



INGREDIENTS, INC.

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December 2, 2004

United States Food and Drug Administration
Attn: Dockets Management Branch
Room Number 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Citizen Petition of MGP Ingredients Inc.

Dear Sir or Madam:

MGP Ingredients Inc. ("MGPI") submits this citizen petition to the United States Food and Drug Administration to advocate its position regarding nutrient content claims for carbohydrates. This citizen petition is presented under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act and in accordance with requirements established in the relevant federal regulations.

Thank you for your full consideration. Please contact me if you have any questions.

Sincerely,

Dr. Sukh Bassi
Chief Science Officer

Enc.

*Citizen Petition of: MGP Ingredients, Inc.
1300 Main Street
Atchison, Kansas
66002-0130*

Citizen Petition Statement of Intent

The undersigned MGP Ingredients Inc. ("MGPI") submits this citizen petition to the Food and Drug Administration ("FDA") under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and in accordance with requirements established in 21 C.F.R. 101.69, to respectfully request the FDA Commissioner promptly take action to issue, modify and/or clarify the regulations relating to nutrient content claims for carbohydrates in food labeling.

Action Requested

FDA should expeditiously promulgate a simple and pragmatic regulatory scheme that is based on sound science and market realities to govern nutrient content claims for carbohydrates. This action would create a level playing field, where the food industry participants and consumers can clearly understand the lawful scope of such claims.

MGPI specifically advocates two actions in this regard. First, we request that any proposed regulations on carbohydrate labeling specifically exclude dietary fiber from the total carbohydrate count of a particular food product. Second, we request that FDA allow food industry participants to determine fiber content based on the AOAC Method 991.43 test, a widely accepted methodology for measuring fiber content. This test will provide a uniform process for determining the dietary fiber content of any given food product.

Statement of Grounds

A. Background

1. MGP Ingredients Inc.- Supporting the Innovations of Food Manufacturers

MGPI is a Kansas corporation headquartered in Atchison, Kansas. Incorporated in 1957, MGPI is the successor to a business founded in 1941 by Cloud L. Cray, Sr. One of the primary motivations for Mr. Cray when he founded the original company was to produce industrial alcohol to support the Allied war effort during World War II. Following the war, production and marketing emphasis shifted to beverage alcohol, concentrating first on serving large suppliers and bottlers, and later on meeting the needs of smaller firms around the country as well.

From its relatively modest beginnings during World War II, MGPI grew to become what is believed to be the largest producer of vital wheat gluten, specialty wheat proteins and premium wheat starch in the United States. Currently it has over 500 employees and conducts manufacturing and processing operations at three facilities. Although it remains one of the largest producers of beverage alcohol in the country, in recent years MGPI's business strategy has been to focus on the development and marketing of specialty protein and starch products. In fiscal 2002 and 2003 it received approximately \$25 million under a government program designed to assist manufacturers of wheat gluten in transitioning from the historical vital wheat gluten business to new markets. It used these funds to defray costs related to specialty wheat protein and starch products to help accelerate its growth in these markets. During fiscal 2004, its sales of specialty ingredients increased by more than 100% over the prior year. The greatest portion of this increase occurred in sales of specialty protein and starch products sold to manufacturers of food products.

MGPI's specialty wheat starches are used primarily as an additive in a variety of food products to affect their appearance, texture, tenderness, taste, palatability, cooking temperature, stability, viscosity, binding and freeze-thaw characteristics. For example, MGPI's starches are used to improve the taste and mouth feel of cream puffs, éclairs, puddings, pie fillings, breading and batters; to improve the size, symmetry and taste of angel food cakes; to alter the viscosity of soups, sauces and gravies; to improve the freeze-thaw stability and shelf life of fruit pies and other frozen foods; to improve moisture retention in microwavable foods; and to add stability and to improve spreadability in frostings, mixes, glazes and sugar coatings.

MGPI's Food application wheat proteins include products in the Wheatex®, FP™ and Arise® series and Pasta Power™. Wheatex® Series consists of texturized wheat proteins made from vital wheat gluten by changing it into a pliable substance through special processing. The resulting solid food product can be further enhanced with flavoring and coloring and reconstituted with water. Texturized wheat proteins are used for meat, poultry and fish substitutes, extenders and binders. The Arise® series of products consists of specialty wheat proteins that increase the freshness and shelf life of frozen, refrigerated and fresh dough products after they are baked. Certain ingredients in this series are also sold for use in the manufacture of high protein, lower net carbohydrate products. Pasta Power™ is a specialty wheat protein that is a cost-effective replacement for whole eggs and egg whites and enhances the strength, texture, quality and functionality of fresh, frozen and flavored pasta products.

