Nestlé Infant Nutrition
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July 14, 2011

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Ave, N.W.
Washington, D.C. 20580

RE: Interagency Working Group of Food Marketed to Children: Proposed Nutrition Principles: FTC Project No. P094513

Nestlé Nutrition represents Gerber Products Company and the PowerBar® Brand.

Gerber Products Company has an 80 year history of helping parents raise happy, healthy infants and toddlers and is the leading manufacturer of foods specifically designed for infants and toddlers in the United States. In 2002, we launched our ***Start Healthy Stay Healthy***™ Nutrition System which continues to be the heart of all we do today. The ***Start Healthy Stay Healthy*** ™ System is a science based initiative to deliver appropriate products, tools and information to support healthy growth and development and help parents establish healthy eating habits for their children. As part of this program, we sponsored the largest dietary intake surveys of American Infants and toddlers called FITS, "The Feeding Infants and Toddlers Study". The first FITS study was conducted in 2002 and included dietary intake data for 3,000 U.S. infants and toddlers and resulted in the publication of over 21 peer-reviewed scientific papers. The second FITS study of comparable magnitude was conducted in 2008 and initial findings were presented at the American Dietetic Meeting in October 2009 and at the American Academy of Pediatrics annual meeting in 2010. Data from FITS has proven immensely valuable to Gerber as well as to the scientific community, government and health professionals.

While the nutrition needs of performance athletes varies considerably from the needs of very young children, Gerber and PowerBar are united under a common goal of supporting nutrition, health and wellness

The PowerBar® brand has been nourishing performance athletes since 1983. It was then that the first PowerBar® bars were developed to fuel elite athletes. In 1986, PowerBar Inc. was founded and officially started selling the original energy bar to athletes. The

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brand is dedicated to promoting sports and fitness, health, and wellness to all athletes - from world class champions to those beginning to explore the world of fitness or competitive sport. PowerBar® products are designed with a strong emphasis on sports nutrition science and innovated to provide convenient nutrition options for athletes.

The PowerBar® portfolio includes fueling products such as gel packs, bars and beverages to help athletes restore and replenish nutrients lost during training and competition. In addition, PowerBar offers protein containing products in the form of bars and beverages. These products provide a convenient source of high quality proteins to support the growth and repair of lean muscle tissue.

The variety of product offerings under the PowerBar® brand have provided extremely valuable nutrition tools to athletes of every caliber for many decades and continues to promote a healthy lifestyle through diet and exercise to consumers of all ages.

Nestle Nutrition welcomes the opportunity to provide comments on the important questions and issues raised in the Interagency Working Group Proposed Nutrition Principles for food marketed to children between 2 and 17 years of age.

Summary

Nestle Nutrition acknowledges that overweight and obesity are of grave concern especially with respect to the number of young children affected by these conditions. The Gerber Products Company has invested significant resources into our Feeding Infants and Toddlers Studies (2002 and 2008) which provide valuable data and insight into dietary intakes and food patterns of the youngest Americans from 0 to 4 years of age. In addition, we develop our products, tools and consumer and medical materials and information with the goal of promoting healthy growth and development as well as the establishment of healthy eating habits for young children. Habits, which research suggests, could last into older childhood.

Through FITS, we are well aware of the inappropriate food choices that are frequently found in the diets of very young children – usually starting at around 1 year of age with the introduction to the food eaten at the family table. In addition, nutrient gaps begin to appear in the diets of young children also starting at about 1 year of age (Siega-Riz, Butte, JADA Dec 2010).

While we commend the IWG for its efforts toward a laudable goal – improving the health status of the next generation - we question the appropriateness of prescriptive nutrition

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criteria. Such criteria attempts to define "healthy food" and restrict advertising to only those "healthy foods" while ignoring how people really eat, the role of parents and other caregivers in teaching good eating habits and the nutrition needs of select population groups – young children under 4, young endurance athletes, and nutritionally "at risk" children.

