral, any changes may introduce trade-offs regarding nutrition, health benefits and incentives for participation. In addition, introduction of new foods as alternative nutrient sources or to supply new nutrients, especially if additions are more expensive, will cut quantities of existing components of the package. We assume that the USDA would not make any such changes without strong evidence to demonstrate that the changes in the types of foods offered in the package are necessary and will, in fact, provided the added benefit. The dietary preferences of participants, their nutrient needs, and consequences of changes must be taken into account to design an alternative to the current package. More information is needed before implementing major changes on a program wide basis.

Choices of Milks

Regarding *types* of foods offered, in 1999, the National Association of WIC Directors (NAWD) recommended that reduced-fat milks should be offered as the standard milk for women and for children over two years of age [46].

The American Academy of Pediatrics recommends children 1-2 years of age should consume whole milk [47]. For those 2 years old and older, offering choices accommodates preferences, and thus may encourage and maintain dairy nutrient intake. In specific cases where weight or high blood lipids are a problem, lower fat options are justified, especially when supported by nutrition education efforts. WIC participants currently have the options of whole, reduced fat (2%), low-fat (1%), fat free milk or fluid buttermilk, as well as reduced lactose milk. There is no strong evidence that limiting choices will have positive effects on body weight or fat intake of the WIC population, and if preferred types of milk are not available, it may result in a decreased calcium intake. Given the evidence emerging that shows a link between higher dairy food intake and reduced body weight and body fat (see Question #5), more information about the effects of limiting choices on intake is needed before a single, standard type of milk is offered. In addition, the effects on weight management of mandating the fat content of a single, supplemental food is questionable [9].

Dairy Food Preferences

Data from CSFII 1994-1996 show ethnic and racial differences in consumption of types of milk and other dairy foods [1]. Among children 1-2 years, all white, black and Hispanic (incl. Mexican Americans and other Hispanics) children consumed mainly whole milk. In white children older than 2 years, low fat milk (including 1% and 2%) was the main type of milk consumed. In blacks of all ages, consumption of whole milk predominated except in males 60 and over. In Hispanics, whole milk was consumed by the majority of Mexican Americans and other Hispanics of all ages. Cheese was commonly consumed by whites, blacks and Hispanics, and made a significant contribution to their calcium needs. Despite described preferences, saturated fat and total fat intake were very similar among all groups, indicating that differing intakes of whole milk do not necessarily increase total saturated fat intakes.

Data on dairy preferences are presented to address concerns that changing the type of milk offered could result in reduced intakes. Low calcium intakes are recognized as a major public health problem in the U.S., with more than 75% of Americans not meeting current calcium DRIs for age groups. Research shows that reduced calorie diets containing three or more servings of milk, cheese and yogurt can be effective for weight loss [48]. Furthermore, regular consumption of dairy foods is not associated with increased body weight [49, 34, 50, 51, 52]. Because studies have found a significant relationship between increased calcium/dairy product intake and decreased body weight and fat, the effect on obesity of cutting fat in dairy vs. maintaining dairy intake should be considered.

Understanding the Science of Lactose Intolerance

In 1999, NAWD recommended that alternative sources of calcium-rich foods be offered in WIC packages to address cultural and religious preferences as well as those who are lactose intolerant [46].

A high incidence of lactose intolerance among some ethnic groups has been suggested as a reason to offer alternatives to dairy for WIC participants. Some ethnic groups are more likely than others to experience a reduction in the expression of lactase as they age (lactase non-persistence or deficiency). This may lead to a reduced ability to digest lactose, the main sugar in milk. Gas-producing bacteria in the gut ferment the lactose, and may cause characteristic symptoms of bloating, flatulence, abdominal pain and diarrhea. Symptoms result when the amount of lactose consumed exceeds the body's ability to break it down into its constituent sugars, glucose and galactose. Therefore the term lactose intolerance should be used more precisely to refer to the symptomatic response to a defined lactose load (i.e., tolerant to 12 grams of lactose; intolerant to 24 grams). Whether an individual experiences symptoms depends on the level of lactase activity remaining, the amount of lactose consumed, gastrointestinal transit and the ability of the colon microflora to metabolize lactose. Lactose intolerance is not determined solely by genetic predisposition, and actual symptoms occur at a lower rate than studies using breath hydrogen tests might indicate. Therefore, racial backgrounds or ethnicities are not sufficient reasons to recommend alternatives to dairy.

Results of double-blind, randomized, crossover trials indicate that most individuals (African-Americans, other minorities and Caucasians) with primary lactase deficiency can tolerate one cup (240 ml) of milk with a meal or two cups (480 ml) if consumed in divided doses with breakfast and dinner [30, 31]. Most recently, the same investigators found that women with lactase non-persistence can eat a dairy-rich diet that includes milk, yogurt and cheese, supplying about 1,500 mg of calcium per day, without impediment [32, 33].

Perceptual, cultural and behavioral issues contribute to reduced intake of dairy among some groups such as African Americans and Asian Americans. Researchers examining the food preferences and eating attitudes of three generations of women, for example, found that drinking milk (or coffee) with meals is more preferred by white than African-American women [53]. They found that the African-American college-age women's low preference for drinking milk at meals was more similar to that of African-American mothers and grandmothers than to those of white women students their own age.

A study conducted by the National Dairy Council and the NMA to evaluate dairy intake, lactose intolerance and dairy alternative intake by African Americans, known as the African American Lactose Intolerance Understanding Study (AALIUS) used a National database that tracks eating occasions of specific foods (NPD group, Chicago, IL) [54]. Combined with CSFII serving sizes, daily nutrient intakes were calculated. The results indicate that African Americans, compared to the balance of population, consume significantly more fat and sugar (and thus calories), and significantly less calcium. African American children and adults drink significantly less milk, especially at dinner, though most drink whole milk. Only 7% of African American children drink milk at dinner, compared to 45% in the balance of population. Instead, they drink fruit drinks, soda and fruit juice, which reflect adult beverage intakes. Using calcium fortified fruit juices as an alternative to milk could exacerbate over-consumption of sweetened drinks by this population.

Two studies have shown that the incidence of lactose intolerance is much lower than estimated by studies using breath hydrogen tests. In AALIUS, among 2,016 African American adults and 1,084 U.S. adults matched for ethnicity to the 2000 census, only 24% reported having lactose intolerance. Not surprisingly, of those who experienced lactose intolerance symptoms regularly, they tended to cut dairy out of their diets. However, if they could avoid symptoms, 85% said they would be willing to add more milk and dairy products to their diet. In African Americans, soy beverages are not widely consumed, and those who are lactose intolerant prefer reduced lactose dairy options to soy beverages [54]. Another study found that 15% of whites, 27% of blacks and 19% of Hispanics believed themselves to be lactose intolerant [55]. The most used dairy alternatives were calcium-fortified orange juice and calcium supplements, which lack the complement nutrients found in dairy foods.