In the markets that MGPI operates in, the demand for ingredients to support the manufacture of low carbohydrate products has grown exponentially in recent years. Thus, MGPI has a unique and informed basis to recommend a realistic remedy to the current marketplace dilemma wherein there is no discernible standard as to what constitutes an accurate and/or lawful nutrient content claim for carbohydrates in food product labeling.

2. The Growth of Low Carbohydrate Food Products in the Context of an American Health Care Crisis

One can hardly walk through a grocery store aisle, scan a restaurant menu, or watch a television show without encountering repeated examples of low carbohydrate food products and a broad marketing emphasis on the advertised medical benefits of a low carbohydrate lifestyle. The powerful emergence of these products comes in the wake of what in recent years has become America's most pressing health care crisis - obesity. Without dispute, obesity has reached epidemic proportions and there is no clear solution in sight.¹ The obesity crisis, widely reported in the media and broadly acknowledged by political and food industry leaders, has spurred the federal government into action. If left unchecked, obesity not only threatens the individual health and well being of millions of Americans, but also imposes a substantial burden on the health care network of doctors, hospitals, insurers and patients that collectively struggle with rapidly rising health care costs.²

In response to the obesity crisis in America, new and innovative diets have been designed by food industry participants as a method of controlling or reducing individual weight. Many of the popularized diets such as the "Atkins" diet, the "South Beach" diet and the "Zone" diet focus on a drastic reduction of (or certain types of) carbohydrates.³ Without debating the efficacy of such diets, one thing is clear - American consumers have embraced the low carbohydrate diet craze in large numbers and continue to call

¹ Prepared remarks for keynote address by Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of the FDA for World Obesity Congress & Exposition, July 12, 2004, <http://www.fda.gov/oc/speeches/2004/worldobesity0712.html>. ("[t]his issue commands the closest attention of the Department of Health and Human Services and, in particular, of the agency I have the honor to represent, the Food and Drug Administration. I am talking, of course, about the epidemic of overweight and obesity . . . [a]nd a major problem it is: overweight and obesity affect about two out of every three Americans -- and, what is even more alarming, 15 percent of our children and adolescents. These extra pounds are ruinous to health by increasing the risks for a host of diseases that are inflating our nation's morbidity and mortality statistics. According to the most recent estimates, obesity is a causative factor in as many as 400,000 deaths each year"); Prepared remarks for Testimony before the Subcommittee on Education Reform Committee on Education and the Workforce, United States House of Representatives: "The Obesity Crisis in America" Statement of Richard H. Carmona, M.D., M.P.H., F.A.C.S. Surgeon General, U.S. Public Health Service, Acting Assistant Secretary for Health, Department of Health and Human Services. ("As Surgeon General, I welcome this chance to talk with you about a health crisis affecting every state, every city, every community, and every school across our great nation. The crisis is obesity. It's the fastest-growing cause of disease and death in America.").

² *Id.* ("The costs of obesity-associated health care and lost productivity are currently estimated at \$117 billion a year.").

³ www.atkins.com ("When following the Food Guide Pyramid, Americans consume at least 300 grams of carbohydrate daily. The Atkins Nutritional Approach™, on the other hand, advises considerably lower carbohydrate intake"); www.southbeachdiet.com ("The South Beach Diet . . . teaches you to rely on the right carbs and the right fats."); www.DrSears.com (the official site of the "Zone" diet) ("Success with the Zone Diet depends upon restricting the amount of carbohydrates consumed while maximizing the vitamins and minerals derived from them.").

upon food manufacturers for more products that are consistent with low or modified carbohydrate diets. Whether the strong consumer demand for such products is temporary or permanent remains unclear, but the demand is undeniably present and companies in all sectors of the food industry have responded with products that prominently advertise a range of carbohydrate claims.

3. Federal Regulatory Oversight for Food Labeling

Much of carbohydrate-related advertising takes place in the form of food labeling, which of course is an area of nearly-exclusive federal oversight through FDA, the United States Department of Agriculture, the Federal Trade Commission and other federal regulatory agencies.