Furthermore, we believe the proposed criteria could result in reasonable foods being unnecessarily restricted from advertising due to the restrictive nature of the proposed criteria, especially in light of the fact that there is no evidence to show that implementation of the proposed program will have an impact on the rate of childhood overweight and obesity.

Foods for Children under 4 years of age

Gerber Products Company is the leading maker of foods specifically designed for this age range. However, we do not advertise to this age group. We specifically market, advertise and provide information to parents, other caregivers, and health professionals. While the IWG guidelines are meant to define what foods can be advertised and marketed to children, our concern is that the criteria proposed by the IWG will become the "defacto" definition of healthy foods for children regardless of whether or not they are advertised directly to children. This would result in the establishment of criteria without the appropriate, necessary, and invaluable notice and comment procedures required of the regulatory process. Given that there is no regulatory definition of healthy foods, main dishes, or meals for children under 4 years of age and since their nutrient needs vary greatly from the needs of older children and adults, we believe the IWG proposed criteria should explicitly exclude foods specifically designed for children under 4 years of age. The RACCs (Reference Amount Customarily Consumed), Daily Values (DV) and Reference Daily Intakes (RDI) as well as the nutrition claim framework defined by regulation are completely different for this population group. While it is understood that the Dietary Guidelines for Americans apply to children and adults 2 years of age and older, it is important to note that these are general guidelines and not precise nutrient recommendations.

Special Nutrition Needs

In addition to the special nutrient needs of children under 4 years of age, the IWG proposal also ignores other groups of children who may have unique nutritional needs or are "at risk" nutritionally. Specifically, children who are underweight or with failure to thrive and very active children and teen athletes who may benefit from specialized nutrition products are not addressed in the IWG guidelines. Products designed to meet

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the specialized needs of these groups will often have a nutrient profile that falls outside the nutrition guidelines proposed by the IWG. For example, a complete nutrition drink designed for "picky eaters" or children who are underweight will provide 3 g of saturated fat, 25g of total sugars and 180 mg of sodium in a 240 calorie serving. This product is meant to provide the nutrition that a child would get from a complete meal. Additionally, since product acceptance is critical for these specialized nutrition products, advertising and marketing are important in promoting acceptance among children.

Sports Nutrition Needs of Children and Adolescent Athletes

Children and adolescents that participate in sports team activities and /or high intensity activities should be considered a specialized nutrition needs group. Approximately 30 – 40 million young athletes participate in organized youth sports in some capacity. Due to this age group's unpredictable growth, energy requirements differ when compared to that of an adult athlete (particularly adolescents who experience very rapid growth). Children are not as capable of utilizing glycogen or working in the same anaerobic capacity as adults. Furthermore, very active boys and girls aged group 9-18 yrs old conservatively need at least 850 calories per day more than their sedentary counterparts. *Sports Nutrition, a practice manual for professionals, 4th edition ADA* advises Sports Dietitians for young athletes to provide a list of high carbohydrate snacks and beverages to serve as pre event snacks. They are also recommended to provide a list of post event snacks containing protein, carbohydrate and fluids. Overall, young athletes are not as efficient at physical movements as adults which results in a relative increase in energy expenditure per kg of body weight.

Children and adolescents have less efficient thermoregulation than adults therefore closer attention has to be paid to hydration during high intensity activity particularly in high temperature climates. The surface area to mass ratio in children is much greater than in adults. This causes greater fluid and energy requirements in young athletes compared to adults. This is also the reason there is greater heat absorption in children. A study has observed that dehydration was avoided by boys who consumed fluid that was slightly flavored and contained sodium and carbohydrates. The fluids used in this study were similar to sports drinks. *Rivera-Brown AM et al., Drink composition, voluntary drinking, and fluid balance in exercising, trained, heat-acclimatized boys. J Appl Physiol. 1999;86:78-84.*

Thus, a fixed or arbitrary classification of foods as "healthy" or not, can deter the use of foods that would indeed be appropriate for segments of the population such as children engaged in sports.

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Children and adolescents are in the process of maturing and learning and therefore require specific education on nutrition concepts. Nestle Nutrition considers products specifically designed to support endurance sport activity such as those included in the PowerBar portfolio to be an appropriate contributor to nutrition for young athletes.

