

January 25, 2007

Mr. Mark Bradley
Program Manager
USDA/AMS/TM/NOP
Room 4008-So.
Ag Stop 0268
1400 Independence Ave., SW
Washington, DC 20250

Dear Mr. Bradley:

Enclosed are several petitions requesting the inclusion of non-organically produced agricultural substances onto the National List section 205.606.

- Whey Protein Concentrate 35% Protein
- Whey Protein Concentrate 80% Protein
- Whey Protein Isolate

We are submitting them as separate petitions; however you may choose to group them as whey derivatives.

I am the Stonyfield Farm Inc. contact and can be reached at:

Stonyfield Farm Inc.
10 Burton Drive
Londonderry, NH 03053
603 437 4040 x 2270

Please contact me if you have any questions or if I can provide anymore information. We appreciate your consideration of our request.

Sincerely,

Nancy B. Hirshberg
VP of Natural Resources

Petition for: Whey Protein Concentrate, 35% Protein

Item A

Category

Non-organically produced agricultural products allowed in or on processed products labeled as "organic". §205.606.

Item B

1. The common name of the substance.

Whey Protein Concentrate 35%, also referred to as WPC 35.

2. The manufacturer.

There are numerous manufacturers of Whey Protein Concentrates throughout the globe. Some of the better known entities include Arla, Supoto, New Zealand Milk Producers, Davisco, and Parmalat. Stonyfield Farm buys our non-organic WPC from outside of the U.S. as there is no WPC 35 available in the US that can document that it is made from milk from cows that have not been treated with rBGH. See Item B #12 for more explanation.

3. The intended or current use of the substance.

Whey Protein Concentrate is used in cultured dairy and yogurt products. We use it in our organic frozen yogurt products at a level of less than 1%.

4. The handling activities for which the substance will be used and its mode of action.

Whey Protein Concentrate 35% is used in frozen yogurt products to maintain the physical texture and consistency that would otherwise be contributed by the fat. We use the WPC 35 in our non-fat and low fat frozen yogurt as a "fat replacer".

5. The source of the substance and a detailed description of its manufacturing or processing procedures.

Whey Protein Concentrate 35 is manufactured from mozzarella cheese whey using an ultra-filtration process to remove a large portion of the lactose and minerals. The process does not involve use of chemicals. Whey Protein Concentrate is spray-dried and sold as a dry ingredient.

6. A summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations.

None are known to exist.

7. Information regarding EPA, FDA, and State regulatory authority registrations.

Whey Protein Concentrate 35% is classified as a food, not a food additive. It is a human food ingredient in use for many years and considered GRAS (Generally Recognized As Safe) based on its history of use as human food.

8. The Chemical Abstract Service (CAS) numbers of the substance and labels of products that contains the petitioned substance.

The CAS Number is not known. A sample label is attached.

9. The substance's physical properties:

Whey Protein Concentrate 35% protein is a cream-colored, free flowing powder with a bland, clean, fresh odor free of oxidized notes, containing 33% to 37% protein, not more than 5% fat, not more than 9% ash, and not more than 6% moisture.

Chemical mode of action including:

(a) chemical interactions with other substances, especially substances used in organic production;

Whey Protein Concentrate 35% is a human food ingredient. It is not intended for use in organic crop or livestock production.

(b) toxicity and environmental persistence;

Whey Protein Concentrate 35% is a GRAS (Generally Recognized As Safe) human food ingredient. The components of Whey Protein Concentrate (whey protein, lactose, essential minerals) are biodegradable and easily assimilated by animals and soil bacteria.

(c) environmental impacts from its use or manufacture;

Whey Protein Concentrate 35% is a value-added means of using whey resulting from cheese operations for human food. It is produced from dairy cheese whey by a process of ultra-filtration that separates much of the lactose and salts and does not involve use of chemicals. The separated lactose can be recovered and sold.

(d) effects on human health;

Whey Protein Concentrate 35% is a GRAS (Generally Recognized As Safe) human food ingredient. Whey Protein Concentrate is a source of high quality whey provides high quality when protein, lactose, and nutritionally essential minerals.

(e) effects on soil organisms, crops, or livestock.

The components of Whey Protein Concentrate (whey protein, lactose, and essential minerals) are biodegradable or assimilable by soil bacteria and livestock.

10. Safety information about the substance.

An MSDS for Whey Protein Concentrate is attached.

11. Comprehensive research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions.

The Committee on Nutrition of the American Academy of Pediatrics (Pediatrics 1999; article attached) points out that children, especially adolescents, consume less than recommended optimal levels of calcium and that low-fat dairy products, including low-fat yogurts, are good sources of calcium that are not high in fat.

12. A "Petition Justification Statement" which provides justification for inclusion of a non-organically produced agricultural substance onto the National List.

We use WPC 35 in our frozen yogurt for several reasons:

- **Fat replacer:** the WPC 35 gives the frozen yogurt a more desirable mouth-feel that more closely mimics a more full fat ice cream. Given the obesity epidemic and the fact that so many Americans don't get enough calcium, a calcium rich non-fat or low-fat dessert product is an important dietary option for many people.
- **Texture:** The WPC 35 used in our frozen yogurt is essential in the functionality of the finished product due to its structural and water binding capabilities. The structural benefits that the protein provide affect the texture of the product in terms of mouthfeel/creaminess in nonfat and lowfat products, ice crystal formation and the uniformity and dispersion of air within the finished product. In this product, water binding helps in the shelf life of the product, protecting it against defects that occur as the product undergoes freeze-thaw cycles often known as freezer burn (due to fluctuation in freezer temps, consumer bringing the product in and out of the freezer).

Why we cannot get organic WPC 80:

Organic WPC 35 is a by-product of cheese production. Thus the supply depends on the volume of sales of organic cheese, and is not directly related to the demand for use in yogurt. There are many small cheese producers around the U.S. whose whey is either being diverted into the conventional market, or sent down the drain, as it is not economically feasible to collect, consolidate, segregate and process it into an organic whey product. Currently in the U.S., the organic whey that is processed is made into either whey powder (used in dry cheese powders for things like macaroni and cheese or other prepared meals) or demineralized whey powder (used in organic infant formulas and organic protein bars).

Processors capable of manufacturing WPC are choosing to manufacture whey powder instead of WPC for several reasons:

1. Converting the thin organic whey into whey powder requires fewer processing steps than making WPC, and the yields, although not good by conventional measure, are better than the multi-process WPC methods.
2. Typical organic whey output from any one cheese plant is quite small by dairy industry standards. It rarely exceeds 100,000 lbs which yields about 1900 lbs of WPC 35. Even consolidating whey from several plants doesn't produce a lot of WPC and the quantity of lactose is too small to be economically processed. Losing out on the sale of the lactose component makes the economical equation for the processor even less desirable.
3. The small processing runs result in a rather poor recovery when the start up and shut down measures that are taken to "flush" any conventional (non-organic) product from the processing equipment.

Currently there is a market for everything that is being made into whey powder so given the considerations previously mentioned, there is little incentive to produce a more specialized, higher protein concentrate product (such as WPC 35) than basic whey powder. WPC contains higher amounts of protein, for example, whey powder contains approximately 12% protein, while WPCs may have 35, 50, or 80 % protein levels. Two companies in the US collect the majority of the whey from organic cheese processing- Sunopta and Davigo. Davigo (Minnesota) occasionally makes WPC but cannot guarantee a supply as they do not know on any regular basis how much organic cheese will be produced in their plants. Sunopta has said that they can sell their whey as whey powder so they are not interested in making WPC.

For all of the above reasons, Stonyfield Farm has not been able to find anyone in the U.S. who would be willing to make organic WPC 35 for us and who could supply our volumes on an on-going basis. As the organic cheese industry grows it is our hope that more economy of scale will be realized and there will be more potential for organic protein powders in the U.S.

Overseas:

Organic WPC is made in Europe, but because dairy standards in Europe are significantly lower than the NOP standards, it does not qualify for NOP organic. New Zealand does have NOP milk and cheese and whey making capabilities. They are planning on having some WPC available within the next few years. We do not know yet whether the volume will be able to meet the needs of the marketplace. There is no organic WPC in Canada. The organic dairy market is in its infancy and still very small. We are committed to sourcing organic WPC in organic form as soon as it becomes available.

Since we use the WPC in our frozen yogurt which is not a Grade A product, we will be able to use a non-US NOP organic WPC 35 if one comes available. However, to

be used in Grade A products such as yogurt, it would need to be made in an IMS listed plant which at this time, means only produced in the U.S.