Government regulation of food labeling is an old enterprise, with ties back many hundreds of years to the Roman Empire.⁴ Modern-era food labeling oversight in the United States saw its birth at the turn of the twentieth century with the passage of legislation such as the Pure Food and Drug Act ("PFDA") in 1906. The PFDA was the Congressional response to widespread fear among the American public at that time that the integrity of the food supply was in question. Congress continued to enact additional food protection legislation during the early 1900s, culminating in the passage of the key piece of legislation that gave the FDA its primary grant of regulatory authority over food labeling, the FDCA. In the years that followed, the FDCA was amended and expanded by several major pieces of legislation. The primary legislation relevant to food labeling is the Nutritional Label and Education Act ("NLEA") of 1990, which further delineated FDA's authority to regulate food labeling. FDA has also promulgated regulations that dictate the scope and breadth of precisely what may and may not appear on a food label. One of major areas subject to these regulations is nutrient content claims.

Nutrient content claims describe the amount of a nutrient in the food (such as "sodium free" or "low fat"). These claims may not be made unless they are defined by FDA in regulations. While consumers need not be concerned with the exact definition for each claim, those who want more detailed information need only look to the nutrition label on the side or back of the package. Such claims are addressed in FDA regulations, but to date the FDA has not specified how these claims may be applied to the total carbohydrate count for a particular food product.

4. The Need for Regulations Governing Carbohydrate Nutrient Content Claims

Nearly all of the citizen petitions submitted to FDA on carbohydrate labeling have advocated for new regulations to govern carbohydrate nutrient content claims. MGPI strongly agrees with these petitioners. Currently, the marketplace contains a confusing

⁴ *Food Labeling -- Then and Now*, 2 JPHARML 171 (1994) (citing *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM.L.J. 2-73 (1984)).

mix of labeling, much of it inconsistent with FDA labeling rules. Clear regulatory guidance on this labeling issue will serve several important purposes.

Regulations or other guidance will give food industry participants an appropriate framework for labeling. The vast majority of companies seek to fully comply with FDA regulatory guidance, but in this case very little guidance exists upon which to rely. Clear regulatory guidance will also serve to educate consumers regarding product choices. By formally establishing labeling standards for low carbohydrate products, the FDA will ultimately protect and educate consumers by promoting the use of consistent, understandable labels. Several prominent health-care authorities have stated that fair and adequate labeling is a critical component of the battle against obesity. Further, regulatory guidance on this critical labeling issue will resolve the uncertainty that currently exists in the marketplace and create a more stable, competitive playing field.

B. Approach of Submitted Citizen Petitions.

Over the past several months, FDA and CSFAN have received numerous citizen petitions from an array of food industry participants. These citizen petitions advance different views and suggest a variety of approaches for FDA to consider as it develops regulations for carbohydrate content labeling. While nearly all petitioners agree that there is a need for consensus and a common regulatory scheme to create certainty in the marketplace and aid consumers interested in "low-carbohydrate" and "net-carbohydrate" products, there is far less agreement about how to accomplish this task.

1. Application of existing terms generally accepted.

In several of the petitions submitted thus far, the FDA is urged to expand already existing descriptor definitions to include specific amounts of carbohydrates. Although there is some variation as to what these amounts should be, there appears to be relatively broad support for this concept.⁵ Multiple petitions support the following:

- a. Carbohydrate free. "Free" has historically been used to describe a food product that has an inconsequential level of a nutrient. Petitioners state that such an approach is appropriate for products labeled as "carbohydrate free." Petitioners suggest that "carbohydrate free" be permitted "on foods, (except main dish and meal products), that contain less than 0.5 gram per reference amount and per labeled serving." For main dishes and meal products, petitioners recommend the 0.5 gram or less limitation be applied based on a per labeled serving basis.

⁵ See e.g. "Nutrient Descriptor Claims for the Carbohydrate Content of Food" submitted by the Grocery Manufacturers of America, February 4, 2004; "Petition for Nutrient Content Claims" submitted by Unilever United States Inc., April 16, 2004; "Nutrient Content Claims for the Carbohydrate Content of Foods", submitted by Kraft Foods North America, Inc., December 1, 2003.

b. Low carbohydrate. "Low" is recognized by the FDA as a claim to identify foods that are "distinctly low" in a given nutrient relative to recommended intake amounts. Several petition advocate that for foods generally, the term "low" (in a carbohydrate context) be defined as 2% of the daily reference value (DRV) of 300 grams, resulting in a "low carbohydrate" definition of 6 grams or less. This would again apply also for "meal-type" products (i.e. meal products and main dishes) but with a 100 gram standard.

c. Reduced or less carbohydrate. "Reduced" and "less" are relative descriptors that are used to compare nutrient content between foods. There is support to utilize terms such as "reduced" or "less" for foods (except meal-type products) that contain 25% less carbohydrate than an appropriate reference food. In the same respect, it is suggested that these terms be permitted for meal-type products that contain 25% less carbohydrate, per 100 grams, than an appropriate reference food.

