

The Definition of Dietary Fiber¹

"Dietary fiber is 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."

EXECUTIVE SUMMARY

Establishing a definition for dietary fiber has historically been a balance between nutrition knowledge and analytical method capabilities. While the physiologically based definitions most widely accepted have generally been accurate in defining the dietary fiber in foods, scientists and regulators have tended, in fact, to rely on analytical procedures as the definitional basis in fact. As a result, incongruencies between theory and practice have resulted in confusion regarding the components that make up dietary fiber. In November 1998, the president of the American Association of Cereal Chemists (AACC) appointed a scientific review committee and charged it with the task of reviewing, and if necessary, updating the definition of dietary fiber. The committee was further charged with assessing the state of analytical methodology and making recommendations relevant to the updated definition. Over the course of the next year, the committee held three workshops (two of them public forums), accepting input and debate from scientists who could be present in person. In addition, an international website, available to all web users worldwide, was set up to receive comments from scientists. Results of the workshops were reported in a timely fashion in CEREAL FOODS WORLD (1-9) and on the website to assure that all interested parties were provided with additional opportunity for comment. After due deliberation, an updated definition of dietary fiber was delivered to the AACC Board of Directors for consideration and adoption. The updated definition includes the same food components as the historical working definition used for almost 30 years (a very important point, considering that most of the research of the past 30 years delineating the positive health effects of dietary fiber are based on that working definition). But the updated definition more clearly delineates the makeup of dietary fiber and its physiological functionality. As a result relatively few changes will be necessary in analytical methodology. Current methodologies, in particular AACC Approved Method of Analysis (10) 32-05 (AOAC Official Method of Analysis (11) 985.29) or AACC 32-07 (AOAC 991.43) will continue to be sufficient and used for most foods. A small number of additional methods will be necessary to quantitate the dietary fiber levels in foods containing fibers such as fructans (polymers and oligomers of fructose, inulin), modified dextrins, and/or synthetic dietary fiber analogues.

DIETARY FIBER DEFINITION

"Dietary fiber..."-The term to be defined. Since the term dietary fiber was coined by Hipsley (12) in 1953, the exact definition of the term has been controversial as scientists have studied various aspects of the food supply and dietary fiber's impact upon health.

"...is the edible part..."-Obviously to be part of the diet, a component of food must be edible. Part indicates that dietary fiber makes up only a portion of the whole food or food product.

"...of plants..."-Dietary fiber has traditionally been considered to be plant sourced. Proposals have been put forth to consider the undigestible portions of animal-based foods as dietary fiber or more explicitly, edible fiber (13). However, the scientific community has not followed up on these proposals, and significant research on non-plant sources of carbohydrates resistant to digestion has not been carried out.

"...or analogous carbohydrates..."-Carbohydrate(s) of structure(s) analogous to those of naturally occurring dietary fibers have been shown to demonstrate the physiological properties of the respective materials to which they are analogous. These analogous carbohydrates are produced during food processing, by chemical and/or physical processes affecting the digestibility of starches, or by purposeful synthesis.

"...that are resistant to digestion and absorption in the human small intestine..."-Resistance to digestion and absorption is the key to dietary fiber's unique position in the human diet. To be bioavailable, nutrients other than dietary fiber must be broken down, solubilized, or otherwise modified and absorbed through the walls of the small intestine to be available for bodily functions. Dietary fiber is unique in that it must pass through the small intestine undigested to reach the large intestine where it continues to impart its functionality.

"...with complete or partial fermentation in the large intestine."-The positive health effects of dietary fiber are related, in part, to the fact that measurable fermentation of dietary fiber occurs in the large intestine. Fermentation has a positive impact on laxation, on colonic pH, and produces by-products to which positive physiological effects have been ascribed.

"Dietary fiber includes polysaccharides..."-Polysaccharides such as cellulose and hemicellulose are the mainstay of dietary fiber. For many dietary fibers, the large molecular size of the cellulose gives fiber its "fibrous" appearance. For other dietary fibers, the polysaccharides such as beta-glucans provide the gummy, gelatinous nature characteristic of soluble dietary fibers. All nondigestible, fermentable polysaccharides, whether they are polyglucoses such as cellulose or beta-glucans, or polyfructoses such as inulin, or heteropolymers such as arabinoxylans and arabinogalactans, or analogous carbohydrates, are included in the definition of dietary fiber.

"...oligosaccharides...-Oligosaccharides, short-chain polysaccharides which, by convention, are chains with a degree of polymerization (DP) between 3 and 10, exhibit some of the same physiological properties as their larger counterparts and thus are included

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in this definition. Some fractions of oligosaccharides have been included methodologically in practice for some fibers since the first formal definition of dietary fiber was proposed (14).

"...lignin..."-Although lignin is not a polysaccharide *per se*, lignin is intricately tied to the dietary fiber polysaccharides in foods and increases the resistance to digestion.

"...and associated plant substances."-Waxes, cutin, and suberin are indigestible fatty acid derivatives which, like lignin, are intricately tied to the dietary fiber polysaccharides, often serving as chemical cross-links between various of the other components and increasing resistance to digestion.

"Dietary fibers promote beneficial physiological effects..."-For a component of the diet to be considered important to nutrition and health, it must have either a negative or positive impact. In the case of dietary fiber, the historical definitions have been used as the basis for the substantial body of scientific research that has shown the positive physiological benefits that are to be expected from dietary fiber. Analogous carbohydrates fitting the dietary fiber definition demonstrate at least one of the positive physiological effects included in this definition.

"...including laxation..."-Laxation is a very important physiological effect that results from increasing the dietary fiber component of one's diet in place of other food components. It is a physiological effect that is almost taken for granted, and imparts positive feelings to the individual consuming the dietary fiber along with other benefits of improved laxation.

"...and/or..."The use of "and/or" is included in the definition of dietary fiber effects because not all dietary fibers impart all of the positive physiological effects, but can be expected to impart at least one of them.

"...blood cholesterol attenuation and/or blood glucose attenuation."-To attenuate in a scientific context means to adjust a parameter to a proper level (usually lower) or to adjust it to a desired level. When a signal or other parameter is attenuated, it is adjusted so it is neither too high, nor too low. Research over the past several decades has shown that increased consumption of dietary fibers and high fiber foods produces a positive adjustment in levels of serum cholesterol, a biomarker related to the risk of coronary disease. An increased consumption of dietary fiber and high fiber foods in place of other foods in a particular meal also produces a measurable reduction in the peak level of serum glucose after eating, an effect generally deemed as beneficial to health, particularly in susceptible individuals. Although not all fibers and high fiber foods in all studies have exhibited these beneficial properties (and thus, the inclusion of and/or in the definition), the weight of evidence indicates these positive attributes for increased dietary fiber consumption are important and relevant.

This definition reflects several very important concepts:

Dietary fiber has been defined on the basis of the properties it exhibits that have been characterized as part of the extensive worldwide research effort of the past 30 plus years. This research effort has correlated the positive health effects of dietary fiber with its increased consumption. This definition makes reference to the plant components accepted as being present in the defined dietary fiber that imparted the positive health effects.

Analogous dietary fiber is defined as those materials, not necessarily intrinsic to a part of a plant as consumed, but that exhibit the digestion and fermentation properties of fiber. Analogous fiber, in addition to the requisite digestion and fermentation properties, must also exhibit a positive potential health benefit that has been ascribed to dietary fiber. This inclusion clearly acknowledges that certain food ingredients, whether they are plant extracts, concentrates, modified carbohydrates, or compounds produced by design, exist, and should be recognized as dietary fiber when considering their nutritional properties and labeling requirements when part of a food.

The definition, as written, clearly delineates the meaning of dietary fiber and analogous fiber, and defines the important and relevant functional properties of all dietary fibers.

THE PROCESS

In November of 1998, the president of AACC appointed a scientific review committee and assigned the committee the task of reviewing, and if necessary, updating the definition of dietary fiber. Dr. Dennis Gordon of North Dakota State University was appointed to chair the committee. The balance of the committee members were from academia, government (and government retirees), and industry. A complete listing of the committee members is provided in Appendix A. After initial teleconference meetings, a decision was made to establish a website "Defining Dietary Fiber" to provide ample opportunity for interested scientists worldwide to provide comments. The website was opened on May 12, 1999, and was available for approximately nine months, during which time committee activities were broadcast and input was received. A wide variety of opinions from scientists spread throughout the world. In many cases multiple participants carried out written internet discussions.

The committee held three workshops, two of them as public forums. In June 1999, the AACC Dietary Fiber Definition Committee in cooperation with the Carbohydrate Technical Committee of the International Life Sciences Institute of North America (ILSI NA) held a workshop in Washington DC. Key regulatory and health scientists from the USFDA, USDA, NIH, CDC, academia, and industry were invited. A preliminary definition for dietary fiber was authored for future consideration and feedback (15). In July 1999, during the Institute of Food Technologists meeting in Chicago, IL, the committee held a second dietary fiber definition workshop. The purpose of this workshop was to gather feedback from food, nutrition, and analytical scientists on the preliminary definition resulting from the June workshop, further discuss the scientific basis for a definition, and produce a refined definition if necessary and possible. Continual feedback from the website combined with committee teleconferences in August and September of 1999, resulted in a version of the dietary fiber definition in the fall of 1999 very similar to the final definition that was adopted. In the course of the committee's efforts many ideas and suggestions were received from others. Most ideas and suggestions received were for specific aspects of a complete statement. Few scientists offered a complete definition of dietary fiber. Far fewer included any substantiation. Suggestions offered were typically unaccompanied by either an explanation, a rationale, or relevant references.