Other Considerations:

Because all Stonyfield Farm products are made with milk from cows that have not been treated with rBGH, and WPC is made from a conglomeration of many sources of whey from cheese production, in order to be sure our WPC is rBGH free, we buy our WPC for our smoothies from outside the U.S. in countries where rBGH is prohibited.

MATERIAL SAFETY DATA SHEET

1. PRODUCT INFORMATION

PRODUCT IDENTIFIER:

SKU #33712

TRADE NAME:

WHEY PROTEIN CONCENTRATE

SYNONYMS:

WPC35, Whey Protein Product, Whey Serum Proteins

MANUFACTURER:
SUPPLIER:
EMERGENCY PHONE # :
PRODUCT USE:

Product has primary application in food products.

2. HAZARDOUS INGREDIENTS

INGREDIENTS:
non-hazardous {dairy} ingredients
WEIGHT (%):

 95.8% solids minimum (4.2% moisture maximum)
 **** no hazardous ingredients ****

HEALTH RATING:

0 – minimal

{see section 6 for additional details}
FIRE RATING:

0 – minimal

REACTION RATING:

0 – minimal

3. PHYSICAL DATA

numbers are for information only and are not to be considered a technical specification
PHYSICAL STATE:

solid / powder

BOILING POINT:

not applicable

DENSITY (free flowing, g/cc):

 approximately 0.50 to 0.55 *(not a technical specification)*
VAPOUR DENSITY:

not applicable

% VOLATILES:

0%, although up to 5.0% by weight water

SOLUBILITY IN WATER (mL/50mL):

 0.1 mL *insoluble material, typical*
{@ 20°C (10% w/v solution)}
ODOUR THRESHOLD:

no data available

pH (10% w/v solution):

6.0 to 6.6

APPEARANCE AND ODOUR:

 free flowing powder; light cream to light orange colour
 odour neutral

4. FIRE OR EXPLOSION HAZARD

FLAMMABLE:

no

FLASH POINT:

no data available

AUTOIGNITION TEMPERATURE:

no data available

EXTINGUISHING MEDIA:

Use media appropriate for surrounding fire: water spray or TYPE A, B, and / or C extinguisher

HAZARDOUS COMBUSTION PRODUCTS:

 none, although under extreme circumstances (in the presence of highly oxidative materials) may produce the combustion products of CO₂ and CO

UNUSUAL FIRE & EXPLOSION HAZARDS:

fine dust possible - normal care needs to be taken to avoid dusting of material to prevent a powder explosion or fire under certain conditions

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02 January 2002

5. REACTIVITY DATA

STABILITY:
highly stable

INCOMPATIBLE PRODUCTS:
highly oxidative materials

HAZARDOUS DECOMPOSITION PRODUCTS:
none

HAZARDOUS POLYMERIZATION:
will not occur

6. TOXICOLOGICAL PROPERTIES**EFFECTS OF SINGLE (ACUTE) EXPOSURE:****INGESTION**

- this product contains lactose, as such those who are lactose intolerant may experience some discomfort and some digestive problems associated with this condition; acuteness of discomfort and or problem varies with each individual
- in addition, those who are allergic to milk proteins should be cautioned, as this product is a potential allergen due to presence of milk proteins

SKIN ABSORPTION
not applicable

INHALATION
dust irritation, respiratory ailments may be aggravated by dust

SKIN CONTACT
dust irritation

EYE CONTACT
dust irritation

TLV or PEL
no data available

EFFECTS OF REPEATED (CHRONIC) OVEREXPOSURE:
no evidence of adverse effects from available information

OTHER EFFECTS OF OVEREXPOSURE:
no evidence of adverse effects from available information

MEDICAL CONDITIONS AGGRAVATED by OVEREXPOSURE:
respiratory ailments may be aggravated by dust
may be irritating to eyes

FIRST AID:

EYES
irrigate with warm water, seek medical attention if irritation develops or continues

INHALATION

remove to fresh air, if not breathing give artificial respiration and seek medical attention immediately

7. PREVENTATIVE MEASURES

NOTE:
avoid dusting of material

RESPIRATORY PROTECTION:
a suitable mask should be used to avoid breathing the dust

SPECIFIC ENGINEERING CONTROL:
Ventilation - local exhaust preferred
mechanical acceptable

ACTION TO TAKE FOR SPILLS:
mop, wipe or sweep up material, and remove to approved disposal container and dispose in accordance with any Federal, Provincial (State) or Municipal (Local) regulations

8. SPECIAL HANDLING & STORAGE REQUIREMENTS

No requirements exist with this product; however, the following recommendations should be considered in using this product:

To maintain optimum flavour and quality of product, transport and store in a cool (10 to 20°C), clean, dry (RH <65%) environment. Product should not be exposed to direct sunlight, strong odours or open air for extended periods of time. Frequent rotation of stock is recommended for freshness of flavour and product. Shelf life under recommended storage conditions: 9 months optimal, 12 months maximum.

9. ADDITIONAL INFORMATION

NONE



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JOB#: STY 06142-01	CLIENT CONTACT: Carol Billings	ACCT MGR: _____
FILE NAME: MECH-GottaHaveJava_Yog.ai	DIE: v14_16TS-C16-0	PROD MGR: _____
REV#: 0	TITLE: Yogurt - Pint	
	UPC#: 0-52159-00215-2	

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AMERICAN ACADEMY OF PEDIATRICS

Committee on Nutrition

Calcium Requirements of Infants, Children, and Adolescents

ABSTRACT. This statement is intended to provide pediatric caregivers with advice about the nutritional needs of calcium of infants, children, and adolescents. It will review the physiology of calcium metabolism and provide a review of the data about the relationship between calcium intake and bone growth and metabolism. In particular, it will focus on the large number of recent studies that have identified a relationship between childhood calcium intake and bone mineralization and the potential relationship of these data to fractures in adolescents and the development of osteoporosis in adulthood. The specific needs of children and adolescents with eating disorders are not considered.

Approximately 99% of total body calcium is found in the skeleton, with only small amounts found in the plasma and extravascular fluid. Serum calcium exists in 3 fractions: ionized calcium (approximately 50%), protein-bound calcium (approximately 40%), and a small amount of calcium that is complexed, primarily to citrate and phosphate ions. Serum calcium is maintained at a constant level by the actions of several hormones, most notably parathyroid hormone and calcitonin. Calcium absorption is by the passive vitamin D-independent route or by the active vitamin D-dependent route.¹

Understanding calcium needs for different age groups requires a consideration of the variable physiologic requirements for calcium during development. For example, during the first month of life, the regulatory mechanisms that maintain serum calcium levels may not be entirely adequate in some otherwise healthy infants, and symptomatic hypocalcemia can occur. However, in general, hypocalcemia is uncommon in healthy children and adolescents, and the primary need for dietary calcium is to enhance bone mineral deposition.

Calcium requirements also are affected substantially by genetic variability and other dietary constituents. The interactions of these factors make identification of a single unique number for the calcium "requirement" for all children impossible.²⁻⁴ However, several recent dietary guidelines have considered the data about calcium requirements and recommended calcium intake levels that are calculated to benefit most children (Table 1).^{2,3}

In addition to calcium intake, exercise is an important aspect of achieving maximal peak bone mass.

There is evidence that childhood and adolescence may represent an important period for achieving long-lasting skeletal benefits from regular exercise.⁵ For example, Welten et al⁶ showed in a large Dutch cohort of children that regular weight-bearing activity had a greater influence on peak bone mass than dietary calcium.

IDENTIFICATION OF MINERAL REQUIREMENTS DURING CHILDHOOD

Overview

It is recognized that a very low calcium intake can contribute to the development of rickets in infants and children, especially those consuming very restrictive diets (eg, a macrobiotic diet).⁷ There are no reliable data on the lowest calcium intake needed to prevent rickets or on the relationship among ethnicity, vitamin D status, physical activity, and diet in the causation of rickets in children fed low-calcium diets.^{8,9}

Recent data support the possibility that a low bone mass may be a contributing factor to some fractures in children. A relationship between the adolescent growth spurt and the risk of fractures has been shown.^{10,11} Goulding et al¹² reported lower bone mass at multiple sites in a group of 100 girls aged 3 to 15 years with distal forearm fractures compared with age-matched girls. For girls aged 11 to 15 years in the study by Goulding et al¹² a lower calcium intake was reported for those with fractures compared with the control subjects. Wyshak and Frisch¹³ similarly reported that high calcium intakes seem to exert a protective effect against fractures in adolescent boys and girls. They also reported a positive relationship between cola beverage intake and bone fracture. Whether this is attributable to a potential effect of excessive phosphorus in the colas impairing bone mineral status or to the lack of calcium intake related to the substitution of colas for dairy products is uncertain. However, a direct harmful effect of a high phosphorus intake affecting the bone mineral status is unlikely in older children and adults.² Further data on the relationship between calcium intake and fractures are needed before the magnitude of increased fracture risk at different calcium intake levels can be assessed. However, it is reasonable to conclude that low calcium intakes may be an important risk factor for fractures in adolescents. This risk may be an issue that adolescents can more readily relate to than a long-term risk of osteoporosis.