MGPI supports extending the use of existing content descriptors to include specific definitions for carbohydrates. These terms are familiar to the public, and should help consumers identify the relative carbohydrate content of different food products in the marketplace.

2. Lack of Consensus on Carbohydrate Definition.

Another aspect of the carbohydrate labeling debate made clear by the petitions and outside writings on the subject is that there is in fact little agreement about what should or should not be considered carbohydrates. The various petitions submitted to FDA reflect differing views and approaches as to what should be considered, defined, and labeled as carbohydrates. This issue is where we see discussion within the food industry about the use of terms like "net-carbs", "net effect carbs", and "functional fiber." In all cases however, these terms are simply different ways to describe the fact that certain foods, while technically carbohydrates under existing regulatory definitions, are not wholly digested in the small intestine, and therefore are digested like, and have the physiological benefits of, dietary fiber.

MGPI does not disagree with any of these view points. All of the petitioners and the food industry as a whole are looking for effective ways to market products to consumers who wish to follow a low-carbohydrate diet and realize the health benefits of such a diet in their daily lives.

What is needed is a simple and effective way for consumers and the industry to determine the true level of carbohydrate in any food on the market. It would be burdensome and difficult for the government to define several new terms, and such an approach would likely result in more confusion in the marketplace, not less. In addition, the before mentioned content descriptors will be of little value unless and until there is

agreement on what exactly should be considered carbohydrate content. In order to effectively utilize these and other descriptors that the FDA may employ for carbohydrate content, the food manufacturing industry needs to have a single, accurate, and fair method of making this determination that will then be passed on to the consumer.

C. Need for an Accepted, Scientific Definition.

MGPI believes that FDA should initially simplify the existing definition of "Total Carbohydrate" to exclude dietary fiber, which would simplify the existing labeling practices and make it easier for consumers to understand the nutritional information on food products.

1. MGPI supports the simple approach that dietary fiber should be excluded from the Total Carbohydrate definition.

Under current FDA regulations, dietary fiber is not excluded from the "total carbohydrate" definition that is required on the current "Nutrition Facts" panel.⁶ Under this definition, any part of the food that is not protein, fat, moisture, or ash is included within the total carbohydrate content. The "Nutrition Facts" panel further divides carbohydrates into "dietary fiber" and "sugars" which does provide helpful information to the consumer, but may be confusing to the consumer who is trying to reconcile these amounts with the "total carbohydrate" amount. In addition, food manufactures can provide additional information on a voluntary basis, including sugar alcohols and starches.

MGPI believes the current regulatory scheme, both mandatory and voluntary, has created a wide range of interpretations that have led to the current confusion in the marketplace. A simplification of these regulations is an important step in setting up a level playing field within the industry and providing the consumer with nutritional information that is easy to understand.

2. Regulatory Change Simplifies Calculation for Carbohydrate claims
FDA may approve.

By adding dietary fiber content as part of the food to be excluded from "total carbohydrate" content, FDA would achieve this streamlining and simplification in one simple step. When combined with the scientific methodology for accurately determining the dietary fiber content of all food described below, FDA would provide the certainty in the marketplace that the food industry has been seeking throughout this process.

⁶ 21 C.F.R. 101.9, "Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food."

In addition, under this system the food industry participants will be able to accurately determine if their products are indeed "zero-carb", "low-carb", represent a "good source of carbohydrate", and meet the definitional standards of any and all carbohydrate content claims the FDA may approve. Under this improved regulatory framework, there would not be a need for food producers to make additional claims that FDA would then have to define. Dietary fiber, from whatever source or individual ingredient, would not be counted as total carbohydrate, and therefore there would be no incentive to distinguish these ingredients using terms such as "functional fiber", "net carbs", "net effective carbs" and other descriptors that are inconsistent in the current marketplace.