At the AACC Annual Meeting in Seattle, WA, in November of 1999, a final workshop was held. The purpose of the workshop was to collect additional input regarding regulatory, analytical, nutritional, and physiological aspects of dietary fiber in light of the previous year's effort. The committee concluded the definition of dietary fiber was "Dietary fiber is the remnants of the edible part of plants and analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the human large intestine. It includes polysaccharides, oligosaccharides, lignin and associated plant substances. Dietary fiber exhibits one or more of either laxation (fecal bulking and softening; increased frequency; and/or regularity), blood cholesterol attenuation, and/or blood glucose attenuation.

Reading the definition shows it is obvious that the committee deemed it necessary:

- To clarify the constituent make up of dietary fiber; to recognize that a primary characteristic of dietary fiber is resistance to digestion and absorption in the small intestine.
- 2) To recognize that a primary characteristic of dietary fiber is fermentation in the large intestine
- 3) And to include key physiological impacts demonstrated in the past 30 plus years of research.

The constituents of foods that will be included with this updated definition are not significantly different than those included with

the definition put forth by researchers almost 30 years ago (see history section below). This is important, because food composition has not significantly changed, and furthermore, the research demonstrating the positive health benefits has been based on the working definitions used since the early 1970s. The three physiological functions having a significant body of scientific evidence at this point in time are included. Clarification is now provided on the need to modify methodology to fit the definition, rather than *vice versa*, and thus to include those highly soluble fiber components that previously have not been adequately quantitated. Further, clarification is provided that carbohydrates analogous in function to dietary fiber are included in dietary fiber with the provision that said analogous carbohydrate(s) adequately demonstrate physiological functionality.

Feedback received by the committee subsequent to the Seattle meeting indicated that the wording of the definition was a bit cumbersome, therefore the committee reconvened to reassess the exact phraseology. The result was the adoption of the final proposed definition "Dietary fiber is 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." This was forwarded to the AACC Board of Directors in March of 2000.

THE HISTORY OF DIETARY FIBER DEFINITION

Historical Overview

Historically, there has been consensus since the late 1970s, that "Dietary Fiber consists of the remnants of edible plant cells, polysaccharides, lignin and associated substances resistant to (hydrolysis) digestion by the alimentary enzymes of humans." This definition defines a macro constituent of foods which includes cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, and pectins and associated minor substances such as waxes, cutin, and suberin. The physiological definition was reaffirmed amongst scientists internationally in surveys in 1992 and 1993, and as the outcome of a consensus workshop under the auspices of AOAC International in 1995. Methodology commensurate with nearly all aspects of the definition (AOAC 985.29) was adopted and became the *de facto* defining method. Minor gaps between the definition, and the current Official Methods, i.e. fibers not isolated by the methods, but covered by the definition will require method development, validation, and adoption to assure inclusion of all components that make up dietary fiber.

It is generally believed that Hipsley (16) in 1953 first applied the term "dietary fiber" as a shorthand term for the nondigestible constituents that make up the plant cell wall. These constituents were known to include cellulose, hemicellulose, and lignin. This term "dietary fiber" was clearly an attempt to distinguish some property or constituent of the food above and beyond what was then being measured by the crude fiber method.

History (see also Appendix B)

Between 1972 and 1976, Trowell, Burkitt, Walker, and Painter (17–20) (and colleagues) adopted the term coined by Hipsley, i.e. "dietary fiber," in conjunction with a number of health related hypotheses they were developing, consequently referred to as their "dietary fiber hypotheses." This term was used to describe the remnants of plant components that are resistant to hydrolysis by human alimentary enzymes. Thus, it was a physiological-botanical description, related to indigestibility in the human small intestine, with plant cell walls being the major source of digestion-resistant material. If we look at the components involved, they would include cellulose, hemicellulose, lignin, and associated minor substances such as waxes, cutin, and suberin. Edibility of the fiber was implied. Because scientists do not work in a vacuum, probably

certain other obvious fiber properties were implicit as well. Properties associated with the stringy fiber of celery and other vegetables, the character of edible peels on fruits, as well as the resistance cereal bran has to grinding were implicit in the definition as well. The "dietary fiber hypotheses" postulated the inverse relationship between dietary fiber consumption and the incidence of colon cancer and heart diseases found in populations. Publication of the "dietary fiber hypotheses" led to numerous dietary fiber research projects in nutrition, analysis, food technology and other areas.

In 1976, the dietary fiber definition was broadened (21) to include all indigestible polysaccharides (mostly plant storage saccharides), such as gums, modified celluloses, mucilages, oligosaccharides, and pectins. The 1976 definition was primarily a physiological definition (based on edibility and resistance to digestion), broadened on the basis of the chemical knowledge obtained in the interim years. The broadened definition included cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, and pectins and associated minor substances such as waxes, cutin, and suberin. Some of the nondigestible polysaccharides were included in the definition because they were found to have the physiological actions that we attribute to dietary fiber, but could not necessarily be chemically identified as having their origins in the cell wall. The 1976 definition quickly gained widespread acceptance.

Driven by the growing knowledge about the benefits of dietary fiber consumption, numerous researchers began developing methods attempting to quantitate the portion of foods that provided the physiological functionality. Asp (22,23) of Sweden, Schweizer (24) of Switzerland, Theander (25–27) of Sweden, Southgate (28– 30) of the United Kingdom, and Furda (31,32), Baker (33,34), Van Soest (35,36), and Heckman (37) of the United States, amongst others developed procedures aimed at achieving this goal. Researchers focused primarily on removing the digestible portions of the food from the digestion-resistant portions, using select enzymes as their primary tool. Various degrees of success were achieved, with success in part limited by digestion activity present in commercially available enzymes that was not present in human enzymes.

In the late 1970s, Prosky (38) began to seek consensus on a dietary fiber definition in the scientific community. He also sought consensus on methodology commensurate with the definition to quantitate dietary fiber in foods for nutrition improvement and labeling purposes by gathering the opinions of over 100 involved scientists worldwide. By the time of the 1981 Spring Workshop of the Association of Official Analytical Chemists in Ottawa, Canada (39), general consensus was achieved on pursuing methodology that would quantitate the fraction of food as defined by Trowell et al. in 1976. The methodological research works of Asp, Furda, and Schweizer (and colleagues) were deemed to be the best approaches to achieving this quantitation. In a cooperative effort led by Prosky, these researchers along with DeVries and Harland, with the objective of quantitating the macronutrient component in foods in line with the definition, arrived at a single method deemed suitable for a multinational collaborative study. Interest and support for this approach for quantitating the digestion-resistant portion of foods was so high that 43 laboratories in 29 countries agreed to participate in the study.

After initial disappointment with this enzymatic-gravimetric methodology during a first collaborative study, minor modifications in the method protocol were made, a rugged accurate method was obtained, and a successful collaborative study was completed (40,41). The method was adopted as the first Official Method of Analysis for Total Dietary Fiber (42), i.e. AOAC Official Method 985.29, Total Dietary in Foods-Enzymatic-Gravimetric Method. Among the keys to success in achieving adequate methodology were specifications on enzyme purity and on precise handling of the digestion steps of the method. Strict attention has to be paid to assure the enzymes used are digesting the food components normally digested in the human system and not digesting the digestion-resistant components of the sample. This is to assure both adequate performance of the method and accuracy in keeping with the dietary fiber definition.

Routine use of the method spread rapidly worldwide as the analytical and nutrition research communities continued to realize the positive effects of increased dietary fiber in the diet. Because the method was designed to effectively quantitate those food components commensurate with the dietary fiber definition accepted in Ottawa, and because of its widespread acceptance and use, AOAC Official Method 985.29 became the de facto operational definition of dietary fiber. The method was endorsed and adopted by other organizations as well (e.g. AACC's Approved Methods of Analysis 32-05). As the important nutritional distinctions between insoluble and soluble dietary fiber emerged, Official Method 985.29 was modified to allow the isolation and quantitation of the insoluble and soluble dietary fiber fractions. The distinction between the two fiber fractions is somewhat arbitrary, based on the solubility of the soluble fraction in a pH-controlled enzyme solution, as is the case in the human alimentary system; however, the solution in the laboratory is much more dilute. The de facto defining method depends on the soluble fiber being precipitated in a mixture of 1 volume of aqueous enzyme solution, and 4 volumes of 95% ethanol, a solution long used by analytical chemists to separate complex from simple molecules. While this is the case in the method, the dietary definition per se does not imply insolubility or precipitation in aqueous ethanol as a requirement. The modified methodology was validated by collaborative study and adopted as Official Method 991.42, Insoluble Dietary Fiber in Food and Food Products-Enzymatic-Gravimetric Method, Phosphate Buffer. (Later, in 1993, Official Method 993.19, Soluble Dietary Fiber in Food and Food Products-Enzymatic-Gravimetric Method, (Phosphate Buffer) was adopted. This occurred after practical experience and improvements in techniques allowed the quantitation of soluble fiber directly as opposed to determining soluble dietary fiber as the difference between total dietary fiber (985.29) and insoluble dietary fiber (991.42). Method 993.19 treats the filtrate of 991.42 with 4 parts alcohol to precipitate the soluble dietary fiber, which is then isolated and quantitated gravimetrically.)