Maintaining adequate calcium intake during childhood is necessary for the development of a maximal peak bone mass. Increasing peak bone mass may be

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
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TABLE 1. Dietary Calcium Intake (mg/d) Recommendations in the United States^{2,3*}

Age	1997 NAS ³	1994 NIH ²
0 to 6 mo†	210	400
6 mo to 1 y†	270	600
1 through 3 y	500	800
4 through 8 y	800	800 (4–5 y) 800–1200 (6–8 y)
9 through 18 y	1300	800–1200 (9–10 y) 1200–1500 (11–18 y)

* Recommended intakes were provided in different forms by each source cited. The Food and Nutrition Board of the National Academy of Sciences (NAS) released Recommended Dietary Allowances until 1997. In 1997, it chose to use the term *adequate intake* for the recommendations for calcium intake but indicated that these values were to be used as Recommended Dietary Allowances. The NIH Consensus Conference did not specify a specific term but indicated that these values were the “optimal” intake levels. Dietary recommendations by the NAS are set to meet the needs of 95% of the identified population of healthy subjects. The NAS guideline should be the primary guideline utilized.

† For infant values, the 1994 NIH Consensus Conference indicated values for formula-fed infants, whereas the 1997 NAS report used the infant fed human milk as the standard.

an important way to reduce the risk of osteoporosis in later adulthood.^{2,14} This is a more difficult end point to identify than the development of rickets or fractures. Therefore, surrogate markers of mineral status are used to assess the consequences of differing levels of calcium intake. The primary surrogates used are optimization of calcium balance or achievement of greater bone mass in children with increased calcium intake.^{3,14,15}

In children with chronic illnesses, fractures may occur during childhood secondary to mineral deficiency associated with the disease process or the effects of therapeutic interventions (ie, corticosteroids) on calcium metabolism.¹⁶ However, minimal data generally are not available on the risks and benefits of increasing calcium intake in children with chronic illnesses above current dietary recommendations. Supplementation of vitamin D along with calcium may be necessary for a maximal response.¹⁷

Methods

Multiple approaches are used to assess mineral requirements in children. They include the following: 1) measurement of calcium balance in persons with various levels of calcium intake; 2) measurement of bone mineral content, by dual-energy radiograph absorptiometry or other techniques, in groups of children before and after calcium supplementation; and 3) epidemiologic studies relating bone mass or fracture risk in adults with childhood calcium intake.

The calcium balance technique consists of measuring the effects of any given calcium intake on the net retention of calcium by the body. This approach has been the most commonly used to estimate requirement for minerals. Its usefulness is based on the rationale that virtually all retained calcium must be used, especially by children, to enhance bone mineralization. It therefore is reasonable to expect that the dietary intake that leads to the greatest level of calcium retention is the intake that will lead to the

greatest benefit for promoting skeletal mineralization and decreasing the ultimate risk of osteoporosis.^{18,19}

The substantial limitations involved in obtaining and interpreting data about calcium balance are well known. These include substantial technical problems with measuring calcium excretion and the difficulty obtaining dietary intake control in children. Both of these are necessary for adequate balance studies. These problems have been partly overcome by the development of stable isotopic methods to assess calcium absorption and excretion.²⁰ Nevertheless, more data are needed to establish the “optimal” level of calcium retention at different ages and the effects of development on calcium balance.⁶

A major advance in the field during the last 25 years has been the development and improvement of methods to measure total body and regional bone mineral content by using various bone density techniques. Currently, the technique used in many studies is dual-energy radiograph absorptiometry. This technique can rapidly measure the bone mineral content and bone mineral density of the entire skeleton or of regional sites with a virtually negligible level of radiation exposure. Furthermore, recent enhancements in the precision of the technique have made it particularly suitable for assessing the effects of calcium supplementation on bone mass in children of all ages.²¹

Several groups have directly assessed the effects of calcium supplementation on bone mass by using dual-energy radiograph absorptiometry or similar techniques.^{22–25} These studies, however, also have limitations. First, most supplementation studies done in children involved relatively short-term supplementation of 1 to 2 years. This period may be inadequate to fully assess the long-term benefits of calcium supplements on bone mineral density. The second is that these studies generally have been done using only 1 level of supplementation, which frequently has been given in pill form. This limited dosing approach makes it difficult to identify an optimal intake level or determine the relative benefits of dietary calcium versus supplements as a method of increasing calcium intake in children.

Several investigators have performed population-based epidemiologic studies relating childhood or adult bone mass or fracture risk to calcium intake in childhood. Although many of these studies are limited by their retrospective design, they have generally shown a positive association between calcium intake in childhood and childhood and adult bone mass. Not all studies have shown a benefit, however, and further data about this relationship are needed.^{3,26–28}

RECOMMENDATIONS BY AGE GROUP

Overview

The specific requirements for calcium intake by infants, children, and adolescents have been extensively reviewed by 2 panels in North America since 1994.^{2,3} A summary of their recommendations is shown in Table 1.

Infants

The optimal primary nutritional source during the first year of life is human milk. No available evidence shows that exceeding the amount of calcium retained by the exclusively breastfed term infant during the first 6 months of life or the amount retained by the human milk-fed infant supplemented with solid foods during the second 6 months of life is beneficial to achieving long-term increases in bone mineralization. Available data demonstrate that the bioavailability of calcium from human milk is greater than that from infant formulas or cow's milk, although this comparison has not generally been made at comparable intake concentrations, ie, such as found in human milk.²⁹ Nevertheless, it has been deemed prudent to increase the concentration of calcium in all infant formulas relative to human milk to ensure at least comparable levels of calcium retention. Relatively greater calcium concentrations are found in specialized formulas, such as soy formulas and casein hydrolysates, to account for the potential lower bioavailability of the calcium from these formulas relative to cow's milk-based formula. Specific concentration requirements cannot be set readily, but all formulas marketed should have demonstrated a net calcium retention at least comparable to that of human milk. Research data are not available to justify the use of very high levels of calcium in infant formula for full-term infants.

Premature infants have higher calcium requirements than full-term infants while in the nursery. These may be met by using human milk fortified with additional minerals or with specially designed formulas for premature infants.³⁰ After hospitalization, there may be benefits to providing formula-fed premature infants formulas with higher calcium concentrations than those of routine cow's milk-based formulas.³¹ The optimal concentrations and length of time needed for such formulas are unknown.

Children

Few data are available about the calcium requirements of children before puberty. Calcium retention is relatively low in toddlers and slowly increases as puberty approaches. Most available data indicate that calcium intake levels of about 800 mg/d are associated with adequate bone mineral accumulation in prepubertal children. The benefits of greater levels of intake in this age group have been studied inadequately.^{20,32} One study found a benefit of calcium supplements to children as young as 6 years of age.¹⁶ However, further supporting data are needed for this finding. Perhaps of most importance in this age group is the development of eating patterns that will be associated with adequate calcium intake later in life.

Preadolescents and Adolescents

The majority of research in children about calcium requirements has been directed toward 9- to 18-year-olds. The efficiency of calcium absorption is increased during puberty, and the majority of bone formation occurs during this period.^{15,20,21,32,33} Data

from balance studies suggest that for most healthy children in this age range, the maximal net calcium balance (plateau) is achieved with intakes between 1200 and 1500 mg/d. That is, at intake levels above this, almost all of the additional calcium is excreted and not used. At intakes below that level, the skeleton may not receive as much calcium as it can use, and peak bone mass may not be achieved.^{2,3,9,15,18-20} Virtually all the data used to establish this intake level are from white children; minimal data are available for other ethnic groups. The exact level that is best for a given person depends on other nutrients in the diet, genetics, exercise, and other factors.