Gerber and PowerBar, as leaders in early childhood nutrition and feeding and sports nutrition, have carefully reviewed the IWG proposed criteria and given the potentially far-reaching impact of such guidelines we welcome the opportunity to offer our comments on some of the specific questions raised in the IWG proposal.

Section IV. Questions for Comment: Nestle Nutrition Responses to specific questions raised by the IWG

Proposed Nutrition Principles: General Questions

Q (1) Congress directed the Working Group to develop proposed nutrition principles for foods marketed to children and adolescents up to the age of 17. Does the prevalence of obesity in both children and adolescents warrant the same approach to limits on food marketing for both age groups? Given the wide age range, should there be two sets of nutrition principles, one for younger children (2-11 years) and one for adolescents (12-17 years), based on differences in the nutritional needs and recommended caloric intake of adolescents compared to younger children?

Response: As stated previously, Nestlé Nutrition believes that foods specifically for children under the age of 4 should be excluded from this proposal or specific criteria consistent with their needs should be developed and included in the guidelines. Children in this age group have different nutrient and food group needs including different daily values used for label development and vastly different caloric needs (1,000 vs. 2,000 calories per day typically) They also consume smaller serving sizes but at frequent eating occasions.

Since not specifically related to our business, we are not providing a recommendation on the appropriateness of separating the criteria for younger children versus older children.

Additionally, we request that the IWG consider foods marketed to other sub-populations where exemptions or special considerations may need to be given relative to the nutrition principles – specifically teen athletes and very active children as well as children with issues of underweight or failure to thrive.

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Q (2) The Working Group recognizes that companies often engage in brand advertising and marketing, without reference to a specific food product in the brand line. How should the nutrition principles be adapted to accommodate advertising and marketing of a general brand or an entire product line as opposed to specific food products or menu items?

Response: Consideration should be given to exactly what type of advertisements this criteria would apply. For example, leveraging a Brand name (without a product mention) to sponsor team events should not require that all of the products in the portfolio meet the criteria. In addition, use of a brand name for nonfood advertisements should not require compliance with these criteria (e.g. Ronald McDonald House, Heinz Field, Gerber Life Insurance, Hershey Park, etc.).

Q (3) The proposed nutrition principles do not include a separate proposal setting targets for nutrients to encourage, including specific nutrients of concern as identified in the 2010 DGA, such as calcium, potassium, fiber, magnesium, and vitamins A, C, and E. Should the Working Group recommendations include targets for nutrients to encourage and, if so, how should the recommendations address the issue of nutrients added to foods through fortification as opposed to nutrients that are inherent in foods?

Response: Criteria for "nutrients to encourage" may be appropriate to develop as an alternative to meeting Food Group requirements. We do not think it is necessary nor is there justification for requiring both nutrients to encourage and meaningful levels of key food groups for the same product.

Should nutrients to encourage become part of the criteria and if the criteria are still intended to be applied to foods for children 2-4 years of age, we would encourage the IWG to include specific nutrients for young children (2-4 years). FITS data (2008 and 2002) has shown that there are gaps or shortfall nutrients in the diets of many young children. Sufficient intakes of certain nutrients can be hard to meet by food groups alone because there are limited foods with these nutrients or because foods with these nutrients are unlikely to be consumed in large enough quantities to meet the nutrient needs of the population. For example, FITS 2008 data indicates that the majority of young children between 1 and 4 do not get adequate amounts of vitamin E. Foods containing inherent vitamin E include nuts, seeds and cooking oils. These foods are not consumed in sufficient quantity for a variety of reasons – one example is that nuts are discouraged because they can represent a choking hazard. For very young children, the only way to ensure adequate intakes of vitamin E is by inclusion of fortified foods in the

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diet. In addition to vitamin E, nutrients to encourage for children 1-3 years include iron, vitamin D, potassium and essential fatty acids – specifically alpha linolenic acid.

