Proposed Policy: Definition and Energy Value for Dietary Fibre

Bureau of Nutritional Sciences
Food Directorate, Health Products and Food Branch
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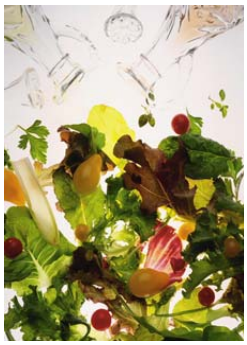


Canada

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Purpose of the Consultation

In line with its policy on openness and transparency, Health Canada is seeking comments from stakeholders on a revised definition for dietary fibre and a revised policy on energy value for dietary fibre. The definition is discussed in Part A of this document and the energy value in Part B. All interested parties are invited to submit written comments on any section of this report.

How to get involved

This consultation is open for comment starting **December 9, 2010** until **February 7, 2011** (60 calendar days). Comments on these proposals should be submitted electronically by February 7, 2011 to: fibre@hc-sc.gc.ca

Nutrition Evaluation Division

Bureau of Nutritional Sciences

Food Directorate

Health Canada

PART A: Proposed Definition for Dietary Fibre

A.1 Introduction

The beneficial effects of dietary fibre are now well established. A recent review by Anderson et al (2009) indicated that high levels of dietary fibre intake are associated with significantly lower prevalence rates for coronary heart disease and stroke. Furthermore, increased consumption of dietary fibre improves serum lipid concentrations (Brown et al, 1999) as well as blood glucose control in diabetes (Anderson et al, 2004), in addition to promoting regularity (Cummings, 2001).

The U.S. Food and Nutrition Board of the Institute of Medicine (IOM) has set an adequate daily intake of total fibre in foods at 25 g and 38 g for women and men, respectively, based on the intake level observed to protect against coronary heart disease (IOM, 2005). The *Panel on Dietetic Products, Nutrition and Allergies* of the European Food Safety Authority, citing bowel function as the most suitable criterion for establishing adequate intake, recommends a daily intake of 25 g of dietary fibre for normal laxation in adults (EFSA, 2009).

In Canada, surveys of nutrient intakes from foods indicate that mean dietary fibre intakes ranged from 14.3 to 16.6 g/d for women and from 16.5 to 19.4 g/d for men, in 2002 (Table 8.13, CCHS 2.2, Health Canada and Statistics Canada, 2004). This intake is well below the IOM recommendations for dietary fibre and reflects a limited consumption of whole-grain cereals, fruits, vegetables, and pulses considered to be the best natural sources of dietary fibres. The discrepancy between fibre intake and recommendations has provided food manufacturers the opportunity to help the Canadian population meet target intakes by developing new fibre-like products such as non-digestible oligosaccharides, resistant starch, resistant maltodextrin, and other modified and synthetic substances. These products are not considered to be fibre under the current definition in use in Canada. This document proposes to expand the definition to include a broader range of products with demonstrated safety and efficacy as fibre to be labelled and sold as such in Canada. The expanded definition will more closely align with other jurisdictions, and recognizes that these products may play an important role in helping consumers achieve fibre intakes approaching the recommended guidance levels.

In Canada, the definition in use was developed by the Department of National Health and Welfare's Expert Advisory Committee on Dietary Fibre in 1985:

"Dietary fibre consists of the endogenous components of plant material in the diet which are resistant to digestion by enzymes produced by humans. They are predominantly non-starch polysaccharides and lignin and may include, in addition, associated substances" (Health and Welfare Canada, 1985).

In 1988, as new products were developed or isolated that had some of the properties of dietary fibre, Health Canada published the *Guideline Concerning the Safety and*

Physiological Effects of Novel Fibre Sources and Food Products Containing Them, which expanded on the 1985 definition and confirmed that these products would be considered as sources of fibre. Novel fibre is defined as follows:

"Novel Fibre or Novel Fibre Source means a food that is manufactured to be a source of dietary fibre, and

- *that has not traditionally been used for human consumption to any significant extent, or*
- *that has been chemically processed, e.g. oxidized, or physically processed, e.g. very finely ground, so as to modify the properties of the fibre contained therein, or*
- *that has been highly concentrated from its plant source"* (Health Canada, 1988).

The rationale for developing this guideline centered on addressing potential safety issues unique to novel sources of fibre and a desire that the product not be misrepresented to the Canadian public. Indeed, if a novel fibre source or novel fibre-containing product is not safe for human consumption, it would be in violation of Subsection 4(a) of the *Food and Drugs Act*. Similarly, if a product is represented as containing dietary fibre, but does not have the beneficial physiological effects expected of dietary fibre, the product would be in violation of Subsection 5(1) of the *Food and Drugs Act*. The guideline indicates that both safety and efficacy of the fibre source must be established in order for the product to be identified as a source of dietary fibre in Canada, and the physiological efficacy must be demonstrated through experiments using human subjects. Health Canada identified three physiological effects (improving laxation or regularity, normalization of blood lipid levels, and attenuation of blood glucose responses), at least one of which must be demonstrated by a novel fibre to be accepted as dietary fibre (Health Canada, 1997).

During the last decade, many countries and scientific bodies have revised their dietary fibre definitions in order to include the fibre-like products newly developed, based on their chemical nature and their physiological properties. These scientific bodies and countries include: the American Association of Cereal Chemists (AACC), the Australia New Zealand Food Authority (ANZFA) now Food Standards Australia New Zealand (FSANZ), the U.S. Food and Nutrition Board of the Institute of Medicine (IOM), France (AFSSA now ANSES), FAO/WHO, the Codex Alimentarius Commission, and the European Food Safety Authority (EFSA). The current international trend in defining dietary fibre is to specify the chemical aspects as well as the resistance to digestion in addition to requiring that a fibre have beneficial physiological effects.

Four Canadian experts took part in the process of the U.S. IOM definition of dietary fibre (IOM, 2001), and this work was supported by Health Canada, because there was a possibility that the new definition would be implemented both in the USA and Canada. Health Canada has also been actively involved in the development of the Codex dietary fibre definition. This definition, adopted in June 2009, reflects a consensus which was achieved through 15 years of collaboration and negotiation involving Codex Member State governments and Codex Observer organizations.

In light of positions taken on dietary fibre by the IOM and Codex, and also as a result of the increased interest and inquiries on the part of the food industry, Health Canada is now reviewing its dietary fibre definition. Part A of this report presents: a) an overview of the most recent dietary fibre definitions from other jurisdictions; b) the issues related to the current Canadian definition; c) a proposed definition and an analysis of its impact.

A.2 Overview of dietary fibre definitions in other jurisdictions

During the past decade, the following scientific bodies and countries have undertaken a complete review of their dietary fibre definitions.