Several controlled trials have found an increase in the bone mineral content in children in this age group who have received calcium supplementation.²²⁻²⁵ However, the available data suggest that if calcium is supplemented only for relatively short periods (ie, 1 to 2 years), there may not be long-term benefits to establishing and maintaining a maximum peak bone mass.^{34,35} This emphasizes the importance of diet in achieving adequate calcium intake and in establishing dietary patterns consistent with a calcium intake near recommended levels throughout childhood and adolescence. Unfortunately, long-term studies evaluating the consequences of maintaining currently recommended calcium intakes beginning in childhood or early adolescence are not available. Most available epidemiologic data, recently reviewed by the National Academy of Sciences and the National Institutes of Health, support the view that maintaining such a diet will increase peak bone mass and lower the incidence of fractures.^{2,3}

Recent data obtained in African American adolescents suggest a link between lower diastolic blood pressure and increased calcium intake. Further studies are necessary to evaluate this relationship in children of multiple ethnicities and age groups.³⁶

ACHIEVING RECOMMENDED INTAKES

The gap between the recommended calcium intakes and the typical intakes of children, especially those 9 to 18 years of age, is substantial (Table 1). Mean intakes in this age group are between approximately 700 and 1000 mg/d, with values at the higher side of this range occurring in males.³ Preoccupation with being thin is common in this age group, especially among females, as is the misconception that all dairy foods are fattening. Many children and adolescents are unaware that low-fat milk contains at least as much calcium as whole milk.

Knowledge of dietary calcium sources is a first step toward increasing the intake of calcium-rich foods. Table 2 gives typical amounts of calcium for some common food sources. The largest source of dietary calcium for most persons is milk and other dairy products.³⁷ Other sources of calcium are, however, important, especially for achieving calcium intakes of 1200 to 1500 mg/d. Most vegetables contain calcium, although at low density. Therefore, relatively large servings are needed to equal the total intake achieved with typical servings of dairy products. The bioavailability of calcium from vegetables

TABLE 2. Approximate Calcium Contents of 1 Serving of Some Common Foods*

Food	Serving Size		Calcium Content
Milk†	1 cup	240 mL	300 mg
White beans	½ cup	110 g	113 mg
Broccoli cooked	½ cup	71 g	35 mg
Broccoli raw	1 cup	71 g	35 mg
Cheddar cheese	1.5 oz	42 g	300 mg
Low-fat yogurt	8 oz	240 g	300–415 mg
Spinach cooked‡	½ cup	90 g	120 mg
Spinach raw‡	1½ cup	90 g	120 mg
Calcium-fortified orange juice	1 cup	240 mL	300 mg
Orange	1 medium	1 medium	50 mg
Sardines or salmon with bones	20 sardines	240 g	50 mg
Sweet potatoes	½ cup mashed	160	44

* Adapted from Raper et al,³⁷ Weaver,^{38,39} and Weaver and Plawecki.⁴⁰

† Low-fat milk has comparable or greater calcium levels than whole milk.

‡ The calcium from spinach is essentially nonbioavailable.

is generally high. An exception is spinach, which is high in oxalate, making the calcium virtually nonbioavailable. Some high-phytate foods, such as whole bran cereals, also may have poorly bioavailable calcium.^{38–40}

Several products have been introduced that are fortified with calcium. These products, most notably orange juice, are fortified to achieve a calcium concentration similar to that of milk. Limited studies of the bioavailability of the calcium in these products suggest that it is at least comparable to that of milk.⁴¹ It is likely that more such products will soon become available. Breakfast foods also are frequently fortified with minerals, including calcium. Calcium intakes on food labels are indicated as a percentage of the “daily value” in each serving. This daily value is currently set as 1000 mg/d. Therefore, it is important to instruct families about reading and interpreting food labels.

Several alternatives exist for children with lactose intolerance. Lactose intolerance is more common in African American, Mexican Americans, and Asian Pacific Islanders than in whites.⁴² Many children with lactose intolerance can drink small amounts of milk without discomfort. Other alternatives include the use of other dairy products, such as solid cheeses and yogurt, that may be better tolerated than milk. Lactose-free and low-lactose milks are available. Increasing the intake of nondairy products, such as vegetables, may be helpful, as may the use of calcium-supplemented foods.

For children and adolescents who cannot or will not consume adequate amounts of calcium from any dietary sources, the use of mineral supplements should be considered. Although supplements vary in their bioavailability, they may have bioavailability comparable to or greater than that of dairy products.⁴³ Decisions about their use must be made on an individual basis, keeping in mind the usual dietary habits of the person, any individual risk factors for osteoporosis, and the likelihood that the use of the supplement will be maintained.

CONCLUSION

Recent studies and dietary recommendations have emphasized the importance of adequate calcium nutrition in children, especially those undergoing the

rapid growth and bone mineralization associated with pubertal development. The current dietary intake of calcium by children and adolescents is well below the recommended optimal levels. The available data support recent recommendations for calcium intakes of 1200 to 1500 mg/d beginning during the preteen years and continuing throughout adolescence as recommended by the National Institutes of Health Consensus Conference² and the National Academy of Sciences.³ Currently, evidence is inadequate to alter the dietary recommendations for children with chronic illnesses or those taking medications, such as corticosteroids, that alter bone metabolism. However, an effort should be made to achieve at least the recommended intake levels. The provision of adequate vitamin D also may be important for children with chronic illnesses.

RECOMMENDATIONS

1. Pediatricians should actively support the goal of achieving calcium intakes in children and adolescents comparable to those in recently recommended guidelines.^{2,3} The prevention of future osteoporosis, as well as the possibility of a decreased risk of childhood and adolescent fractures, should be discussed as potential benefits to achieving these goals. Currently, relatively few children and adolescents achieve dietary calcium intake goals.
2. To emphasize the importance of calcium nutrition, pediatricians should consider including the following questions about dietary calcium intake.
 - What do you drink, either white or chocolate milk, with your meals?
 - Do you drink milk with meals, snacks, or cereal or any other time during the day?
 - Do you eat cheese, yogurt, or other dairy products such as cottage cheese?
 - Do you drink calcium-fortified juices or eat any calcium-fortified foods?
 - Do you eat any of the following: broccoli, tofu, oranges, or legumes (dried beans and peas)?
 - Do you take any mineral or vitamin supplements?
3. For children and adolescents whose calcium intake seems deficient, specific information about the sources of dietary calcium should be pro-

vided. Adolescents may need to be reminded that low-fat dairy products, including skim milk and low-fat yogurts, are good sources of calcium that are not high in fat.

COMMITTEE ON NUTRITION, 1998–1999
Susan S. Baker, MD, PhD, Chairperson
William J. Cochran, MD
Carlos A. Flores, MD
Michael K. Georgieff, MD
Marc S. Jacobson, MD
Tom Jaksic, MD, PhD
Nancy F. Krebs, MD

LIAISON REPRESENTATIVES
Donna Blum-Kemelor, MS, RD
US Department of Agriculture
William Dietz, MD, PhD
Centers for Disease Control and Prevention
Gilman Grave, MD
National Institute of Child Health and Human Development
Suzanne S. Harris, PhD
International Life Sciences Institute
Van S. Hubbard, MD, PhD
National Institute of Diabetes and Digestive and Kidney Diseases
Ann Prendergast, RD, MPH
Maternal and Child Health Bureau
Alice E. Smith, MS, RD
American Dietetic Association
Elizabeth Yetley, PhD
Food and Drug Administration
Doris E. Yuen, MD, PhD
Canadian Paediatric Society

SECTION LIAISONS
Scott C. Denne, MD
Section on Perinatal Pediatrics
Ronald M. Lauer, MD
Section on Cardiology

CONSULTANT
Steven A. Abrams, MD

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January 25, 2007

Mr. Mark Bradley
Program Manager
USDA/AMS/TM/NOP
Room 4008-So.
Ag Stop 0268
1400 Independence Ave., SW
Washington, DC 20250

Dear Mr. Bradley:

Enclosed are several petitions requesting the inclusion of non-organically produced agricultural substances onto the National List section 205.606.

- Whey Protein Concentrate 35% Protein
- Whey Protein Concentrate 80% Protein
- Whey Protein Isolate

We are submitting them as separate petitions; however you may choose to group them as whey derivatives.