Young children (2-4), as well as young athletes, undernourished children and those with developmental or physical disabilities often rely on fortified foods to meet their nutritional needs. It may be easy to forget that fortification and enrichment of foods with critical nutrients like folic acid and iron, have contributed to the reduction of nutrient deficiencies and to reduced risk of disease (e.g. folic acid). As long as fortification is consistent with the principles delineated in FDA's Fortification Policy, fortified foods should be considered as important and relevant to the diet as foods with inherently high levels of key nutrients.

Q (4) The proposed nutrition principles do not include limits on portion size or calories for foods marketed to children. Should the Working Group recommendations address portion size or calories directly or is over-consumption adequately addressed by the recommendations that all foods marketed to children make a meaningful contribution to a healthful diet and minimize consumption of saturated fat, *trans* fat, and added sugars?

Response: We do not believe that portion size or calories should be part of the nutrition criteria when considering young children (2-4 years) or children with special nutrition needs including children who participate in endurance sport. One reason for excluding these criteria is simply because of the challenges related to practical implementation. For example, it would be extremely difficult to apply such criteria across a product line with varying package sizes. If you are advertising Brand X Snack Mix and this product is sold in both a multi-serve bag with a serving size of 1 oz and a single serve bag with a serving size of 1.75 oz. but only the 1 oz serving size complies – how do you structure an advertisement for the one package that meets the guidelines?

Caloric needs vary among children 2- 17 and this becomes further complicated when you consider sex, weight and activity level of the child. Additionally, children with special nutrition needs may require extra calories for growth or to support athletic performance. Setting calorie targets and portions is also difficult without taking into consideration the food category. For example – serving sizes and calories found in nutritious foods vary widely. See examples below. If calorie and portion requirements are established it should be by food category.

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Calories and Portions of Select Foods

Food	RACC	Typical Serving Size (children 4+ and adults)	Calories per serving
1% Lowfat milk	240 mL	1 cup	100 calories
Peanuts	30 g	1 oz (28 g)	170 calories
Apple	140 g	1 small (149 g)	77
Granola bars	40 g	2 bars (42 g)	190

For young children, it may be more important to educate parents on understanding children's hunger and fullness cues and encourage them to let their children learn to self-regulate rather than encouraging calorie counting and portion restriction. Furthermore, a child's appetite can vary from meal to meal and day to day. Especially for young children, it's important to provide for a nutritionally balanced week rather than a nutritionally balance day or meal. In 2003, Gerber worked with an expert ADA panel to develop the Infant and Toddler Feeding Guidelines (Butte, JADA, March 2004) which included recommendations and information on hunger and fullness cues for children up to 2 years of age. Since that time, we have expanded these to include cues for children up to 4 years of age. Educating parents on hunger and fullness cues is just one aspect of the Start Stay Healthy Nutrition System.

Q (5) The Working Group proposal recommends that the industry focus its efforts on improving the nutrition profile of products that fall within ten specific categories of foods most heavily marketed to children. While this approach would address a substantial majority of all products marketed directly to children, some foods marketed directly to children do not fall within any of the specified categories. Examples include hot dogs, jams and jellies, and sauces and dressings. Are there specific food products or categories of foods that should be added to or dropped from the proposed list? What are the advantages and disadvantages of focusing on the most heavily marketed foods rather than on all foods marketed to children?

Response: We agree that the condiment category should be excluded from the criteria because the amounts consumed are typically small and many of the foods in this category contribute important nutrients to the diet such as the essential fatty acids and vitamin E found in dressings. In addition, these foods are often used to enhance the acceptability of other foods (e.g. jelly on whole wheat bread, salad dressing on salad).

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Gerber has developed many weekly menus using our unique *Start Healthy Stay Healthy* Menu Planner (gerber.com). Many of these weekly menus will not provide adequate amounts of total fat, essential fatty acids or vitamin E without added fats, oils or dressings and fortified foods. The Start Healthy Stay Healthy Menu planner is a tool developed by Gerber and is available to both consumers and health care professionals.

