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To Whom It May Concern,

Within in the last few days, it has come to my attention that your office is seeking comments on a number of issues relating to food components, foods, nutrition and health. A colleague in the UK alerted me to your call for comments.

And while traveling at the moment, and your deadline for comments is just a day away, I humbly offer a few comments and questions related to my comments. I have not had, almost none, the adequate time to read all the information you have compiled, and I feel my comments might not specifically focus on your needs.

My colleague's bringing to my attention your call for comments was precipitated by the request for comments from our FDA regarding revision of food labeling regulations and specifically the *Nutrition Facts* panel. I am assuming that your call for comments has some relation to consumer education in the UK, and possibly to your food labeling standards.

While I submitted a lengthy letter of comments on a number of issues to the FDA, I provide these comments to you now with focus on the topic of dietary fiber.

One topic that caught my attention in your request is the presentation of a hypothesis and what research could be accomplished to test the hypothesis.

A few colleagues and I are hypothesizing that dietary fiber is an essential nutrient. A brief summation of our hypothesis is presented and in the context of the FDA addressing the food labeling of dietary fiber, setting a new Daily Value (DV) and other issues.

The intestine has multiple functions based on its physical, biochemical and physiological complexity. The intestine maintains its own ecosystem, the microbiome, most of which are obligate anaerobes within tissues that requires oxygen. There are microbiome systems associated with many areas of the body, but these organisms do not have the diversity, the sheer magnitude of the intestine, and the massive need for energy to grow and survive. The intestine and its microbiome survive in a symbiotic relationship. Dietary fiber's unique properties are it does provide for physical stimulation as it passes through the intestine while not digested in the small intestine, but a majority is fermented in the large intestine.

In the US, dietary fiber is defined as a statutory nutrient for the purposes of food labeling by the FDA. The US Institute of Medicine (IOM) describes it as a non-essential nutrient, because no dietary fiber deficiency symptoms are documented. However, one could argue that chronic constipation and its sequelae, including diverticular disease and hemorrhoids, are chronic disease endpoints. These endpoints were not considered for setting US DRI, specifically Adequate Intake (AI) values. Rather cardiovascular disease was used to establish the AI values for dietary fiber. The premise and convictions are that DF is essential to the initial and primary function of the intestine that is movement-laxation and then serves as the major and essential source of energy for the microbiome.

Why is DF a nutrient, how necessary is it and to be more specific how much is needed, and finally, is it an essential nutrient? These are the specific questions I ask the SCAN Secretariat.

While it is impossible to have a DF free diet comprised of usual foods, in the few instances of prolonged parenteral nutrition in humans, the intestine atrophies, nutrient digestion and absorption is greatly reduced in both the small and large intestine, and the lack of the microbiota creates health consequences, and possibly most significantly, the acquired/adaptive immune system is impaired. The gut microbiome also signals the CNS. These observations and dietary fiber's quintessential properties can be expanded upon beyond the presence of the microbiota and voiding of waste, laxation. Research data is accumulating that demonstrates how DF; 1) provides bulk (i.e. insoluble DF) and along with soluble DF, including

non-digestible oligosaccharides, DP 3-10, fosters intestinal maturation and movement; 2) affects the morphology, physiology, and cell distribution of the intestinal mucosa including an increased number of goblet cells; 3) contributes to the total number of bacteria per gram of feces and the metabolism by these bacteria; 4) distributes energy released in fermentation between the host and the bacteria via SCFA and; 5) affects the immune system.

In summary, I have presented a brief outline on my hypothesis that dietary fiber is an essential nutrient. My questions to the SCAN Secretariat are restated and expanded upon.

Why is dietary fiber a nutrient?

How necessary is it in the diet, and to be more specific, how much is needed?

In the US, it is estimated that dietary fiber intakes are approximately one-half of current AI recommendations of 25g and 38g/day for women and men, respectively. Since current dietary patterns/intakes, cannot meet recommended needs, what is the SCAN Secretariat's opinion and position of adding various forms of extracted/modified/synthesized to foods and beverages?

Is dietary fiber an essential nutrient?

I again offer my apology for not having read all the information you have provided to help in addressing your call for comments. However, with the thought that my comments to the FDA might have some relevance to your deliberations, I extract and provide my comments to the FDA that specifically relate to dietary fiber.