With a generally accepted "gold standard" definition (Trowell's 1976 definition) and a benchmark method (AOAC 985.29) in place, research scientists added improvements to the method or developed alternative approaches to arrive at the same quantitation. Lee, Mongeau, Li, and Theander (and colleagues) developed, validated through collaborative study, and moved to gain Official adoption the Official Methods 991.43, Total, Soluble, and Insoluble Dietary Fiber in Foods-Enzymatic-Gravimetric Method, MES-Tris Buffer, 992.16, Total Dietary Fiber, Enzymatic-Gravimetric Method, 993.21, Total Dietary Fiber in Foods and Food Products with ≤2% Starch, Nonenzymatic-Gravimetric Method, and 994.13, Total Dietary Fiber (Determined as Neutral Sugar Residues, Uronic Acid Residues, and Klason Lignin)-Gas Chromatographic-Colorimetric-Gravimetric Method (Uppsala Method), respectively. While these methods utilized different approaches to quantitate the digestion-resistant portion of the food sample, the benchmark for accuracy was the de facto defining method, AOAC 985.29. Consequently, all the methods developed and adopted as Official Methods are based on the "gold standard" definition, i.e. "Dietary Fiber consists of the remnants of edible plant cells, polysaccharides, lignin and associated substances resistant to (hydrolysis) digestion by the alimentary enzymes of humans.". This definition defines a macro-constituent of foods which includes cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, and pectins and associated minor substances such as waxes, cutin, and suberin.

In 1992, to reaffirm that the scientific community was pursuing the appropriate path with regard to dietary fiber methodology, Lee and Prosky (43) conducted an international survey of 147 involved professionals. Sixty-five percent of the scientists supported the current physiological definition as "remnants of plant cells, polysaccharides, lignin, and associated substances resistant to hydrolysis (digestion) by the alimentary enzymes of humans. An additional 5% of scientists favored using this physiological definition in combination with a chemical definition. Fifty-nine percent supported the inclusion of digestion-resistant oligosaccharides. In a follow up survey in 1993 (44), 65% of the respondents favored inclusion of nondigestible oligosaccharides, and 80% supported the inclusion of resistant starch. At the AOAC International Workshop on Definition and Analysis of Complex Carbohydrates and Dietary Fiber held in Memphis, TN, in 1995, there was general agreement on the need for a physiological definition of fiber, and the inclusion of digestion-resistant oligosaccharides in that definition. In summary, the surveys and workshop determined:

- 1) "The term "dietary fiber" should be preserved."
- 2) "The definition of dietary fiber should be based on chemical and physiological perspectives. Currently, dietary fiber is defined as either the sum of lignin and polysaccharides that are not hydrolyzed by human alimentary enzymes (i.e., dietary fiber is the sum of resistant starch, nonstarch polysaccharides, and lignin), or the remnants of plant components resistant to human alimentary enzymes." (In this case the former definition received more support than the latter.)
- 3) "Oligosaccharides that escape the human small intestine are considered dietary fiber. This finding suggests that the definition of dietary fiber should be revised to include resistant or unavailable oligo- and polysaccharides and lignin that are resistant to hydrolysis."

The workshop participants acknowledged that the *de facto* defining methodology (AOAC 985.29) did not quantitate some unique components of dietary fiber. In particular, the ethanol precipitation step excludes many non-digestible water-soluble oligosaccharides and polysaccharides, including fructans of nearly all degrees of polymerization. Polydextrose, an analogous carbohydrate, which has some polymers with a DP as high as 120, is also not precipitated. Since methodology was lacking for some portions of dietary fiber, it behooves researchers to develop, validate, and adopt appropriate methodology commensurate with the definition.

THE CONSTITUENTS OF DIETARY FIBER

While the makeup and appearance of dietary fiber may seem obvious at first glance, i.e. the stringy material in celery, the bran portion of the wheat kernel, etc., chemical characterization turns out to be more complex. Publications by the early researchers in dietary fiber indicate that the constituent makeup of dietary fiber has been the topic of scientific discussion for nearly as long as the term has been used (45-50). These early discussions concluded that the constituents of dietary fiber are the same constituents making up dietary fiber today. Analyses of foods for this constituent makeup forms the basis for the dietary fiber values used in data tables. These analytical results are also used in the research upon which the purported health benefits of dietary fiber are based. Specifically, the definition of dietary fiber preferred by scientists worldwide in a 1979 survey (51,52) included cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, pectins, and associated minor substances such as waxes, cutin, and suberin.

The current regulatory situation in the US, as well as in a number of other nations, with regard to dietary fiber labeling is arbitrary due to its reliance on methodology as opposed to being based on an accurate definition. This was also the case with the labeling of fats, fats labeling too being based upon proximate method definitions, until the Nutrition Labeling and Education Act (NLEA) regulations (53), which clearly defined fat as the sum of the fatty acids expressed as their triglycerides present in foods. Protein labeling has been somewhat less arbitrary, there being various conversion factors (for nitrogen to protein content) developed for various commodities through the decades to most accurately reflect true protein content. As with fats, protein was more accurately defined under NLEA when the required use of the protein digestibility amino acid score was included in the daily values for protein content in foods. With the current dietary fiber labeling situation, i.e. labeling based on methodology as opposed to definition, compounds can be designed, or isolated and concentrated, that will be considered dietary fiber because they are enzymatically non-digestible and are insoluble in 4 parts ethanol, 1 part water. These compounds are considered dietary fiber by current regulatory standards. However, other compounds can be designed, or isolated and concentrated, that are non-digestible in the small intestine, fermentable in the large intestine, and exhibit positive physiological effects, but are not considered dietary fiber under arbitrary, method driven, labeling protocols. This issue, in part, arises as a result of history. When definitions for dietary fiber, and consequently methods developed, were under consideration in the 1970s, some of the food components with dietary fiber characteristics and properties were relatively unknown and certainly not well researched. Thus methods developed at that time may have been believed to be all-inclusive, but in fact were not.

Fructans, i.e. inulin and oligomers of fructose (polymerized fructose often having a glucose molecule on the non-reducing end), are clearly included in this definition, just as they were in the previous working definition. Unfortunately, they have historically not been properly quantitated and included in the dietary fiber total value for foods due to the limitations of the proximate methods adopted for dietary fiber determination. Fructans are present in a wide variety of sources at various levels (54). As such, fructans have always been a part of the diet. Just as celluloses and hemicelluloses are components of the foods in our diets, so too are fructans. And, just as the celluloses and hemicelluloses have been concentrated from their respective plant sources and are readily accepted for use as fiber ingredients for foods and supplements (e.g. partially hydrolyzed guar gum, gum arabic, psyllium seed husks, pectin, cellulose from wood pulp, etc.), so too have inulin and oligofructans been isolated and concentrated for these purposes. Unfortunately, due to the reliance on methodology as the de facto definition of fiber for regulatory purposes in the past, fructan-containing products were never properly labeled, i.e. fructans were never properly included in the dietary fiber quantity. A definition need not, and as a matter of practice should not, be governed by analytical methodology per se. In a regulatory situation, regulations should not be promulgated that cannot be enforced, but methodology must be adapted to a definition rather than vice versa.^a Methods have now been developed and adopted as Official Methods of Analysis for the accurate quantitation of fructans in foods (see below), so the quantity can be added to the other fibers present to give the total dietary fiber content of the food.