A.2.1 American Association of Cereal Chemists (AACC)

In March 2000, a scientific committee appointed by the AACC adopted the following dietary fibre definition:

"Dietary Fibre 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 fibre includes polysaccharides, oligosaccharides, lignin, and associated plant substances. Dietary fibres promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation" (AACC Report, 2001).

This definition makes reference to the plant components accepted as being present in the defined dietary fibre that impart the positive health effect. Analogous dietary fibre 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 fibre. In addition to the requisite digestion and fermentation properties, analogous fibre must also exhibit a positive potential health benefit that has been ascribed to dietary fibre. This definition clearly acknowledges that certain food ingredients, whether they are plant extracts, concentrates, modified carbohydrates, or synthetic compounds produced intentionally to be sources of fibre, should be recognized as dietary fibre when considering their nutritional properties and labelling requirements (AACC, 2001).

A.2.2 Food Standards Australia New Zealand (FSANZ), previously Australia New Zealand Food Authority (ANZFA)

An Expert Working Group established in 2000 by the ANZFA adapted the above AACC definition (ANZFA, 2000) and the modified version was published in the ANZ Food Standards Code in August 2001 to read now as follows:

"Dietary Fibre means that fraction of the edible part of plants or their extracts, or synthetic analogues that

(a) *are resistant to the digestion and absorption in the small intestine, usually with complete or partial fermentation in the large intestine; and*

(b) *promote one or more of the following beneficial physiological effects –*

a. *laxation;*

b. *reduction in blood cholesterol;*

c. *modulation of blood glucose;*

and includes polysaccharides, oligosaccharides (DP>2)[1] *and lignin"* (Standard 1.2.8, Food Standards Code, FSANZ).

A.2.3 Institute of Medicine (IOM)

In the United States, the Food and Drug Administration (FDA) and the Department of Agriculture (USDA) require dietary fibre to be listed in the Nutrition Facts panel on food packaging, but have never defined the term. In order to identify dietary fibre, the FDA uses analytical methods accepted by the Association of Official Analytical Chemists International (AOAC) or, if no AOAC method is available or appropriate, other reliable and appropriate analytical procedures (CFR, Title 21, § 101.9(g)(2)). In 2001, the IOM *Panel on the Definition of Dietary Fibre* responded to FDA's request to provide definition for dietary fibre by considering its role in human physiology and health. Based on the Panel's deliberations, consideration of public comments, and subsequent modifications, the following definitions have been developed:

"Dietary Fibre consists of nondigestible carbohydrates and lignin that are intrinsic and intact in plants.

Functional Fibre consists of isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.

Total Fibre is the sum of Dietary Fibre and Functional Fiber" (IOM, 2005).

The IOM used a two-pronged approach to define edible and nondigestible carbohydrates, and thus recognized the diversity of nondigestible carbohydrates in the human food supply: plant cell wall and storage carbohydrates that predominate in foods, carbohydrates contributed by animal foods, and isolated and low molecular weight carbohydrates that occur naturally or have been synthesized or otherwise manufactured. These definitions allow for flexibility to incorporate new fibre sources developed in the future (provided that beneficial physiological effects in humans are demonstrated).

The IOM panel (2001) accepted the three established measures of physiological efficacy identified by Health Canada in 1988. These are attenuation of postprandial blood glucose

[1] DP: degree of polymerization or number of monomeric units

concentrations, attenuation of blood cholesterol concentrations, and improved laxation. However, the panel did not provide a list of specific physiological benefits for functional fibres because such a list would become quickly outdated as new health effects of nondigestible carbohydrates were identified and characterized. The intent was to promulgate definitions that had overall long-term applicability.

A potential concern with a new label term "*Functional Fibre"* is that it is unfamiliar to most consumers, and could be confusing. In addition, functional fibre may be seen as inferior or "artificial" (AACC Report, 2003), or as superior to dietary fibre. In the latter case, this could increase the demand for products with functional fibre, leading consumers to reduce their selection of natural sources of dietary fibre in the form of fruits, vegetables, and whole grains, thus causing a net decrease in total fibre intake or a reduction in the overall quality of the diet (Jones et al, 2006). The IOM panel recognized that an education process would be necessary to help consumers understand the difference between dietary fibre and functional fibre.

A second issue with the IOM definition is that it is complicated for label compliance purposes, because it requires the food composition analysis after the addition of functional fibre. There is currently no methodology that allows a distinction between intrinsic fibre and functional fibre once they occur mixed in a food product. This creates a need for new methods to accurately measure dietary and functional fibre in finished food products.

In 2007, in response to the IOM definition, FDA published an advance notice of proposed rulemaking requesting comment on whether it should continue to use the AOAC methods to determine dietary fibre, or adopt the IOM definition (72 Fed. Reg. 62149). As of March 12, 2010, no proposed rule with respect to dietary fibre has been published.

A.2.4 FAO/WHO

In July 2006, at a meeting convened by FAO/WHO and held in Geneva, the experts agreed that the definition of dietary fibre should be more clearly linked to health, and after discussion, the following definition was proposed:

"Dietary fibre consists of intrinsic plant cell wall polysaccharides" (Cummings and Stephen, 2007).

The established epidemiological support for the health benefits of dietary fibre is based on diets that contain fruits, vegetables and whole-grain foods, for which the intrinsic plant cell wall polysaccharides are a good marker. Although isolated or extracted fibre preparations have been shown to have physiological effects experimentally, the FAO experts considered that these effects could not be translated into health benefits directly because the epidemiological evidence points to fruits, vegetables and whole-grain foods as beneficial, and in a normal diet, these polysaccharides are part of the plant cell wall

complex and do not exist individually (Cummings and Stephen, 2007). This definition excludes a number of products that could legitimately satisfy the requirement to demonstrate beneficial physiological effects as fibre sources, including: synthetic, isolated or purified oligo- and polysaccharides, resistant starches, as well as storage polysaccharides such as guar gum and inulin. Another concern with this definition is that no reference to the non-digestibility of the components is made, since the FAO experts considered that non-digestibility cannot be measured in the laboratory. However, as stated by AACC International (AACC letter, 2007), in dietary fibre definitions, digestibility is related solely to the alimentary enzymes of humans, and this can be simulated in *in vitro* laboratory experiments employing for example pancreatic enzymes.

A.2.5 European Food Safety Authority (EFSA)

As no harmonized definition of dietary fibre was available at the European Union level, at the request of the European Commission, the *Panel on Dietetic Products, Nutrition and Allergies* of EFSA issued a scientific opinion on dietary reference values for carbohydrates and dietary fibre, and the draft opinion was subjected to a public consultation before its finalisation (EFSA Journal, 2009). The comments received were taken into account and the document was revised without any changes to the proposed dietary fibre definition (EFSA Journal, 2010).

