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Name of Petitioner: Kraft Foods North America, Inc.
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Subject of the Petition: Nutrient Content Claims for
the Carbohydrate Content of Foods

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Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
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To Whom It May Concern:

As Director of Nutrition for Kraft Foods North America, Inc. (Kraft), I submit this Petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to seek approval of the following claims characterizing the level of carbohydrate in food:

- “Carbohydrate free”
- “Low carbohydrate”
- “Reduced carbohydrate”
- “Less carbohydrate”
- “Excellent source of carbohydrate”
- “Good source of carbohydrate”

As explained more fully below, definition of these terms is needed to facilitate consumer understanding of the range of carbohydrate content that may be consumed consistent with current dietary recommendations and to promote fair competition in the marketplace. All of the information specified in 21 C.F.R. § 101.69 is included within or attached to this Petition.

I. INTRODUCTION

The role of carbohydrate in human nutrition has been the subject of intense interest in recent years. This interest has been fostered not only by scientific research and journal publications, but also by a proliferation of books, articles, TV interviews, and other anecdotal information in the popular press. As a result, grocery stores, restaurants and other foodservice operators, and consumers are demanding that food manufacturers characterize the carbohydrate content of their products. Due to the demands we have been receiving, Kraft began to examine how to characterize the carbohydrate content of food in a scientifically sound and responsible way.

As part of our assessment, we considered the consensus dietary recommendations for macronutrients as well as the current cacophony of carbohydrate claims in the marketplace. We also examined the sources of carbohydrate in the food supply, dietary intake data, and regulatory precedent for nutrient content claims. Additionally, we evaluated our available market research on consumer interest in and understanding of carbohydrate information.

Dietary recommendations for macronutrients were issued in 2002 by the National Academy of Sciences, Institute of Medicine (IOM). IOM, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*, at 11-1 (2002) (the "Macronutrient Report"). The Macronutrient Report confirms that a range of carbohydrate (45 to 65% of calories) may be consumed as part of a healthful diet. The Macronutrient Report also establishes a Recommended Dietary Allowance (RDA) for carbohydrate of 130 g/day, and recommends ranges for consumption of fat (20 to 35% of calories) and protein (10 to 35% of calories).¹ Active management of dietary carbohydrate intake is one tool that can help consumers balance consumption of carbohydrate, fat, and protein within a calorie target appropriate for the consumer's weight and activity level. In other words, control of carbohydrate content, along with direct or indirect control of fat, protein, and calories, is one way to build a diet that is consistent with the prevailing expert recommendations.

To date, FDA has not defined nutrient content claims for the total carbohydrate content of food. Accordingly, the agency considers claims such as "reduced carbohydrate," "low carbohydrate," and "good source of carbohydrate" to be undefined nutrient content claims that are not permitted in food labeling under section 403(r)(1)(A) of the FFDCA.² Despite the lack of a legal basis for use, such claims are

¹ Values given for fat and protein are for adults.

² See, e.g., FDA Warning Letter dated April 25, 2003 to PureDe-lite Products, Inc. (ONPLDS 01-03); Letter to C. Gordon Brown, Ph.D., Carbolite Foods, from L. Robert

surprisingly common in the marketplace. Indeed, stores that claim to specialize in “low carbohydrate” items are emerging, restaurants are adding menu items designed to appeal to “carb counters,” and an increasingly large number of manufacturers claim to offer “low carbohydrate” product lines; at the same time, others talk about products that are “packed with carbs” for energy.³ The carbohydrate levels of items marketed under the various carbohydrate banners vary widely, even among similarly positioned products (e.g. “low carbohydrate”).

We know from our market research that many consumers are very interested in carbohydrate management, but lack knowledge about carbohydrate consumption in the context of the total daily diet. In particular, quantitative market research we just completed using the Internet, which involved over 8,000 Primary Grocery Shoppers, shows 68% are interested in limiting carbohydrate and 43% claim to be limiting carbohydrate at the present time. Yet among households claiming to limit carbohydrate, 37% answered “don’t know” when asked to identify the maximum number of grams of carbohydrate that should be consumed in a day and over 50% thought the daily maximum grams of carbohydrate consumed should be less than the 130 gram RDA in the Macronutrient Report. From other research we also know that many consumers, especially those seeking to fuel athletic performance, are interested in products that provide carbohydrate energy and diets that approach the higher end of the recommended carbohydrate consumption range. Of course, individuals with diabetes have a longstanding interest in carbohydrate information and would particularly benefit from a consistent carbohydrate labeling policy.

In seeking definitions for carbohydrate nutrient content claims, Kraft does not intend to imply that carbohydrate management is preferred to any other scientifically sound dietary approach. We are convinced, however, that FDA must act very promptly to establish rules for carbohydrate nutrient content claims, both to educate the public

Lake, Director of Regulations and Policy, Center for Food Safety and Applied Nutrition (Jan. 15, 2003) (Docket 02P-0462).

³ Examples include the “Low Carb Store” at <http://www.thelowcarb.com/>; the Blimpie Carb Counter menu at http://www.blimpie.com/framesets/sfs_nutrition.htm; the press release issued by The Hain Celestial Group on October 8th, which can be accessed at the Wall Street Journal on-line http://online.wsj.com/article/0,,PR_CO_20031008_001806,00.html; Russell Stover Low Carb candies at <http://www.russellstover.com/jump.jsp?itemType=CATEGORY&itemID=83>; and Maxim Energy Bars at <http://www.maxim.nl/products/bars.html>. Illustrative materials from these web sites are attached and provided as pdf files for convenient reference.

and to provide guidance to manufacturers, retailers, and others making these increasingly prevalent claims.

II. BACKGROUND: CARBOHYDRATE IN HUMAN NUTRITION

Carbohydrate is a diverse group of macronutrients that may be divided into four categories, based on chemistry: sugars (including monosaccharides and disaccharides), oligosaccharides, polysaccharides, and sugar alcohols. Macronutrient Report, at 6-1. For food labeling purposes, sugars, sugar alcohol, dietary fiber, and “other carbohydrate” (e.g., starch) are included in the Nutrition Facts box declaration for “total carbohydrate.” 21 C.F.R. § 101.9(c)(6).

The primary function of carbohydrate is to supply energy to cells in the body, especially the brain. The Macronutrient Report established two reference intakes for carbohydrate that are of direct relevance to this Petition: an RDA of 130 g/day for children over the age of one year and adults (excluding pregnant and lactating women, for whom RDAs of 175 g/day to 210 g/day, respectively, were set), and an Acceptable Macronutrient Distribution Range (AMDR) of 45 to 65% of calories from carbohydrate. Macronutrient Report, at 6-15 to 6-22, 11-1. These recommendations apply to digestible carbohydrate in the diet. An Adequate Intake (AI), varying by life stage and gender from 19-38 grams per day, was established for carbohydrate that qualifies as fiber (including total fiber, dietary fiber, and functional fiber).⁴ Both the RDA for carbohydrate and the AMDR concept are new recommendations.