A National Institutes of Health Expert Panel recommends dairy foods as the preferred source of calcium, followed by calcium-fortified foods and then calcium supplements.[i] Studies in children, adolescents and adults have shown that increasing dairy food intake improves the intake of several other nutrients [56-60]. Because dairy foods provide much more than calcium, it is recommended that those who are lactase non-persistent do not cut dairy from their diets, and instead consider trying simple strategies that can allow consumption of dairy products. Research has shown that if dairy foods continue to be eaten after childhood, tolerance to lactose can be increased by adaptation of gut bacteria [61, 62]. In those who experience symptoms, regular consumption of dairy can lead to reduction of symptoms, and consumption of up to three servings of dairy foods with meals can be tolerated without symptoms [63]. As mentioned earlier, eating dairy foods with meals was shown to be successful in the DASH trial in the African American cohort, who consumed three servings of dairy per day without any adverse symptoms.

These comments are included to correct some of the misinformation that has circulated about lactose intolerance. U.S. residents do not consume enough calcium, and it is unfortunate that misperceptions about lactose intolerance may be among the reasons. It would be a tragedy to alter a successful program such as WIC based on misinformation. It is understandable how an unpleasant experience after drinking milk might create a learned food aversion and avoidance of milk drinking. However, estimates of lactose intolerance among ethnic minorities, and their need for non-dairy, calcium-rich alternatives, have been routinely overestimated. Population-wide incidence figures for lactose maldigestion were based on studies employing a breath hydrogen test using a challenge dose of 50 gm of lactose in water. While effective for diagnosing lactose maldigestion, this test grossly overestimates the likelihood that an individual will experience symptoms of intolerance after consuming a glass of milk

(12 gm of lactose) with a meal. Research demonstrates that nearly all individuals diagnosed as lactase non-persistent can tolerate the amount of lactose in a glass of milk.

Dairy Alternatives to Milk – Cheese and Yogurt

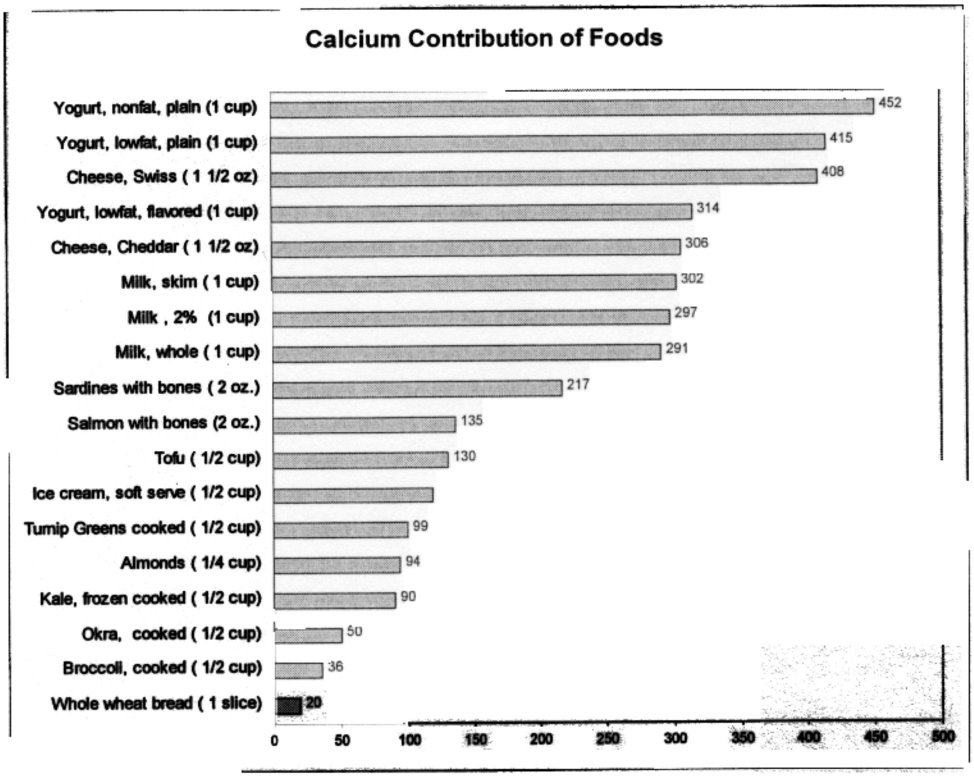
Yogurt and cheese contain less lactose than milk, and studies show that these dairy foods may be easier to digest than milk for those with lactase non-persistence [64]. Cheese and yogurt contain calcium and other diary nutrients, although cheese is a more concentrated source of nutrients. WIC allows substitution of four quarts of milk for one pound of cheese, for up to four pounds of cheese. However, not all states allow the full exchange, in part due to the higher cost of cheese than milk. Comments collected from WIC nutritionists and Dairy Council dietitians indicate that cheese is popular in the WIC program due to its flavor, convenience and versatility. Children and adults like it, and parents can offer it as a snack to kids, or incorporate it into many dishes, depending on the type of cheese purchased.

Yogurt is a fermented food that is popular in cultures that may or may not regularly consume fresh milk, and it may be an acceptable milk alternative for those with lactase non-persistence or to fit some cultural food patterns. Yogurt is an appropriate alternative to milk and/or cheese. Although milk drinking in some cultures is limited to children, or is not an integral part of the cultural foodways, cheese and yogurt are often acceptable. The option of choosing three dairy foods – milk, cheese and yogurt – offers flexibility while maintaining the supply of key dairy nutrients.

Non-dairy Calcium Sources

Non-dairy calcium choices can be offered to WIC participants who cannot consume milk because of a medical or other special dietary need. For these individuals, it will be difficult to meet calcium needs without dairy foods, and alternative sources of calcium will be needed to meet recommendations. Education will be critical to help WIC dietitians and participants choose alternatives wisely. A number of non-dairy foods, such as fish with bones, beans and some green leafy vegetables such as broccoli and kale contain calcium (see Figure 1), but of varying amounts and bioavailability [65]. Calcium may be poorly absorbed from foods rich in oxalic acid (spinach, sweet potatoes, rhubarb, and beans) or phytic acid (unleavened bread, raw beans, seeds, nuts and grains, and soy isolates) [66]. In green vegetables that contain calcium, fractional absorption of calcium ranges from 5% (spinach) to roughly 50% (bok choy and broccoli) [65]. This wide range, coupled with varied calcium content, yields a wide spread in the number of servings needed to equal the calcium in a glass of milk. For example, 16 servings of spinach or more than four servings of broccoli equal the calcium absorbed from one glass of milk [65]. Unpredictable market availability and varying prices introduce even more uncertainty regarding government recommendations to rely on these foods for calcium nutrition.