The term **Total Carbohydrate** should be retained on food labels as presently defined, and is the sum of all starches, sugars, dietary fiber and, sugar alcohols. Not on the food label, but could there be some value in helping the consumer learn about different forms of starch (e.g., amylose, amylopectin and, resistant starch), sugars (e.g., glucose, fructose, sucrose and, high fructose corn syrup), dietary fiber (e.g., insoluble, soluble, and soluble non-digestible oligosaccharide DP 3-10 [NDO: DP 3-10]) and, other carbohydrates (e.g., sugar alcohols and, uncommon

sugars (e.g., tagatose and allulose). The objective would be to educate consumers about these carbohydrates; they are in their foods and diets and these carbohydrates are safe. Too often today the consumer is bombarded through various medias that carbohydrates are bad. An example is presented of taking the information on the food label and expanding it to help the consumer better understand and appreciate the foods they eat.

Dietary Fiber (DF), is the sum of all non-digestible carbohydrate (poly- and oligosaccharides ≥ 3 DP units) naturally in foods or added to foods and beverages, not digested in the small intestine and passed to the large intestine where majorities are fermented. Dietary fiber is more than a statutory nutrient. It is an essential nutrient. The quintessential properties of DF are its ability to promote laxation and serve as the source of energy for the intestinal bacteria, the microbiota-microbiome. There is so much more to know and understand about the physiological benefits of the process generally described as laxation and influenced by dietary fiber. However, laxation has no sex appeal for the food industry or the consumer, or in health messages and or health claims.

It is said that specific carbohydrates may have different physiological effects (e.g., different types of dietary fiber). While there is truth in this statement, but no diet provides a single source of dietary fiber. Just as the AOAC methods for dietary fiber give a single gravimetric value for insoluble and, soluble dietary fiber components precipitated with alcohol, only one value is reported on the food label. Mention must be made that the latest AOAC Methods (e.g. 2009.01 and 2011.25) for dietary fiber analyses include HPLC protocols for a new class of dietary fiber and are the NDO:DP 3-10. To further expand on the concept that dietary fiber is a single entity, when consumed, the body used all the different forms and sources as a single entity and in synergistic ways to promote laxation and serve as a fuel for the intestinal bacteria. A good analogy to the synergistic effects of different sources of dietary fiber yet referring to only one term on the food label is the multitude of microorganisms that exist in the gut and their synergetic effects. These organisms go by one term the microbiota and the more recent term, microbiome.

My comments lead to an important omission by the FDA is discussing dietary fiber. While the FDA might wish to coordinate/complement their definition with some similarity to the Codex definition, neither the FDA nor Codex comment or recognize the increasing use of the soluble non-digestible oligosaccharides in the DP range of 3-10, NDO:DP 3-10, and slightly higher. It is the increasing use of this class of dietary fiber that spearheaded the efforts to have AOAC methods to measure the amount of these compounds in foods and beverages (Nishibata, et.al., 2009, 57:7659-7665). However, with the use of HPLC protocols that are inherent in AOAC Methods 2001.09 and 2011.25, the exact chemical identify of these NDO: DP3-10 can be determined. Many of these NDO:DP 3-10 are promoted as prebiotics (i.e., increase the growth of one or more lactic acid bacteria in the gut) and find extensive application/incorporation in beverages and, baby foods/formula. The FDA took a correct step in including oligosaccharides of $DP \geq 3$. While the data is lacking to prove the beneficial physiological effects for human health of these NDO:DP 3-10, they are almost quantitatively fermented and therefore increase levels of short chain fatty acids (SCFA) and total bacterial counts in the feces. A great deal more work much be accomplished to demonstrate that the increased level of one of more bacterial species have beneficial physiological effects on human health.

My opinions on why dietary fiber is an essential nutrient to have beneficial physiological effects on human health are summarized.

The intestine has multiple functions based on its physical, biochemical and physiological complexity and maintains its own ecosystem, the microbiome, most of which are obligate anaerobes within tissues that requires oxygen. There are microbiome systems associated with many areas of the body, but these organisms do not have the diversity, the sheer magnitude of the intestine, and the massive need for energy to grow and survive. The intestine and its microbiome survive in symbiotic relationship. Dietary fiber's unique properties are it does provide for physical stimulation as it passes through the intestine while not digested in the small intestine, but a majority is fermented in the large intestine. While DF is defined as a statutory nutrient for the purposes of food labeling by the FDA, it is described as a non- essential nutrient by the IOM because no fiber deficiency symptoms are documented. However, one could

argue that chronic constipation and its sequelae, including diverticular disease and hemorrhoids, are chronic disease endpoints not considered for setting DRI values particularly since cardiovascular disease was used to establish the Adequate Intake values for fiber. The premise and convictions are that DF is essential to the function of the intestine and serves as the major and essential source of energy for the microbiome. Why is DF a nutrient, how necessary is it and to be more specific how much is needed, and finally, is it an essential nutrient?