Analogous fibers, i.e. modified celluloses, synthesized polymers, and resistant starches, have been the center of scientific discussion for fiber scientists for some time. Modified celluloses such as methyl cellulose and hydroxypropylmethyl cellulose have long been accepted as dietary fiber simply because they are quantitated by the Official dietary fiber methods utilized since the mid 1980s. Synthesized carbohydrate polymers such as polydextrose often have had more studies completed regarding their functional and physiological properties than the aforementioned celluloses, but have not necessarily been considered dietary fiber because they are not quantitated using the said dietary fiber methods. Resistant starches, whether purposefully manufactured through heat and chemical modification (such as non-digestible dextrins manufactured using heat and acid), by selecting (or debranching) and purifying high-amylose starches that crystallize into non-digestible form(s), or produced by typical food processing procedures such as extrusion cooking, may or may not have been quantitated as dietary fiber depending upon whether or not they were quantitated

by the dietary fiber method(s). All these analogous fibers demonstrate some characteristics of dietary fiber, and determination of whether or not they demonstrate the physiological benefits of dietary fiber will determine whether or not they should be labeled as such. Resistant starches, in particular, require special consideration. By definition, resistant starches are resistant to digestion and absorption in the human small intestine. This resistance can provide benefits by reducing the caloric value of the food while providing energy to the bacteria of the colon, thus enhancing healthy fermentation there (55). This resistance is found in retrograded amylose, physically trapped starch, digestion-resistant starch granules, and fragments of chemically and thermally modified starches. Resistant starch has been somewhat arbitrarily divided into subcategories (56) based on analytical chemical tests rather than on research of physiological benefits. Resistant starch is not the only starch that reaches the colon to serve as energy for fermentation. Other portions of the starch in foods reach the colon as well, the quantity being somewhat dependent upon the makeup of the diet. Further, the relative quantity of resistant starch in foods is often constantly changing with the exception of the chemically or thermally treated starches. Resistant starch found in raw or immature fruits and/or vegetables often decreases with ripening or cooking. Resistant starch in the form of retrograded amyloses, physically trapped starches, and starch in granules is usually rendered digestible upon cooking. From a research perspective, such starches can be characterized and studied with regard to their potential benefits, but from a dietary fiber definition perspective and from an analytical perspective for regulatory food labeling, the food must be at a degree of ripeness typically eaten, and the resistant starch must remain resistant to enzymatic digestion through accepted standard sample treatments such as gelatinization as would be expected to occur during food processing and preparation. Thus, the resistant starches which consistently resist digestion in well-designed fiber assays (57) should be classified as dietary fiber. The resistant starch needs to be resistant to digestion by properly chosen enzymes after relevant sample treatment steps such as gelatinization. Additional resistant starch may demonstrate the physiological and beneficial effects of dietary fiber; however, from a practical perspective they cannot be considered dietary fiber since their resistance to digestion cannot necessarily be controlled in other than experimental situations, and thus cannot be properly labeled.

The updated definition of dietary fiber includes the same constituents as the historical definition but the verbiage has been expanded to detail the makeup and proven physiological effects of the dietary fiber. The emphasis should no longer be based on methods as defining. Thus, dietary fiber includes all non-starch polysaccharides resistant to digestion in the small intestine and fermentable in the large intestine. Non-starch polysaccharides include celluloses, hemicelluloses such as arabinoxylans and arabinogalactans, pectins, modified celluloses, fructans (oligomers and polymers of fructose, i.e. inulin), gums, and mucilages. Oligosaccharides, such as oligofructans, include the lower molecular weight analogues of the digestion-resistant polysaccharides. Analogous carbohydrates, i.e. polysaccharides having the digestion resistance, fermentation, and physiological properties of naturally sourced dietary fibers, are included. Lignin and the plants substances associated with the non-starch polysaccharides are an integral part of the fibrous portion of plants. Lignin, a polyfunctional polymer is intimately formed with and infiltrates the cellulose of plant cell walls and is very resistant to digestion, even with strong acid. Likewise waxes and cutin, found as waxy layers at the surface of the cell walls, are made up of highly hydrophobic, long-

^a Proximate analyses often are used to determine the quantity of food constituents which are not a single concise or multiple concise additive chemical entities. Although a "proximate" assay, of necessity, is said to define the desired result, it is generally understood that the proximate assay be designed to reflect the definition of its respective "analyte." For example, while Kjeldahl nitrogen is the proximate assay method for protein, different calculation factors are used to convert from nitrogen to protein for different matrices, thus achieving a more accurate measurement of protein, defined as the polyaminoacids present in that matrix.

chain hydroxy aliphatic fatty acids and are resistant to digestion and probably render the associated tissues resistant to digestion (58). Suberin, while not well characterized, is hypothesized to be a highly branched and cross-linked combination of polyfunctional phenolics, polyfunctional hydroxyacids, and dicarboxylic acids (59) that are likely linked to the cell wall with ester linkages. Evidence of its intimate interaction with other dietary fiber components is the fact that only suberin-enriched fractions, but never purified suberin, have been prepared. And finally, phytate (phytic acid), tannins and saponins that are part of the dietary fiber complex are included. The constituents of dietary fiber are summarized in the table below.

CONSTITUENTS OF DIETARY FIBER

Non-Starch Polysaccharides and Resistant Oligosaccharides
Cellulose
Hemicellulose
Arabinoxylans
Arabinogalactans
Polyfructoses
Inulin
Oligofructans
Galactooligosaccharides
Gums
Mucilages
Pectins
Analogous Carbohydrates
Indigestible Dextrins ^b
Resistant Maltodextrins (from corn and other sources)
Resistant Potato Dextrins
Synthesized Carbohydrate Compounds
Polydextrose
Methyl cellulose
Hydroxypropylmethyl Cellulose
Indigestible ("resistant") Starches ^c
Lignin

Substances Associated with the Non-Starch Polysaccharide and Lignin Complex in Plants

Waxes Phytate

Cutin

Saponins

Suberin

Tannins

THE NUTRITION/PHYSIOLOGY OF DIETARY FIBER

"Dietary fiber is 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."

Clearly, a physiological basis for the definition of dietary fiber is necessary. If it were not for the physiological effects of dietary fiber, there would be no interest in the subject on the part of either researchers, consumers, regulators, and manufacturers. The objective of ethical nutrition research is to determine those physiological factors (nutrition factors) that improve and optimize the quality of life in terms of increasing life span, and/or improved health resulting from improved body function and increased overall comfort. The term dietary fiber was coined and its definition refined based on observations of positive health effects related to consumption of diets rich in this component.^d At various times in history, links between insufficient dietary fiber consumption and constipation, diverticular disease, hiatus hernia, appendicitis, varicose veins, hemorrhoids (piles), diabetes, obesity, coronary heart disease, cancer of the large bowel, gallstones, duodenal ulcers, breast cancer, and blood clotting have been hypothesized. Obviously some, but not all, of these hypotheses have proven valid. Foods are very complex biosystems, especially with regard to how they are processed in the human body. Dietary fiber is no exception. Multiple components make up dietary fiber in foods as discussed above. For those hypotheses that have proven valid, dietary fibers isolated from particular sources have not necessarily been shown to induce all the positive effects but have been shown to produce one or more of them, particularly when they are part of high fiber foods. Three physiological impacts characteristic of insufficient dietary fiber consumption have proven to be consistently present as a result of almost 50 years of research. These physiological impacts of insufficient dietary fiber intake are constipation, increased risk of coronary heart disease, and increased fluctuation of blood glucose and insulin levels. Inclusion of these key physiological properties in the definition of dietary fiber is not only prudent, but it would be scientifically short-sighted to exclude health effects that the body of scientific evidence supports. As scientific evidence accumulates on the other hypothesized links between dietary fiber and health, it will behoove scientists in the future to update the definition to reflect the changing state of knowledge.

Including the physiological effects of the nutrient in the nutrient's definition is not unique to dietary fiber. Indeed, wherever a nutrient group, or a nutrient, covers a broad mixture of components, physiological functionality is either apparent or defined. Protein in food, from a nutrition-labeling standpoint must have demonstrated physiological function as assessed by the protein digestibility adjusted amino acid score (PDAAAS) procedure (60). The term vitamins, although no longer restricted to amine compounds, nonetheless can only apply to compounds essential for one or more body functions and those compounds cannot be synthesized in amounts adequate to meet the normal physiological needs of humans (61). The body of evidence amassed on the physiological effects of dietary fiber(s) is substantial and continues to grow. The majority of the research has been conducted on dietary fiber(s) eaten as part of the food of which they are a component, or as isolates from that food. As the knowledge of dietary fiber grows, and the expertise of food scientists increases, the opportunity and ability to synthesize "dietary fiber," i.e. analogous carbohydrates will increase. The analogous carbohydrates must demonstrate one or more of the beneficial physiological properties observed during the research on dietary fiber.

Laxation

Laxation is a very important physiological effect that results from increasing the dietary fiber component of one's diet in place

^b Typically produced by acid or thermal treatments of starch hydrolysates, rendering the hydrolysate or portions thereof indigestible.

^c Includes only those starches that are resistant to digestion in humans and resistant to digestion in properly designed analytical methods that include gelatinization steps to simulate cooking and processing.