Figure 1

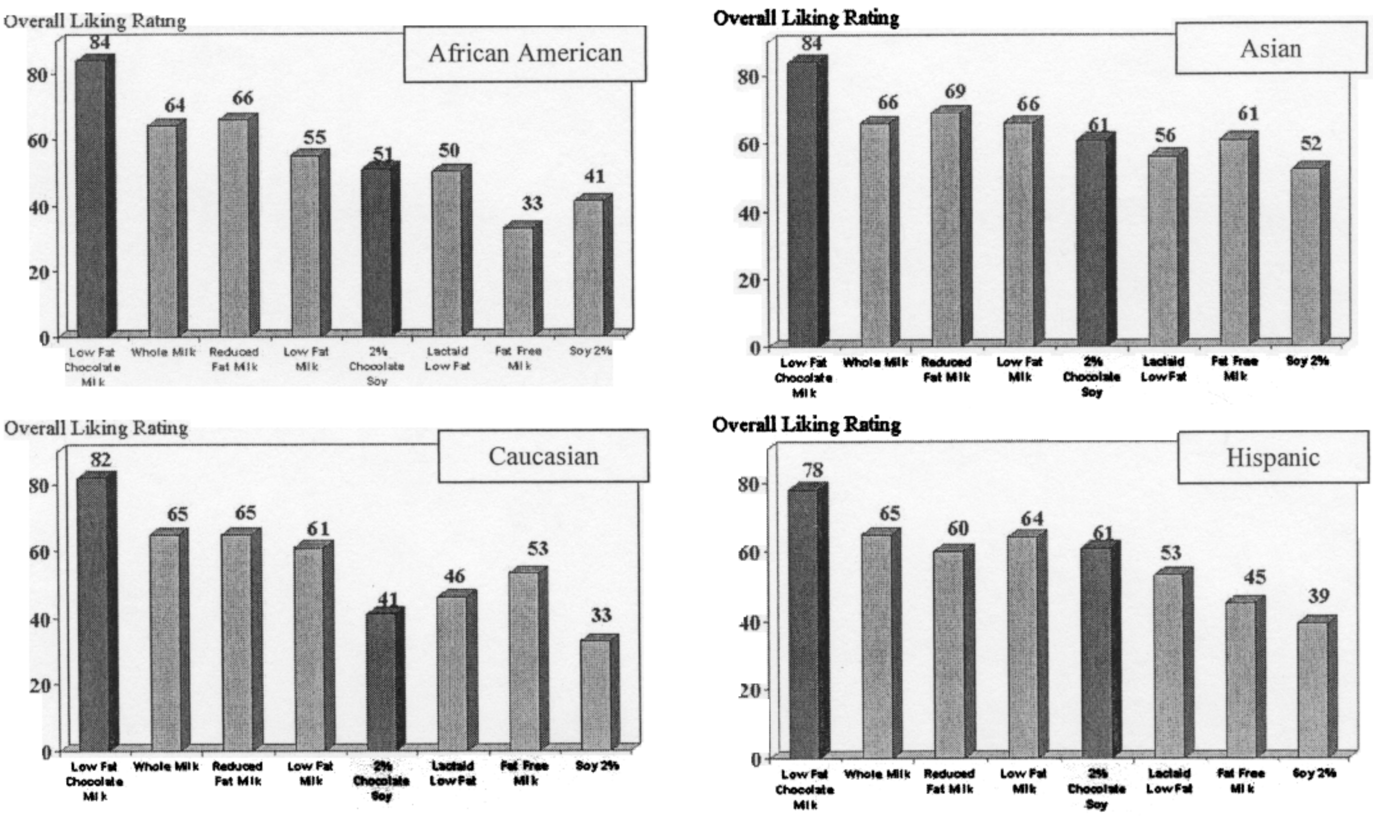


Soy foods are not appropriate substitutions for dairy foods. Tofu can be made by different methods to solidify the tofu curds. Tofu processed with calcium salts can produce a tofu that provides calcium per serving equivalent to a glass of milk. However, not all tofu is made with calcium, and there is no standard of identity for tofu. In the USDA nutrient data base, tofu can be found that contain 32, 103, 350 or 683 mg of calcium per 100 g edible portion. Calcium-fortified foods such as soy beverages also have no standard of identity, which allows variability in processing and nutrient content. Some soy beverages attempt to imitate milk by adding calcium and other nutrients to pressed soybeans, but studies show they can contain poorly bioavailable calcium. In a study examining the calcium available from milk and soy beverages fortified with the same calcium content as milk, only 75% of the calcium from soy beverages was absorbed into the bloodstream compared to milk [67]. Due to lack of nutritional equivalency between soy beverages and milk, soy beverages are not an adequate substitute for dairy foods. In addition to serious problems with bioavailability, soy beverages are also inconsistent in their fat content, fortification, and added sugar/flavor.

Dr. Robert Heaney, a nationally-recognized calcium expert, has tested many calcium-fortified foods in his lab, including products from various cereal, beverage, and supplement companies. Regarding several samples of soy and rice beverage recently analyzed, he reported in testimony regarding Child Nutrition programs, that the "calcium settled down into the bottom of the carton on the supermarket shelf, as a heavy sludge, and although there was an instruction on the carton to "shake before using", our experience was that it would have taken a hardware store paint shaker to suspend the calcium in some of them" (Dr. R.P.Heaney, Comments presented before the U.S. House of Representatives Committee on Education and the Workforce, re: Reauthorization of the Child Nutrition Act and the Richard B. Russell National School Lunch Act, October 7, 2003).

In a taste test of soy beverages and different types of milk, preferences among African American, Asian, Caucasian and Hispanic children and teens ages 8-16 years were measured (see Figure 2) [68]. Drinks tested included whole, reduced fat and low fat, fat-free and reduced lactose milks. The soy beverages tested were a major brand's 2% fat white and chocolate flavors. Whole, reduced fat and low fat milks were rated as "excellent" or "very good" by all. The chocolate soy beverage was consistently rated more favorably than the white soy beverage. Among all racial and ethnic groups, the white soy beverage was rated the least favorably of all drinks tested. African Americans, Caucasians and Hispanics tested did find the white soy beverage acceptable, rating it as "poor" or "needs major reformulation." Asians felt it was "acceptable, but needs work." In addition to poor taste acceptability, calcium from soy products can cost more than three times the cost of milk [69].