In the Draft Scientific Opinion, dietary fibre is "*defined as non-digestible carbohydrates plus lignin.*"

The Panel considers that the definition of dietary fibre should include all carbohydrate components occurring in foods that are non-digestible in the human small intestine. This includes non-starch polysaccharides, resistant starch, resistant oligosaccharides, and other non-digestible, but quantitatively minor components, especially lignin, when naturally associated with the dietary fibre polysaccharides.

A concern with the EFSA definition is that it does not mention the requirement to demonstrate beneficial physiological effect.

A.2.6 Codex Alimentarius Commission

The definition adopted in July 2009 by the Codex Alimentarius Commission describes dietary fibre as one of three categories of carbohydrate polymers. It is worded as follows (Codex, ALINORM 09/32/26):

"Dietary fibre means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- *Edible carbohydrate polymers naturally occurring in the food as consumed,*

- *Carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,*
- *Synthetic carbohydrates polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities."*

A first footnote included in the provision indicated that *lignin and other compounds (proteic fractions, phenolic compounds, waxes, saponins, phytates, cutins, phytosterols, etc.) intimately associated with the plant poly- and oligo-saccharidic fraction of the fibre are included in the fibre definition. However, when these substances are extracted or even re-introduced into a food containing non digestible polysaccharides, they cannot be defined as dietary fibre. A second footnote suggested that the decision on whether to include carbohydrates from 3 to 9 monomeric units should be left to national authorities*.

The footnote 1 appended to the dietary fibre definition was amended as follows at the 31th Session of the Codex Committee in November 2009 (Codex, ALINORM 10/33/26):

"*When derived from a plant origin, dietary fibre may include fractions of lignin and/or other compounds associated with polysaccharides in the plant cell walls. These compounds also may be measured by certain analytical method(s) for dietary fibre. However, such compounds are not included in the definition of dietary fibre if extracted and re-introduced into a food*."

A.2.7 Comparison of definitions

Table 1 compares the characteristics of dietary fibre definitions from some other jurisdictions with the current Canadian definition.

Table 1. Characteristics of various dietary fibre definitions

Jurisdictions	Health Canada		US IOM, 2005			Codex, 2009			ANZFA, 2000 (now FSANZ)			FAO, 2007
Sub classification	Dietary fibre (1985)	Novel fibre (1988)	Dietary fibre	Functional fibre	Total fibre	1st category	2nd category	3rd category	1st category	2nd category	3rd category	Dietary fibre
Terminology	Endogenous NSP	Chemically and physically modified, concentrated fibre, finely ground fibre	Intrinsic / intact ND CHOs	Isolated, manufactured, synthesized ND CHOs	Sum of dietary and functional fibre	Edible CHO polymers in foods as consumed	CHO polymers obtained from food raw materials and processed (chem/phys/ or enzyme)	Synthetic CHO polymers	Fractions of edible parts of plants (but not excluding microbiological, fungal or animal sources)	Plants extracts (but not excluding microbiological, fungal or animal sources)	Analogous CHO	Intrinsic plant cell wall polysaccharides
Resistant to human enzymes	Yes	Implied	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Intact and naturally occurring in food	Yes	No	Yes	No	Yes	Yes	No	No	Yes	No	No	Yes
Animal derived ND CHO	No	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Synthetic ND CHO	No	No	No	Yes	Yes	No	No	Yes	No	No	Yes	No
ND mono and disaccharides	No	No	No	No	No	No	No	No	No	No	No	No
ND oligosaccharides	No	No	Yes	Yes	Yes	Decision left to national authorities	Decision left to national authorities	Decision left to national authorities	Yes	Yes	Yes	No
Resistant starch	No	No	Yes (RS1, RS2, RS3)	Yes (RS4)	Yes	Yes (RS1, RS2, RS3)	Yes (RS4)	No	Yes (RS1, RS2, RS3)	Yes (RS2, high amylose)	Yes (RS4)	No
Lignin as part of the plant matrix	Yes	Implied	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No
Demonstration of health benefits	No	Yes	No	Yes	Yes	No	Yes	Yes	No	Yes	Yes	No
List of health effects	No	Yes	No	No	No	No	No	No	No	Yes	Yes	No

ND: nondigestible; CHO: carbohydrates; NSP: non-starch polysaccharides.

A.3 Advantages and limitations of the current Canadian dietary fibre definition

The current Canadian definition for dietary fibre has three clear advantages. First, the beneficial physiological role of novel fibres must be demonstrated (and reviewed by Health Canada) before acceptance as dietary fibre. This means that the mention of "dietary fibre" in a Nutrition Facts table is consistent with the public's expectation of an associated physiological benefit and with the notion that dietary fibre is "good for you."

The second advantage of the current Canadian dietary fibre definition is that the term novel fibre is used only within the Health Canada review process and in the Canada's *Guide to Food Labelling and Advertising*. Once the physiological effects are established, the novel fibre is marketed as a dietary fibre, whereas under the IOM definition, the term functional fibre would be used for marketing material classified as functional fibre, and that could be confusing for the consumer without an appropriate education process.

The third advantage of the current Canadian dietary fibre definition when compared to the IOM definition is related to the availability of official analytical procedures. Effectively, endogenous and novel fibres would be measured together in the final food sample and would not be separated in food label Nutrition Facts tables.

The major issue (from a general industry point of view) with the current Canadian definition is that it was formulated before many new fibre-like substances were developed. Since that time, these substances, based on their chemical nature and their physiological properties, have been recognized by scientific bodies and governments as dietary fibre. The Canadian dietary fibre definition is now very restrictive compared with other jurisdictions (Jones et al, 2006). This is evidenced by the relatively low numbers of materials accepted as dietary fibre by Health Canada. In fact, from 1985 to November 2010, only 9 novel fibres have been approved in Canada. It should be noted, however, that the low numbers of accepted novel fibres may also be related to the difficulty in attributing physiological efficacy to purified forms of dietary fibre. The major limitations of the Canadian dietary fibre definition are:

1) The term "polysaccharides" excludes oligosaccharides (DP 3-9) such as fructooligosaccharides and galactooligosaccharides.
2) The term "non-starch" excludes resistant starches (RS1, RS2, RS3, and RS4) and all starch derived compounds, such as maltodextrin.
3) Because all dietary fibre must be of plant origin, neither animal undigested fibre-like materials (e.g. chitosan) nor synthetically derived products (e.g. polydextrose) can be considered dietary fibre.