The RDA represents the “average daily dietary nutrient intake level sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.” *Id.* at 1-2. The 130 g RDA for carbohydrate is based on the amount of carbohydrate utilized by the brain, which uses glucose almost exclusively for its energy needs. *Id.* at 6-10 to 6-12, 6-16. The IOM determined that consumption of carbohydrate at the RDA level would be sufficient to provide the central nervous system with adequate glucose without reliance upon alternative fuels (e.g., protein, triacylglycerols). *Id.*

In contrast to the RDA, which establishes a specific target intake for carbohydrate, the AMDR identifies a range of recommended carbohydrate intakes

⁴ Carbohydrate may be wholly or partially non-digestible by human enzymes, in which case they may be classified scientifically as dietary fiber. FDA has historically classified dietary fiber as a carbohydrate for food labeling purposes, so this Petition does not distinguish dietary fiber from other carbohydrate. Instead, we leave fiber nutrient content claims to the rules already established to encourage fiber consumption.

expressed as a percentage of total energy. AMDRs for macronutrients were set at the intake levels that the IOM found to be (1) associated with a reduced risk of chronic disease, including coronary heart disease, obesity, diabetes, and/or cancer; (2) sufficient to ensure adequate intake of essential nutrients; and (3) sufficient to allow for adequate energy intake and physical activity, in the interest of energy balance. *Id.* at 11-3. The IOM considered the AMDRs for fat and carbohydrate together, in part because these macronutrients may be used somewhat interchangeably as a source of energy. The resulting AMDRs for dietary fat, carbohydrate, and protein represent the relative intakes of these nutrients in the total diet that the IOM believes best promote health and minimize the risk of chronic disease. *Id.* at 11-27.

The AMDRs for carbohydrate, fat, and protein confirm that macronutrient requirements are substantially interrelated. Thus, the need for balance in macronutrient intake is an important consideration in defining nutrient content claims for carbohydrate. For example, in defining “low,” it is important to identify carbohydrate levels that are sufficiently low to be of use in carbohydrate management, but not unduly low, resulting in inadequate carbohydrate intake and fat or protein intake in excess of the AMDR recommendations.

The AMDR approach is new and provides more concrete guidance than previous dietary recommendations. In 1989, the landmark report of the National Research Council, *Diet and Health*, recommended that fat be limited to no more than 30% of calories and carbohydrate provide more than 55% of total calories. National Research Council, *Diet and Health, Implications for Reducing Chronic Disease Risk*, at 670-72 (National Academy Press, 1989). The new AMDR recommendations are more specific, are more informative, offer more flexibility, and in the case of carbohydrate, set for the first time a maximum recommended intake level (i.e., 65% of calories).

III. STATEMENT OF PROPOSED DESCRIPTIVE TERMS

This Petition seeks to extend availability of six existing nutrient content descriptors—“free,” “low,” “reduced,” “less,” “good source,” and “excellent source”—to claims describing carbohydrate. Under the current regulatory framework, the general meaning of these terms is well-established, as follows:

- “Free” is used to indicate foods that contain a nutrient at inconsequential levels.
- “Low” is used to identify foods that are “distinctly low” in a designated nutrient as compared to an appropriate reference value.

- Relative terms, such as “reduced” and “less,” are used to convey nutritionally meaningful differences in nutrient content among food products.
- “Excellent source” is used to bring attention to foods that contain exceptional levels of a nutrient with respect to the levels found naturally in food.
- “Good source” is used to describe the level of a nutrient in food that constitutes a dietarily significant contribution toward the daily value for the nutrient.

Consistent with the rules governing other nutrient content claims, use of the proposed terms would be subject to the general requirements specified in 21 C.F.R. § 101.13.⁵

A. “Carbohydrate Free”

In defining “free” claims, FDA has historically looked to the level of a nutrient that is reasonably classified as physiologically insignificant and at or near the reliable limit of detection. 49 Fed. Reg. 15510 (Apr. 18, 1984) (establishing the meaning of “free” in the context of sodium); 56 Fed. Reg. 60421, 60433 (Nov. 21, 1991) (proposal to implement NLEA); 58 Fed. Reg. 2302, 2320 (Jan. 6, 1993) (final rule). The agency has, therefore, used the amount that may be declared as “0” in nutrition labeling as the basis for existing “free” claims in both foods generally and in main dish and meal products (collectively referred to as meal-type products). See, e.g., 21 C.F.R. § 101.61(b)(1)(i) (defining “sodium free” as less than 5 mg per reference amount and per labeled serving, or in the case of a meal product or main dish product, per labeled serving). FDA has defined “free” and synonymous terms (e.g., “no,” “without”) in this manner for calories, fat, saturated fat, cholesterol, sodium, and sugars.

The same approach is warranted for carbohydrate claims. By regulation, FDA has provided that carbohydrate is to be declared as “0 g” in nutrition labeling if it is present in a food at a level of less than 0.5 g. 21 C.F.R. § 101.9(c)(6). This level, which represents the amount of carbohydrate that is deemed nutritionally insignificant, likewise provides an appropriate basis for characterizing a food as “carbohydrate free.”

⁵ We note, however, that the disclosure requirement in section 403(r)(2)(A)(ii) of the FFDCA would be inapplicable due to the ubiquity of carbohydrate in the food supply. Carbohydrate is “usually present in [a] food or in a food which substitutes for the food,” as provided in section 403(r)(2)(A)(ii)(I) and 21 C.F.R. 101.13(d). Thus, there is no need to disclose the usual absence of carbohydrate with language like “a carbohydrate free food.”

Accordingly, Kraft proposes that “carbohydrate free” be permitted on foods, except main dish and meal products, that contain less than 0.5 g per reference amount and per labeled serving. For main dish and meal products, the limitation of less than 0.5 g of carbohydrate would apply on a per labeled serving basis.

Foods that may qualify for the use of the term “carbohydrate free,” as proposed, include eggs, salad dressings and other condiments, sugar-free soft drinks, sugar-free gelatin desserts, tuna and other fish products, and most natural cheeses. In addition, many meat and poultry products regulated by the Food Safety and Inspection Service (FSIS) would be eligible to bear the proposed term, if approved by FSIS.

B. “Low Carbohydrate”

The regulatory basis for “low” claims is firmly rooted in FDA precedent and policy dating back more than twenty-five years. See 42 Fed. Reg. 37166 (July 19, 1977) (providing a basis for a definition of “low calorie”). The agency’s approach to the definition of “low” claims has been flexible, taking into account the unique circumstances surrounding each nutrient for which “low” has been defined.

1. Regulatory Precedent

The regulatory basis for defining “low” claims was most recently articulated in the FDA rulemakings to implement the Nutrition Labeling and Education Act of 1990 (NLEA). 56 Fed. Reg. at 60439-60441. At that time, FDA reaffirmed its basic interpretation of “low” as conveying a level that is “distinctly low” relative to overall recommended intakes, but neither inconsequential from a nutritional perspective nor an amount that would require consumption of solely “low” foods to meet dietary recommendations. *Id.* at 60439.

FDA determined that the most logical starting point for a “low” definition is the level of a nutrient that FDA has defined as “measurable” from a nutritional perspective: 2% of the reference value for the nutrient. *Id.* Assuming the number of servings of foods and beverages consumed to be 20 servings per day, FDA reasoned, persons selecting only foods designated as “low” in a nutrient would consume no more than 40% of the reference value for that nutrient. *Id.* at 60439-60440. This amount, in FDA’s judgment, allowed ample room for consumers to select a variety of foods, some that are “low” in a nutrient, and some that are not, and still meet dietary recommendations. *Id.* at 60440.

FDA also recognized that this approach may require adjustment to account for nutrient-specific circumstances, such as the ubiquity of the nutrient in the food supply. To assess the ubiquity of a nutrient, FDA examined the extent to which the nutrient is “present” in USDA-defined food categories used for the organization of food composition data, and used this information to classify the nutrient as (1) ubiquitous if it

is present in over 75% of food categories, (2) moderately distributed if it is present in 51 to 75% of food categories, or (3) not widely distributed if it is present in 50% or fewer of food categories. *Id.* FDA considered a nutrient to be “present” in a food category if the nutrient may be found in over half of the foods in the category at a level of 2% of the reference value or greater. *Id.*

Based on this classification scheme, FDA developed a “general rule of thumb” for establishing a tentative definition of “low.” For ubiquitous nutrients, FDA used 2% of the reference value as the definition for “low”; for nutrients that are moderately distributed, FDA applied a factor of 2 (i.e., 2 x 2%, or 4% of the reference value); for nutrients that are not widely distributed, FDA applied a factor of 3 (i.e., 3 x 2%, or 6% of the reference value). *Id.* FDA then evaluated the tentative definition of “low” in light of past policy, public health recommendations, and other available data and information, rounding or adjusting as appropriate. *Id.* This flexible approach has been used to define “low” for a range of nutrients, including fat, saturated fat, sodium, cholesterol, and calories.