Figure 2: Taste Test Results
Chocolate & White Milks, Chocolate & Soy Beverages



WIC and the Food Guide Pyramid

In 1999, NAWD recommended that food packages should offer a standard portion of the recommended number of servings from each food group in the Food Guide Pyramid; offer new choices of grain products; offer choices of fruits and vegetables in addition to or in partial or full replacement of juice for all women and children; add folic acid, magnesium, zinc, B6 and fiber as target nutrients; and to reduce quantities of protein for children [46].

Because the Food Guide Pyramid and Dietary Guidelines are undergoing revisions, which may include changes in the number of servings of different food groups, integration of the Food Guide Pyramid and WIC is premature. Furthermore, though the Food Guide Pyramid is appropriate for a teaching tool, the Dietary Guidelines and Food Guide Pyramid were designed for people in the general, healthy population, not for the "nutritionally at-risk" population served by WIC. The Dietary Guidelines were "intended for healthy children (ages 2 and older) and adults of any age," which excludes infants and children aged 1-2 [70]. The populations of women in WIC have special needs, and the Food Guide Pyramid does not provide guidance on pregnancy and lactation.

While the National Dairy Council supports consumption of fruits, vegetables and whole grains, nutrient intake from current WIC packages should not be compromised by the addition of these foods. Cost barriers have contributed to limited fruit and vegetable intake in the WIC population, and adding these foods would likely introduce cost challenges to formulating a new WIC package. Due to the high cost of fruits and vegetables, other foods in the package would need to be cut, along with the nutrients supplied. How would the pros and cons of adding foods containing vitamins A and C and fiber be balanced with the loss of other nutrients, possibly calcium and vitamin D from milk, or iron and folate from cereal? It is inappropriate to assume that proposed changes will provide nutritional benefits without a rigorous assessment. Changes in the package that involve exchanges for foods containing the same nutrients are less problematic. For example, because fruits and vegetables contain vitamins A and C, it makes more sense nutritionally to replace some or all of the juice with fruits and vegetables. This nutritional benefit should be weighed against the financial cost of the change, but the nutritional benefits are easier to recognize in this type of exchange. Another example of an acceptable exchange is the addition of yogurt as another calcium source, discussed in Question #3. In this case, nutrients supplied remain the same, but more variety is offered, which may increase incentives for participation.

Implementing all of NAWD's recommendations would change the fundamental nature of the WIC program, introduce new cost constraints and force cuts of foods/nutrients and/or quantities of foods. Where in the package, and from which participants, would the cuts come to pay for these changes? The consequences of changes to a large, successful program like WIC should be evaluated systematically before making changes to the program. If changes are justified scientifically, but introduce new costs, additional funding would facilitate changes. Any changes to the program should be evidence based.

Estimated Healthcare Savings Associated With Adequate Dairy Food Intake

The economic impact of adequate consumption of dairy products across the population has been addressed in a paper accepted for publication in the January issue of the *American Journal of Hypertension* [71]. Although this paper does not focus on the WIC population, it is relevant to the general U.S. population including those in the WIC program. Based on several decades of data from prospective longitudinal studies and randomized controlled trials, adequate intake of dairy foods, with their broad complement of essential nutrients, is shown to be a common factor in the reduction of the disease burden of several medical conditions.

These authors searched the medical literature for studies that assessed: 1) the relationship between dairy product consumption and the prevalence of osteoporosis, high blood pressure and overweight, or 2) the financial impact of utilizing calcium or dairy intake as a major component of the intervention. In addition to those described above, low calcium/dairy intake also is linked to Type-2 diabetes, kidney stones, certain outcomes of pregnancy, and some cancers. Summarizing the available evidence of the net benefits of increased dairy food intake on these conditions, their outcomes, and their costs, first- and fifth-year direct healthcare cost savings were conservatively estimated.

The authors estimate that increasing dairy food intake to 3-4 servings per day would be associated with an annual reduction of 5% in the incidence of obesity in Americans, increasing by an additional 5% per year, yielding a 25% reduction at five years. Using that estimate of impact, first-year healthcare savings related to obesity reduction would approach $2.5 billion and at five years would exceed $37.5 billion.

On the basis of the collective observations for hypertension, the authors project a virtually immediate 40% reduction in the prevalence of mild to moderate hypertension with an increased dairy product intake to 3-4 servings/day. First-year healthcare cost savings would approach $14 billion, and be sustained for a cumulative savings at five years of $70 billion.

For purposes of savings for osteoporosis, the authors used a conservative estimate of a 20% reduction in fracture risk related to dairy intakes that provide, with other food calcium sources, 1000–1500 mg Ca/day. Direct costs for all osteoporotic fractures combined were estimated to be $17 billion for the first year. A 20% reduction translates to $3.5 billion savings each year, achievable by year two of the higher intake, reaching cumulative savings of $14 billion over five years.

For the other conditions assessed in this study, stroke ($20 billion), CAD ($16.5 billion), type-2 diabetes ($37.5 billion) nephrolithiasis ($2.5 billion), pregnancy ($15 billion) and colorectal cancer ($0.75 billion), the five-year savings were equally impressive. This analysis demonstrated that if adult Americans increased their intake of dairy foods to 3-4 servings/day, healthcare savings within the first year would be approximately $26 billion and fifth-year cumulative savings would exceed $200 billion.

3. **Should the quantities of foods in the current WIC food packages be adjusted? If yes, by how much and why? Discuss cost implications.**

Regarding *quantities* of foods offered, in 1999, NAWD recommended that the quantity of milk for children should be reduced, and cheese should be reduced to 2 servings per day for women and children in order to be consistent with the Food Guide Pyramid and to cut fat [46].

As discussed above, using the Dietary Guidelines for Americans and the Food Guide Pyramid to develop food packages for this population is not appropriate for its intended use. The Dietary Guidelines were "intended for healthy children (ages two and older) and adults of any age." In addition, two servings of dairy per day for teens and women will not meet current calcium DRIs [8].

The current package contains about 3 servings of dairy per day for children, and between 3 and 4 servings for women. In a report by the Center for Nutrition Policy and Promotion (CNPP) on the nutritional status of WIC participants, the package was found to exceed the 1989 RDAs for calcium and protein [72]. In the same report, the CNPP also reported that WIC children 1-3 years old "appear to benefit from the WIC package for most nutrients, especially for protein, calcium iron, folic acid, magnesium, and vitamin E." Four year olds also met the majority of their nutrient needs, with the exception of zinc and energy. Women in the program did not do as well: pregnant and breastfeeding women did not meet the 1989 RDAs for iron, calcium, folic acid, zinc and magnesium; nonbreastfeeding women consumed significantly low amounts of calcium, vitamin C and magnesium. Evaluating these data using 1997 calcium DRIs would result in a higher percentage of calcium needs being met for children 1-3 years, but even fewer women meeting their calcium needs.