Thus, FDA would not have to promulgate additional regulations defining such terms, and avoid considerable time, effort, and cost to both the federal government and the food industry, the latter of which would invariably struggle to comply with a new matrix of carbohydrate content claim definitions.

3. Proposed Changes would be Consistent with International Carbohydrate Labeling Practice.

More so than ever, the food industry operates in a global marketplace. Food labeling is not only relevant and meaningful to American consumers, but also to the broader international community where United States food products may be consumed. In the course of establishing low carbohydrate regulations, it is important to be mindful of the international impact of food labeling. To this end, MGPI stresses the need to strive for increased international consistency in labeling practices, which will in turn benefit regulatory authorities, industry and consumers alike.

D. MGPI Proposed Solution: Define dietary fiber as carbohydrate content not digested in the small intestine, as determined by AOAC Method 991.43 test.

The final piece of the solution is to have an accurate, fair, and accepted methodology to determine the carbohydrate and dietary fiber content in any given food product. This again eliminates the need for FDA and the food industry to adopt a whole new set of content claim definitions that to this point have only created confusion in the marketplace. Consumers will benefit from accurately knowing the carbohydrate content, as well as the fiber content. Dietary fiber also provides many well documented health benefits.

1. Scientific Definition of Dietary Fiber and Related Health Effects.

The Expert Committee on Dietary Fiber Definition of the American Association of Cereal Chemists defines dietary fiber as "the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignin, and associated plant substances. Dietary fibers

promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation”.

Dietary fiber is a special type of carbohydrate that passes through the human digestive system, without being broken down into nutrients. Dietary fiber is broken down in the gut by microbial fermentation. Fermentation occurs in a number of discrete steps. The first of which is hydrolysis of polysaccharides to smaller molecules (oligosaccharides). They are further hydrolyzed to simple sugars and then to short chain fatty acids (SCFA), including acetic, propionic, and butyric acids. In humans, butyrate is a preferred energy source for colonocytes.

Due to the many documented health benefits of dietary fiber, consumers will further benefit from this approach because they will have a more accurate measurement of both the carbohydrate and fiber content of labeled food products. Some of the many health benefits of dietary fiber include:

Fighting Obesity

A fiber-rich meal is usually less energy dense because dietary fiber accounts for a large part of its volume. When ingested, dietary fiber takes up more space in the stomach and slows nutrient absorption, which is related to the increased satiety and limited spontaneous intake of energy.

Reduction of Diabetic Health Risks

Type II diabetes is the most common form of diabetes. More than seventeen million individual in U.S. are diagnosed as type II diabetics. Slow digestion of foods and attenuated absorption of glucose (sugar) into the blood stream is known to be helpful to normalize blood sugar and insulin level after the diet. According to the study of Harvard School of Public Health and Nutrition, a diet low in cereal fiber and rich in high glycemic index foods is particularly bad for developing diabetes. This kind of diet doubled the risk of type 2 diabetes when compared to a diet high in cereal fiber and low in glycemic index foods.

Reducing Risk for Heart Disease

High intake of dietary fiber has been related to reducing the risk of heart disease for many years. In a Harvard study, dietary fiber intake was linked to a forty percent lower risk of coronary heart diseases. Beta glucan in oats and psyllium husk have been sufficiently studied for the FDA to authorize a health claim that foods meeting specific compositional requirements and containing 0.75 g or 1.7 g of soluble fiber per serving, respectively, can reduce the risk of heart disease. These two dietary fibers are specifically included in the most recent National Cholesterol Education Program of the American Heart Association guidelines

Reducing Diverticular Disease and Constipation

Diverticulitis, an inflammation of the intestine, is one of the most common age-related disorders of the colon in Western society. In North America, one-third of all those over age 45 and two-thirds of those over age 85 are afflicted with this disease. Long term follow-up study shows eating dietary fiber was associated with about 40 percent lower risk of diverticular disease (Aldoori et al J. Nutr 1998; 128:714-9).

Constipation is one of the most common gastrointestinal complaint in the U.S. and is of particular concern to the elderly. The large intestine responds to the larger and softer mass of residue produced by a higher fiber diet by contracting, which moves the contents towards excretion. The gastrointestinal tract is highly sensitive to dietary fiber and consumption of fiber seems to relieve and prevent constipation. Many fiber sources, including cereal brans, psyllium seed husk, methylcellulose, and a mixed high-fiber diet increase stool weight, thereby promoting normal laxation.