2. Distribution of Carbohydrate in the Food Supply

Kraft has concluded that carbohydrate is most appropriately classified as ubiquitous in the food supply. This determination is based upon an assessment of the extent to which carbohydrate is likely to be present in USDA-defined food categories set out in USDA nutrient databases, as well as survey data concerning carbohydrate intake in the United States.

The most recent version of USDA’s nutrient database, the USDA Nutrient Database for Standard Reference, Release 16, identifies twenty-three food categories: (1) beverages, (2) fruits and fruit juices, (3) snacks, (4) breakfast cereals, (5) legumes and legume products, (6) nuts and seeds, (7) soups, sauces, and gravies, (8) cereal grains and pasta, (9) fast foods, (10) meals, entrees, and side dishes, (11) baked products, (12) sweets, (13) baby food, (14) vegetables and vegetable products, (15) dairy and egg products, (16) fats and oils, (17) finfish and shellfish, (18) lamb, veal, and game, (19) poultry, (20) beef, (21) pork, (22) sausage and luncheon meats, and (23) spices and herbs. Food products in categories 1-13 are reasonably expected to contain carbohydrate at significant levels (i.e., at least 2% of the reference value, or 6 grams) in over 50% of the foods. Food products in categories 14 and 15, which contain vegetables and vegetable products and dairy and egg products, might reasonably be expected to contain carbohydrate at significant levels; however, while not exhaustive, our review of these categories reveals that is not the case. Carbohydrate is not expected to be present at significant levels in categories 16 through 23, which contain foods that consist primarily of fat (fats and oils), protein and fat (fish, meat, and poultry), or carbohydrate consumed at very low levels (spices and herbs).

Kraft concludes that, for purposes of defining a “low carbohydrate” claim, the ubiquity of carbohydrate should be evaluated on the basis of 17 food categories. Baby foods should be excluded because foods intended for infants and children under the age of two are not permitted to bear nutrient content claims unless expressly authorized by regulation. 21 C.F.R. § 101.13(b)(3). Baby foods would not be eligible to bear the carbohydrate claims proposed in this Petition. In addition, to account for realistic eating patterns, foods in the categories for meat, poultry, fish, and similar foods should be counted as one category, as such foods generally are interchangeable in the diet. If baby foods are excluded and categories 17 to 22 are counted as one, carbohydrate reasonably may be expected to be present in 13 of the 17 categories, or approximately 76%. Accordingly, when realistic intake patterns are taken into account, carbohydrate is most reasonably classified as ubiquitous.

The ubiquity of carbohydrate in the food supply is confirmed by data from the Continuing Survey of Food Intakes by Individuals (CSFII) (1994-1996, 1998). Median carbohydrate intake is approximately 220 to 330 g/day for men and 180 to 230 g/day for women, representing 49 to 50% of energy intake. CSFII (1994-1996, 1998) (cited in Macronutrient Report, Appendix E, Tables E2-E3). In contrast, median intake of total fat, which FDA has classified as moderately distributed in the diet, ranged from 65 to 100 g/day for men and 48 to 63 g/day for women, representing 32 to 34% of total energy. *Id.* (Tables E5-E6). Median intake of protein during 1994-1996 and 1998 ranged from 71 to 101 g/day for men and 55 to 62 g/day for women, representing approximately 15% of total calories. *Id.* (Tables E16-E17). These data confirm that a large proportion of energy is obtained from carbohydrate-containing foods.

3. Proposed Definition

a) Foods Generally

Based upon the ubiquity of carbohydrate in the diet, Kraft proposes that “low” in carbohydrate be defined as 2% of the daily reference value (DRV) of 300 grams, resulting in a “low carbohydrate” definition of 6 grams or less. Regulatory precedent suggests that an eligible food would need to meet the definition of “low” on the basis of the reference amount customarily consumed (RACC), the labeled serving, and, where the reference amount is 30 grams or less, per 50 grams. 58 Fed. Reg. at 2318-2319.

Although Kraft initially considered including the “50 gram rule” in the proposed regulation that is part of this Petition, with the goal of expediting FDA action, we have a longstanding concern that the “50 gram” requirement undercuts the usefulness of nutrient content claims and, therefore, is not sound policy. For example, because the current rules for “low fat” apply the “50 gram rule” to foods with a RACC of 30 g or less, a food with a one ounce serving size on the label must contain less than

1.6 grams fat per serving, instead of less than 3 grams per serving, which reasonably defines “low fat” foods with serving sizes over 30 grams. Thus, there is only a bit over one gram of fat difference between a “fat free” and a “low fat” food with a 30g RACC and a one ounce serving size on the label. Consequently, far fewer “low fat” foods are available as choices for consumers. While we recognize that FDA has rejected arguments against application of the “50 gram rule” in the past, to the best of our knowledge the issue has not been considered for a number of years. Thus, we ask the agency to take the first step toward bringing food labeling rules up to date by deleting the “50 g” requirement from the rule FDA proposes for “low carbohydrate” foods. Accordingly, the language regarding the 50 gram requirement in the draft regulation we are providing appears in italics with the note that Kraft urges FDA to delete the language from the regulation published in response to this Petition.

b) Meal-type Products

In defining “low” and similar claims, FDA has distinguished meal products and main dish products from other foods because such products vary widely in serving size. 58 Fed. Reg. at 2375-2376. To promote consistency among products bearing nutrient content claims, the agency has required that meal and main dish products qualify for nutrient content claims such as “low” on the basis of 100 grams. *Id.* at 2379. In light of this long-standing approach, Kraft proposes that “low carbohydrate” be defined as 6 grams or less of carbohydrate per 100 g for meal products as defined in 21 C.F.R. § 101.13(l) and main-dish products as defined in 21 C.F.R. § 101.13(m).

4. Relationship to Current Dietary Recommendations

The proposed definition of “low carbohydrate” is consistent with current dietary recommendations for carbohydrate, as established by the IOM in the Macronutrient Report. As noted previously, the Macronutrient Report established two important reference intakes for carbohydrate: an RDA of 130 g/day for children over the age of one year and adults (excluding pregnant and lactating women, for whom RDAs of 175 g/day to 210 g/day, respectively, were set) and an AMDR of 45 to 65% of calories from carbohydrate. These reference intakes establish a minimum target intake for digestible carbohydrate, expressed in grams, and a desirable range of digestible carbohydrate intake, expressed as a percentage of total energy. The reference intakes for carbohydrate do not include fiber, for which separate reference intakes, in the form of Adequate Intake (AI) levels, were established.

Assuming consumption of 16 to 20 servings of food and beverages per day, a person consuming an average of 16 to 20 “low carbohydrate” foods would consume 96 to 120 g per day of carbohydrate. This level of carbohydrate approaches the RDA of 130 g, even if it is assumed that intake includes some dietary fiber, which does not count towards the RDA. For example, consumption of 96 g of total

carbohydrate, including 25 g of dietary fiber, results in an intake of 71 g digestible carbohydrate. Because carbohydrate is ubiquitous in the food supply, it is unlikely that a person would consume only "low" carbohydrate foods on a sustained basis, and it is reasonable to expect that the RDA of 130 grams would be met in most circumstances. In the unusual instances in which the RDA would not be met, alternative sources of glucose for the brain are available from dietary protein and fat. Finally, the rulemaking process itself will provide an excellent opportunity for FDA and health professionals to educate the public about the RDA, which will help to ensure adequate carbohydrate intake from appropriate foods on a consistent basis.