The WIC package for children 1-5 years contains 3.2 servings of milk per day. Although the dairy component of the package exceeds children's DRIs for calcium, protein and vitamin D, maintaining current levels of dairy food intake in WIC children will help establish intake patterns needed as they grow. In December 2003, Dr. Connie Weaver wrote an editorial regarding an article published in the Journal of the American Dietetic Association, which found that higher dairy and calcium intake in children was associated with lower percent body fat in children [73]. In the editorial, she noted that the study indicated that "food patterns are likely largely established by age 5" [74]. These findings indicate that the children served by the WIC program are at critical ages for learning good habits like regular milk drinking. These lessons will serve WIC children well as they enter periods of rapid growth and bone deposition during ages 9-18, when 3-4 servings per day of dairy are needed to meet the 1300 mg calcium DRI. Because dairy provides more than nine essential nutrients, their overall diet quality will be improved.

The dairy protein in the WIC package does not exceed the Institute of Medicine's Acceptable Macronutrient Distribution Ranges (AMDRs) of protein for children. For their calorie needs, 5-20% of calories for children 1-4 years old should come from protein (about 13-51 g), and 10-30% of calories for children 4-8 years should come from protein (about 42-127 g). There are 25.6 g of high quality dairy protein in the WIC package.

The WIC package for pregnant and breastfeeding women contains 3.7 servings of dairy per day, which supplies only 85% of calcium DRIs for young women up to 18 years old, and 111% for those above 18 years. The maximum package for nonbreastfeeding postpartum women contains 3.2 servings of dairy per day, which supplies only 74% of the calcium DRI for young women up to18 years old and 90% for women above 18 years. In the U.S., only 12% of 9-18 year old females meet calcium requirements. When pregnancy occurs during this period of active growth, calcium status can be severely compromised. Two servings of dairy would provide only 60% of the calcium DRI for pregnant, breastfeeding and nonbreastfeeding postpartum women older than 18 years and only 46% of women younger than 18 years. It is difficult, especially for teens and adults, to meet calcium requirements with two servings per day of dairy foods, thus pregnant teenagers in WIC would be particularly at risk for inadequate calcium intakes based on two servings of dairy per day. Two servings would provide current vitamin D DRI for these groups; however, as mentioned in Question #1, some experts feel that current vitamin D recommendations are inadequate, especially during pregnancy.

It seems reasonable to develop an exchange system that adds yogurt to the current system for exchanging milk for cheese. The options of milk, cheese and yogurt could add variety to the WIC package, accommodate preferences and enhance overall diet quality. If non-dairy sources of calcium are substituted for milk, it will be very difficult to meet both calcium and vitamin D DRIs by WIC participants.

Cost Implications

Comparing costs of different sources of calcium and dairy nutrients can illustrate some of the cost benefits of dairy foods. Unfortunately, few published studies are available on the topic. One study which calculated the mean cost to absorb the amount of calcium contained in a glass of milk from different foods and supplements took into account serving size, calcium per serving, fractional absorption, mean cost and mean cost to absorb 300 mg of calcium [69]. The costs per 300 mg of absorbed calcium from calcium supplements and Total cereal were $0.10-0.31; skim, 2% and whole milk, and calcium-fortified orange juice were in the next group at $0.65-0.69. The greens had the biggest range, from $0.88 for turnip greens, to $3.33 for frozen broccoli. Calcium-fortified soy beverage and tofu processed with calcium chloride cost $2.00 and $2.11. Cheese and plain low-fat yogurt cost $1.00 and $1.25. Milk was found to have the lowest cost for a natural food source of calcium. Regional, packaging and other pricing issues could alter these prices, but the data show that milk is among the cheapest ways to get calcium plus the full complement of dairy nutrients, that green vegetables are quite variable in cost (in addition to calcium content and availability), and calcium from soy products is more than three times the cost of milk.

In another study, a standard school meal was analyzed to determine the nutrient contributions per penny and per 100 kcal for meal components. The meal was made of five components: entrée, milk, vegetable/fruit, grain/bread and miscellaneous.

Grain/bread was the least expensive and the fruit/vegetable component was the most expensive. Milk had the highest nutrient density for calcium (175.24 mg/100 kcal) and protein (5.77 g/100 kcal) per kcal. Per penny, milk provided the most calcium, with 14.15 mg compared to 5.96 mg in the grain bread. The entrée and milk contributed more protein per 100 kcal. Milk is an inexpensive and nutrient dense food that can improve the nutrient density of a mixed meal [75].

4. **Recognizing that the WIC Program is designed to provide supplemental foods that contain nutrients known to be lacking in the diets of the target population, what nutrients should be established as priority nutrients for each category of WIC participant, e.g., pregnant women, children 1-5, etc.? Please provide the scientific rationale for them.**

The nutrient most likely to be in short supply in a typical American diet is calcium [1]. The federal interagency task forces on U.S. health goals that produced the plans for "Healthy People 2000" and "Healthy People 2010," identified calcium deficiency as a problem of sufficient magnitude to warrant a national effort. CSFII data clearly shows that, of nutrients evaluated for percent of individuals who do not meet the RDA, calcium shows the highest percentage at more than 70%.

It seems clear that there is a need for more research to determine the target nutrients in low-income populations. Until such evidence is available, changing the target nutrients cannot be justified. Many studies demonstrate that calcium has multiple, lifelong health benefits, especially to women, infants and children. In combination with the high percentage of women, teens and children who do not consume sufficient calcium, this evidence provides a clear rationale for calcium to remain in the target group of WIC nutrients.

As outlined elsewhere in these comments, dairy foods are the best food source of calcium due to their complement of nutrients, good bioavailability, ease of purchase and low cost. Government, nutrition and medical professionals recommend food as the preferred source of calcium. The National Institute of Child Health and Human Development reports that "low-fat milk or low-fat milk products are the best sources of calcium because they contain large amounts of calcium along with additional nutrients to help the body better absorb calcium. They also are already a part of the diet of most Americans. In addition to calcium, milk provides eight other essential nutrients, including vitamin D, potassium and magnesium, which are all essential for optimal bone health and human development" [76]. The American Academy of Pediatrics (AAP), Committee on Nutrition, recommended that pediatricians encourage the use of milk, cheese, yogurt and other calcium-rich foods to meet children's calcium recommendations [47]. In "Healthy People 2010," U.S. Department of Health and Human Services recognizes dietary calcium sources such as milk and milk products, canned fish with soft bones, dark green leafy vegetables such as kale, mustard and turnip greens, tofu made with calcium, tortillas made from lime-processed corn and calcium fortified foods and beverages. The report goes on to state that with "current food selection practices, use of dairy products may constitute the difference between getting enough calcium in one's diet or not" [7].