Recommendations to increase dietary fibre intake have resulted in food manufacturers producing foods containing a wide variety of ingredients that are not digested in the small intestine. Because many substances, potentially classified as dietary fibre, are already consumed in Canada, the end result of not recognizing these substances as dietary fibre is

that our dietary fibre intake may be underestimated, relative to other countries where these materials are included. It has also been suggested that innovation and competitiveness in the Canadian food processing industry are undermined by the current fibre policy (Michaelides and Cooper, 2005). A number of Canadian companies are withholding the launch of products formulated with carbohydrate polymers not recognized as dietary fibre in Canada, or are selling them only in the international market (Ruderman, 2005).

On the basis of this analysis, it is apparent that there is a need to update the 25 year-old Canadian dietary fibre definition.

A.4 Proposed definition of dietary fibre

"Dietary fibre consists of naturally occurring edible carbohydrates (DP>2) of plant origin that are not digested and absorbed by the small intestine and includes accepted novel dietary fibres.

Novel dietary fibre is an ingredient manufactured to be a source of dietary fibre. It consists of carbohydrates (DP>2) extracted from natural sources or synthetically produced that are not digested and absorbed by the small intestine. It has demonstrated beneficial physiological effects in humans and it belongs to the following categories:

- *has not traditionally been used for human consumption to any significant extent, or*
- *has been processed so as to modify the properties of the fibre, or*
- *has been highly concentrated from a plant source."*

A.4.1 Distinguishing features of Dietary Fibre and Novel Fibre

Dietary fibre - Dietary fibre has traditionally been considered to be of plant origin. In fact, the original studies determining the physiological effects of consuming diets high in dietary fibre used plant material to increase dietary fibre intakes or assessed populations with significant differences in unprocessed plant material intake. In the context of this proposed definition, dietary fibre refers to all raw plant foods that have a history of use and/or that have been traditionally processed or cooked.

Carbohydrates that are not digested and absorbed in the small intestine include the oligosaccharides and the polysaccharides. In this proposed definition, a degree of polymerization (DP) superior to 2 is intended to exclude mono- and disaccharides as well as sugar alcohols. Some of those substances (e.g. fructose, lactose, lactulose and polyols) could be classified as fibre because they are slowly and incompletely absorbed from the small intestine, and are fermented by bacteria in the large intestine. However, these

materials have been demonstrated to produce an osmotic laxative effect, which is not a typical characteristic of dietary fibre. Therefore, nondigestible monosaccharides, disaccharides, and sugar alcohols are not considered to be dietary fibre.

Plant polysaccharides include starches, non-starch polysaccharides such as: cellulose, beta-glucans, polyfructoses (such as inulin), hemicelluloses (such as arabinoxylans and arabinogalactans), gums, mucilages, and pectic substances. Plant oligosaccharides include fructo-oligosaccharides, galacto-oligosaccharides, etc.

Starch from plants is usually hydrolyzed and absorbed in the human small intestine. However, it is now known that some starch escapes digestion in the small intestine and is fermented in the colon. This nondigestible portion of the starch was called "resistant starch" by scientists (Englyst et al, 1982; Asp, 1992) although this term has not been defined by any government agency (Goldring, 2004). Resistant starch (RS) is not a homogenous entity and the resistance to degradation by human enzymes in the small intestine is dependent on a number of natural or processing phenomena which make up the four subcategories of resistant starch (Englyst et al, 1996; Woo and Seib, 2002). Starch becomes inaccessible to α-amylase because of physical encapsulation (RS1 found in grains or seeds) or its physico-chemical properties (RS2 found in unripe bananas or native potato starch, and high amylose starch in corn). Resistant starch can also be created during normal processing of a food (RS3 or retrograded starch) (Tungland and Meyer, 2002), or specifically manufactured to be resistant to endogenous human enzymes (RS4). This subcategory (RS4) is a growing segment of commercially available resistant starches. Early dietary fibre definitions did not include resistant starch because it was not yet recognized as such. There is now a consensus that resistant starch physiologically behaves like dietary fibre and it is widely accepted as a fibre source. In the above proposed definition, RS1, RS2, and RS3, as naturally occurring or created during normal processing of a food would be considered as dietary fibre.

The resistance to hydrolysis by human digestive enzymes and to absorption in the small intestine has been accepted by common consensus and represents the key to the unique position of dietary fibre in the human diet. However, in the proposed definition, the term "nondigestible" has not been used because most of the substances are either partially or completely digested/fermented by the bacteria of the large intestine. And, it is the material entering the colon that is the important fraction of the total carbohydrate with respect to dietary fibre. Given that a few products are not fermented to any significant extent – usually the highly lignified cell wall material – a reference to the colonic fermentation is not included in the proposed definition so as not to exclude the non-fermentable substances.

Some minor substances such as lignin, waxes, cutin, suberin, phytate, tannin, although not carbohydrates, are an integral part of dietary fibre and are intricately tied to the plant polysaccharides, often serving as chemical cross-links between various components and increasing resistance to digestion in the small intestine. These substances, as well as

some proteic fractions are analyzed with the polysaccharides in some gravimetric methods (Lee et al, 1992; Prosky et al, 1992, 1994). Therefore, they are included in the definition of dietary fibre when they are part of the plant cell wall matrix, but they cannot be defined as dietary fibre if they are extracted and introduced into a food.

Novel fibre - Contrary to the 1988 definition for novel fibre, which included only isolated plant material, this proposed novel fibre definition includes nondigestible carbohydrates extracted from their plant, animal or microbial sources and modified through physical, chemical, or enzymatic means. Nondigestible carbohydrates obtained by purposeful synthesis are also included. Potential new sources of dietary fibre include the substances identified below:

- Extracted substances from agricultural crop by-products and from raw plant materials;
- Extracted substances from animals : chitin, chondroitin;
- Extracted substances from seaweeds : carrageenan, alginates;
- Modified celluloses : methyl cellulose, hydroxypropylmethyl cellulose;
- Manufactured resistant starch : RS4;
- Substances of microbial origin : yeast beta-glucan, xanthan gum;
- Partially hydrolyzed carbohydrates : guar gum, inulin;
- Synthetically manufactured substances: polydextrose, fructo-oligosaccharides, calcium polycarbophil, resistant maltodextrins.