I am the Stonyfield Farm Inc. contact and can be reached at:

Stonyfield Farm Inc.
10 Burton Drive
Londonderry, NH 03053
603 437 4040 x 2270

Please contact me if you have any questions or if I can provide anymore information. We appreciate your consideration of our request.

Sincerely,

Nancy B. Hirshberg
VP of Natural Resources

Petition for: Whey Protein Concentrate, 80% Protein

Item A

Category

Non-organically produced agricultural products allowed in or on processed products labeled as “organic”. §205.606.

Item B

1. The common name of the substance.

Whey Protein Concentrate 80%, also referred to as WPC 80.

2. The manufacturer.

There are numerous manufacturers of Whey Protein Concentrates throughout the globe. Some of the better known entities include Arla, Supoto, New Zealand Milk Producers, Davigo, and Parmalat. Stonyfield Farm buys our non-organic WPC from outside of the U.S. as there is no WPC 80 available in the US that can document that it is made from milk from cows that have not been treated with rBGH. See Item B #12 for more explanation.

3. The intended or current use of the substance.

Whey Protein Concentrate is used in cultured dairy and yogurt products. We use it in our organic ‘light’ (nonfat) smoothies at a level of less than 1%.

4. The handling activities for which the substance will be used and its mode of action.

Whey Protein Concentrate is used in cultured dairy and yogurt products to maintain the physical texture and consistency that would otherwise be contributed by the fat. We use the WPC 80 in our light smoothies as a “fat replacer”. Using Whey Protein Concentrate increases the amount of high quality dairy protein in the yogurt.

5. The source of the substance and a detailed description of its manufacturing or processing procedures.

Whey Protein Concentrate is manufactured from fresh cheese whey using an ultra-filtration process to remove a large portion of the lactose and minerals. Low temperature processing ensures retention of both nutritional and functional properties. Whey Protein Concentrate is spray-dried and sold as a dry ingredient.

6. A summary of any available previous reviews of the petitioned substance by State or private certification programs or other organizations.

None are known to exist.

7. Information regarding EPA, FDA, and State regulatory authority registrations.

Whey Protein Concentrate is classified as a food, not a food additive. It is a human food ingredient in use for many years and considered GRAS (Generally Recognized As Safe) based on its history of use as human food.

8. The Chemical Abstract Service (CAS) numbers of the substance and labels of products that contains the petitioned substance.

The CAS Number is not known. A sample label is attached.

9. The substance's physical properties:

Whey Protein Concentrate 80 is a cream-colored, spray-dried, soluble milk protein powder. It contains approximately 80% protein, 4% moisture, 5.5% fat, 5% carbohydrate (lactose), and 3.5% minerals.

Chemical mode of action including:

(a) chemical interactions with other substances, especially substances used in organic production;

Whey Protein Concentrate is a human food ingredient. It is not intended for use in organic crop or livestock production.

(b) toxicity and environmental persistence;

Whey Protein Concentrate is a GRAS (Generally Recognized As Safe) human food ingredient. Whey Protein Concentrate contains over 80% protein of high biological quality that is easily assimilated by animals and soil bacteria.

(c) environmental impacts from its use or manufacture;

Whey Protein Concentrate is a value-added means of using whey resulting from cheese operations for human food.

(d) effects on human health;

Whey Protein Concentrate is a GRAS (Generally Recognized As Safe) human food ingredient. Whey Protein Concentrate is a source of high quality whey protein used extensively in infant formula and yogurt, and for protein fortification.

(e) effects on soil organisms, crops, or livestock.

The components of Whey Protein Concentrate (whey protein; minor amounts of fat, lactose, and essential minerals) are biodegradable or assimilable by soil bacteria and livestock.

10. Safety information about the substance.

An MSDS for Whey Protein Concentrate is attached.

11. Comprehensive research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions.

The Committee on Nutrition of the American Academy of Pediatrics (Pediatrics 1999; article attached) points out that children, especially adolescents, consume less than recommended optimal levels of calcium and that low-fat dairy products, including low-fat yogurts, are good sources of calcium that are not high in fat.

12. A "Petition Justification Statement" which provides justification for inclusion of a non-organically produced agricultural substance onto the National List.

We use WPC 80 in our smoothies for several reasons:

- **Fat replacer:** the WPC 80 gives the non-fat smoothies a more desirable mouth-feel than non-fat smoothies made without it. Given the obesity epidemic and the fact that so many Americans don't get enough calcium, a calcium rich non-fat product is an important dietary option for many people.
- **Texture:** The protein in the WPC 80 binds with water to create a smoother, more refreshing product that cannot be achieved with other organic products such as organic non-fat dry milk (NFDM). NFDM would create a thicker, denser, heavier product. Stonyfield Farm consumer research indicated that people preferred a creamy, but smooth drink, not dense or chalky. Of the prototype tested 83% liked the smoothness, but they wanted it creamier – which could only be achieved without making it too thick or dense (so still light) by adding WPC. (Stonyfield Farm consumer research available to NOP and NOSB on request.)
- **Nutritional enhancement:** While serving the important role of enhancing texture and mouth-feel, the WPC adds protein, which is in great demand by many dieters today.

Why we cannot get organic WPC 80:

Organic WPC 80 is a by-product of cheese production. Thus the supply depends on the volume of sales of organic cheese, and is not directly related to the demand for use in yogurt. There are many small cheese producers around the U.S. whose whey is either being diverted into the conventional market, or sent down the drain, as it is not economically feasible to collect, consolidate, segregate and process it into an organic whey product. Currently in the U.S., the organic whey that is processed is made into either whey powder (used in dry cheese powders for things like macaroni and cheese or other prepared meals) or demineralized whey powder (used in organic infant formulas and organic protein bars).

Processors capable of manufacturing WPC are choosing to manufacture whey powder instead of WPC for several reasons:

1. Converting the thin organic whey into whey powder requires fewer processing steps than making WPC, and the yields, although not good by conventional measure, are better than the multi-process WPC methods.
2. Typical organic whey output from any one cheese plant is quite small by dairy industry standards. It rarely exceeds 100,000 lbs which yields 7,000 lbs of whey solids and about 850 lbs of WPC 80. Even consolidating whey from several plants doesn't produce a lot of WPC and the quantity of lactose is too small (about 4000 lbs) to be economically processed. Losing out on the sale of the lactose component makes the economical equation for the processor even less desirable.
3. The small processing runs result in a rather poor recovery when the start up and shut down measures that are taken to "flush" any conventional (non-organic) product from the processing equipment.

Currently there is a market for everything that is being made into whey powder so given the considerations previously mentioned, there is little incentive to produce a more specialized, higher protein concentrate product (such as WPC 80) than basic whey powder. WPC contains higher amounts of protein, for example, whey powder contains approximately 12% protein, while WPCs may have 35, 50, or 80 % protein levels. Two companies in the US collect the majority of the whey from organic cheese processing- Sunopta and Davigo. Davigo (Minnesota) occasionally makes WPC 80 but cannot guarantee a supply as they do not know on any regular basis how much organic cheese will be produced in their plants. Sunopta has a market for all of their whey as powder so are not interested in making WPC.

For all of the above reasons, Stonyfield Farm has not been able to find anyone in the U.S. who would be willing to make organic WPC 80 for us and who could supply our volumes on an on-going basis. As the organic cheese industry grows it is our hope that more economy of scale will be realized and there will be more potential for organic protein powders in the U.S.

Overseas:

Organic WPC is made in Europe, but because dairy standards in Europe are significantly lower than the NOP standards, it does not qualify for NOP organic. New Zealand does have NOP milk and cheese and whey making capabilities. They are planning on having some WPC 80 available within the next few years. We do not know yet whether the volume will be able to meet the needs of the marketplace. There is no organic WPC 80 in Canada. The organic dairy market is in its infancy and still very small. We are committed to sourcing organic WPC in organic form as soon as it becomes available.

Since we use the WPC 80 in our light smoothies which are not Grade A products, we will be able to use a non-US NOP organic WPC 80 if one comes available. However,

Petition for Whey Protein Concentrate, 80% Protein
Stonyfield Farm Inc., January 2006

to be used in Grade A products such as yogurt, it would need to be made in an IMS listed plant which at this time, means only produced in the U.S.

Other Considerations:

Because all Stonyfield Farm products are made with milk from cows that have not been treated with rBGH, and WPC is made from a conglomeration of many sources of whey from cheese production, in order to be sure our WPC is rBGH free, we buy our WPC for our smoothies from outside the U.S. in countries where rBGH is prohibited.