While it is impossible to have a DF free diet comprised of usual foods, in the few instances of prolonged parenteral nutrition in humans, the intestine atrophies, nutrient digestion and absorption is greatly reduced in both the small and large intestine, and the lack of the microbiota creates health consequences, and possibly most significantly, the acquired/adaptive immune system is impaired. The gut microbiome also signals the CNS. These observations and DF's quintessential properties can be expanded upon beyond the presence of the microbiota and voiding of waste, laxation. Research data is accumulating that demonstrates how DF; 1) provides bulk (i.e. insoluble DF) and along with soluble DF, including NDO:DP 3-10, fosters intestinal maturation and movement; 2) affects the morphology, physiology, and cell distribution of the intestinal mucosa including an increased number of goblet cells; 3) contributes to the total number of bacteria per gram of feces and the metabolism by these bacteria; 4) distributes energy released in fermentation between the host and the bacteria via SCFA and; 5) affects the immune system.

Regarding the proposed use of AOAC Methods 2009.01 and 2011.25, I agree with the additional statement, that these methods, "or an equivalent method AOAC method of analysis as given in the "Official Methods of Analysis of the AOAC International, 1999 Edition" will suffice in the measurement to report a single value for DF on the food label. The exclusive use or mention of AOAC Methods 2009.01 or 2011.25, which are comprehensive methods, may not always be necessary. There are approximately 25 AOAC Approved Methods for the measurement of all non-digestible oligosaccharides in foods and are acceptable methods for dietary fiber analyses. The FDA should be more clear that all AOAC methods are applicable and can be used for DF analyses and reporting of DF values on food labels.

In every case, all information on the nutrient content of foods, and reported on the food label, is based on chemical analyses. This statement is especially relevant to the carbohydrate complexity of DF in and added to foods. It is well known that no analytical method can differentiate the non-digestible carbohydrates in foods, dietary fiber, from added dietary fiber to foods. For the past 24 years, the *de facto* definition of DF was that the residues recovered and reported as measured by AOAC Methods 985.29 or 991.43. Irrespective of the use of more comprehensive methods for the measurement of DF, and the call for proven physiological effects, the amount of DF reported on the food label is its *de facto* definition.

These comments now refer back to dietary fiber as a statutory nutrient, a nutrient and more correctly an essential nutrient. The FDA and other health professionals/organizations should be more informative in explaining why DF is a nutrient, an essential nutrient, and thus explain why it is a mandatorily nutrient to be reported on the food label. Before it is stated that dietary fiber will attenuate blood cholesterol and or blood glucose and or blood insulin levels, it should be stated that dietary fiber is there mainly for the intestine, to have it develop, function, move (laxation) and maintain a microbiota-microbiome population. Important questions remains to be answered. How does an increase in intestinal bacteria levels contribute to more than increases in SCFA concentration, or changes in their ratios, and do these values have beneficial physiological effects on human health beyond the dynamic function termed laxation?

The FDA asks for comments on the definitions of dietary fiber. Extensive comments are available on the definition of dietary fiber and the distractions of a few individuals in Codex establishing its definition of dietary fiber (Gordon, D.T., 2007, CFW, 52:112-123).

The FDA is asked to consider adopting the AACCI definition for dietary fiber (Anonymous, 2000, CFW, 45:325; Anonymous, 2001, CFW, 46:112-126) with a few modifications.

The AACCI definition for dietary fiber states:

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.

To slightly modify this definition with greater understanding, these two simple additions are suggested. After the term oligosaccharides, the term ≥ 3 DP units be added, and change the last sentence to read, *Dietary fibers when consumed in adequate amounts can promote beneficial physiological effects for human health, and the most readily achieved are its ability to promote normal laxation and provide the necessary energy for growth and maintenance of the intestinal bacteria.*

The modified AACCI definition is short, inclusive of all non-digestible carbohydrates and, makes no excessive statements about physiological benefits. Comments on dietary fiber ability to attenuate blood cholesterol, triglyceride, glucose and or insulin are best accomplished in a citizen's petition or health claim submittals.

Dietary Fiber again is one value on the food label. Dietary fiber is plural. This single value does not separate source, physical properties, chemical composition, or physiological effects. The FDA decision to just have one value for all forms of DF on the food label is correct.

Why is there not a call to demonstrate the physiological benefits of endogenous dietary fiber in foods? The literature is replete with clinical studies that report on the positive effects of added dietary fiber.

The FDA states, "we tentatively conclude that a regulatory definition of dietary fiber should be one that emphasizes its physiological effect that is beneficial to human health." Again the FDA's proposal to have a single definition for DF is wise and prudent and for reasons stated on page 11909. But the clause to demonstrate beneficial physiological effects for human health should be dropped-omitted in the final rules.