Interest in dietary fibre arises from its association with beneficial physiological effects. However, during the last 30 years, clinical trials, epidemiological studies and meta-analysis have shown that not all fibres and high-fibre foods in all studies have exhibited beneficial health effects (Salmeron et al, 1997; Fuchs et al, 1999; Bonithon-Kopp et al, 2000; Luo et al, 2000; Jacobs et al, 2002; Ylonen et al, 2003; Hodge et al, 2004). Thus, it appears likely that some naturally occurring dietary fibre and some "novel" dietary fibres are physiologically inactive. Indeed, there are questions about the role of dietary fibre *per se* in bringing about the physiological effects normally associated with foods high in dietary fibre and there is speculation about the actual role of dietary fibre in disease reduction. On the other hand, randomized controlled trials with viscous fibres have clinically demonstrated their usefulness in reducing serum cholesterol and serum triglycerides. In the proposed definition for novel fibre, carbohydrates that are not digested and absorbed in the small intestine will be recognized as dietary fibres, only if at least one measurable positive health impact is scientifically demonstrated by clinical studies. The new definition does not specify the physiological effect(s) required to be demonstrated, in order to maintain the flexibility to allow for new effects supported by scientific evidence that may only be apparent in the future.

The dietary fibre-associated physiological effects which are presently well established and acknowledged by the scientific community include: improved laxation; attenuation of blood glucose responses; and, normalization of blood lipid levels. However, some emerging benefits are currently under investigation. Stimulation of the growth of specific intestinal bacteria, the impact on the immune system, and the modification of mineral absorption are some examples of hypothesized links between dietary fibre and health.

A.4.2 Rationale for the proposed definition

The essential components of the proposed definition of dietary fibre are the chemical structure, the site of digestion, the acceptable sources of fibre, and a reference to measurable beneficial effects. First of all, the term "carbohydrate" used in place of "non-starch polysaccharides" will allow the inclusion of oligosaccharides and resistant starch which were excluded as dietary fibre.

In the first part of the definition, emphasis is put on dietary fibre present in plant foods, because foods naturally high in dietary fibre also contain a variety of vitamins, minerals and other phytochemicals that may act as a biological "package." Thus, from a nutritional viewpoint, it is important to promote the consumption of whole foods naturally high in dietary fibre such as wholegrain cereals, pulses, fruits and vegetables. This approach is similar to the approach that served as the basis for the 1985 definition where "dietary fibre" corresponded to the material that occurred naturally in foods. Contrary to the IOM definition, the term "intact" is not used in the proposed definition to characterize the endogenous non digestible carbohydrates in plants. The proposed definition recognizes that traditional processes or cooking methods may alter the three-dimensional plant matrix, which means that some fibre is no longer intact. The AACC Report (2003) identified some examples of no longer intact dietary fibres: physically removed bran, beta-glucan separated from oatmeal during cooking, crushed parts of kernels, etc.

The second part of the definition refers to the novel fibre category. The original description of dietary fibre by Trowell in 1972 is more a physiological concept than an exact description of any carbohydrate in the diet (FAO/WHO, 1998). From this perspective, we can assume that there is room to recognize new materials as dietary fibre when these materials have the required features to demonstrate dietary fibre effects. Thus, isolated materials from a wide range of carbohydrate sources, as well as modified or synthetically manufactured fibre like-substances are included in our proposed definition. The difference from the 1988 novel fibre definition is that all sources (animal, synthetic, etc.) rather than only plant materials would be considered as potential fibre if beneficial physiological effects can be clinically demonstrated.

For novel fibres, a physiological effect should be scientifically demonstrated by clinical studies when a declaration or claim is made. This requirement is already in the current

Canadian dietary fibre policy (Health Canada, 1988) and is in compliance with Subsection 5(1) of the *Food and Drugs Act* that prohibits selling or advertising any food in a manner that is false, misleading or deceptive. Demonstration of the beneficial health effects of dietary fibres is also recommended by the US Institute of Medicine and the

Codex Alimentarius Commission, and is mandatory in other jurisdictions such as Australia, New Zealand and France. In Japan, certain dietary fibres are considered as part of the FOSHU (Foods for Specified Health Uses) and require scientific evidence to support any claims (Nakajima, 2004; Manley, 2006).

In addition to positively contributing to physiological systems in the human body and in order to comply with Section 4 (a) of the *Food and Drugs Act*, dietary fibres should be proven safe for human consumption before being accepted for use in foods or as fibre supplements and concentrates. If dietary fibres are derived from materials with no history of safe use as foods, they should be first reviewed and approved as novel food ingredients prior to sale (Division 28 of Part B of the *Food and Drug Regulations*). Manufacturers or importers are required under these regulations to submit information to Health Canada regarding the product in question as outlined in the *Guidelines for the Safety Assessment of Novel Foods* (Health Canada, 2006).

A.5 Impact of the proposed definition of dietary fibre

Changing the definition of dietary fibre is expected to impact industry and consumers as well as have implications for labelling and analytical methodology. These implications are addressed in order to ensure that resulting regulations or policies can be implemented and enforced.

A.5.1 For the food industry

The main benefit of the proposed definition is that food manufacturers would have a greater variety of potential dietary fibre material available to support product innovation, competitiveness and investment in the Canadian food industry. In addition, the Dietary Reference Intakes (DRI) report for macronutrients, including dietary fibre, has set a daily recommended intake value for dietary fibre of 25 g/d (women) and 38 g/d (men) (IOM, 2005). These recommendations will provide manufacturers with an opportunity to help the Canadian population meet target intakes by developing new products containing higher amounts of nondigestible carbohydrates.

The proposed definition maintains the requirement to submit safety data and to demonstrate the beneficial physiological effects of the new material in order to claim that a product contains dietary fibre. Although protocols to demonstrate efficacy of a new product are not specified as part of the proposed definition, it is recognized that food

manufacturers need information on the characteristics and types of studies required to demonstrate beneficial physiological effects. Currently, guidelines for clinical trials are available (Health Canada, 1997). These could be revised to reflect new scientific evidence of physiological efficacy of fibres.

A.5.2 For the consumer

Canadians are knowledgeable about dietary fibre. The results of the 2008 Tracking Nutrition Trends VII survey (Canadian Council of Food Nutrition, 2008) indicated that a large majority understands that some types of dietary fibre can help reduce blood cholesterol (74%) and that a diet high in fibre may help prevent colon cancer (78%). This same survey also reported that when choosing the foods they eat, 81% of Canadians consider the fibre content. However, knowledge and good intentions do not translate into appropriate dietary habits, as Canadians' fibre intake is relatively low (mean dietary fibre intakes ranging from 14.3 to 16.6 g/d for women and from 16.5 to 19.4 g/d for men, CCHS 2.2, Health Canada and Statistics Canada, 2004) compared with the recommendations.

The proposed definition of dietary fibre would increase consumer access to more innovative food products providing a greater range of identifiable sources of dietary fibre. This in turn could potentially increase consumers' dietary fibre intake without a significant change in eating patterns, which may improve health outcomes.