The proposed definition of "low" is also consistent with the AMDR for carbohydrate, which represents the "range of intakes for a particular energy source that is associated with a reduced risk of chronic disease while providing adequate intakes of essential nutrients." Macronutrient Report at S-5. The AMDR for carbohydrate is 45 to 65% of total calories; the proposed definition is based on the 300 g DRV for carbohydrate, which corresponds to 60% of energy when consumed as part of a diet that contains 2000 total calories. The 300 g DRV currently used on food labels is within the range of carbohydrate intakes recommended by the IOM and thus provides an appropriate basis for a definition of "low carbohydrate." While we recognize that the AMDR concept is calorie based, adjusting the labeled carbohydrate value for dietary fiber does not appreciably change the approach. If dietary fiber is considered, the proposed definition would be based on 275 g digestible carbohydrate (300 g less 25 g for dietary fiber), which corresponds to approximately 55% of energy in a 2000 calorie diet, and the value for "low" would be 5.5 g, which may be readily rounded up to 6 g for the "low" definition. Additionally, by basing the definition of "low" on the DRV that is used in food labeling, consistency with existing labeling policy is maintained.

Selection of 6 g or less as the definition for "low carbohydrate" also allows the flexibility necessary for healthful carbohydrate consumption in a population with diverse macronutrient needs. As noted previously, persons consuming 16 to 20 servings of food and beverages per day and selecting only "low carbohydrate" foods would consume 96 to 120 g of carbohydrate per day. An intake level of 120 g corresponds to 40% of the DRV for carbohydrate. Consistent with FDA's reasoning in establishing a basis for "low" claims for ubiquitous nutrients pursuant to the NLEA, this level "provides for a quantitatively low amount in food that is sufficiently restrictive to allow consumers to select a variety of foods, including some that are "low" in a nutrient and some that are not "low," and still meet current dietary recommendations." 56 Fed. Reg. at 60440. For individuals consuming carbohydrate at the lower end of the recommended range or at lower calorie levels, for whom a DV closer to 225 g per day would be applicable, the 96 -120 g per day level still would be sufficiently restrictive to allow selection from a wide variety of foods.

The proposed definition of “low” is also consistent with dietary recommendations for individuals with diabetes. The *Exchange Lists for Meal Planning*, which have long been used in the dietary management of diabetes, identify as “free food” that may be consumed in moderation (with no more than three servings daily, consumed at appropriate intervals) any food or drink that contains less than 20 calories or less than or equal to 5 g carbohydrate. American Dietetic Association & American Diabetes Association, *Exchange Lists for Meal Planning* (2003) (consumer education pamphlet). The concept of “free foods” has been carried over to “carbohydrate counting” plans for individuals with diabetes, which similarly advise that foods containing carbohydrate in the amount of 0 to 5 g and consumed in moderation need not be “counted” toward a prescribed daily carbohydrate allotment. American Dietetic Association & American Diabetes Association, *Basic Carbohydrate Counting* (consumer education pamphlet) (advising individuals how to calculate “carbohydrate servings” in food for purposes of the dietary management of diabetes mellitus). The proposed definition of “low carbohydrate” as 6 grams or less is close to and consistent with this dietary advice.

We recognize that the proposed definition is not the only scientifically valid approach for establishing rules defining a “low carbohydrate” claim. The IOM established separate reference intakes for digestible carbohydrate and fiber, and fiber is universally recommended for increased consumption (with no AMDR), so a reasonable case can be made for excluding fiber from consideration in determining whether the “low” criterion of 6 grams of carbohydrate is met.⁶ Such a proposal, however, would be inconsistent with current nutrition labeling requirements. Under 21 C.F.R. § 101.9, dietary fiber, sugars, and “other carbohydrate” are all included within the “total carbohydrate” declaration. If the eligibility criteria for “low” exclude fiber, the “total carbohydrate” value declared for foods bearing “low carbohydrate” claims could vary considerably depending upon the amount of fiber in the food, a result FDA may find unacceptable under the existing regulatory scheme. However, since fiber is universally recommended for increased consumption (with new higher AI’s), exclusion of fiber from the carbohydrate claims may actually encourage consumers to use foods with higher fiber, such as whole grain foods, to construct diets with lower available carbohydrate.

As a result of the IOM Macronutrient Report and the forthcoming report on the use of the IOM Dietary Reference Intakes in food labeling, FDA may well decide to require that fiber and digestible carbohydrate be declared separately in nutrition labeling, which would clearly provide the necessary foundation for their disparate treatment in carbohydrate nutrient content claim criteria. In the meantime, however, it is

⁶ FDA also might consider whether to provide guidance on the deduction of other types of carbohydrate, such as sugar alcohols.

imperative that FDA act to bring consistency to “low carbohydrate” and other carbohydrate nutrient content claims in the marketplace.

5. Eligible Foods

Foods that may qualify for the use of the term “low carbohydrate,” as proposed, include salad dressings, processed and cottage cheeses, soy-based veggie burgers, select vegetables (e.g., broccoli), and meal products. In addition, many meat and poultry products regulated by the FSIS would be eligible to bear the proposed term, if approved by FSIS.

C. Comparative Carbohydrate Claims: Reduced and Less

The descriptors “reduced” and “less” are relative terms that may be used, where authorized, to facilitate nutrient comparisons between foods. Existing definitions for “reduced” and “less” specify (1) the reference foods that may be used as a basis for comparing the level of nutrients in one food with the level of those nutrients in another food; (2) the information about the foods being compared that must accompany the claim; and (3) the minimum amount of a nutrient, expressed as a percentage reduction, by which the food must differ from the reference food in order to make a relative claim. See, e.g., 21 C.F.R. §§ 101.13(j) (general requirements for relative claims), 101.62(b)(4) (defining “reduced fat”). The existing regulations for “reduced” and “less” also prohibit use of a relative claim for a nutrient that is present at a “low” level in the reference food. See, e.g., 21 C.F.R. § 101.62(b)(4)(iii). To date, FDA has authorized use of the relative nutrient content descriptors “reduced” and “less” to facilitate nutrient comparisons for calories, fat, saturated fat, cholesterol, sodium, and sugars.

The minimum percentage reduction has been used to ensure that products eligible to bear these relative terms qualify on the basis of a nutritionally significant difference in nutrient content as compared to a suitable reference food. 58 Fed. Reg. at 2348-2350. In adopting the existing definitions for “reduced” and “less,” FDA determined a minimum 25% reduction to be nutritionally significant. *Id.*

The general principles relied upon in adopting existing definitions for “reduced” and “less” are equally applicable to carbohydrate. Accordingly, Kraft proposes that the claims “reduced carbohydrate,” “less carbohydrate,” and similar terms be allowed on foods, except meal-type products, that contain 25% less carbohydrate than an appropriate reference food. For meal-type products, Kraft proposes that the claims “reduced carbohydrate,” “less carbohydrate,” and similar terms be authorized for use on products that contain 25% less carbohydrate, per 100 grams, than an appropriate reference food. Finally, Kraft proposes that existing criteria for the general use of “reduced” and “less” claims also be extended to carbohydrate claims, including criteria for appropriate reference foods, specifications for accompanying label

statements, and the limitation that “reduced” and “less” not be allowed where the reference food meets the definition of “low” for the relevant nutrient.

Examples of foods that may be eligible to bear “reduced carbohydrate,” “less carbohydrate,” and similar claims are bread, breakfast cereals, grain-based snack bars, and meal-type products.