Q (6) The Working Group is seeking comment on the proposed adjustments to the nutrition principles for main dish and meal products. For instance, should main dishes and meals make meaningful contributions from at least two and three food groups respectively, as proposed under Principle A? Should the targets set under Principle B be tied to a 100-gram amount, a labeled serving, a 40-gram portion, or some combination of these? What would be the advantages or disadvantages of using a 100-gram basis to set food group contributions and nutrient targets for all individual foods, main dishes, and meals?

Response: The current FDA requirement to provide 40 g portions of food from at least 2 food groups for meals and main dishes {21 CFR 101.13 (l)} is too large for children 2-4 years of age. These amounts do not reflect appropriate serving sizes or food group contributions for this age range nor is it consistent with FDA's rationale for the development of the 40 g portions for adult foods (based on ½ the RACC).

Q (8) Under both the Option 1 and Option 2 proposals for Principle A, companies can aggregate contributions from more than one of the specified food categories to meet the meaningful amount
targets for individual foods. Does this approach diminish the meaningful contribution to the diet by allowing small contributions from multiple food groups? Should the principle recommend that the entire contribution come from one food group?

Response: No, the entire contribution should not be from one food group. The use of healthy ingredients at any level should be encouraged and the IWG has appropriately allowed these foods to be included toward meeting the food groups. However, we do have some concerns regarding the specific options.
Option 1: This assumes that there is no minimum amount of a food group that can be counted toward meeting the meaningful contribution of 50% by weight. For purposes of calculating the 50% contribution in Option 1, we would recommend that added water in the recipe be omitted.

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Option 2: There does not appear to be justification for requiring that the food group contributions be "proportionate". This option does not allow for small amounts of healthy ingredients to be counted toward meeting a meaningful contribution.

Additionally, the food group amounts currently specified in the principles are too large for young children (2-4 years). In general, young children require about half the calories and food group amounts that adults need with the exception of dairy (2 cups vs. 3 cups). Table 2 shows that the "meaningful amounts" defined by the IWG are between 37% and 70% of the total daily amount recommended for children 2-4 years of age. These "meaningful amounts" clearly could not be achieved in a RACC or labeled serving size for a child of this age without encouraging overconsumption.

Table 2:

Food Group	IWG Meaningful Amount	Daily Amount* 2-4 year old	Percent of Daily Need
Milk fat free /low fat	0.75 cup (6 fl oz)	2 cups	37.5%
Vegetable	0.6 cup	1 cup	60%
Fruit/Fruit juice	0.5 cup	1 cup	50%
Meat	1.4 oz	2 oz eq	70%
Egg	1 egg or egg equiv	Included in meat	50%
Dry beans	0.3 cups cooked dry beans	Included in meat	
Grains	0.75 oz equiv whole grains (≈21 g)	3 oz eq (total grains) ≈85 g	25% total grains or 50% of whole grain goal
Nuts and seeds		Not typically recommended	

*AAP Consensus Statement and MyPyramid Plan for 1,000 calorie diets.

The "meaningful contributions" that are part of Option 2 are also required per RACC. RACCs exist for a large number of foods for ages 4 years and up. However, there are very few RACCs for foods for children under 4 years of age (21 CFR 101.12). Some of these RACCs are also very small: 7 g to 20 g per RACC. These small RACCS make it virtually impossible to achieve "meaningful amounts' as currently defined.

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Finally, the following notation in the IWG Report needs further clarification: "*For individual foods, if the amount of the specific food group exceeds the RACC, the RACC can be substituted as the amount necessary to make a meaningful contribution to a healthful diet*". As written, this can be interpreted that the entire RACC would need to consist solely of the food group, and it's unclear if this is the intent.

Q (9) The list of food groups that make a meaningful contribution to a healthful diet under Principle A includes both the basic food groups to encourage as identified in the 2010 DGA – fruits, vegetables, whole grains, fat-free and low-fat milk products – as well as other food categories that are compatible with an overall healthful diet – fish, lean meat and poultry, beans, nuts and seeds, and eggs. Are there food categories that should be added to or eliminated from Principle A?