A.5.3 For nutrition labelling in Canada

In Canada, the amount of dietary fibre is one of the 13 core nutrients that must be declared in the Nutrition Facts table (*Food and Drug Regulations*, item 10 of the table following B.01.401). The amount of both soluble and insoluble fibre may be separately declared as additional information (*Food and Drug Regulations*, items 10 and 11 of the table following B.01.402). Furthermore, the content claims "source of fibre", "high source of fibre", and "very high source of fibre" can be made for foods containing respectively a minimum of 2, 4, or 6 grams of dietary fibre per serving (*Food and Drug Regulations*, Table following B.01.513, items 41-43).

Under the current policy, the amount of dietary fibre from novel fibre sources is included as part of the total dietary fibre declaration in the Nutrition Facts table once its safety and physiological benefit have been demonstrated in accordance with Health Canada's Food Directorate Guideline No. 9, *"Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them"* (Health Canada, 1997). Likewise, nutrient content claims can also be made for foods containing the approved novel fibre sources. The list of the approved fibres can be found in Chapter 6 of the *Guide to Food Labelling and Advertising* of the Canadian Food Inspection Agency.

Contrary to nutritional labelling, which is part of the *Food and Drug Regulations*, dietary fibre is not defined by these *Regulations*. Therefore, the proposed definition of dietary fibre would not change the existing rules for the total fibre declaration on the Nutrition Facts table.

Dietary fibre contributes to the energy content of the diet through the absorption of fermentation products such as short chain fatty acids. Because the fermentation process is anaerobic, less energy is recovered from dietary fibre than the 4 kcal (17 kJ) per gram obtained from aerobic glycolysis. Thus, a value of less than 4 kcal (17 kJ) per gram may be used for the dietary fibre content of a food if a specific energy value can be substantiated by scientific evidence. Currently, there is no agreed-upon acceptable procedure available in Canada for food manufacturers wishing to demonstrate a value lower than 4 kcal (17 kJ) /g for their fibre product. This issue is addressed in Part B of this document.

A.5.4 Analytical issues

With the proposed definition of dietary fibre, various nondigestible carbohydrates that demonstrate beneficial health effects would be considered as dietary fibre. It is therefore apparent that a new, comprehensive dietary fibre methodology would be required to accommodate the fibre definition. Specifically, the method(s) would be required: a) to quantify resistant starch as well as carbohydrates with a DP>2; and b) ideally, to exclude polymers and oligomers not shown to have physiological effects.

The Codex Committee on Nutrition and Foods for Special Dietary Uses faced the same challenge after the adoption of their fibre definition. The issue was addressed at the 31th Session held in Germany in November 2009 (Codex, ALINORM 10/33/26), and the Committee proposed a draft list comprising 19 dietary fibre methods merged into the four following groups: general methods that do not measure the lower molecular weight fraction; general methods that measure both the higher and the lower molecular weight fraction; methods that measure individual specific components; and other methods.

For regulatory/nutrition labelling purposes, ingredient developers and food manufacturers would be required to use accepted methods for quantifying fibre. Procedures for measurement of specific dietary fibres have already been developed.

For assessing compliance and measuring the total dietary fibre content of a food, the Canadian Food Inspection Agency (CFIA) would require a method which targets the full range of dietary fibre included in the scope of the proposed definition. To that purpose, the AOAC 2009.01 Official Method represents the best analytical approach since it measures total dietary fibre (including resistant starch and non-digestible oligosaccharides). Furthermore, this method eliminates potential issues of double accounting when a carbohydrate fraction is partially or completely measured by a

combination of specific methods. As an example, by adding the result from the AOAC method 2002.02 (specific for resistant starch) to the Prosky method (AOAC 985.29) result, which also measures some of the resistant starch, there would be an overestimation of dietary fibre by the amount of resistant starch measured by AOAC 985.29.

However, by using the AOAC 2009.01 method, it might be impossible to exclude polymers and oligomers shown to have no physiological effects. As a matter of fact, analytical methods address chemistry of the fibre regardless of the physiological effect.

In light of the methods of analysis for dietary fibre proposed by the Codex Committee on Nutrition and Foods for Special Dietary Uses, the general and specific methods listed in Table 2 are proposed for consideration. They are all AOAC methods which have been scientifically validated. This list would be revised as new substances are identified dietary fibres and new analytical methods are developed and validated to measure them.

Table 2. Proposed methods for quantifying dietary fibre

Method (Reference)	Components measured	Procedure Type	Comments
General methods for total, soluble and insoluble dietary fibre			
AOAC 985.29, 991.42 and 993.19 (Prosky et al., 1985, 1992, 1994)	Total, insoluble and soluble dietary fibre, lignin, some inulin, and some resistant starch (RS).	Enzymatic-gravimetric	Oligosaccharides, resistant maltodextrin and polydextrose are not quantified. No specific value for RS is provided
AOAC 991.43 (Lee et al, 1992)	Total, insoluble and soluble dietary fibre, lignin, some inulin, and some RS.	Enzymatic-gravimetric	Oligosaccharides, resistant maltodextrin (RMD) and polydextrose are not quantified. No specific value for RS is provided
AOAC 992.16 (Mongeau and Brassard, 1993)	Total, insoluble and soluble dietary fiber, lignin, and some chitin.	Enzymatic-gravimetric	Inulin, oligosaccharides, polydextrose, RS and RMD are not quantified
AOAC 2001.03 (Gordon and Okuma, 2002)	Total, insoluble and soluble dietary fibre (including maltodextrins).	Enzymatic-gravimetric and liquid chromatographic	
AOAC 2009.01 (Mc Cleary et al, 2010)	Total, insoluble and soluble dietary fibre, lignin, RS, and oligosaccharides.	Enzymatic-gravimetric-high pressure liquid chromatographic	
AOAC 994.13 (Theander et al, 1995, Uppsala method)	Total dietary fiber including resistant starch (RS3) is calculated as sum of individual neutral sugars, uronic acid residues and Klason lignin	Enzymatic, gas chromatographic	To be used to monitor changes in composition and content
Methods for specific components			
AOAC 997.08 (Hoebregs, 1997)	Inulin, fructooligosaccharides	Enzymatic-ion exchange chromatographic	
AOAC 999.03 (McCleary et al, 2000)	Inulin, fructooligosaccharides	Enzymatic-spectrophotometric	
Modified AOAC 991.43 (Lee et al., 1995)	Psyllium-containing products	Enzymatic-gravimetric	
AOAC 992.28 (Zygmunt and Paisley, 1993)	β-D-glucan	Enzymatic-spectrophotometric	Specific after enzymatically hydrolysing all other carbohydrate polymers
AOAC 995.16 (McCleary and Codd, 1991)	β-D-glucan	Enzymatic-spectrophotometric	Specific after enzymatically hydrolysing all other carbohydrate polymers
AOAC 2001.02 (de Slegte, 2002)	Galactooligosaccharides	Enzymatic-ion exchange chromatographic	
AOAC 2000.11 (Craig et al, 2001)	Polydextrose	Enzymatic-ion exchange chromatographic	Peak obtained as a single "hump." Carbohydrate quantified by total area under peak (refractive index).
AOAC 2002.02 (McCleary and Monaghan, 2002)	Resistant starch (RS2 and RS3)	Enzymatic	Results in line with in vivo data

PART B Proposed Policy on Energy Value for Dietary Fibre

B.1 Introduction

In Canada, a caloric value of 4 kcal (17 kJ)/g is applied for the fibre portion of a product, unless a specific energy value is available for the fibre source and has been approved by Health Canada. Advances in scientific knowledge indicate that an energy value of 2 kcal (8 kJ)/g for dietary fibre is more accurate.