^d Concern about the constituency and state of foods eaten was expressed long before the term dietary fiber was coined. "And this I know, moreover, that to the human body it makes a great difference whether the bread be fine or coarse; of wheat with or without the hull, whether mixed with much or little water, strongly wrought or scarcely at all, baked or raw and a multitude of similar differences; and so, in like manner, with the cake; the powers of each, too, are great, and the one nowise like the other. Whoever pays no attention to these things, or, paying attention, does not comprehend them, how can he understand the diseases which befall a man?" from *The Genuine Works of Hippocrates*, translated by Francis Adams, 1939, The Williams and Wilkins Company, Baltimore, MD, USA.

of other food components. It is a physiological effect that is almost taken for granted, and clearly imparts comfort and positive feelings to the consumer. The discomfort of constipation, and the potential for increasing the risk of other diseases resulting from constipation such as diverticular disease and hemorrhoids cannot be understated. Positive nutrition effects include improved body function and increased overall body comfort. Improved laxation fits in both categories. Increased dietary fiber in the diet results in an increase in fecal bulk, reduced transit time of fecal material through the large intestine, increased frequency of defecation, improved regularity of defecation, and reduced hardness of stools. Accompanying this there is typically a shift to a lower colonic pH, an increase in intestinal microflora populations and a change in intestinal microflora species distributions, all considered beneficial. Softer stools result in less discomfort to the colon and anus at time of elimination and less strain on the muscles involved in defecation. In 1986 (62) the cost of gastrointestinal diseases was estimated at \$17 billion per year, \$1.2 billion of it for over the counter and prescription drug products for gastrointestinal diseases, and \$450 million for laxatives. The cost is continuing to increase. In 1999, the spending for laxatives had increased to \$870 million (63). An Australian health survey (conducted via the postal service) completed by 14,761 young (18-23 years), 14,070 middle-aged (45-50 years), and 12,893 older (70-75 years) women reported in 2000 (64) showed constipation as a problem for 14.1% of the young, 26.6% of the middle-aged, and 27.7% of the older women. Hemorrhoids affected 3.2% of the young, 17.7% of the middle-aged and 18.3% of the older women. One third of the young women and half of the middle-aged and older women had sought help for their constipation. In a telephone interview conducted between June and September of 1997 of 10,018 individuals in the United States regarding 15 constipation-related symptoms (65), an overall constipation rate of 14.7% was found, with some 45% of the individuals with constipation reporting having had the condition for 5 years or more.

Burkitt et al, in 1972 (66), compared various population groups and found that those on high fiber diets produced stools of 150-980 (average 275 for children, 470 for adults) grams/day, with transit times of 19-68 hours (average 33.5 for children, 35.7 for adults). Those on low fiber produced stools of 39-195 (average 173 for children on a high fruit diet, 110 for teenagers, and 104 for adults) grams/day with transit times of 28-144 hours (average 48 for children on a high fruit diet, 76.1 for teenagers, and 83.4 for adults). The group consuming a mixed diet in terms of dietary fiber content produced stools of 48-488 (average 165 for children, 185 for teenagers, 155 for nurses, 175 for hospital patients, and 225 for vegetarians) grams/day with transit times of 18-118 hours (average 45.2 for children, 47.0 for teenagers, 44.0 for nurses, 41.0 for hospital patients, and 42.4 for vegetarians).

In an 80-day metabolic trial using 24 adult male subjects (67), coarse wheat bran, fine wheat bran, cellulose, and ethanolextracted cabbage fiber baked into breads were compared to a basal diet. Total feces, fecal dry matter, total fecal water, and number of defecations were all increased for the coarse bran, the fine bran and the cellulose. Only the number of defecations was significantly increased for the ethanol-extracted cabbage fiber. Transit times were reduced for the coarse bran, fine bran, and cellulose as well, the coarse bran and cellulose significantly so.

Jenkins et al (68) demonstrated a dose-response correlation of 0.983 between soft white winter wheat fiber intake added to the diets of 73 subjects and daily fecal weight, with the effect stabilizing after one week of supplementation.

In a study completed by 81 postoperative, orthopedic patients, addition of wheat bran to the diet promoted spontaneous bowel elimination, improved bowel function and decreased the need for laxatives, although it did not eliminate constipation completely (69).

Stool weights of less than 100 g/day have been associated with constipation and correlations have been established between dietary fiber intake and stool weight (70).

In a study comparing cellulose and barley bran flour to their respective unsupplemented diets, involving 22 subjects, barley bran For 16 healthy young males, diets containing 0, 30, and 60 g/day of soy fiber showed increases in daily fecal excretion and stool frequency with reduced transit times for the fiber-supplemented liquid diets, although stool sizes remained relatively unchanged (72).

Inulin, when taken at 20 grams/day and 40 grams/day increased stool frequency in 9 of 10 constipated elderly female subjects while decreasing the percentage of dry weight in the feces (73).

A human study of 120 healthy volunteers evaluated the effect of 4, 8, and 12 grams of polydextrose intake per day on physiological function (74). Bowel function (frequency and ease of defecation) improved, fecal weight (wet and dry) increased and fecal pH decreased in proportion to polydextrose intake.

Two studies with 12 healthy human volunteers in each comparing the effects of 7 grams/day of isphagula husks (psylium), 30 grams/day of polydextrose, and mixtures of 2 grams/day psylium with 10 or 30 grams per day of polydextrose intake found that fecal weight and softness increased for all treatments compared to unsupplemented control diets (75).

An increase in fecal bulk and a decrease in fecal pH were observed with the consumption of 15 grams per day of polydextrose (76).

In a study of indigestible dextrins, consuming 35 g/day for 5 days resulted in increased stool weights and frequencies while the water content remained unchanged (77).

In a study of 128 healthy volunteers with a tendency to constipation, consumption of beta-1,4-galactooligosaccharides resulted in softer stools and increased defecation frequency (78).

Fourteen female subjects of ages 69-87 suffering from constipation were given 9 grams/day of galactooligosaccharides in yogurt, which increased the average defecation frequency from 5.9 to 7.1 per week and seemed to make defecation easier based on individual responses (79).

The consensus report of the European Non-Digestible Oligosaccharides concluded there is convincing evidence that consumption of non-digestible oligosaccharides stimulates bowel habit (80).

Jenkins et al (81) conclude that in most studies, inulin or oligofructose produce a small increase in fecal bulk. According to Gibson et al (82), doses of 10-20 g/day produce a 1.3 g increase in fecal weight for each gram of oligofructose consumed as compared to a 2.0 gram increase for inulin from chicory roots.

Partially-hydrolyzed guar gum given 3 times a day in 12 gram dosages as a beverage after every meal, increased fecal weight and output frequency in eight healthy men over the course of a fourweek study (83).

Fifteen women aged 18-48 years suffering from constipation consumed 8.2 grams/day of partially hydrolyzed guar gum in addition to an average daily intake of 9.2 grams/day of other dietary fibers. Defecation frequency increased by 37% and fecal moisture increased from 69.1 to 73.8% (84).

Adding 20 grams of partially-hydrolyzed guar gum per liter of enteral feeding solution resulted in a significant decrease in cases of diarrhea in a study involving 100 patients on total or supplemental enteral nutrition (85).

In tests with ileal cannulated dogs, both galactooligosaccharides and indigestible maltodextrin-like oligosaccharides increased fecal weights (86).

Blood Cholesterol Attenuation

Reduced risk of developing and consequently dying from coronary heart disease (CHD) was amongst the earliest observations of workers in dietary fiber research, with subsequent inclusion in the "dietary fiber hypothesis" (87,88). The quest for an extended life span and greater comfort has certainly been a driving force for the numerous studies undertaking research on the impact of increased dietary fiber consumption on coronary heart disease risk since that time. Coronary heart disease and the associated risk thereof is a long-term onset disease, and correlations between dietary fiber intake and the disease rely primarily upon epidemiological studies (89). A 12-year study of 859 southern California men and women showed that a 6-gram increment in daily fiber intake was associated with a 25% reduction in ischemic heart disease mortality (90). There is no short-term marker for coronary heart disease per se to use as an index to effectively measure the effect of experimental diet changes. However, total plasma cholesterol and lowdensity lipoprotein-associated (LDL) cholesterol are accepted as biomarkers indicative of changes in risk level of the disease. Reductions of total and LDL-cholesterol levels toward prescribed norms are considered acceptable measures of reduction in risk of CHD. Therefore, research in this arena has primarily focused on the ability of dietary fibers, when consumed at high versus low levels, to reduce cholesterol. A recent meta-analysis of 67 controlled studies focusing on soluble dietary fibers showed a significant reduction in serum cholesterol with increased dietary fiber intake (91). Oat products (25 studies), psyllium (17 studies), pectin (7 studies), and guar gum (18 studies) were examined. A 1992 review (92) concluded that wheat fiber and cellulose do not consistently reduce serum cholesterol, whereas pectin, guar, oat fiber, and legumes do. Scientific consensus on the evidence for the role of dietary fiber in reducing the risk of CHD has long been acknowledged. In 1993 the regulations for the Nutrition Labeling and Education Act allowed claims that high fiber foods, i.e. whole grains, fruits and vegetables, may be effective in reducing CHD risk (93). Subsequently, specific claims for oat and oat bran products and psylium products have also been allowed (94), based in part of the results of extensive meta-analyses of the research data accumulated on these two foods in recent decades.

In a group of 10 hospital employees, three normal weight, three overweight, and four obese with elevated serum cholesterol, diets high in fiber resulted in significant reductions in serum cholesterol (95).

In a study of 17 subjects with elevated cholesterol, an intake of 150 grams/day of rolled oats (50 g at breakfast, 100 g throughout the day) resulted in a significant reduction of total and LDL cholesterol (96).