5. Keeping in mind that foods provided by WIC are designed to be supplemental, can the WIC food packages be revised (beyond what is allowed under current regulations) to have a positive effect on addressing overweight concerns? If so, how? Please be specific.

The complex nature of obesity makes determining causes and solutions to the obesity epidemic challenging. Concern has been raised about the high rate of obesity among low-income populations, such as WIC participants. It is well-known that calorie balance between the overall diet and physical activity is the key to bodyweight management. In addition, it seems appropriate to mention that perpetuating the idea that there are "good foods" or "bad foods" is not productive, and that all foods can fit in a healthful eating style [77]. Because the foods in WIC make up only part of the total diet, information about the overall dietary patterns of WIC participants is necessary to determine eating habits that could be contributing to weight gain. Examination of food and beverage choices and preferences of participants is also needed. To develop a plan to address obesity, it is unlikely that the culturally diverse WIC population will respond to a single type of intervention, but instead may require educational materials tailored to particular cultural groups with varying dietary patterns, activity levels, perceptions and beliefs about what constitutes healthy weight and how to control weight. Focusing only on WIC supplied foods will have limited success in helping participants control weight. This topic area is one that requires more information before institutional changes are made.

Some studies indicate that overweight can exist in homes that experience food insecurity [78, 79, 80]. This apparent paradox requires further evaluation before effective recommendations can be made regarding revisions to the WIC food package to address weight. Cutting dietary fat of WIC participants by offering reduced fat products may seem sensible on the surface, but it doesn't address the fundamental problems of poor diets superimposed on food insecurity. National confusion about whether the best approach to weight loss is cutting fat or calories should cause the WIC program to pause before prescribing that approach. If cutting fat results in cuts to dairy nutrient intake, the weight problem may be exacerbated. In the following section, new research is described that indicates that dairy products may contribute to body weight regulation through their influence on the ability of adipose tissue to store, mobilize and oxidize depot fat. These data indicate that dairy should be considered as a food with the potential to help control bodyweight and body fat rather than to be cut out of the diet.

Animal Model Studies

To assess the impact of increased dairy intake on weight gain, weight loss and body fat, studies have been conducted in transgenic mice that express the agouti gene specifically in adipocytes (aP2-agouti) [51, 52]. Zemel and colleagues evaluated the effects of diets containing high levels of sucrose and fat and graded levels of calcium from $CaCO_3$ or dairy (nonfat dry milk) on body weight and body fat gain for 6 weeks [49]. Compared to a low calcium control diet, in animals consuming 'medium' calcium diets, weight gain was reduced by 26% and 29% from either $CaCO_3$ or dairy respectively ($p<0.04$), without changes in food intake. On a 'high' calcium diet, body weight was reduced by 39% ($p<0.04$). Total fat pad mass was reduced 36% by all three elevated calcium diets, whereas the reduction in abdominal fat pad mass was greater on the 'medium' and 'high' dairy diets than on the higher $CaCO_3$ diets. Core temperature increased about 0.5°C in response to all three higher calcium diets ($p<0.03$). The low calcium diet caused a 67% reduction in lipolysis while the higher calcium diets stimulated lipolysis by 3.4 to 5.2 fold ($p<0.015$) [49].

In another animal study, the same group evaluated the effect of graded levels of calcium from $CaCO_3$ or dairy (nonfat dry milk) on body weight and lipid metabolism in aP2-agouti transgenic mice made overweight, then fed an energy-restricted diet [81]. A low-calcium diet ad lib resulted in ~100% increase in adipocyte calcium levels, a 29% increase in body weight and a doubling of total fat pad mass, whereas the higher calcium diets resulted in a 50% reduction in adipocyte calcium levels ($p<0.001$). Energy restriction of animals consuming the low-calcium control diet had no effect on adipocyte calcium levels but did result in an 11% decrease in body weight ($p<0.001$). However, greater body weight reductions of 19%, 25%, and 29% were observed in animals consuming the high $CaCO_3$, and medium and high dairy diets. Thus, in this animal model, dietary calcium facilitates reduction of adipose tissue mass and body weight by modulating energy metabolism, serving to reduce energy storage and increase thermogenesis. These data indicate that increasing dietary calcium attenuates diet-induced adiposity by modulating adipocyte intracellular calcium and thereby coordinately regulating lipogenesis and lipolysis.

Human Studies

Epidemiologic studies have identified strong inverse relationships between body weight and dietary calcium and dairy product intake [49, 34, 50. 51, 52]. In their 1984 analysis of the NHANES I database, McCarron et al. [32] reported a statistically significant inverse association between calcium intake and body weight. More recently, this relationship was also observed in an analysis of the NHANES III database in which investigators found "a profound reduction in the odds of being in the highest quartile of adiposity associated with increases in calcium and dairy product intake" [49].

Although randomized controlled trial data directly assessing the calcium/weight association remain limited, a review of studies of calcium's effect on bone mass or blood pressure confirms the observational reports [82]. In a study of 82 young girls, Cadogan et al. [83] reported the impact on bone mineral acquisition of providing one pint of milk/day for 18 months. Mean calcium intake of the milk group was 1125 mg/day compared to 703 mg/day for the control group. Total bone density increased significantly in the milk-supplemented group, compared to the control group ($p=0.017$), and the milk group showed non-significant trends toward greater gain of weight as lean body mass and reduction in percentage of body fat.

Lin et al. [84] examined the effects of calcium intake on changes in body composition during a 2-year exercise intervention in 54 normal-weight young women consisting of three resistance-exercise sessions and one hour per week of jumping rope. Mean calcium intake was 781 mg/day and dairy calcium was 537 mg/day. At the end of 2 years, there were no significant differences in body composition between exercisers and non-exercisers, although lean mass gain was greater in the exercisers at the end of two years. Total calcium and dairy calcium per kcal were negatively related to changes in body weight and body fat. Thus, those with higher calcium intakes gained less weight and body fat than those with low intakes. These researchers concluded that the effect of calcium was specific to dairy calcium because total calcium and dairy, when adjusted for energy, predicted changes in body weight and body fat whereas non-dairy calcium did not.

Davies et al. [85] reevaluated five clinical trials originally designed to determine skeletal end points to determine the association between calcium intake and body weight. In this study, BMI and change in body weight were regressed against calcium intake per protein intake. Significant negative slopes of BMI regressed against calcium to protein ratio was found for individual studies and in combined analysis. The pooled slope was -0.186 $kg/m^2/mg/g$ ($p<0.01$). The odds ratio for being overweight for calcium intakes below the median intake was 2.25 ($p<0.02$). These results indicate that a 100 mg increase in calcium intake may result in a 0.82 kg/year decrease in body weight in young women, 0.038 kg/year in middle-aged women, and 0.052 kg/year in older women.