D. “Excellent Source of Carbohydrate” and “Good Source of Carbohydrate”

1. Regulatory Precedent

FDA has previously defined several claims intended to emphasize the presence of a nutrient in food, including “excellent source” and “good source.” In the NLEA rulemakings, FDA determined that “excellent source” claims could be used on foods that contain 20% or more of the reference value of a nutrient, and “good source” and similar claims could be used on foods that contain 10-19% of the reference value for eligible nutrients. 58 Fed. Reg. at 2343. The agency viewed the “excellent source” descriptor as characterizing a nutrient level that was exceptional with respect to the levels found naturally in food, while “good source” was judged as a “mid-level” claim that describes an amount of a nutrient that is dietarily significant, but not exceptional. 58 Fed. Reg. at 2345. In defining “excellent source” and “good source” claims, FDA emphasized as a matter of policy the need for nutrient content claims to promote a diet containing a wide variety of foods. With this interest in mind, the agency took steps to ensure that the “excellent source” and “good source” definitions were consistent with the levels of nutrients occurring naturally in foods, and would allow a reasonable number of foods to qualify for the claims. 56 Fed. Reg. at 60442-60443; 58 Fed. Reg. at 2344.

In the regulations implementing the NLEA, FDA expressly declined to define “excellent source” or “good source” for carbohydrate. The agency reasoned that such a claim did not adequately distinguish between complex carbohydrate, which were recommended for increased consumption, and sugars, which were recommended for decreased consumption. 56 Fed. Reg. at 60444; 58 Fed. Reg. at 2345. FDA also declined to define “good source of complex carbohydrate,” because there were no quantitative recommendations for “complex carbohydrate” and the term was difficult to define. 56 Fed. Reg. at 60444; 58 Fed. Reg. at 2345. Significantly, at the time of the 1993 NLEA rulemaking, an RDA for carbohydrate and quantitative recommendations regarding added sugars did not exist.

2. Proposed Definitions

As a result of the Macronutrient Report, a reasonable basis now exists for defining the nutrient content claims “excellent source of carbohydrate” and “good source of carbohydrate.” The IOM established several quantitative recommendations for

carbohydrate that were not in existence during the NLEA rulemakings, including an RDA of 130 g, an AMDR of 45 to 65% of calories, and a suggested maximum intake of 25% or less of energy from added sugars. The RDA applies to all digestible carbohydrate, and does not distinguish between sugars and other digestible carbohydrate. At the same time, the suggested maximum intake of added sugars seeks to prevent excessive intake of sugars. Read together, these recommendations establish that digestible carbohydrate in general has a role to play in human nutrition, but that attention must be given to building an overall diet with an optimal carbohydrate profile.

Promotion of appropriate, nutrient-dense foods that contain carbohydrate at dietarily significant levels would assist consumers who seek to increase carbohydrate consumption to the maximum level recommended by the IOM, as well as consumers who wish to consume high levels of carbohydrate for specific purposes such as athletic performance. Accordingly, Kraft proposes that FDA define "excellent source of carbohydrate" to mean 10% of the 300 g DRV for carbohydrate, or 30 g per reference amount customarily consumed. This amount of carbohydrate is found in numerous foods that are widely regarded as rich in carbohydrate, including rice, pasta, and select breakfast cereals. It also corresponds, approximately, to 20% of the 130 g carbohydrate RDA, or 26 g. A definition based on 20% of the DRV would not be appropriate for a "excellent source of carbohydrate" claim because few, if any, carbohydrate-containing foods contain 60 g of carbohydrate per reference amount. Such a definition would therefore be of little assistance to consumers and would not promote consumption of a variety of carbohydrate-containing foods.

To describe foods that contain carbohydrate at more moderate, but nonetheless significant, levels, Kraft also proposes that FDA define "good source of carbohydrate." Because "good source" is most naturally defined in relationship to "excellent source" levels, Kraft proposes that "good source of carbohydrate" be defined as 5% of the 300 g DRV for carbohydrate, or 15 g. This amount is half the level of carbohydrate promoted as an "excellent source," and would allow foods such as breads, fruit, and starchy vegetables like potatoes to bear a "good source of carbohydrate" claim. This amount of carbohydrate also corresponds, approximately, to 10% of the 130 g RDA, or 13 g. In addition, the 15 g carbohydrate level corresponds to one carbohydrate "exchange" in the American Dietetic Association and American Diabetes Association's *Exchange Lists for Meal Planning*.

Although the RDA provides scientific support for defining "excellent source" and "good source" claims for carbohydrate, a focus on the amount of carbohydrate, without regard to carbohydrate type, does not adequately reflect the totality of IOM recommendations for carbohydrate, including recommendations for added sugars. To ensure that the overall carbohydrate profile of foods bearing the claim is useful to building a diet consistent with the IOM recommendations, Kraft further

proposes that foods bearing either a “excellent source of carbohydrate” or “good source of carbohydrate” claim also contain no more than 6 g of sugars. Fruits and vegetables are recommended for increased consumption regardless of naturally occurring sugar content, so Kraft proposes to exempt them from the qualifying sugars criterion applicable to other foods, whether consumed alone or as part of another food product, such as a cereal.

The 6 g limitation for sugars is advisable to harmonize the IOM RDA for digestible carbohydrate with the IOM recommendation that added sugars provide no more than 25% of energy. A limitation of 6 g is consistent with the proposed definition of “low carbohydrate,” and thus represents a level of sugars, including added sugars, that is “distinctly low.” For a 2000 calorie diet, the limitation corresponds to 1.2% of energy, or approximately 5% of maximum recommended intake of added sugars for this level of calories. Finally, a 6 g limitation for sugars is also consistent with the eligibility criteria for cereal within the Women, Infants, and Children (WIC) program, which must contain not more than 6 g sucrose and other sugars per ounce. 7 C.F.R. § 246.10(c).

E. Basis for Proposed Terms

The nutrient content claims proposed in this Petition are truthful and not misleading, as required by section 403(a) of the FFDCA. If approved, the proposed claims would extend to carbohydrate the use of established nutrient content descriptors, namely, “free,” “low,” “reduced,” “less,” “good source,” and “excellent source.” The proposed claims are consistent with the latest recommendations for carbohydrate intake as well as dietary guidelines for individuals with diabetes.

Of course, the existing general requirements governing the use of nutrient content claims would apply to carbohydrate claims, just as is the case for other nutrient content claims. Specifically, all nutrient content claims are governed by the requirements for type size, presentation, and additional qualifying information, if any, set forth in 21 C.F.R. § 101.13. When warranted, the referral statement requirements in 21 C.F.R. § 101.13(h) direct the consumer to examine the nutrition information for fat, saturated fat, cholesterol, or sodium content. The draft regulation provided as part of this Petition incorporates these requirements.

IV. NUTRITIONAL BENEFIT TO THE PUBLIC

FDA-defined nutrient content claims for carbohydrate would benefit the public by addressing a demonstrated need for education and establishing rules for fair competition based upon sound science. The proposed nutrient content claims are timely and could bring reasoned consistency to the marketplace without the considerable expenditure of FDA resources that would be required to do so through enforcement actions.

A. The Proposed Rule Would Help Consumers Better Understand the Role of Carbohydrate in a Healthy Diet, Reducing the Potential for Confusion

Consumers lack knowledge about the role of carbohydrate in the context of the total daily diet and desire reliable information. According to our recent market research, consumers are unable to identify either the amount of carbohydrate recommended for daily consumption or the level that would reasonably be deemed “low.” In addition, Kraft has found consistently that significant numbers of consumers, over 60%, report an interest in limiting carbohydrate consumption, while many others prefer carbohydrate to fat or protein as a source of energy. Thus, we are confident that consumers would be receptive to trustworthy claims and would benefit from a rulemaking to define appropriate carbohydrate claims.