The purpose of this section of the document is to analyze the Canadian and the international situation and to propose a new policy regarding the energy value for dietary fibre, as an internationally harmonized energy value for fibre will improve consistency in food labelling across jurisdictions.

B.2 Current Canadian policy

In Canada, the metabolizable energy value of a food is required to be reported on food labels in the Nutrition Facts table. The *Food and Drug Regulations* defines the energy value of foods to be the amount of energy made available to a person's body when the constituents of the food, including protein, fat, carbohydrate and alcohol, are metabolized following ingestion of the food [*Food and Drug Regulations B.01.001*].

The *Guide to Food Labelling and Advertising (GFLA)* indicates that the energy value of foods should be calculated by the Atwater method, using specific factors from the latest revisions of *USDA Agriculture Handbook No. 8: Composition of Foods* (1984). However, average factors may also be used in place of specific factors provided that the energy values are in reasonable agreement with the more accurate average values determined according to Merrill and Watt. The acceptable average values are 4 kcal (17 kJ) /g for protein, 9 kcal (37 kJ) /g for fat, 4 kcal (17 kJ) /g for carbohydrate, and 7 kcal (29 kJ) /g for alcohol (Section 6.4 of the *GFLA*).

The metabolizable energy value is most applicable to constituents such as protein, fat, and available carbohydrates that are completely digested in the small intestine. However, a number of carbohydrates are partly or not at all digested in the small intestine and are fermented in the large bowel to short chain fatty acids (SCFA) and gases. These carbohydrates include the non-digestible oligosaccharides, resistant starch and non-starch polysaccharides. Although SCFA are an important direct source of energy for the colonic mucosa, the process of fermentation is metabolically less efficient than absorption in the small intestine and these carbohydrates provide the body with less energy.

Specific energy values are currently accepted in Canada for some fibre sources and non digestible carbohydrates, such as, 0.6 kcal (2.5 kJ) /g for the dietary fibre portion of wheat bran and 2.4 kcal (10 kJ) /g for wheat bran itself, 2.2 kcal (9.2 kJ) /g for inulin, 2.0 kcal (8 kJ) /g for fructooligosaccharides, and 1 kcal (4 kJ) /g for polydextrose (Sections

6.4.2 and 6.4.3 of the *GFLA*). In the past, these decisions have been based on data from animal studies or on regression equations taking into account the energy derived from anaerobic fermentation and the energy excretion in urine and stool from human and animal experiments. Currently, there is no agreed-upon acceptable method in Canada for food manufacturers wishing to demonstrate a value lower than 4 kcal (17 kJ) /g for their fibre products.

B.3 International situation

In 1997, FAO/WHO held an Expert Consultation on Carbohydrates in Human Nutrition (FAO/WHO, 1998), and in 2002, a Technical Workshop on Food Energy – Methods of Analysis and Conversion Factors (FAO, 2003). Both expert consultations recommended that, for nutritional and labelling purposes, the energy value should be set at 2.0 kcal (8 kJ) /g for carbohydrate which reaches the colon. It was also indicated that 70 percent of the fibre in traditional foods is assumed to be fermentable. The recommended energy value was based on studies published by Roberfroid et al (1993) and Livesey and Elia (1995).

In the USA, for calorie calculation, the amount of insoluble fibre can be subtracted from the total carbohydrate content (e-CFR, Title 21, § 101.9(c)(1)(i)(C)). Therefore, the energy value assigned to insoluble fibre is 0 kcal/g and the energy value for soluble fibre is 4 kcal (17 kJ) /g (IOM, 2001).

In Australia and New Zealand, the energy value assigned to unavailable carbohydrate (including dietary fibre) is 2 kcal (8kJ) /g (Standard 1.2.8, Food Standards Code, FSANZ).

In Japan, the government adopted guidelines for calculation of the caloric value of dietary fibres under which fermentable fibre is assigned a value of 2 kcal (8kJ) /g (Goldring, 2004).

In 2004, the Nordic Nutrition Recommendations covering the Nordic European countries Denmark, Finland, Iceland, Norway and Sweden assigned an energy value of 2 kcal (8kJ) /g for dietary fibre (Nordic Nutrition Recommendations, 2004).

In the European Union, the energy value of 2 kcal (8kJ) /g for fibre was established in 2008. The Commission to the European Union considered the use of an appropriate average fibre value based on the FAO report of the technical workshop on food energy (FAO, 2003). The provision for the above Directive 2008/100/EC will apply in the European Member States beginning in October 31, 2012 (Official Journal of the European Union, October 29, 2008).

B.4 Proposed policy

Under the proposed policy, an energy value of 2 kcal (8kJ) /g would be used for the dietary fibre portion of a food. If manufacturers would like to declare an energy value less than 2 kcal (8kJ) /g, scientific evidence to support the declaration would be required. General guidance on acceptable methodology for determining the energy value for dietary fibre is presented in the appendix.

B.5 Impact analysis

The parties affected by this proposal are: the food industry, including the importers and manufacturers of fibre ingredients; the government (Health Canada and CFIA as standard setting and enforcement agencies, respectively); and consumers.

Food industry – The adoption of this policy would benefit large and small fibre manufacturers who would not be required to carry out studies in order to claim values ranging from 2 up to less than 4 kcal (8 up to less than 17 kJ) /g for dietary fibre. For food manufacturers wishing to claim a value lower than 2, there would be an option to submit supporting evidence to Health Canada.

Government – The workload of Health Canada would decrease with the availability of an acceptable methodology for demonstrating energy values lower than 2 kcal (8kJ) /g, as there would be no need to pre-approve protocols submitted by the food industry. Health Canada would assess only scientific evidence obtained according to the guidance in the Appendix.