Melanson et al. [86] have recently suggested, using whole body, indirect calorimetry, that high calcium intake promotes fat oxidation, supporting similar conclusions by Zemel et al. in their animal model [49].

Recent findings in animals and in humans demonstrate that there are greater effects on body weight from dairy foods than might be predicted from their calcium content alone. In the CARDIA study, high dairy food consumption was associated with a 30% reduction in the development of obesity in overweight young adults over ten years [34]. A consistent reduction in the incidence of obesity was observed in overweight individuals (≥ 25 kg/m^2) with increasing consumption of dairy foods (p for trend <0.001). Other components of IRS also were improved by higher dairy intakes including hypertension, abnormal glucose tolerance and dyslipidemia. The 10-year cumulative incidence of obesity in overweight individuals with the lowest dairy consumption (<1.5 servings/day) was 64.8% compared to 45.1% in those with the highest dairy consumption (≥ 5 servings/day). The odds of obesity were considerably reduced with both reduced-fat dairy (OR 0.84, 95% C, 0.70-1.02) and full-fat dairy (OR 0.84, 95% CI 0.73-0.97). The odds of obesity were lower by nearly 20% for each daily eating occasion of dairy products.

A recent clinical study, published in abstract form [87], compared the effects of supplemental calcium and dairy products for 24 wks on weight loss during energy restriction in 32 obese adults. Body weight loss was 26% greater in the supplemental calcium group (1200 – 1300 mg Ca/day), but was 70% greater in subjects consuming identical levels of calcium supplied from 3-4 servings of dairy/day (milk, cheese, yogurt) compared to the low-calcium control group (total calcium intake: 400-500 mg/day) ($p<0.01$). When compared with the low-calcium diet, fat loss (by DEXA) in the high supplemental calcium and high dairy groups was augmented by 38% and 64%, respectively ($p<0.01$). Participants who consumed the high supplemental calcium diet or the high dairy diet also showed significantly greater ($p<0.001$) fat loss in the trunk area than did those who consumed the low-calcium diet. These findings are consistent with two other abstract reports by these same authors [88, 89]. In all these studies the dairy calcium intake in the group of adults experiencing the marked improvement in measures of adiposity was equivalent to 3-4 servings of dairy products per day.

Fewer published studies are available examining the relationship between dairy foods and body weight and body fat in children, but an association between higher dairy intake and lower body fat has been observed in several studies. A study of 53 boys and girls (25 boys, 27 girls) 2-5 years old, whose diet, growth and body composition had been measured every six months from 2 months to 5 years old, reported higher calcium and dairy food intake were significantly associated with reduced body fat [90]. These researchers published a follow-up study in December 2003 that included data for the children through 8 years old [73]. In 8 year olds, the relationship between higher dairy foods and reduced body fat continued to be significant in three statistical models. In the same study, lower intakes of carbonated and sweetened drinks were associated with lower intakes of calcium.

In an editorial on the article in the same journal, Dr. Connie Weaver points out that the follow-up study indicates that food patterns are likely largely established by age 5 [74]. In addition, "the magnitude of the impact of increasing calcium intake on offsetting weight gain approaches the 0.37 kg/year experienced by many adults." These data support the importance of regular dairy food consumption in pre-schoolers to develop good dietary habits.

In 323 14 year old girls, dairy and calcium consumption was associated with lower percent body fat measured by iliac skin-fold thickness [91]. A study of 196 nonobese 8-12 year old girls, who were part of the MIT Growth and Development Study, found no association between dairy food intake and BMI or percent body fat [52]. These data provide support for encouraging dairy food consumption in girls and teens that sometimes fear that dairy foods contribute to weight gain. These findings are similar to data from a study of 1432 children in first through third grades, in which dairy and calcium intake were not associated with changes in BMI or percent body fat [92]. In a study of 3-12 years old who participated in the Framingham Study, no association was found of an adverse impact on body fat change due to dairy intake. Based on BMI and skin-fold measurements, the data suggest that low dairy intake could be associated with higher percent body fat in growing children [93].

Coincident with the rise in obesity rates in children has been a gradual increase in consumption of soda and sweetened drinks and a decrease in milk consumption. A recently published study examined the effect of changing childhood dietary habits and increases in childhood obesity [94]. In adolescents, between 1977-1979 and 1994, soft drink intake increased in girls by 65% and in boys by 74% [95], and daily milk intake decreased from 72% to 57% in girls [96]. The authors provide evidence that the exchange of milk for soda may be contributing to weight problems in children and adolescents by three possible mechanisms: 1) decreased energy expenditure with the consumption of soft drinks or high-sugar beverages than with that of mixed-nutrient beverages, such as milk; 2) increased food intake due to decreased satiety and fullness sensations with high-sugar beverages; or 3) decreased milk intake consumption coincident with the rise in soft drink intake. The latter mechanism would dilute the effect of dairy foods on weight and body composition, replacing nutrient-dense milk with empty calories. A study of beverage intake in mothers and their 5-year old daughters found that the girls' and mothers' choices followed similar patterns, and illustrated the trade-off between soft drinks and milk [97]. Mothers who drank milk had daughters who drank more milk and fewer soft drinks, and those mothers and daughters who drank more soft drinks consumed less milk and calcium. Beverage trade-offs for milk may be a significant contributor to poor dietary quality and weight problems.

6. Are there other concerns that affect foods issued through the WIC food packages that should be considered in designing the food packages? For example, should WIC provide options to address allergies (the ADA notes that the most common food allergies are to milk, eggs, peanuts, soybeans, tree nuts, fish, shellfish and wheat), cultural patterns or food preferences?

Lactose intolerance and cow's milk allergy are often confused, but they are different conditions. Food allergies occur in about 6% of children [98], with cow's milk allergy present in about 1-3% of the population. Cow's milk allergy occurs most often in children under three, and is rare in older children and adults. Alternatively, lactose intolerance rarely occurs in young children, unless it is secondary to a condition that alters function of the intestinal enzymes. Because genetic predisposition for lactase deficiency results in changes in lactase activity with age, it occurs almost exclusively outside of childhood. The rather non-specific nature of symptoms of both lactose intolerance and milk food allergy contribute to confusion about the conditions and misdiagnosis is not uncommon. WIC has an opportunity to educate and correct misinformation about these conditions in infants, children and adults in the program.