A twelve-week study utilizing 208 healthy men and women demonstrated that consuming oat products along with the AHA fat-modified eating style resulted in approximately 3% lower serum cholesterol than the reduced-fat diet alone (97). A study of 156 patients on a diet of various levels of beta-glucan (in the form of oat meal and oat bran) allowed the researchers to conclude the study "demonstrates that an acceptable form of water-soluble fiber, beta-glucans in oat cereals, is effective in lowering serum cholesterol levels in conjunction with a low-fat diet in a dosedependent manner" (98). Seventy-one free-living men and women with hypercholesterolemia demonstrated significant reductions in serum cholesterol with 50 g/day of oat bran and 42.5 g/day of processed oat bran (99). In an alternating sequence diet scheme using eight men with hypercholesterolemia, a reduction in total serum cholesterol was demonstrated for oat bran (100 g/day) (100). A study of 236 participants put on the AHA diet, and the AHA diet supplemented with oatmeal supported previous findings that inclusion of oatmeal in a fat-modified diet is helpful in lowering serum cholesterol, particularly in individuals with elevated serum cholesterol levels (101).

In ten healthy male subjects, soy hull fiber and hard red spring wheat bran were shown to decrease total cholesterol while not affecting high-density lipoprotein cholesterol (102).

In a review of some rat model studies, Anderson and Hanna (103) report serum cholesterol reductions ranging from 11-32% and corresponding liver cholesterol reductions ranging from 17-52% with feeding of soluble or viscous fibers.

A fiber-based dietary supplement consisting of 75% soluble fiber (approximately equal parts of psylium and pectin) and 25% insoluble fiber (equal parts of soy, pea, and corn fibers) given in 10gram (40 subjects) and 20-gram (39 subjects) dosages, respectively, showed decreases in total cholesterol and LDL-cholesterol and decreases in LDL/HDL ratio compared to a placebo group (48 subjects) (104). Changes over a 15-week period for the placebo group, the 10-g supplement group, and the 20-g supplement group were: Total cholesterol; 0.4%, -5.8%, -4.9%; LDL cholesterol; -0.4%, -8.1%, -7.3%; LDL/HDL; 1.0%, -5.6%, -8.7%, respectively. The supplement was taken immediately before a meal and was mixed into a beverage.

In a 14-day study comparing 18 non-insulin-dependent diabetic subjects taking 8 grams/day of fructooligosaccharides to 10 non-insulin-dependent diabetics taking 5 grams/day of sucrose, the subjects upon taking fructooligosaccharides showed a significant (8%) decrease in total serum cholesterol and a significant (10%) decrease in LDL cholesterol while HDL cholesterol and triglyceride levels were not significantly affected (105).

In the 10-year Coronary Artery Risk Development in Young Adults study involving 2,909 healthy black and white adults aged 18-30 years, increased intake levels of dietary fiber were associated with lower levels of serum high-density lipoprotein and low-density lipoprotein cholesterol (106).

In a study of hyperlipidemic patients with non-insulin-dependent diabetes mellitus, administration of 20 grams of indigestible dextrin with each meal for 12 weeks resulted in reduced fasting serum cholesterol (107).

Partially hydrolyzed guar gum given 3 times a day in 12-gram dosages as a beverage after every meal, significantly decreased the serum cholesterol in eight healthy men over the course of a fourweek study (108).

In a study involving twelve healthy male volunteers, 22-23 years of age with body mass indices of $25.7 + -1.2 \text{ kg/m}^{-2}$ (mean +/– s.e.m.) comparing a rice-based cereal and a rice-based cereal containing 18% inulin, a decrease in total serum cholesterol of 7.9% and serum triglycerides of 21.2% was observed (109).

In a study with twelve hypercholesterolemic men, a weak trend toward total serum cholesterol reduction was noted when 20 grams of inulin was substituted for sucrose per pint of ice cream, with one pint of ice cream being consumed daily. The decreases were serum cholesterol concentration dependent, subjects with serum cholesterol levels of >250 ng/dl tending to have the greatest reductions (110).

In a conflicting report (111), based on a study involving 20 patients with Type 2 diabetes, 15 g/day of fructooligosaccharides did not significantly lower serum cholesterol when compared to 4 g/ day of glucose.

In a feeding study with rats on an 8-week high-sucrose diet with and without 5% supplementation with either indigestible dextrin or pectin, serum cholesterol was significantly reduced with the supplementation (112).

The nature of a fiber can sometimes have an effect on the amount of cholesterol reduction. In some cases the viscosity of the fiber in solution is important. An investigation of beta-glucan with and without treatment by degrading enzymes supported the hypothesis that higher molecular weight beta-glucan is more effective than lower molecular weight beta-glucan in increasing bile acid excretion (113). A synthetic fiber, hydroxypropylmethylcellulose, shown to reduce plasma cholesterol and produce a positive plasma cholesterol profile in humans (114) produces significant differences in the relative cholesterol attenuation as a function of viscosity when studied in hamsters (115). On the other hand, native and partially hydrolyzed psyllium had comparable effects on cholesterol metabolism in rats (116).

Dietary fiber may be reducing total body cholesterol, even when a significant reduction in serum cholesterol does not occur. Oda et al. (117) showed that rats on diets supplemented with soluble fiber fractions from oat, barley or wheat had lower liver cholesterol even though their plasma cholesterol was not significantly lower. Insoluble dietary fiber fractions also lowered liver cholesterol, but not significantly.

Blood Glucose Attenuation

Diabetes and the numerous other health maladies that accompany it have been a concern of the human population since the inception of recorded medical research. Each year it continues to extract a tremendous toll in both money and human misery. Diabetes is of increasing concern, as it appears the number of cases of diabetes (particularly Type II diabetes) will increase substantially in the next few decades. Increasing from 30 million estimated cases worldwide in 1985 (118) to 120 million cases in 2000 (119), the number of cases is estimated to rise to 220 million in 2010 (120), and further to 300 million in 2025 (121). An association between insufficient dietary fiber intake and increased risk of diabetes has been postulated as far back as 1973 (122,123). Although a direct and irrefutable linkage between insufficient dietary fiber intake and diabetes has not been established, significant research since that time has indicated decreased risk of the disease with increased dietary fiber consumption. Shortly thereafter, Kiehm et al (124), Anderson and Ward (125), Rivellese et al (126) and Simpson et al (127) designed and carried out a series of studies that showed beneficial effects of high fiber diets for individuals afflicted with the disease. Beneficial effects of increased dietary fiber consumption were shown for both Type 1 and Type 2 diabetics and included improved glucose tolerance, reduced insulin requirements, increased peripheral tissue insulin sensitivity, decreased serum cholesterol, decreased serum triglycerides, better weight control, and potentially consistently lower blood pressure (128). Soluble dietary fibers, either as part of a food or as a supplement well mixed with food appear to exhibit the greatest therapeutic effect (129-131). Anderson et al (132) in 1987 summarized a number of studies that used adequate controls, were two weeks or longer in a metabolic ward, or six weeks or longer in ambulatory populations, had a minimum of eight subjects, and an increase of 20 gm/day of fiber from foods or 8 gm/day from supplements. Of the eight studies of supplemented diets reviewed, and the 11 studies of high fiber food diets reviewed, 17 studies reported decreased fasting blood glucose levels ranging from 6-39%, 13 of which were statistically significant. One of the means of directly measuring an immediate physiological effect of dietary fiber and high fiber foods is the attenuation of glucose levels in the blood for several hours after ingestion of the food. Ingestion of a given amount of glucose causes a rapid rise in serum glucose levels, reaching a peak level in 30 to 60 minutes after ingestion. This is followed by a fairly rapid decline in serum glucose over the next 30 to 60 minutes as the body's insulin secretion increases in response to the increased glucose level. After approximately two hours the serum glucose level typically returns to a level equal to or lower than the level just prior to glucose ingestion. For foods that are easily and rapidly digested, the serum glucose response closely follows the pattern of glucose when ingested. For other foods, such as high fiber foods, the rise in serum glucose is much slower and does not reach as high a maximum level. Similarly, the decline in serum glucose level after reaching the peak is less rapid. This change in serum glucose behavior can be measured in a number of ways. One can measure the change in level from preingestion to the peak level, or the change in slope in the rise of glucose level. The most common approach, referred to as the glycemic index approach (133), involves measuring the area under the serum glucose peak following the ingestion of the food, and comparing it to the area under the serum glucose peak following the ingestion of a standard dose of glucose. Thus the glycemic index is indicative of an attenuated serum glucose and consequent insulin response following food ingestion. The glycemic index was shown to correlate to dietary fiber content by Wolever in 1990 (134). By 1995 data from almost 600 glycemic index tests had been accumulated on a wide variety of foods (135).

Wolever and Jenkins (136) showed that guar gum, adequately mixed into a food, reduced the postprandial blood glucose response by 44%, pectin reduced it by 29%, psyllium by 29%, other gelling fibers (gum tragacanth, methyl cellulose, locust bean gum, agar, Konjac mannan) by 23%, wheat bran by 27%. Other non-gelling fibers, besides wheat bran, that were studied reduced post-prandial blood glucose response by 17%, but the result was not considered statistically significant even though five of the seven fibers showed a glucose response reduction, one showed a reduc-

tion and an increase, and one fiber showed a glucose response increase. In a study of guar, pectin, gum tragacanth, methylcellulose and wheat bran, Jenkins et al (137) showed that each flattened the glucose response, with the reduction in mean peak rise in blood glucose concentration being positively correlated to viscosity. Wood et al (138) demonstrated that oat gum (14.5 g) gave similar patterns of glucose and insulin reduction as did guar gum (14.5 g) in humans when mixed into 500 mL of water containing 50 g of glucose.