Response: The basic food groups are included under Principle A. However, the descriptions and/or options to meet the food groups either lack detail or are overly limiting. The IWG should evaluate whether the foods required to meet the food groups are readily available for commercial use and whether they present cost effective or practical options for both industry and for consumers. Some examples include:

- Availability of extra lean ground beef or poultry (5%) – Is this a product that is readily available; is it cost effective?
- Beans are required to be cooked dry beans. Why are canned beans not an option?
- Fat free and low fat cheese may not be widely available for commercial use, may not be functional in the product being developed, and may not meet the standard of identity for real cheese.

In addition, about 1/2 of very young children (2-4 years) have total fat intakes below the Acceptable Macronutrient Distribution Range (AMDR) and since the primary sources of fats are dairy or meats intakes of essential fatty acids could be less than adequate (FITS 2008). Restricting food choices to only those lowest in fat may not be in the best interest of healthy growth and development for children 2-4 years.

While the IWG included four food groups that deliver on meat/meat equivalency (meat, eggs, beans, nuts and seeds), only whole grains were included for the grain group. Enriched grains should also be included as an important way to deliver grain nutrition. No

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one disputes the importance of whole grains in a healthy diet. However, all current Dietary recommendations state that half of grain servings should be from whole grains. Grain foods are a substantial part of the US diet and enriched grains contribute significantly to iron and folic acid intake. Iron is critical for brain and cognitive development. Women of child bearing age (including those in the teen years) should get adequate amount of folic acid in the event of and to help support a healthy pregnancy. Enriched wheat flour has significantly more folic acid per 15 g grain equivalent than whole grain wheat flour (6.8% DV vs. 1.65% DV per 15 g) and an equivalent amount of iron.

We know from FITS data that over half of the food sources of folate and 40% of the food sources of iron in diets of 2-3 year olds come from cereals, breads and rolls, pasta and crackers and pretzels. While much of the cereal consumption is whole grain, the majority of the products in the other categories are not. However, they are mostly enriched grain foods (unpublished data –FITS 2008).

We request that the IWG acknowledge that food group contributions can be determined by the manufacturer using the method most appropriate for their products. In addition, there are several specific areas regarding food group contributions that we think deserve clarification:

- For the Beans/meat group – we recommend that peas be included as either a vegetable or as a meat alternative.

- Fruit and vegetable group – Should be based on fruit/vegetable equivalency so that dry fruits and vegetables can be accounted for appropriately. Further clarification is requested on whether fruit and vegetable juices account for meaningful amounts in both Options 1 and 2 (fruit and vegetable juices are specifically mentioned in Option 2 but not Option 1)

- Dairy – milk solids should be an optional method of accounting for cheese and yogurt and other "non-liquid" milk ingredients toward the milk food group contribution.

Food	Serving	Solids	Calcium	Milk equivalency
Milk, low fat NDB 01082	1 cup (240 mL)	24.6	30.5% DV	1 cup
Milk, low fat NDB 01082	0.75 cup (180 mL)	18.45	23% DV	0.75 cup

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Cheddar Cheese, low fat NDB 01168	1 oz (28 g)	10.45	11.8% DV	0.42 cup
Parm Cheese topping fat free NDB 01185	1 tbsp (5g)	4.57	4% DV	0.18 cup
Parm Cheese, grated NDB 01032	1 tbsp (5 g)	3.96	5.5 % DV	0.16 cup

Q (10) The 2010 DGA recommend consuming a variety of vegetables, especially dark green and red and orange vegetables and beans and peas. Given that children consume starchy vegetables disproportionately to other subgroups like dark-green and red and orange vegetables, should Principle A include recommendations for specific subgroups of vegetables?

Response: Variety of fruit and vegetable consumption should be encouraged but should not be part of the nutrition principles since there is no practical way to implement such a requirement.

Q (11) The Working Group has included two possible approaches for Principle A. What are the advantages and disadvantages of Option 1 (based on weight) and Option 2 (based on amounts per RACC)?

Response: Please see our comments under Question 8.