The following data were gathered in a very recent quantitative Internet study of over 8,000 Primary Grocery Shoppers. When asked about the maximum amount of carbohydrate that should be consumed each day, neither households limiting carbohydrate intake nor households claiming to be on a specific carbohydrate-limiting diet were able to identify reliably carbohydrate consumption levels that would be consistent with the recommendations in the Macronutrient Report.

Among Carb Limiting Households

	≤20	21-50	51-100	101-150	151-200	201-250	251-300	>300	Don't Know
Max number of grams per day	15%	25%	11%	5%	3%	2%	1%	*	37%
	0	1	2	3	"4-6"	"7-9"	"10-12"	"13-15"	>15
Max number of grams for dinner entrée	3%	3%	4%	6%	20%	17%	18%	12%	17%
Max number of grams for lunch entrée	2%	6%	9%	10%	27%	17%	12%	7%	9%
Max number of grams for snack	15%	12%	16%	13%	20%	10%	5%	4%	5%

Among Carb Limiters on a Specific Diet

	≤20	21-50	51-100	101-150	151-200	201-250	251-300	>300	Don't Know
Max number of grams per day	21%	34%	12%	7%	4%	1%	1%	*	20%
	0	1	2	3	"4-6"	"7-9"	"10-12"	"13-15"	>15
Max number of grams for dinner entrée	3%	3%	4%	7%	20%	16%	18%	10%	18%
Max number of grams for lunch entrée	2%	6%	9%	11%	27%	16%	12%	7%	8%
Max number of grams for snack	16%	13%	16%	12%	20%	10%	5%	5%	3%

Similarly, in a qualitative survey conducted by Kraft as part of an ongoing, Internet-facilitated dialogue with 245 women selected based on interest in weight reduction, there was no consensus regarding the level of carbohydrate that should be present in a snack food marketed as “low in carbohydrate”.

Interestingly, in the qualitative survey many participants repeatedly stressed the importance of moderation. These consumers indicated that they cannot eliminate carbohydrate, and do not wish to do so, but do strive to limit carbohydrate

intake in an appropriate manner. Reported strategies for limiting or moderating carbohydrate intake included consumption of carbohydrate from vegetables instead of breads or pasta, eating foods higher in fiber, eating more protein and vegetables versus starches and sweets, eating fewer snacks, and controlling portion size. These comments corroborate the suggestion that active management of carbohydrate intake can be one reasonable way to reach dietary goals.

B. The Carbohydrate Levels to be Described Are Significant from a Nutritional Perspective

1. Active Management of Carbohydrate Intake Is a Legitimate Nutritional Goal

The Macronutrient Report effected an important shift in dietary recommendations. Previous recommendations, such as those set forth in *Diet and Health*, incorporated limitations for fat, but suggested liberal consumption of carbohydrate, at levels equal to or preferably exceeding 55% of total calories. With the Macronutrient Report, specific recommendations about healthful limits of carbohydrate intake are provided for the first time. These recommendations continue to recognize carbohydrate as an important nutrient in the American diet. Indeed, the IOM suggests that a majority of calories, up to 65%, may come from carbohydrate as part of a healthful diet, but also advises that the percentage of calories from carbohydrate may be reduced to 45%, with corresponding increases in protein and fat intake consistent with the established AMDRs. Therefore, the IOM recommendations establish a reasonable scientific basis for identifying active control of carbohydrate intake as a worthy nutritional goal.

In light of the AMDR for carbohydrate of 45 to 65% of total calories, the availability of foods bearing consistently defined carbohydrate nutrient content claims would assist consumers attempting to interpret the barrage of information appearing on food labels as well as in the popular press and advertising. Availability of the claims as proposed also would assure that use of these terms in the marketplace is linked appropriately to consensus public health recommendations.

2. The Carbohydrate Levels to be Described in the Proposed Claims Are Based in Regulatory Precedent

Adherence to established precedent ensures that the levels characterized by the proposed claims are both of nutritional significance and consistent with the overall regulatory scheme. The terms that are the subject of this Petition are based on established agency precedent concerning use of "free," "low," "reduced," "less," "good source," "excellent source" and synonymous claims. As discussed previously, "carbohydrate free" and similar terms proposed for definition are meaningful because they imply the absence of carbohydrate in a serving of food; the proposed definition of

“low carbohydrate” is meaningful because it is based upon 2% of the reference value used for labeling purposes; “reduced” and “less” are meaningful because a minimum 25% difference is required for their use. The proposed “good source” and “excellent source” claims are meaningful due to the significant contribution to the DV made by foods containing 15 or more or 30 or more grams of carbohydrate per serving, respectively.

C. Definition of Carbohydrate Nutrient Content Claims Would Bring Consistency to the Marketplace, Where the Proliferation of Illegal Carbohydrate Claims Is Fostering Widespread Consumer Confusion

Clarity and consistency of carbohydrate information would be valuable benefits of a rulemaking to establish science-based definitions of nutrient content claims for the carbohydrate content of food. In the current environment, meaningful management of carbohydrate intake by consumers is hindered by the proliferation of illegal and inconsistent carbohydrate information on food labels, in retail stores, in restaurants, and other settings. The terms proposed in this Petition can be used as a tool to facilitate a wide range of dietary intakes that are consistent with dietary recommendations. The rulemaking process alone would generate considerable publicity and would provide a valuable opportunity for the agency, qualified health professionals, and other trusted sources of dietary guidance to educate consumers about appropriate carbohydrate intake for health maintenance and for weight loss. Our research and interactions with consumers, as described above, suggest that consumers would be receptive to guidance about the proper amount of carbohydrate in a healthful diet.

V. CARBOHYDRATE CONTENT OF FOODS

Because carbohydrate is a mandatory nutrient that must be declared in nutrition labeling, reliable data to characterize the carbohydrate content of food are widely available in private and public databases. Data concerning the carbohydrate content of select foods that would qualify to bear the proposed nutrient content claims are presented in Tables 1-4 below. These data are derived from the USDA Nutrient Database for Standard Reference, Release 16 and from the Kraft Foods Nutrient Database.

Table 1

Foods That Would Qualify As “Carbohydrate Free”

FOOD	RACC	GRAMS of CARBOHYDRATE
Meat	55 g	0
Poultry	55 g	0
Tuna Fish	55 g	0
Oscar Mayer Smoked Ham, water added 96% fat free*	55 g	0
Jell-O Sugar Free Gelatin*	½ cup	0
Crystal Light Sugar Free Soft Drinks*	240 mL	0
Oil, sesame, salad, olive, cooking, peanut, soybean	1 tbsp	0
Egg raw, poached	50 g	0
Mustard	1 tsp	0
Cheddar Cheese	30 g	0

Source: USDA Nutrient Database for Standard Reference (Release 16)

*Kraft Foods Nutrient Database for Products

Table 2
Foods That Would Qualify As “Low Carbohydrate”

FOOD	RACC	GRAMS of CARBOHYDRATE
Meatless soy protein burger	85 g	5
Broccoli, raw	85 g	5
Asparagus, boiled	85 g	4
Frankfurter	55 g	4
Tomato, raw ripe	85 g	3
Louis Rich Chicken Breast Strips, grilled*	55 g	3
Cheese, cottage, creamed, large or small curd	110 g	3
Salad dressing, Kraft Zesty Italian*	30 g	2
Fat Free Cream Cheese	30 g	2
Natural Cheese Provolone, Mozzarella with whole milk	30 g	1
Reduced Fat Colby or Cheddar Cheese	30 g	1
Spinach, raw	1 cup	1

Source: USDA Nutrient Database for Standard Reference (Release 16)
 *Kraft Foods Nutrient Database for Products