Non-dairy calcium choices can be offered to WIC participants who cannot consume milk because of a medical or other special dietary need. As discussed above, lactose intolerance incidence has been overestimated, lactose intolerance doesn't mean dairy intolerance, and the many health benefits of dairy nutrients make it unwise to cut dairy. Cheese, yogurt and lactose-reduced milk can be well-tolerated, and regular milk, when consumed with meals, can be included in diets of people with lactose intolerance, and regular intakes of dairy build tolerance. The health consequences of cutting dairy and calcium from the diet are serious enough to warrant an education effort to dispel myths about lactose intolerance. The NMA has begun educational efforts to help African Americans obtain better nutrition through the consumption of 3-4 servings of dairy per day. Calcium needs, participant food preferences, dietary habits and explanation of simple strategies to incorporate some dairy into the diet should be incorporated into the counseling on how to manage the symptoms of lactose intolerance.

See Question #2 for more information on lactose intolerance and lactase non-persistence; See Question #9 for more information on cultural patterns.

7. **What data and/or information (cite sources) should the Department consider in making decisions regarding revisions to the WIC food packages, e.g., nutritional needs of the population, ethnic food consumption data, scientific studies, acculturation practices, and participant surveys, etc.?**

Throughout these comments, references have been included to important evidence to be considered. Topics include:

1. Naturally nutrient rich package that dairy delivers
2. Calcium intake in the U.S.
3. Populations who do not meet calcium requirements; consequences of shortfalls
4. Public health implications of not meeting calcium recommendations
5. Health benefits of dairy intake with respect to bone, hypertension, weight management
6. Improvement of overall nutritional quality of diet by including dairy foods
7. Preferences for milk and soy beverages, and other calcium alternatives
8. Understanding the science behind lactase non-persistence and dairy alternatives

Important research remains to be undertaken to better understand the current status and needs of the WIC target population and the potential impact on nutrition, cost and participation of any changes to the WIC program. No matter how well-conceived proposed revisions appear, resultant benefits cannot be assumed, and the USDA has a responsibility to demonstrate a nutritional impact without compromising or displacing participants who are benefiting from the current program. Recommendations include research on:

1. Food preferences of WIC participants
2. Target nutrient needs of WIC population
3. Evaluation of cost and administrative burden of proposed food package changes
4. Evaluation of nutritional consequences of proposed food package changes

5. Overall dietary intake patterns of WIC participants, including both regular and supplemental to understand contribution to overweight and obesity
6. Pilot studies to test feasibility of exchange of current foods with new foods, such as fruits and vegetables for juice
7. Evaluate needs and best methodology for effective nutrition education to address obesity

8. Recognizing that current legislation requires WIC food packages to be prescriptive, should participants be allowed greater flexibility in choosing among authorized food items? If so, how?

Flexibility in choosing foods for filling food prescriptions should meet the same criteria as described below for cultural food packages. Foods 1) should contain at least the same levels of target nutrients and bioavailability, 2) should be equivalent regarding administrative burden and cost and 3) should be widely available in the marketplace.

Within packages and foods that meet these criteria, participants should have the choice between foods that fill given nutrient needs, for example, choosing the type of milk or juice they prefer. A WIC Competent Public Authorities must still provide the framework from which participants make choices.

Improved technology for voucher issuance and redemption, such as Electronic Balance Transfer cards, should be encouraged to simplify the process for both state agencies and participants, and should be supported financially.

9. How can WIC food packages best be designed to effectively meet nutritional needs in culturally and ethnically diverse communities?

Increased diversity among WIC participants has introduced new challenges to the WIC program. Without dairy foods, it is difficult to meet calcium requirements. Cultural food packages for participants who rely on non-dairy calcium sources should meet the following criteria: 1) contain at least the same levels of target nutrients as conventional WIC packages, 2) be equivalent regarding administrative burden and cost, 3) foods should be widely available in the marketplace and 4) have a demonstrated cultural preference.

To offer cultural food packages that meet the needs of the WIC population, studies of cultural food preferences and efficacy of suggested changes should be determined before they are implemented. Costs of implementing the cultural food packages and the source of funds (what will be cut from the existing package budget to pay for the new packages) must also be determined. Costs of calcium containing alternatives alone vary greatly. Add to that the costs of fruits and vegetables and other additions, unpredictable availability during different seasons, and it is clear that a sophisticated balancing act will be required to provide nutrient equivalent and cost-neutral packages.

Non-dairy calcium alternatives should be offered to those who have objections to dairy, however, individuals of all racial backgrounds should also be offered milk, cheese and yogurt as calcium-rich foods without assuming an inability to drink milk or eat cheese based on genetics. As mentioned above, the incidence of lactose intolerance among different races has been overestimated. Furthermore, it is well-established that with acculturation comes adoption of food patterns of the new country. For example, in a study conducted in a Chinese American WIC population, participants drank the milk in the WIC package, but didn't use the cheese [99].

10. Should WIC state agencies be afforded more or less flexibility in designing WIC food packages? Please explain.

States currently have flexibility to tailor packages to meet state restrictions or special nutritional needs, which benefits program administrators and participants. Flexibility in choosing foods for filling food prescriptions should meet the same criteria as described previously. Foods 1) should contain at least the same levels of target nutrients and bioavailability 2) should be equivalent regarding administrative burden and cost and 3) should be widely available in the marketplace.

Improved technology for voucher issuance and redemption, such as Electronic Balance Transfer cards, should be encouraged and supported financially to simplify the process for both state agencies and participants.

11. The WIC program's overall goal is to achieve the greatest improvement in health and development outcomes for WIC participants, achieved partly by providing food that targets nutrients determined to be lacking or consumed in excess in the diets of the WIC population. In addition to targeting these food nutrients, food selection criteria should address necessary operational concerns for the foods - for example, cost effectiveness; appeal to recipients; convenient and economical package sizes; complexity/burden for the WIC administrative structure to manage; etc. It would be helpful if commenters would identify/recommend WIC food selection criteria, describe how criteria interact, indicate relative weighting or importance, and provide supportive rationale.

Question #11 is at the heart of National Dairy Council's statement in Question #7 on research to understand how best to revise the current food packages without compromising participants who are currently benefiting. Criteria for food package component selection should be established based on sound evidence about the nutrient needs and food preferences of the population, foods that best provide target nutrients, costs of alternative/additional foods, most effective use of supplemental foods, and food availability in different markets as well as evaluation of the nutritional, operational, administrative and financial consequences of any changes made.

For the majority of the WIC population, dairy foods are part of their current diet and can provide significant health and cost benefits due to the reasonable cost and nutrient-rich nature of milk, cheese and yogurt. As outlined in the above comments, nutrition, cost profile, availability, freshness, consistency of product and versatility are superior to soy beverages, fortified juices and vegetable sources of calcium.

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