Yokoyama et al (139) demonstrated that adding high fiber barley flour (beta-glucan enriched by milling and sifting) to pasta to increase the dietary fiber level from 4.1% dwb to 17.4% dwb resulted in reducing the area under the glucose response curve by over 50% in free-living, non-diabetic volunteers.

Nishimune et al (140) in 1991 demonstrated a nonlinear inverse correlation between the glycemic index and the dietary fiber content of a food. Further, similar correlations were drawn between the glycemic index and the insoluble dietary fiber component and the soluble dietary fiber component with a stronger dependency on the soluble dietary fiber component. Trout et al (141) demonstrated an inverse correlation between glycemic index and dietary fiber content of 18 starchy foods whether using log:log, semilog, or linear models.

Thorsdottir, Andersson and Einarsson (142) measured the postprandial glucose response of 15 healthy males fed a diet with or without sugar beet fiber added and found a significant reduction when subjects were fed the sugar beet fiber added diet.

Chandalia et al (143) conclude, based on a study of 13 subjects with Type 2 diabetes, that high intakes of dietary fiber above the level recommended by the American Dietetics Association (ADA), particularly fiber of the soluble type, improves glycemic control.

Onyechi et al (144) investigating two high fiber vegetable flours prepared from African plants found reductions in the area under the plasma glucose curve of 38-62% when comparing stews and breads prepared with the fiber added versus controls consisting of the same stews and breads without the fiber added.

In eight diabetic patients fed a fiber-rich diet, isocaloric with two low fiber diets for comparison; the high fiber diet showed significantly lower 2-hour postprandial glucose. The high fiber diet also showed significantly lower fasting blood glucose levels than one of the diets and significantly lower 24-hour urine glucose than both low fiber diets as well (145).

In ten healthy male subjects, soy hull fiber and hard red spring wheat bran were shown to decrease the area under the glucose tolerance curve, and the decrease was correlated to a decrease in total serum cholesterol (146).

In a study of insulin-dependent dogs (147) a diet high in insoluble dietary fiber showed a significantly lower area under the blood glucose curve than did a diet high in soluble dietary fiber or a diet low in dietary fiber. Fructosamine concentration was significantly lower in dogs fed the high fiber diets than the low fiber diet.

In a study of 8 healthy subjects, a 10-gram supplement of fructans isolated from Jerusalem artichokes reduced the area under the blood glucose response curve when fed halfway through a meal of 50 grams of wheat starch baked into bread (148).

In a study involving 120 subjects, ingestion of 12 grams of polydextrose mixed with 50 grams of glucose resulted in a lowering of the area under the glucose tolerance curve by 11% when compared to the ingestion of 50 grams of glucose alone (149).

ANALYTICAL METHODOLOGY

Analytical Methods Issues Overview

Adoption of the proposed definition for regulatory, research, and nutrition purposes will result in little change of analytical methodology, food labels, or food databases from the current situation. Current methodologies will continue to accurately quantitate the amount of fiber in the majority of foods, the exception being those foods containing a significant amount of dietary fiber which is soluble in a solvent mixture of 4 parts alcohol and 1 part water. This exceptionally soluble dietary fiber has heretofore been excluded from the quantity of dietary fiber reported on food labels and entered into database(s) for analytical, as opposed to definitional, reasons. Additional methods, or adjustments to current methods, which assure inclusion of the exceptionally soluble dietary fiber, will increase the reported dietary fiber level of a few foods, particularly foods high in fructans such as onions and leeks. As carbohydrates of analogous structure and behavior to dietary fiber are proven to have efficacy, additional increases in the dietary fiber content of composite foods may be evidenced as appropriate methodologies are adopted. Even though dietary fiber methods must, in practice, be proximate methods, nonetheless the proximate methods should quantitate, as closely as possible, the portion of food that matches the definition of dietary fiber. This is true with proximate methods in general, i.e. different conversion factors are used for nitrogen to protein in different grains, and moisture methods are adjusted to best match the matrices. Active participation by regulatory, industrial, and academic scientists in the defined method assessment procedures and the peer reviews necessary for adoption of Official and Approved methods will be a requisite to assuring that Official and Approved methods adopted for dietary fiber quantitate food components meeting the dietary fiber definition. Methods accurately fitting the definition will minimize regulatory confusion and result in accurate nutrition labeling of food products.

Method Requirements

Adoption of the definition for dietary fiber, i.e. "Dietary fiber is the remnants of the edible part of plants and analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the human large intestine. It includes polysaccharides, oligosaccharides, lignin and associated plant substances. Dietary fibers exhibit one or more of either laxation (fecal bulking and softening; increased frequency; and/or regularity), blood cholesterol attenuation, and/or blood glucose attenuation," will result in relatively few method changes or changes in food labels or food databases. Analytically inclusive components fitting this definition include cellulose, hemicellulose, lignin, gums, mucilages, oligosaccharides, pectins, waxes, cutin, and suberin. Analytical methodology useful for food labeling needs to effectively quantitate all of these components, while excluding all other food components. The analytical method also must quantitate the dietary fiber using a set of standardized conditions which will convert the food to the state of the food as it is most likely to be consumed. That is, the method should not quantitate "resistant starch" as dietary fiber merely because the starch is resistant to digestion because it is ungelatinized as it is found in the food product as labeled and sold, when there is a chance it will be cooked prior to consumption. Thus, a starch gelatinization step is necessary in any method developed for dietary fiber analysis as is a sample digestion step with enzymes that simulate the human digestion system to the closest extent possible in the laboratory.

Since 1981, the definition for dietary fiber that was used as the basis for dietary fiber method development and validation has been: "Dietary Fiber consists of the remnants of edible plant cells, polysaccharides, lignin and associated substances resistant to (hydrolysis) digestion by the alimentary enzymes of humans." Components covered by this definition also included cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, pectins, waxes, cutin, and suberin.

Applicable Methods (see also Appendix C)

In the 1981 definition, as in the proposed definition, dietary fiber is the remnants of the edible parts of plants resistant to digestion in the human small intestine. This resistance to digestion was, and remains, the key focus of the analytical method requirements. The first Official Method of Analysis developed based on the 1981 consensus definition was AOAC 985.29. This was also adopted by AACC as Approved Method of Analysis AACC 32-05. AOAC 985.29 is based on the premise of resistance to digestion. Human digestive enzymes are known to digest fats, proteins, and starch. Utilizing 985.29, the food samples are defatted, then heated to gelatinize the starch (the primary form of starch in foods as consumed), then subjected to enzymatic digestion by protease, amylase, and amyloglucosidase (glucoamylase) to remove the digestible components of the food. The residues are quantitated, and adjusted for protein and ash to assure against a protein contribution from the enzymes, and assure that inorganic materials present in the sample are not quantitated as dietary fiber. The enzymes utilized for starch and protein digestion are required to completely digest representative starch and proteins. (See enzyme purity test section in AACC Approved Method 32-05; also see table 985.29 in Official Method of Analysis 985.29). The method and the enzymes must also pass a purity of activity test to assure against extraneous enzymatic activity, i.e. to assure that the method does not destroy, and the enzymes do not digest any of the dietary fiber components listed above. Substrates to use to assure against extraneous enzymatic activity are listed in the referenced table and section. Other AOAC Official Methods of Analysis and AACC Approved Methods of Analysis adopted since that time have the same or similar method performance requirements, and are listed in Appendix C. While these methods have utilized somewhat different approaches to quantitate the digestionresistant portion of the food sample, the benchmark for accuracy has been the *de facto* defining method, AOAC 985.29.

Additional Methods Requirements

Since the time of the adoption of the consensus definition in 1981, and the adoption of Official Method of Analysis 985.29 in 1985, dietary fiber research has expanded dramatically. This expanded knowledge includes the discovery of "resistant starch," expanded knowledge of the physiological and chemical properties of fructans, including inulin, and the technical capabilities to produce edible carbohydrate-based polymers that are analogous to dietary fiber in their digestive and fermentative behaviors. The analytical methodology adopted in 1985 depends upon the fiber fraction isolated being insoluble in a mixture of 4 parts alcohol and 1 part water. This 4:1 solvent mixture is a traditional chemical means of separating simple sugars and other compounds from the more complex starches and proteins in the samples prior to the analysis of the simpler compounds. In the early 1980s, the 4-part alcohol, 1-part water solvent mixture was believed adequate for precipitating and isolating the dietary fiber from the enzyme digestion media. It is now evident that this mixture is not sufficient for the isolation of all dietary fibers, and additional methods need to be used in conjunction with AACC 32-05 (AOAC 985.29) or their equivalents to address those fibers not precipitated.