Again it is well known and accepted that dietary

fiber is lacking in the diet. People are not accepting the recommendations to eat mainly a plant-based diet. A diet that should have a target of 2,000 - 3,000 kcal for many people, woman and men, has the target of providing 14 g DF /1,000 kcal. With the IOM establishing an Recommended Dietary Intakes (RDI), specifically Adequate Intake (AI) values of 25 and 38 g of dietary fiber for woman and men, respectively, how does the IOM and the FDA propose to help overcome the near 100% shortfall between current dietary fiber intakes and the AI recommendation? The answer to this question is to lift the seemingly worthless embargo on regulating and using added sources of dietary fiber.

The big challenge in accepting that DF can be added to food, is the belief that it violates the principal or belief in "natural"; anything added to food is an "additive" and cannot be as good-effective-wholesome as the natural ingredient in food. However, this attitude challenges the effective addition, fortification-enrichment of foods to correct deficiencies. The most notable examples are the prudent use of iron and folic acid.

The repeated statement that every source of added DF must be documented to show significant physiological effect to improve human health is not a prudent use of time and money to have and follow this rule. This requirement is challenged.

With all due respect to the FDA staff and all the scientists who lobby for this restriction, I ask all to name one source of added DF that does contribute to an intestinal physiological effect. Just being there, in the intestine, even one molecule, there is some effect, but the effect can't be quantitated until a threshold level is reached. What is the threshold of effectiveness and efficacious benefits of DF intake? Will it be 25, 35, 45 g/day. Or is 18 g/day adequate for normal laxation and maintenance of an adequate microbiota-microbiome population? But significantly increasing intakes to 35, 45, 55, 65 g a day will help reduce caloric intakes, which in turn help in weight management, which helps lower blood cholesterol and glucose levels. We must remember that the original dietary fiber hypothesis of Burkett, Trowell, Walker and Painter was based on Africans eating in excess of 80 g of dietary fiber per day. We have a long way to go, and unnecessary regulations will not help correct the current dietary fiber shortfall.

Again the average consumption of DF is approximately 18 g/day. Most young to middle age people do not appear to suffer from constipation. As people age, diet change as do level of activity and with less activity, there is more chance of constipation. In the case of lowering blood cholesterol levels, the IOM decided that 25 g for women and 38 g a day for men of dietary fiber per day was effective. They set these as AI values, and in so doing without saying a word except that dietary fiber is not an essential nutrient, clandestinely declared DF a nutrient. Why is DF a nutrient? It is nutrient because it is necessary for normal intestinal function and directly and indirectly the primary source of energy for the intestinal bacterial. So with this explanation dietary fiber is just not a nutrient but an essential nutrient. It is recognized that it is close to impossible to conduct a clinical trail with no DF, but we have good data that low DF intakes, less than the average intakes, will lead to constipation and diverticulosis.

The FDA and many organizations have gone to great efforts to support and encourage the consumption of whole grains. The recommendation is sound and should be continually promoted. There is a "whole grain stamp" that is an effective marketing strategy. However, the issue of whole grains and dietary fiber present an interesting conundrum. The FDA and many others state that whole grains are a source of dietary fiber. The consumer expects that whole grains provide dietary fiber. Many consumers think whole grains and dietary fiber are synonymous. Yes, whole grains provide dietary fiber, but not much. In fact only two whole grains would supply sufficient dietary fiber in a serving to comply-meet the requirement of the whole grain foods health claim (Gordon, D.T., 2003, CFW, 48:210-214). The real value of enhanced whole grain, whole grain foods, and consumption is to help reduce the calorie content of the diet.

The purpose of these comments is not to disparage whole grains, but just to state that they are not a significant source of dietary fiber in the food supply. A solution to this is to have whole grain foods fortified-enriched with added fiber. While not changing the definition of whole grains, allow for specific levels of dietary fiber to be added. The source and type of DF is left to the food manufacturer to have a food product that is acceptable to the consumer.

It would be of great benefit to all in the food industry and ultimately the consumer, if the FDA would drop any mention of added fiber, but more specifically, drop the requirement that every source of dietary fiber added to foods must demonstrate by clinical experimentation that it has beneficial physiological effects for human health. If any food safe, by GRAS affirmation, carbohydrate is determined to be non-digestible, it is a potential source of dietary fiber to be used on the food supply. However, I challenge chitosan as being a safe source of dietary fiber.