Reducing Risk of Colon Cancer

The fermentability of dietary fiber by microflora in the colon is an extremely important property of dietary fiber. Substantive evidence was shown that consumption of fiber-rich foods is inversely related to risks of both colon and rectal cancers (Howe et al. *J Natl Cancer Inst.* 1992;84:1887-1896). The authors estimated that the risk of colorectal cancer in the US population could be reduced by about 31% with an average increase in fiber intake from food sources of about 13 g/day.

2. AOAC Method 991.43 Test is an Effective Way to Determine and Verify Dietary Fiber content any Food Product..

Numerous countries have adopted AOAC International *Official Methods of Analysis* as the basis for enforcing dietary fiber labeling regulations. Internationally, the generally accepted methods for measurement of dietary fiber are *AOAC Methods 985.29* and *991.43*. These methods consist of enzyme treatment for starch and protein removal, precipitation of soluble dietary fiber by alcohol, isolation, weighing of dietary fiber, and correction for ash and protein in the residue. AOAC method 985.29 had some problems with reproducibility due to varying ash contents. This was due to the formation of insoluble calcium phosphate from the phosphate buffer used and the high level of calcium in the thermostable alpha-amylase then available. The problem was resolved by the introduction of Tris-MES buffer (AOAC Method 991.43) and by the availability of thermostable alpha-amylase containing low levels of calcium as stabilizer.

The generally accepted “gold standard” definition of dietary fiber, i.e., “dietary fiber consists of the remnants of edible plant cells, polysaccharides, lignin, and associated substances resistant to digestion (hydrolysis) by the alimentary enzymes to human” was proposed by Trowell (1976). The benchmark method (AOAC 985.29) based on the

definition was in place, and research scientists made improvements to arrive at the same quantification. Scientists developed, and validated through collaborative study, and gained official adoption of the official method AOAC 991.43, Total, Soluble, and Insoluble dietary fibers in Foods, Enzymic gravimetric method (Mes-Tris Buffer). The method determines total, soluble, and insoluble dietary fiber after enzymatic digestion simulating human digestion. AOAC method 991.43 requires a relatively short time and uses an organic buffer system. The method was designed for food labeling purposes and is practical for all food systems. The consensus definition and method validation can serve as a basis for regulations worldwide with regard to dietary fiber food labeling and health claims. Also, it creates a level playing field for industry, eases the burden on the regulators, and help consumers to understand the marketplace of foods products.

E. Conclusion

In summary, Petitioner requests that the FDA promulgate rules regarding carbohydrate content claims that will provide numerous benefits to the consumer and also create a clear understanding within the food industry regarding how its products can be labeled and sold in the marketplace. This requires a three phase process outlined above:

First, extend existing nutrient content descriptors to carbohydrates, as consumers and producers are already familiar with many of these claims as they related to other components of food products.

Second, remove all dietary fiber from the total carbohydrate content, based on the fact that dietary fiber is not digested with other carbohydrates in the small intestine, and has numerous health benefits that consumers are seeking. Simplifying this definition will assist both consumers and food manufactures.

Third, FDA needs to determine that the true dietary fiber content, and thus also the carbohydrate content, be determined by a uniform test that is accepted by the food manufacturing industry as both reliable and accurate. MGP Ingredients believes that the AOAC Method 991.43 test is widely accepted within the industry and will result in accurate information for all related carbohydrate content claims.

MGP Ingredients urges the FDA to promulgate these rules to create certainty among food producers in the marketplace and to provide consumers with a far greater ability to assess the carbohydrate content, dietary fiber content, and overall health benefits of the foods they purchase.

Environmental Impact

We request categorical exclusion from the requirements of an environmental assessment under 21 CFR 25.30. To the best of our knowledge, no extraordinary

circumstances exist that would merit an environmental assessment, and the requested actions are among those subject to the categorical exclusion provided in 21 CFR 25.32(p).

Economic Impact

We do not anticipate any significant economic impact related to the recommendations contained in this petition.

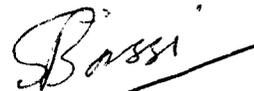
Certification

The undersigned certifies that, to the best of our knowledge and belief, this Petition is a representative and balanced submission that includes unfavorable as well as favorable information, known to MGP Ingredients, which is pertinent to the agency's evaluation.

Respectfully submitted,

MGP INGREDIENTS, INC.
PETITIONER

By



Dr. Sukh Bassi
Chief Science Officer