Table 3

Foods That Would Qualify As An “Excellent Source of Carbohydrate”

FOOD	RACC	GRAMS of CARBOHYDRATE
Cereal, Post Grape Nuts*	55 g	45 g total carbohydrate 5 g sugars
Cereal, Post Shredded Wheat*	55 g	43 g total carbohydrate 0 g sugars
Spaghetti, whole-wheat, cooked	140 g	37 g total carbohydrate 1 g sugars
Corn, yellow frozen kernels boiled	85 g	32 total carbohydrate 3 g sugars
Banana**	140 g	32 total carbohydrate 17 g sugars
Rice, brown, long-grain, cooked	140 g	32 g total carbohydrate 1 g sugars
Raisins, seedless**	40 g	32 g total carbohydrate 24 g sugars

Source: USDA Nutrient Database for Standard Reference (Release 16)

*Kraft Foods Nutrient Database for Products

** Fruit is exempt from 6 g sugar limitation

Table 4

Foods That Would Qualify As A “Good Source of Carbohydrate”

FOOD	RACC	GRAMS of CARBOHYDRATE
Macaroni and Cheese, canned entree	1 cup	29 g total carbohydrate 2 g sugars
Cereal, Post Honey Bunches of Oats*	30 g	25 g total carbohydrate 6 g sugars
Cereals, oats, regular and quick and instant, un-enriched, cooked with water, without salt	1cup	25 g total carbohydrate 3 g sugars
Bread, wheat	50 g	24 g total carbohydrate 3 g sugars
Potato, baked flesh and skin	110 g	23 g total carbohydrate 1 g sugars
Pear**	140	22 g total carbohydrate 14 g sugars
Beans, kidney, all types, mature seeds, canned	130 g	19 g total carbohydrate 0 g sugars
Orange**	140 g	16 g total carbohydrate 13 g sugars

Source: USDA Nutrient Database for Standard Reference (Release 16)

*Kraft Foods Nutrient Database for Products

** Fruit is exempt from 6 g sugar limitation

VI. EFFECT ON FOOD CONSUMPTION AND NUTRIENT INTAKE

The carbohydrate claims proposed in this Petition will facilitate a range of carbohydrate intakes, all of which are consistent with the consensus dietary recommendations established in the Macronutrient Report. Consumers desiring to limit carbohydrate to the lower levels recommended by the IOM (i.e., to 45% of calories) may seek out foods that are promoted as “carbohydrate free,” “low carbohydrate,” and/or “reduced” and “less” carbohydrate. Other consumers may strive to build diets containing carbohydrate at the maximum level recommended by the IOM (i.e., 65% of calories), and may choose to select more foods that are good sources of carbohydrate. Still other consumers may seek out foods at both ends of the carbohydrate spectrum for specific purposes. For example, some consumers may seek foods that are excellent sources of carbohydrate for the purpose of fueling athletic performance. All of these approaches are advantageous from a public health perspective so long as intakes of carbohydrate, protein, and fat remain within the AMDRs recommended by the IOM, and intake of saturated fat, cholesterol, and trans fat are kept low as part of a balanced diet.

A. Free, Low, Reduced, and Less

If approved, the proposed “free,” “low,” “reduced,” and “less” claims will be used to highlight the carbohydrate content of a wide variety of foods, including such diverse foods as cottage cheese, sugar-free soft drinks and gelatin desserts, condiments, bread, and meal-type products. The claims also would be eligible to appear on a number of meat and poultry products, including deli meats and meal-type products containing meat and poultry, if approved by FSIS. Among consumers interested in limiting carbohydrate intake, availability of carbohydrate nutrient content claims is reasonably expected to result in a slight to modest increase in consumption of these and other foods eligible to bear the claims, and to prompt development of similar products and recipes for consumer use. The increased consumption of such foods is expected to reduce, but not dramatically, the amount of carbohydrate consumed relative to fat and protein for consumers interested in limiting carbohydrate intake. This result is not, in and of itself, a concern so long as intakes of carbohydrate, protein, and fat remain within the AMDRs recommended by the IOM, and intake of saturated fat, cholesterol, and trans fat are kept low as part of a balanced diet.

For example, consumers wishing to moderate carbohydrate consumption in a manner consistent with the IOM Macronutrient Report and other authoritative recommendations may choose to increase consumption of lean meats, chicken, fish, and reduced fat cheeses, consume carbohydrate in the form of fruits, vegetables, low fat dairy products, and whole grain breads and cereals, moderate consumption of certain other carbohydrate-containing foods such as sweets, and/or select carbohydrate-reduced versions of such products. Such an approach would result in a

modest decrease in carbohydrate and a modest increase in protein and/or fat consumption.

It is similarly foreseeable that widespread use of the proposed claims may facilitate a reduction in total calories for some consumers. Significantly, some of the foods that will be eligible to bear the proposed claims have few to no calories (e.g., sugar free soft drinks and gelatin desserts). Use of the proposed claims on these foods either will not appreciably affect macronutrient intake, or will assist consumers to achieve modest reductions in total calories and/or consumption of sugars. These changes are positive and in line with the consensus public health recommendations in the Macronutrient Report. In addition, to the extent that lean meats and other high protein and high fiber foods with moderate to low fat content are substituted in moderate amounts for carbohydrate-containing foods, the satiating effect of protein may make it easier for some consumers to reduce total calorie intake.

Although some of the foods eligible to bear the proposed claims may contain dietarily significant levels of fat, saturated fat, sodium, or cholesterol (i.e., levels that would trigger the referral/disclosure statement requirement of 21 C.F.R. § 101.13(h)), there is no reasonable basis for concluding that approval of the proposed claims will result in a significant increase in consumption of these nutrients. To guide consumers regarding recommended intakes of fat, saturated fat, cholesterol, and sodium, referral statements will be required, as is the case for other nutrient content claims. The Nutrition Facts box will further help to provide information about carbohydrate, protein, and fat in the context of the total daily diet.

Moreover, the diversity of foods that would be eligible to bear the proposed claims will facilitate consumer choice and consumption of diets consistent with the IOM recommendations set out in the Macronutrient Report. The availability of a wide range of choices (e.g., lean deli meats, reduced or low fat dairy products) will place consumers in a good position to construct total diets that are consistent with the AMDRs for carbohydrate, fat, and protein as well as IOM recommendations that intake of saturated fat, trans fat, and cholesterol be kept low while consuming a nutritionally adequate diet. As described previously, qualitative Internet discussions we have conducted suggest that consumers readily appreciate the importance of moderation and are unlikely to adopt extreme approaches that would lead to elimination of carbohydrate or significant increases in nutrients recommended for decreased consumption, such as saturated fat.

B. “Excellent Source of Carbohydrate” and “Good Source of Carbohydrate”

Foods eligible for promotion as “excellent sources of carbohydrate,” as proposed, include pasta, rice, fruits, starchy vegetables, and select breakfast cereals.

Foods that would qualify as a “good source” of carbohydrate, as proposed, are whole grain breads, fruits, and legumes. The use of “excellent source” and “good source” claims for carbohydrate, as appropriate, on these and similar foods is expected to increase their consumption, at least among consumers desiring to consume carbohydrate at the higher end of the AMDR. The claims also may serve to raise awareness of the RDA for carbohydrate, leading potentially to greater carbohydrate consumption for some consumers that may presently be aiming for a carbohydrate intake below the RDA.

C. Role of Education

The importance of diets that provide a balanced intake of macronutrients will be reinforced through consumer education activities in which FDA, public health groups, and industry will engage as a result of any rulemaking to define carbohydrate claims. Indeed, if FDA declines to intervene by defining the circumstances under which carbohydrate consumption may be managed appropriately, there exists a risk that consumers may eventually conclude, erroneously, that carbohydrate intake is universally recommended for limitation or that nutrients such as saturated fat need not be a concern. To reach consumers and impact public health as soon as possible, Kraft asks that FDA undertake a rulemaking as described in this Petition to place carbohydrate in an appropriate dietary context for consumers.