Again, I challenge anyone to demonstrate that any non-digestible carbohydrate, insoluble, soluble and or NDO:DP 3-10, does not at least effect some aspect of laxation. And almost any specific chemical unit in these three classes can be partially or totally fermented leading to increased intestinal bacterial growth. The challenge will be at what level of dietary fiber intakes can these increases in total bacterial counts be statistically observed to show an effect? With increases in dietary fiber levels from any source, the big physiological benefits that are constantly referenced, attenuation of blood cholesterol, glucose and or insulin, and decrease in diseases associated with the metabolic syndrome, can only be reduced and long term benefits observed with significant increases in daily dietary fiber intakes and probably in the range of 35-50+ g/day.

While all my comments might appear over zealous, and at times to be pontificating, what can the FDA do to recognize and help improve intakes of dietary fiber? The continued reference to restrictions on the use of added fiber to foods is a disservice to helping increase levels of dietary fiber in the food supply.

I concur with value that the fermentation of soluble dietary fiber provides 2.0 kcal/g of metabolizable energy (Bear et al., J. Nutr, 2014, 144:1023-1029). I concur with the FDA decision to retain a reduction of 4.0 kcal/g for insoluble dietary fiber components. However, it is known that most, with just a few exceptions, insoluble dietary fiber components are fermented to some degree, and thus providing some metabolizable energy to the host. The amount of metabolizable energy will certainly be different for each source and physical size of the insoluble dietary.

I concur with the continued retention and use of the terms insoluble and soluble. Since different calorie values are assigned to these classes of dietary fiber, their being reported, yes optional, on the food label should be retained. However, the issue of the ratio of insoluble to soluble components could become important and significant in the future if the amount of fermentable fiber becomes more relevant as being more easily fermented and thus increasing bacterial growth.

As mentioned, the quintessential properties of DF are its ability to promote laxation and serve as the primary energy source for the intestinal bacteria. However, laxation is more than an increased number of bowel movements. What is most important, is all the many physiological events that occur in the intestine as dietary fiber passes through and, these events are many. And the question that should be asked, and asked again, what is the amount of DF that should be in diet, consumed, that is most, or optimally, beneficial for all these physiological, biochemical and molecular events that occur in the process called laxation. Some of these beneficial physiological functions are thought to be more important than the number of bowel movement or frequency. Question: is it more beneficial for an individual to void 100-150 g of wet weight feces per day in one or two defecations? For most people, one good bowel movement a day is a joy.

So this leads to ask what will be the proposed protocols to measure laxation, if the FDA decides on documentation of beneficial physiological effects to improve human health? Health Canada asks for comparisons of fecal parameters to match at least 50% of the weight produced with an equal weight of wheat bran. To date, only sources of cellulose have been tested and meet this Canadian requirement. So for insoluble sources of dietary fiber, this might be appropriate, but do the results really give an indication of biochemical, physiological and molecular changes in the intestine? The most fundamental and important changes are those resulting from fermentation. And possibly the best index of increased dietary fiber activity would be a measurement of the increase in total bacteria. And, an increase in total bacteria is suggested as the most applicable and useful parameter to access in establishing a beneficial physiological effect to improve human health. More bacteria will produce more fecal mass and along with an insoluble

dietary fiber component in the diet, laxation is adequate or improved.

Some of the most frequently cited physiological effects beneficial to human health are listed. However, there are listed in their order of effectiveness. And it can be more than assumed these physiological benefit only become manifested as dietary fiber intake increase. At average dietary fiber intakes of 18 g/day, in order of increasing importance: 1) laxation, which implies the myriad of events that occur along the entire intestinal tract, from stomach to anus and ultimately defecation; 2) with dietary fiber reaching the large intestine, fermentation occurs, with increasing levels of short chain fatty acid (SCFA), increased levels of the microbiota-microbiome, and numerous degradation products that might be beneficial. Therefore at current average intakes of dietary fiber we are maintaining some level of normal laxation activity and maintaining what appears to be a normal microbiota-microbiome level. However, what is a normal is not known.

Therefore at current average intakes of dietary fiber we are getting increase laxation, intestinal movement, and bacterial growth. But to further enhance beneficial physiological effects, lower blood lipid and glucose levels at a minimum, the consumer will have to consume more dietary fiber.

I have repeated, repeated, the theme of this letter many times. In summary, the most important nutrition information to give the consumer on the food label is the amount of calories in a serving and in the entire package. Recognize that dietary fiber is an essential nutrient. Remove or drop calls for studies to show that the beneficial physiological effects to improve human health are needed for the use of added dietary fiber in foods. Find ways to encourage the addition of dietary fiber to foods.

I am available to offer any additional information in support of my comments and opinions. I can be contacted at

Respectively submitted, Dennis T. Gordon, PhD