Q (12) The food contribution amounts proposed in Option 2 are calculated based on a 2,000 calorie daily diet and assume four eating occasions per day. Should this calculation be adjusted to reflect children's caloric needs and eating patterns?

Response: Young children (2-4 years) should consume about 3 meals and 2-3 snacks daily (AAP). Young children have smaller stomach capacity. To obtain the needed calories and nutrients, they should consume smaller amounts of nutritious foods more frequently. Their calorie and nutrient needs are also very different compared to adults and older children. Therefore, principles based on the needs of adults or even based on needs of older children are not applicable to very young children. We encourage the working group to consider the age group from 2-4 years separate from this proposal. (see also Q8)

Q (13) Principle B provides that any nutrients naturally occurring as part of the food contributions under Principle A are not counted toward the proposed limits for specific

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nutrients under Principle B. This exemption is intended to resolve any inherent inconsistencies between Principle A and Principle B. At the same time, the Working Group recognizes that the calculations involved in partially "netting out" certain nutrients would entail a detailed knowledge of the product recipe or formulation and make it difficult for any third party to verify whether a product meets Principle B. Are there alternative approaches the Working Group should consider in reconciling the provisions of Principles A and B?

Response: We think the proposal that any nutrients naturally occurring are not counted toward limits is appropriate as stated. Since this is a voluntary program we are unclear about the need for third party verification.

In addition, naturally occurring nutrient levels can vary – for example the trans fat content in dairy fat varies based on geographic location and animal diet – therefore, manufacturers should have the option to use nutrient values representative of their source of ingredient supply.

Q (14) Under Principle B, the proposed nutrient targets for individual foods are generally tied to the RACC. The proposal recommends that individual foods with a small RACC (30 grams or less), meet the targets for saturated fat, *trans* fat, added sugars, and sodium per 50 grams (with the exception of the

interim sodium value of 210 milligrams per serving). What are the implications of this approach in particular for smaller serving foods like cereals or for foods marketed in smaller children's portions? What would be the advantages and disadvantages of tying Principle B recommendations to labeled serving instead of the RACC?

Response: As stated previously in this comment, there are relatively few RACCs for food specifically designed for children under 4 years of age (21 CFR101.12). The RACCs that are available should be used if Nutrition Principles based on RACCs are established. Where no RACC exists, we would propose that ½ the adult RACC apply.

There should not be a 50 gram "rule" requirement for "small serving size" foods for children 2-4 years. We reviewed the daily food intakes from FITS 2008 compared to the RACC for toddlers and the adult RACC. Based on this review, with the exception of cereal, even daily consumption of "small serving size" foods does not approach 50 g.

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Intake Data from FITS 2008: Daily consumption of select food categories

Food	RACC (21 CFR 101.12) Per eating occasion	Mean Consumption FITS 2008 Per day for-2-3 year olds	Adult RACC
Cereal , RTE toddler	20 g	About 60 g	30 g or 15 g
Grain snacks, biscuits, toasts	7 g	24- 26 g	15 or 30 g
Bread	NA	30-40 g	50 g
Cheese	NA	31 -33 g	30 g
Grain based bars	NA	27 -32	40 g

Also, we would support and would encourage the IWG to consider including foods that meet FDA's current requirements for the use of "healthy" on labels or in labeling or that meet the requirements of a health claim (e.g. whole grain foods or nuts) as acceptable to be marketed to children, irrespective of other requirements, and assuming the foods are appropriate in other important aspects (e.g. safety).

Regarding the 50 g requirement for saturated fat, current regulations do not require claims for saturated fat to be based on 50 g. Therefore, the requirements for the IWG proposal would be in conflict with FDA regulations.

Q (15) Are there other nutrients or ingredients not currently included in Principle B that the Working Group should recommend be limited in foods marketed to children? If so, what is the evidence regarding the nutrition and health justification for including the nutrient or ingredient?

Response: There are no additional nutrients or ingredients that should be limited.

Q (16) The Working Group proposal recommends a target for added sugars for foods marketed to children. What are the advantages and disadvantages of the proposal for limiting added sugars content as opposed to total sugars content?