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MSDS BULLETIN

MSDS:006
Version 4.1005

Prepared in accordance with EC Directive 2001/58/EC

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY / UNDERTAKING

PRODUCT INFORMATION	
Product name	All NZMP Whey Protein Concentrates
Intended use	Food applications

PRIMARY GLOBAL CONTACT (24 HOUR COVERAGE)	
Company	
Address	
Contact	
Telephone	
Fax	

SECONDARY CONTACT (EUROPEAN CUSTOMERS ONLY)	
Company	
Address	
Contact	
Telephone	
Fax	

2. COMPOSITION / INFORMATION ON INGREDIENTS

Natural product. CAS not known. EINECS not known.

TYPICAL COMPOSITION	WPC 55	HIGH FAT WPC	WPC 80
Protein (as is)	55.0%	55.0 - 72.0%	80.0%
Lactose	33.0%	8.0% - 19.0%	8.0%
Ash	4.7%	5.5%	3.1%
Moisture	3.3%	4.5%	4.1%
Milkfat	4.0%	10.0 - 16.0%	4.8%

3. HAZARDS IDENTIFICATION

Non-hazardous product as specified in Directive 67/548/EEC.

4. FIRST AID MEASURES

Product in eye	Low risk	Rinse with gently flowing clean water for a minimum of 5 minutes. If eye irritation occurs, seek medical attention.
Product on skin	Very low risk	Wipe away excess, wash skin with clean water.
Product inhaled	Low risk	Keep inhalation to a minimum. If large quantities are involved, remove to fresh air. If breathing problems occur, seek medical attention.
Product swallowed	No risk	Product fit for human consumption as a food or food ingredient.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	No restriction
Special risks	Any fine powder is susceptible to fire risk. Keep away from all direct sources of combustion. Whey Protein Concentrate dust is potentially explosive if present at sufficiently high concentrations.

6. ACCIDENTAL RELEASE MEASURES

If spillage occurs, take up dry and wash area with water. Disposal of large quantities should be according to Federal, State and Local Authority Regulations.

7. HANDLING AND STORAGE

Handling	Avoid moisture, keep packaging intact.
Storage	Storage and transport under ambient conditions. Ensure no direct contact with moisture prior to use, and avoid highly humid environments. Ensure product is never stored nor transported in containers or environments with hazardous, chemically dangerous or poisonous goods.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION**Personal protective equipment**

Respiratory protection	Dust mask recommended
Eye protection	Safety glasses recommended
Hand protection	Protective gloves recommended
Industrial hygiene	Wash hands after handling substance

9. PHYSICAL AND CHEMICAL PROPERTIES

pH	6.8 @ 5% solution
Colour	Cream
Odour	Bland/typical
Form	Powder
Ignition temperature	460°C
Explosion limits lower upper	45g/m ³ (in air) not known
Bulk Density	0.4 – 0.5 g/ml
Solubility in water (20°C)	Soluble

10. STABILITY AND REACTIVITY

Conditions to be avoided	None known
Substances to be avoided	None known
Hazardous decomposition products	None known, but as a precaution, breathing apparatus should be worn.

11. TOXICOLOGICAL INFORMATION

No toxic effects when the product is handled appropriately.

12. ECOLOGICAL INFORMATION

No ecological problems are to be expected when the product is handled and used with due care and attention.

13. DISPOSAL CONSIDERATIONS

Product	Disposal in accordance with country, state, and local authority regulations.
Packaging	Disposal should be in compliance with official regulations. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

14. TRANSPORT INFORMATION

Not subject to any transport regulations.

15. REGULATORY INFORMATION**Hazard Labelling according to EC Directives**

Whey Protein Concentrates do not need to be labelled in accordance with EEC directive 67/548.

National regulations

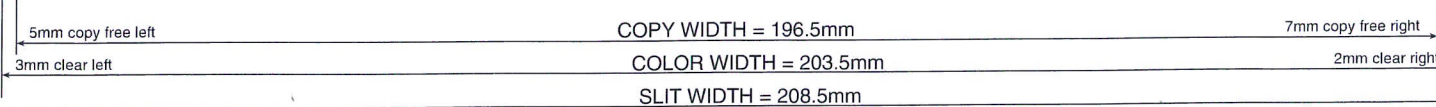
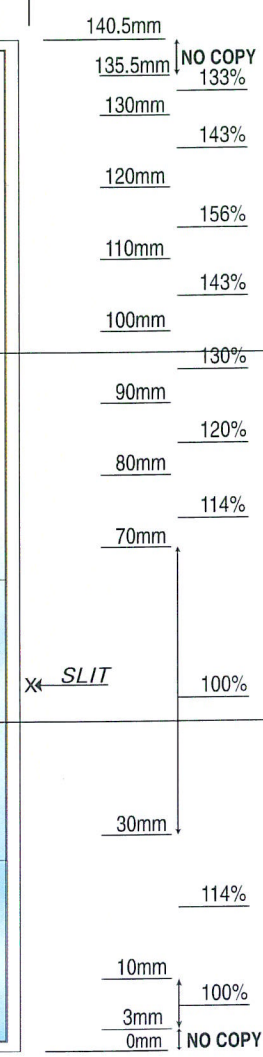
German Water pollution class	Non-water polluting
Swiss Toxic class	F

16. OTHER INFORMATION

The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our product is responsible for ensuring that, where applicable, existing laws and guidelines are observed.

PRELIMINARY TEMPLATE

Distortions will occur in areas where there is a percentage marked. Pull out Graphics and copy at the percentage listed below. Horizontally only.



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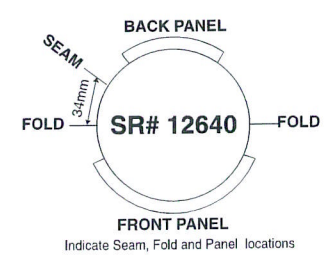


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Preferred Size 100%
Minimum Size 90%

CLIENT Stonyfield	FONTS Gill Sans Helvetica Thesis Sans Tekton	
DESCRIPTION Drinkable Yogurt Light Banana Berry 10oz		
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DATE 12.13.06		

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AMERICAN ACADEMY OF PEDIATRICS

Committee on Nutrition

Calcium Requirements of Infants, Children, and Adolescents

ABSTRACT. This statement is intended to provide pediatric caregivers with advice about the nutritional needs of calcium of infants, children, and adolescents. It will review the physiology of calcium metabolism and provide a review of the data about the relationship between calcium intake and bone growth and metabolism. In particular, it will focus on the large number of recent studies that have identified a relationship between childhood calcium intake and bone mineralization and the potential relationship of these data to fractures in adolescents and the development of osteoporosis in adulthood. The specific needs of children and adolescents with eating disorders are not considered.

Approximately 99% of total body calcium is found in the skeleton, with only small amounts found in the plasma and extravascular fluid. Serum calcium exists in 3 fractions: ionized calcium (approximately 50%), protein-bound calcium (approximately 40%), and a small amount of calcium that is complexed, primarily to citrate and phosphate ions. Serum calcium is maintained at a constant level by the actions of several hormones, most notably parathyroid hormone and calcitonin. Calcium absorption is by the passive vitamin D-independent route or by the active vitamin D-dependent route.¹

Understanding calcium needs for different age groups requires a consideration of the variable physiologic requirements for calcium during development. For example, during the first month of life, the regulatory mechanisms that maintain serum calcium levels may not be entirely adequate in some otherwise healthy infants, and symptomatic hypocalcemia can occur. However, in general, hypocalcemia is uncommon in healthy children and adolescents, and the primary need for dietary calcium is to enhance bone mineral deposition.

Calcium requirements also are affected substantially by genetic variability and other dietary constituents. The interactions of these factors make identification of a single unique number for the calcium "requirement" for all children impossible.²⁻⁴ However, several recent dietary guidelines have considered the data about calcium requirements and recommended calcium intake levels that are calculated to benefit most children (Table 1).^{2,3}

In addition to calcium intake, exercise is an important aspect of achieving maximal peak bone mass.

There is evidence that childhood and adolescence may represent an important period for achieving long-lasting skeletal benefits from regular exercise.⁵ For example, Welten et al⁶ showed in a large Dutch cohort of children that regular weight-bearing activity had a greater influence on peak bone mass than dietary calcium.