VI. ACTION REQUESTED

The following draft regulation provides the criteria proposed in this Petition for the use of carbohydrate content claims. As noted previously, Kraft recommends that the language in italic type below, regarding the “50 gram rule,” be deleted in the regulation FDA proposes. Accordingly, Kraft respectfully requests that FDA amend 21 C.F.R. part 101, subpart D to add the following new section (deleting the language in italic type):

21 C.F.R. § 101.63 Nutrient Content Claims for the Carbohydrate Content of Food

(a) *General requirements.* A nutrient content claim about the level of carbohydrate in a food may only be made on the label or in the labeling of the food if:

- (1) The claim uses one of the terms defined in this section in accordance with the definition for that term;
- (2) The claim is made in accordance with the general requirements for nutrient content claims in Sec. 101.13; and

- (3) The food for which the claim is made is labeled in accordance with Sec. 101.9, Sec. 101.10, or Sec. 101.36, as applicable.

(b) Carbohydrate content claims.

- (1) The terms “carbohydrate free,” “free of carbohydrate,” “no carbohydrate,” “zero carbohydrate,” “without carbohydrate,” “trivial source of carbohydrate,” “negligible source of carbohydrate,” or “dietarily insignificant source of carbohydrate” may be used on the label or in the labeling of foods, provided that the food contains less than 0.5 g of carbohydrate per reference amount customarily consumed and per labeled serving or, in the case of a meal product or a main dish product, less than 0.5 g of carbohydrate per labeled serving.
- (2) The terms “low carbohydrate,” “few carbohydrates,” “contains a small amount of carbohydrate,” “low source of carbohydrate,” or “low in carbohydrate” may be used on the label or in labeling of foods, except meal products as defined in Sec. 101.13(l) and main dish products as defined in Sec. 101.13(m), provided that:
- (i) *The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 6 g or less of carbohydrate per reference amount customarily consumed; or*
 - (ii) *The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 6 g or less of carbohydrate per reference amount customarily consumed and per 50 g of food (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in Sec. 101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the “as prepared” form).*
- (3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in Sec. 101.13(l) or main dish products as defined in Sec. 101.13(m), provided that the product contains 6 g or less of carbohydrate per 100 g.
- (4) The terms “reduced carbohydrate,” “reduced in carbohydrate,” “carbohydrate reduced,” “less carbohydrate,” “fewer carbohydrates” “lower carbohydrate,” or “lower in carbohydrate” may be used on the label or in the labeling of foods, except as limited by Sec. 101.13(j)(1)(i) and except meal products as defined in Sec. 101.13(l) and main dish products as defined in Sec. 101.13(m), provided that:

- (i) The food contains at least 25 percent less carbohydrate per reference amount customarily consumed than an appropriate reference food as described in Sec. 101.13(j)(1); and
 - (ii) As required in Sec. 101.13(j)(2) for relative claims:
 - (A) The identity of the reference food and the percent (or fraction) that the carbohydrate content differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., reduced carbohydrate bread - "33 1/3 percent less carbohydrate than regular bread"); and
 - (B) Quantitative information comparing the level of the nutrient per labeled serving size with that of the reference food that it replaces (e.g., "Carbohydrate content has been reduced from 15 g to 10 g carbohydrate per serving.") is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with Sec. 101.2.
 - (iii) Claims described in paragraph (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for "low carbohydrate."
- (5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in Sec. 101.13(l) and main dish products as defined in Sec. 101.13(m), provided that:
- (i) The food contains at least 25 percent less carbohydrate per 100 g of food than an appropriate reference food as described in Sec. 101.13(j)(1); and
 - (ii) As required in Sec. 101.13(j)(2) for relative claims:
 - (A) The identity of the reference food and the percent (or fraction) that the carbohydrate differs between the two foods are declared in immediate proximity to the most prominent such claim (e.g., Brand X Reduced Carbohydrate Lasagna, "25 percent less carbohydrate per oz (or 3 oz) than our regular Lasagna"); and
 - (B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces (e.g., "Carbohydrate

content has been reduced from 12 g carbohydrate per 3 oz to 9 g carbohydrate per 3 oz.”) is declared adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with Sec. 101.2.

- (iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for “low carbohydrate.”
- (6) The terms “high carbohydrate,” “rich in carbohydrate,” or “excellent source of carbohydrate” may be used on the label and in the labeling of foods, provided that
- (i) the food contains 30 g or more of carbohydrate per reference amount customarily consumed, or, in the case of a meal product or main dish product, 30 g per labeled serving; and
 - (ii) the food contains not more than 6 g sugars, as defined in 21 C.F.R. § 101.9(c)(6)(ii), per reference amount customarily consumed or, in the case of a meal product or main dish product, not more than 6 g sugars per labeled serving, provided that sugars from fresh, frozen, dried, or similarly processed fruits and vegetables shall not be included in assessing whether a food contains 6 g of sugars as long as the level of sugars contributed by the fruits and vegetables is documented and the documentation is available for FDA review upon request.
- (7) The terms “good source of carbohydrate,” “provides carbohydrate,” or “contains carbohydrate” may be used on the label and in the labeling of foods, provided that
- (i) the food contains 15 g or more of carbohydrate per reference amount customarily consumed, or, in the case of a meal product or main dish product, 15 g per labeled serving; and
 - (ii) the food contains not more than 6 g sugars, as defined in 21 C.F.R. § 101.9(c)(6)(ii), per reference amount customarily consumed or, in the case of a meal product or main dish product, not more than 6 g sugars per labeled serving, provided that sugars from fresh, frozen, dried, or similarly processed fruits and vegetables shall not be included in assessing whether a food contains 6 g of sugars as long as the level of sugars contributed by the fruits and vegetables is documented and the documentation is available for FDA review upon request.

(c) *Synonyms for carbohydrate.* The terms “carb” or “carbs” may be used in place of “carbohydrate” in any claim authorized by this section.

VII. CLAIM FOR CATEGORICAL EXCLUSION

The action requested by the Petition is not expected to have a significant effect on the quality of the human environment, and is subject to categorical exclusion pursuant to 21 C.F.R. § 25.32(p). To the knowledge of the Petitioners, no extraordinary circumstances exist.

VIII. CONCLUSION

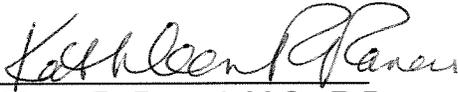
Consumer interest in the role of carbohydrate in a healthy diet is increasing at a rapid pace. Consumer understanding of carbohydrate nutrition, however, is hindered by a proliferation of carbohydrate claims, many of which are illegal and not based on sound science. The 2002 Macronutrient Report establishes that active management of carbohydrate consumption is a legitimate goal, and provides a scientific basis for characterizing the carbohydrate content of foods. To facilitate consumer understanding of the consensus recommendations established in the Macronutrient Report, and to promote consistency in the marketplace, Kraft urges FDA to define the claims proposed in this petition—“carbohydrate free,” “low carbohydrate,” “reduced carbohydrate,” “less carbohydrate,” “excellent source of carbohydrate,” and “good source of carbohydrate”—as soon as possible.

* * * * *

I certify that, to the best of our knowledge, this Petition is a representative and balanced submission that includes unfavorable as well as favorable information, known to Kraft, which is pertinent to the agency’s evaluation.

Respectfully submitted,

KRAFT FOODS NORTH AMERICA, INC
PETITIONER

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