Fructan(s), because of the conformation of the molecule(s), are nearly 100% soluble in the 4-part alcohol, 1-part water mixture. As a result, they will not be isolated as part of the precipitate using 985.29 or equivalent methods. Fructans are part of the "remnants of the edible part of plants that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the human large intestine." Because fructans are not isolated as part of contemporary methodology, the recently adopted AOAC Official Method of Analysis 997.08, Fructans in Food Products, Ion Exchange Chromatographic Method (AACC Proposed Method of Analysis 32-21), or AOAC 999.03, Measurement of Total Fructan in Foods, Enzymatic/Spectrophotometric Method (AACC Proposed Method 32-32), must be used. In addition, a small amount of inulinase enzyme must be added during the enzymatic digestion steps of the contemporary methods to digest the small amount of fructan that co-precipitates with the rest of the fiber to avoid duplicate quantitation (150). Fructans are nonexistent, or occur in small quantities in most foods such as whole grains, fruits, and vegetables which are consumed in significant quantity. It is likely, there will be little impact on the food labels of these foods on a per-serving basis. A few foods, such as onions and leeks, contain high levels of fructans, so the food label of these products may need to be adjusted slightly on a per-serving basis when the inulin content is added to the fiber quantitated by contemporary methodology.

Polydextrose, like fructans, is also nearly 100% soluble in the 4part alcohol, 1-part water mixture, due to the highly branched nature and relatively low molecular weight of the molecule. No significant amount of polydextrose is measured as dietary fiber by AOAC Official Method 985.29 or equivalent, therefore AOAC Official Method of Analysis 2000.11, Polydextrose in Foods by Ion Chromatography, has recently been approved. For foods that contain polydextrose, this method can be used as an adjunct to AOAC 985.29 or equivalent methods in order to determine polydextrose as dietary fiber.

Advancing technical capabilities now allow the production of edible carbohydrate-based polymers that are analogous to dietary fiber in their digestive and fermentative behaviors. Since it is impossible to completely predict the analytical behavior of these analogous carbohydrates relative to the behavior of naturally occurring dietary fibers, methods for the analysis of other, currently available, analogous carbohydrate materials, or for those that may be developed in the future cannot currently be prescribed. Suffice it to say, that those involved with the research and production of such materials are best equipped with the knowledge and resources to develop appropriate analytical methods for their respective materials when used as an ingredient, and quantitated when used as part of a food product.

Subsequent to the adoption of Official Method of Analysis 985.29, researchers discovered that, in some foods, primarily processed grain products, a small percentage of the starch becomes resistant to the enzymatic digestion procedure of the method. This starch is truly resistant to digestion, resisting digestion in the human intestine (actually, additional quantities of starch typically pass into the large intestine with the resistant starch) and during the analytical processes for quantitating dietary fiber. In addition, starch in other foods also resists digestion, either because it is in a granular form, or because it has retrograded into a digestion-resistant crystalline domain. For labeling purposes, it is not clear what portion of this starch, if any, should be considered as dietary fiber. In some cases, the resistant starch is a component of a not fully ripened plant material. In other cases it is the result of incomplete cooking, or of heating and cooling the food product. In any of these cases, there is no consistent means of producing data for labeling purposes. Less than ripe plant materials can be ripened, or can be at various stages of ripeness when consumed. Less then fully cooked, or heated and cooled products can be cooked, or reheated or at various stages of cooling and crystallization, and the quantity of resistant starch changed before consumption. Therefore, for labeling purposes, utilizing the standardized methodology of AOAC 985.29 or equivalent provides the most reliable and accurate assessment of the quantity of digestively resistant starch that can consistently be delivered to the consumer at the time of consumption. For research purposes, other definitions for resistant starch and other methods for the quantitation of the resistant starch thus defined may be in order. But for labeling purposes, the starch that is truly resistant to digestion in a method that standardizes the treatment of the sample to simulate the likely state of the food at the time of consumption and digests the sample with enzymes that simulate the human small intestine is in order.

Adoption of Approved Methods and Official Methods in the Future

Adoption of AOAC International Official Methods of Analysis, and of AACC Approved Methods of Analysis requires adherence to the rigid standards of the Internationally Harmonized Protocol for Collaborative Studies, and thorough peer review. The thorough peer review involves input from regulatory, industrial, and academic sectors *via* participation as methods committee and technical committee members. This level of participation for all sectors, especially the regulatory sector, will need to continue to assure that any methods adopted for quantitation of dietary fiber or its components are relevant, and properly quantitate the food fraction meeting the dietary fiber definition. For individuals and/or organizations maintaining nutrition databases, it may be advisable, where possible, to segregate information on the quantity of fiber obtained using current contemporary methodology from the information on the quantity of fructans and analogous dietary fibers that make up the whole of the dietary fiber quantity. It this way, the data collected over the past 15-20 years will be fully usable for comparative purposes, and the updated data will more accurately reflect the total quantity of dietary fiber being ingested.

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ADDENIDIV A

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APPENDIX B	
Summary History—Dietary Fiber Definition	

Year	Event		
1953	Hipsley coins term "dietary fiber."		
1972-1976	Trowell et al define constituent makeup as part of their "dietary fiber hypotheses." This term was used to describe the remnants of plan cell wall components that are resistant to hydrolysis by human alimentary enzymes.		
1976	Trowell et al broaden definition to add all digestion-resistant polysaccharides (mostly plant storage saccharides), such as gums, modified celluloses, mucilages, oligosaccharides, and pectins. The broadened definition includes cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, and pectins and associated minor substances such as waxes, cutin, and suberin.		
1976-1981	Researchers Asp, Schweizer, Furda, Theander, Baker, and Southgate, among others, develop methods aimed at quantitating food compo- nent meeting definition.		
1979	Prosky begins process of developing worldwide consensus on definition of and methodology for dietary fiber.		
1981	Consensus on dietary fiber definition and analytical approach at AOAC Spring Workshop in Ottawa, Ontario, Canada		
1981-1985	Prosky, Asp, Furda, Scweizer, DeVries and Harland validate consensus methodology in multinational collaborative studies.		
1985	AOAC Official Method of Analysis 985.29, Total Dietary Fiber in Foods-Enzymatic-Gravimetric Method, adopted. Method becomes <i>de facto</i> working definition for dietary fiber.		
1985-1988	Methodology developed and collaboratively studied for insoluble and soluble dietary fiber.		
1991	AOAC Official Method of Analysis 991.42, Insoluble Dietary Fiber in Foods and Food Products, Enzymatic-Gravimetric Method- Phosphate Buffer, adopted.		
1988-1994	Lee, Mongeau, Li, and Theander and colleagues, taking a variety of approaches, develop, validate, and bring to Official Method status, methods fitting the definition of dietary fiber.		
1992	International Survey reaffirms consensus on physiological dietary fiber definition.		
1993	Second International Survey reaffirms consensus on physiological dietary fiber definition and reaffirms inclusive components.		
1995	AOAC International Workshop on Definition of Complex Carbohydrates and Dietary Fiber reaffirms consensus on physiological dietar fiber definition and inclusive components.		
1998	Definition of dietary fiber remains "Dietary Fiber consists of the remnants of edible plant cells, polysaccharides, lignin and associ- ated substances resistant to (hydrolysis) digestion by the alimentary enzymes of humans." This definition defines a macro con- stituent of foods which includes cellulose, hemicellulose, lignin, gums, modified celluloses, mucilages, oligosaccharides, and pectins and associated minor substances such as waxes, cutin, and suberin. AOAC 985.29 and equivalent methods are being used as <i>de facto</i> defining methods for dietary fiber		

1998	AACC assigns Scientific Committee to review definition of Dietary Fil	ber
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APPENDIX C		
Official and Approved Methods for Dietary Fiber Analysis*		

AOAC Official Method of Analysis (151)		AACC Approved Method of Analysis (152)	
Designation	Title	Designation	Title
AOAC 985.29	Total Dietary Fiber in Foods Enzymatic-Gravimetric Method	AACC 32-05	Total Dietary Fiber
AOAC 991.42	Insoluble Dietary Fiber in Foods and Food Products En- zymatic-Gravimetric Method, Phosphate Buffer	AACC 32-20	Insoluble Dietary Fiber
AOAC 991.43	Total, Soluble, and Insoluble Dietary Fiber in Foods- Enzymatic-Gravimetric Method, MES-Tris Buffer	AACC 32-07	Determination of Soluble, Insoluble and Total Dietary Fi- ber in Foods and Food Products
AOAC 992.16	Total Dietary Fiber, Enzymatic-Gravimetric Method	AACC 32-06	Total Dietary Fiber-Rapid Gravimetric Method
AOAC 993.19	Soluble Dietary Fiber in Food and Food Products, Enzy- matic-Gravimetric Method (Phosphate Buffer)		
AOAC 993.21	Total Dietary Fiber in Foods and Food Products with <2% Starch, Nonenzymatic-Gravimetric Method		
AOAC 994.13	Total Dietary Fiber (Determined as Neutral Sugar Resi- dues, Uronic Acid Residues, and Klason Lignin)-Gas Chromatographic-Colorimetric-Gravimetric Method (Uppsala Method)	AACC 32-25	Total Dietary Fiber-Determined as Neutral Sugar Resi- dues, Uronic Acid Residues, and Klason Lignin (Upp- sala Method)
		AACC 32-21	Insoluble and Soluble Dietary Fiber in Oat Products- Enzymatic-Gravimetric Method

* Equivalent AOAC International and AACC Methods are listed horizontally.

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