IDENTIFICATION OF MINERAL REQUIREMENTS DURING CHILDHOOD

Overview

It is recognized that a very low calcium intake can contribute to the development of rickets in infants and children, especially those consuming very restrictive diets (eg, a macrobiotic diet).⁷ There are no reliable data on the lowest calcium intake needed to prevent rickets or on the relationship among ethnicity, vitamin D status, physical activity, and diet in the causation of rickets in children fed low-calcium diets.^{8,9}

Recent data support the possibility that a low bone mass may be a contributing factor to some fractures in children. A relationship between the adolescent growth spurt and the risk of fractures has been shown.^{10,11} Goulding et al¹² reported lower bone mass at multiple sites in a group of 100 girls aged 3 to 15 years with distal forearm fractures compared with age-matched girls. For girls aged 11 to 15 years in the study by Goulding et al¹² a lower calcium intake was reported for those with fractures compared with the control subjects. Wyshak and Frisch¹³ similarly reported that high calcium intakes seem to exert a protective effect against fractures in adolescent boys and girls. They also reported a positive relationship between cola beverage intake and bone fracture. Whether this is attributable to a potential effect of excessive phosphorus in the colas impairing bone mineral status or to the lack of calcium intake related to the substitution of colas for dairy products is uncertain. However, a direct harmful effect of a high phosphorus intake affecting the bone mineral status is unlikely in older children and adults.² Further data on the relationship between calcium intake and fractures are needed before the magnitude of increased fracture risk at different calcium intake levels can be assessed. However, it is reasonable to conclude that low calcium intakes may be an important risk factor for fractures in adolescents. This risk may be an issue that adolescents can more readily relate to than a long-term risk of osteoporosis.

Maintaining adequate calcium intake during childhood is necessary for the development of a maximal peak bone mass. Increasing peak bone mass may be

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
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TABLE 1. Dietary Calcium Intake (mg/d) Recommendations in the United States^{2,3*}

Age	1997 NAS ³	1994 NIH ²
0 to 6 mo†	210	400
6 mo to 1 y†	270	600
1 through 3 y	500	800
4 through 8 y	800	800 (4–5 y) 800–1200 (6–8 y)
9 through 18 y	1300	800–1200 (9–10 y) 1200–1500 (11–18 y)

* Recommended intakes were provided in different forms by each source cited. The Food and Nutrition Board of the National Academy of Sciences (NAS) released Recommended Dietary Allowances until 1997. In 1997, it chose to use the term *adequate intake* for the recommendations for calcium intake but indicated that these values were to be used as Recommended Dietary Allowances. The NIH Consensus Conference did not specify a specific term but indicated that these values were the “optimal” intake levels. Dietary recommendations by the NAS are set to meet the needs of 95% of the identified population of healthy subjects. The NAS guideline should be the primary guideline utilized.

† For infant values, the 1994 NIH Consensus Conference indicated values for formula-fed infants, whereas the 1997 NAS report used the infant fed human milk as the standard.

an important way to reduce the risk of osteoporosis in later adulthood.^{2,14} This is a more difficult end point to identify than the development of rickets or fractures. Therefore, surrogate markers of mineral status are used to assess the consequences of differing levels of calcium intake. The primary surrogates used are optimization of calcium balance or achievement of greater bone mass in children with increased calcium intake.^{3,14,15}

In children with chronic illnesses, fractures may occur during childhood secondary to mineral deficiency associated with the disease process or the effects of therapeutic interventions (ie, corticosteroids) on calcium metabolism.¹⁶ However, minimal data generally are not available on the risks and benefits of increasing calcium intake in children with chronic illnesses above current dietary recommendations. Supplementation of vitamin D along with calcium may be necessary for a maximal response.¹⁷

Methods

Multiple approaches are used to assess mineral requirements in children. They include the following: 1) measurement of calcium balance in persons with various levels of calcium intake; 2) measurement of bone mineral content, by dual-energy radiograph absorptiometry or other techniques, in groups of children before and after calcium supplementation; and 3) epidemiologic studies relating bone mass or fracture risk in adults with childhood calcium intake.

The calcium balance technique consists of measuring the effects of any given calcium intake on the net retention of calcium by the body. This approach has been the most commonly used to estimate requirement for minerals. Its usefulness is based on the rationale that virtually all retained calcium must be used, especially by children, to enhance bone mineralization. It therefore is reasonable to expect that the dietary intake that leads to the greatest level of calcium retention is the intake that will lead to the

greatest benefit for promoting skeletal mineralization and decreasing the ultimate risk of osteoporosis.^{18,19}

The substantial limitations involved in obtaining and interpreting data about calcium balance are well known. These include substantial technical problems with measuring calcium excretion and the difficulty obtaining dietary intake control in children. Both of these are necessary for adequate balance studies. These problems have been partly overcome by the development of stable isotopic methods to assess calcium absorption and excretion.²⁰ Nevertheless, more data are needed to establish the “optimal” level of calcium retention at different ages and the effects of development on calcium balance.⁶

A major advance in the field during the last 25 years has been the development and improvement of methods to measure total body and regional bone mineral content by using various bone density techniques. Currently, the technique used in many studies is dual-energy radiograph absorptiometry. This technique can rapidly measure the bone mineral content and bone mineral density of the entire skeleton or of regional sites with a virtually negligible level of radiation exposure. Furthermore, recent enhancements in the precision of the technique have made it particularly suitable for assessing the effects of calcium supplementation on bone mass in children of all ages.²¹

Several groups have directly assessed the effects of calcium supplementation on bone mass by using dual-energy radiograph absorptiometry or similar techniques.^{22–25} These studies, however, also have limitations. First, most supplementation studies done in children involved relatively short-term supplementation of 1 to 2 years. This period may be inadequate to fully assess the long-term benefits of calcium supplements on bone mineral density. The second is that these studies generally have been done using only 1 level of supplementation, which frequently has been given in pill form. This limited dosing approach makes it difficult to identify an optimal intake level or determine the relative benefits of dietary calcium versus supplements as a method of increasing calcium intake in children.

Several investigators have performed population-based epidemiologic studies relating childhood or adult bone mass or fracture risk to calcium intake in childhood. Although many of these studies are limited by their retrospective design, they have generally shown a positive association between calcium intake in childhood and childhood and adult bone mass. Not all studies have shown a benefit, however, and further data about this relationship are needed.^{3,26–28}

RECOMMENDATIONS BY AGE GROUP

Overview

The specific requirements for calcium intake by infants, children, and adolescents have been extensively reviewed by 2 panels in North America since 1994.^{2,3} A summary of their recommendations is shown in Table 1.

Infants

The optimal primary nutritional source during the first year of life is human milk. No available evidence shows that exceeding the amount of calcium retained by the exclusively breastfed term infant during the first 6 months of life or the amount retained by the human milk-fed infant supplemented with solid foods during the second 6 months of life is beneficial to achieving long-term increases in bone mineralization. Available data demonstrate that the bioavailability of calcium from human milk is greater than that from infant formulas or cow's milk, although this comparison has not generally been made at comparable intake concentrations, ie, such as found in human milk.²⁹ Nevertheless, it has been deemed prudent to increase the concentration of calcium in all infant formulas relative to human milk to ensure at least comparable levels of calcium retention. Relatively greater calcium concentrations are found in specialized formulas, such as soy formulas and casein hydrolysates, to account for the potential lower bioavailability of the calcium from these formulas relative to cow's milk-based formula. Specific concentration requirements cannot be set readily, but all formulas marketed should have demonstrated a net calcium retention at least comparable to that of human milk. Research data are not available to justify the use of very high levels of calcium in infant formula for full-term infants.

Premature infants have higher calcium requirements than full-term infants while in the nursery. These may be met by using human milk fortified with additional minerals or with specially designed formulas for premature infants.³⁰ After hospitalization, there may be benefits to providing formula-fed premature infants formulas with higher calcium concentrations than those of routine cow's milk-based formulas.³¹ The optimal concentrations and length of time needed for such formulas are unknown.

Children

Few data are available about the calcium requirements of children before puberty. Calcium retention is relatively low in toddlers and slowly increases as puberty approaches. Most available data indicate that calcium intake levels of about 800 mg/d are associated with adequate bone mineral accumulation in prepubertal children. The benefits of greater levels of intake in this age group have been studied inadequately.^{20,32} One study found a benefit of calcium supplements to children as young as 6 years of age.¹⁶ However, further supporting data are needed for this finding. Perhaps of most importance in this age group is the development of eating patterns that will be associated with adequate calcium intake later in life.