Response: Certainly the advantage to using total sugars is that this information is readily available on food product labels. However, if total sugars is used the inherent sugar content of ingredients will need to be taken into consideration (e.g. the sugar present in fruit, milk, etc) similar to the way the IWG has allowed for the exclusion of inherent trans fat or saturated fat. If such exclusion is not allowed then the total sugars limit will need to take into consideration the amount of inherent sugar typically contributed by these

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ingredients or foods in the food categories that are the subject of this proposal, including flavored milk, fruit snacks, yogurt). This may require that the nutrition criteria be established by food category rather than through a single set of standards.

For children 2-4 years of age, Gerber would support the development of guidelines for "added sugars" given the lower caloric needs and fewer discretionary calories available in the diets of this population group. This is consistent with our comments to FDA (ANPR comment filed April 2008) supporting a daily value for "added sugars" for children 1-4 years of age. Of course, should the IWG develop an "added sugars" criteria for children 2-4 years, a definition of what constitutes "added sugar" would need to be provided.

For children with special nutrition needs e.g. underweight or "failure to thrive" and teen athletes, sugar is actually a positive nutrient. It is needed to support athletic performance by providing fuel to muscles. For underweight children, sugars can enhance palatability and improve product acceptance. We would encourage the IWG to make the needed exceptions to their proposal to account for these foods.

Q (17) The Working Group proposal recommends an interim goal for limiting sodium content for foods marketed to children of 210 milligrams per serving for individual foods and 450 milligrams per serving for main dishes and meals, with a target date of 2016. Is there a nutrition-based rationale for an alternative interim goal for sodium that the Working Group should consider? The Working Group's final value for sodium is 140 milligrams per RACC for individual foods and 300 milligrams per serving for main dishes and meals, with a target date of 2021. Is there a nutrition-based rationale for an alternative final goal on sodium that the Working Group should consider?

Response: Exceptions should be permitted for sports nutrition products and special nutritional products.

General Feasibility/Marketplace Impact of Proposed Nutrition Principles

Q (18) What impact will the voluntary principles as proposed have on the nutritional quality of foods marketed to children if industry fully adopts them? Specifically, what percentage of foods currently marketed to children would not meet the proposed principles and to what extent could such foods be reformulated to do so?

Q (19) Are there specific foods that are nutritional outliers and warrant special consideration under the proposed nutrition principles, either with additional limits or specific exceptions to proposed principles?

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Response: Yes, as discussed throughout this comment foods that are specifically intended for children 2-4 years of age and foods that fill special nutrition needs of select populations should either be exempt or have their own guidelines.

Q (21) Many food products currently in the marketplace may require substantial reformulation to meet the proposed principles. The Working Group recognizes that such reformulation may present both technical challenges and challenges relating to the palatability and consumer acceptance of the food. What impact will reformulation challenges have on manufacturers' incentive and ability to improve the nutritional quality of the foods they market to children to meet the proposed principles? Given these challenges, what would be the best approach to encourage the greatest participation from the food industry? Should the Working Group develop principles that would encompass a broader range of foods? For example, should the Working Group consider alternative principles drawn from federal food labeling regulations defining the nutrient content claim "healthy" or setting nutrient disclosure levels for other nutrient content claims?

Response: We would encourage the IWG to rethink its proposals in general. Specifically, we would also suggest that any food that currently meets the FDA defined term "healthy" or that qualifies for a Health claim should also be permitted to be advertised to children. We know that many parents think that the foods from the family table are appropriate for children as early as 12 months of age. By addressing a small subset of foods – with strict nutrition principles – we miss an opportunity to educate adults – and specifically parents and caregivers –on what constitutes healthy eating for the whole family. Healthy foods that are available to young children at the family table should also be permitted to be advertised to them.

In conclusion, Nestle Nutrition appreciates the opportunity to provide comments on the Interagency Working Group proposal. We are passionate about the health and nutrition needs of children. If we can provide any additional information, please contact us.

Sincerely,

Cheryl A. Callen
Director Regulatory Affairs
Nestlé Nutrition