Preadolescents and Adolescents

The majority of research in children about calcium requirements has been directed toward 9- to 18-year-olds. The efficiency of calcium absorption is increased during puberty, and the majority of bone formation occurs during this period.^{15,20,21,32,33} Data

from balance studies suggest that for most healthy children in this age range, the maximal net calcium balance (plateau) is achieved with intakes between 1200 and 1500 mg/d. That is, at intake levels above this, almost all of the additional calcium is excreted and not used. At intakes below that level, the skeleton may not receive as much calcium as it can use, and peak bone mass may not be achieved.^{2,3,9,15,18-20} Virtually all the data used to establish this intake level are from white children; minimal data are available for other ethnic groups. The exact level that is best for a given person depends on other nutrients in the diet, genetics, exercise, and other factors.

Several controlled trials have found an increase in the bone mineral content in children in this age group who have received calcium supplementation.²²⁻²⁵ However, the available data suggest that if calcium is supplemented only for relatively short periods (ie, 1 to 2 years), there may not be long-term benefits to establishing and maintaining a maximum peak bone mass.^{34,35} This emphasizes the importance of diet in achieving adequate calcium intake and in establishing dietary patterns consistent with a calcium intake near recommended levels throughout childhood and adolescence. Unfortunately, long-term studies evaluating the consequences of maintaining currently recommended calcium intakes beginning in childhood or early adolescence are not available. Most available epidemiologic data, recently reviewed by the National Academy of Sciences and the National Institutes of Health, support the view that maintaining such a diet will increase peak bone mass and lower the incidence of fractures.^{2,3}

Recent data obtained in African American adolescents suggest a link between lower diastolic blood pressure and increased calcium intake. Further studies are necessary to evaluate this relationship in children of multiple ethnicities and age groups.³⁶

ACHIEVING RECOMMENDED INTAKES

The gap between the recommended calcium intakes and the typical intakes of children, especially those 9 to 18 years of age, is substantial (Table 1). Mean intakes in this age group are between approximately 700 and 1000 mg/d, with values at the higher side of this range occurring in males.³ Preoccupation with being thin is common in this age group, especially among females, as is the misconception that all dairy foods are fattening. Many children and adolescents are unaware that low-fat milk contains at least as much calcium as whole milk.

Knowledge of dietary calcium sources is a first step toward increasing the intake of calcium-rich foods. Table 2 gives typical amounts of calcium for some common food sources. The largest source of dietary calcium for most persons is milk and other dairy products.³⁷ Other sources of calcium are, however, important, especially for achieving calcium intakes of 1200 to 1500 mg/d. Most vegetables contain calcium, although at low density. Therefore, relatively large servings are needed to equal the total intake achieved with typical servings of dairy products. The bioavailability of calcium from vegetables

TABLE 2. Approximate Calcium Contents of 1 Serving of Some Common Foods*

Food	Serving Size		Calcium Content
Milk†	1 cup	240 mL	300 mg
White beans	½ cup	110 g	113 mg
Broccoli cooked	½ cup	71 g	35 mg
Broccoli raw	1 cup	71 g	35 mg
Cheddar cheese	1.5 oz	42 g	300 mg
Low-fat yogurt	8 oz	240 g	300–415 mg
Spinach cooked‡	½ cup	90 g	120 mg
Spinach raw‡	1½ cup	90 g	120 mg
Calcium-fortified orange juice	1 cup	240 mL	300 mg
Orange	1 medium	1 medium	50 mg
Sardines or salmon with bones	20 sardines	240 g	50 mg
Sweet potatoes	½ cup mashed	160	44

* Adapted from Raper et al,³⁷ Weaver,^{38,39} and Weaver and Plawecki.⁴⁰

† Low-fat milk has comparable or greater calcium levels than whole milk.

‡ The calcium from spinach is essentially nonbioavailable.

is generally high. An exception is spinach, which is high in oxalate, making the calcium virtually nonbioavailable. Some high-phytate foods, such as whole bran cereals, also may have poorly bioavailable calcium.^{38–40}

Several products have been introduced that are fortified with calcium. These products, most notably orange juice, are fortified to achieve a calcium concentration similar to that of milk. Limited studies of the bioavailability of the calcium in these products suggest that it is at least comparable to that of milk.⁴¹ It is likely that more such products will soon become available. Breakfast foods also are frequently fortified with minerals, including calcium. Calcium intakes on food labels are indicated as a percentage of the “daily value” in each serving. This daily value is currently set as 1000 mg/d. Therefore, it is important to instruct families about reading and interpreting food labels.

Several alternatives exist for children with lactose intolerance. Lactose intolerance is more common in African American, Mexican Americans, and Asian Pacific Islanders than in whites.⁴² Many children with lactose intolerance can drink small amounts of milk without discomfort. Other alternatives include the use of other dairy products, such as solid cheeses and yogurt, that may be better tolerated than milk. Lactose-free and low-lactose milks are available. Increasing the intake of nondairy products, such as vegetables, may be helpful, as may the use of calcium-supplemented foods.

For children and adolescents who cannot or will not consume adequate amounts of calcium from any dietary sources, the use of mineral supplements should be considered. Although supplements vary in their bioavailability, they may have bioavailability comparable to or greater than that of dairy products.⁴³ Decisions about their use must be made on an individual basis, keeping in mind the usual dietary habits of the person, any individual risk factors for osteoporosis, and the likelihood that the use of the supplement will be maintained.

CONCLUSION

Recent studies and dietary recommendations have emphasized the importance of adequate calcium nutrition in children, especially those undergoing the

rapid growth and bone mineralization associated with pubertal development. The current dietary intake of calcium by children and adolescents is well below the recommended optimal levels. The available data support recent recommendations for calcium intakes of 1200 to 1500 mg/d beginning during the preteen years and continuing throughout adolescence as recommended by the National Institutes of Health Consensus Conference² and the National Academy of Sciences.³ Currently, evidence is inadequate to alter the dietary recommendations for children with chronic illnesses or those taking medications, such as corticosteroids, that alter bone metabolism. However, an effort should be made to achieve at least the recommended intake levels. The provision of adequate vitamin D also may be important for children with chronic illnesses.

RECOMMENDATIONS

1. Pediatricians should actively support the goal of achieving calcium intakes in children and adolescents comparable to those in recently recommended guidelines.^{2,3} The prevention of future osteoporosis, as well as the possibility of a decreased risk of childhood and adolescent fractures, should be discussed as potential benefits to achieving these goals. Currently, relatively few children and adolescents achieve dietary calcium intake goals.
2. To emphasize the importance of calcium nutrition, pediatricians should consider including the following questions about dietary calcium intake.
 - What do you drink, either white or chocolate milk, with your meals?
 - Do you drink milk with meals, snacks, or cereal or any other time during the day?
 - Do you eat cheese, yogurt, or other dairy products such as cottage cheese?
 - Do you drink calcium-fortified juices or eat any calcium-fortified foods?
 - Do you eat any of the following: broccoli, tofu, oranges, or legumes (dried beans and peas)?
 - Do you take any mineral or vitamin supplements?
3. For children and adolescents whose calcium intake seems deficient, specific information about the sources of dietary calcium should be pro-

vided. Adolescents may need to be reminded that low-fat dairy products, including skim milk and low-fat yogurts, are good sources of calcium that are not high in fat.

COMMITTEE ON NUTRITION, 1998–1999
Susan S. Baker, MD, PhD, Chairperson
William J. Cochran, MD
Carlos A. Flores, MD
Michael K. Georgieff, MD
Marc S. Jacobson, MD
Tom Jaksic, MD, PhD
Nancy F. Krebs, MD

LIAISON REPRESENTATIVES
Donna Blum-Kemelor, MS, RD
US Department of Agriculture
William Dietz, MD, PhD
Centers for Disease Control and Prevention
Gilman Grave, MD
National Institute of Child Health and Human Development
Suzanne S. Harris, PhD
International Life Sciences Institute
Van S. Hubbard, MD, PhD
National Institute of Diabetes and Digestive and Kidney Diseases
Ann Prendergast, RD, MPH
Maternal and Child Health Bureau
Alice E. Smith, MS, RD
American Dietetic Association
Elizabeth Yetley, PhD
Food and Drug Administration
Doris E. Yuen, MD, PhD
Canadian Paediatric Society

SECTION LIAISONS
Scott C. Denne, MD
Section on Perinatal Pediatrics
Ronald M. Lauer, MD
Section on Cardiology

CONSULTANT
Steven A. Abrams, MD

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