As an agency responsible for inspection, regulatory compliance testing, and enforcement, CFIA would be affected by this proposed policy. Currently, total carbohydrate (CHO) in food is calculated by subtracting the content of protein, fat, ash and moisture from the weight of the product. It includes sugars, starch, dietary fibre, sugar alcohols, glycerol and polydextrose (Section 6.8 of the *GFLA*). Under the proposed policy, the method used by CFIA to calculate the energy value of food would be modified since a dietary fibre analysis would now be required to calculate the carbohydrates by difference. The new method would be:

CHO = Total solids - [Protein + Fat + Ash + Dietary Fibre],

where CHO = 4 kcal/g, Protein = 4 kcal/g, Fat = 9 kcal/g, and Dietary Fibre = 2 kcal/g. As a result of this modification, the cost and time required for analysis would be increased. There would also be a need to update compliance tools and train staff.

Consumers – The use of a lower energy value for dietary fibre would be more accurate than the 4 kcal (17 kJ) /g and would provide consumers with better information to make judicious food choices.

Appendix

Guidance on acceptable methodology for determining the energy value for dietary fibre

The guidance below would be the acceptable methodology to be used by food manufacturers wishing to declare an energy value of less than 2 kcal/g for approved dietary fibres in Canada.

Since the fermentation occurs in the colon, which is also the absorption site of SCFA (source of energy), it is important to determine the amount of material entering the large intestine and its rate of disappearance. Ileal digesta cannot be readily obtained from humans with a healthy, functioning large intestine. However, from data available on SCFA production and gut physiology, it seems that swine may be the most reliable animal model to estimate SCFA production in human colon (Mc Burney and Sauer, 1993).

Health Canada does not support the use of *in vitro* fermentation techniques (including artificial gut systems) for obtaining primary data to determine the extent of fermentation of dietary fibre, and subsequently to calculate the derived energy. Although considered as a useful tool for assessing the fibre fermentability, *in vitro* systems do not usually harbour the same extent and type of gut bacteria that are found in human gastrointestinal tracts and do not indicate the amount of material entering the colon. However, *in vitro* techniques can be used as corroborating evidence.

Therefore, it is recommended to determine the energy value of dietary fibre by using a combination of human and animal studies. The grams of material disappearing in the colon is multiplied by 2 kcal (8 kJ) /g which represents the theoretical yield for energy obtained from dietary fibre fermentation. The use of complementary *in vit*ro studies is optional. The following steps are required:

A. Human study: The purpose of a balance human study is to measure the total food intake and the total fecal and urine output. For fibre fermentation, urine output is not required. This human balance study would provide the total fibre ingested and the total fibre excreted in order to allow the determination of the amount of dietary fibre fermented during the digestion.

B. Animal experimentation: A balance study with ileal-cannulated pigs is used mainly to determine the amount of ingested material that actually enters the colon. The percentage of ileal digesta obtained from pigs would be combined with the human data to estimate the energy derived from the fibre fermentation by applying a factor of 2 kcal (8 kJ) /g of material fermented.

C. Optional: *In vitro* fermentation techniques may be used to corroborate the fermentability of the pig ileal digesta (using human fecal inoculum). The actual degree of material fermented is obtained from the disappearance of the material across the large intestine (estimated input into the intestine from B and output from A).

References

AACC Report (2001) The Definition of Dietary Fibre. Report of the Dietary Fibre Definition Committee to the Board of Directors of the American Association of Cereal Chemists. Cereal Foods World 46(3):112-126.

AACC (American Association of Chemical Chemists) (2003) Dietary Fibre Technical Committee 2003. All dietary fibre is fundamentally functional. Cereal Foods World 48:128-131.

AACC letter, 2007. http://www.aaccnet.org/definitions/codexresponse.asp

AFSSA (2002) Dietary fibre: definitions, analysis and nutrition claims. Report of the specialist expert committee on human nutrition. Agence Française de Sécurité Sanitaire des Aliments. (A.F.S.S.A.). Maisons-Alfort. FRA. 62p., 6 tabl., réf. 2p. http://www.afssa.fr/Documents/NUT-Ra-Fibres.pdf

Anderson JW, Randles KM, Kendall CWC, Jenkins DJA, (2004) Carbohydrate and fiber recommendations for individuals with diabetes: a quantitative assessment and meta-analysis of the evidence. J Am Coll Nutr. 23:5–17.

Anderson JW, Baird P, Davis RH Jr, Ferreri S, Knudtson M, Koraym A, Waters V, Williams CL. (2009) Health benefits of dietary fiber. Nutr Rev. 2009 Apr;67(4):188-205.

ANZFA (Australia New Zealand Food Authority) (2000) Notice of a Proposed Change to Food Regulation and Further Invitation for Submissions . Application 277. Inulin and Fructooligosaccharides as Dietary Fibre, http://www.foodstandards.gov.au/_srcfiles/A277_FA.pdf.

Asp, N.-G. (1992) Preface: Resistant Starch. Proceedings of the 2nd plenary meeting of EURESTA: European Flair Concerted Action No. 11 on Physiological Implications of the Consumption of Resistant Starch in Man. European Journal of Clinical Nutrition 46, Supplement 2, SI.

Bonithon-Kopp C, Kronborg O, Giacosa A, Rath U, Faivre J (2000) Calcium and fibre supplementation in prevention of colorectal adenoma recurrence: a randomised intervention trial. European Cancer Prevention Organisation Study Group. Lancet 356(9238):1300-1306.

Brown L, Rosner B, Willett WW, Sacks FM, (1999) Cholesterol-lowering effects of dietary fiber: a meta-analysis. Am J Clin Nutr. 69:30–42.

Canadian Council of Food and Nutrition (August 2008) Tracking Nutrition Trends VII.

CFIA (Canadian Food Inspection Agency) (2003) Guide to food labelling and advertising. Chapter 6. http://www.inspection.gc.ca/english/fssa/labeti/guide/ch6ae.shtml#6.8

e-CFR, Title 21, § 101.9(c)(1)(i)(C)). http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div8&view=text&node=21:2.0.1.1.2.1.1.6&idno=21

CFR - Code of Federal Regulations Title 21, § 101.9(g)(2), US FDA, revised April 2009, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=101.9

Codex Alimentarius Commission, ALINORM 09/32/26, Report of the 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, Cape Town, South Africa, 3 - 7 November 2008 http://www.codexalimentarius.net/download/report/710/al32_26e.pdf.

Codex Alimentarius Commission, ALINORM 10/33/26, Report of the 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, Düsseldorf, Germany, 2 - 6 November 2009 (ftp://ftp.fao.org/codex/Alinorm10/al33_26e.pdf)

Craig SA, Holden JF, Khaled MY (2001) Determination of polydextrose in foods by ion chromatography: collaborative study. J AOAC Int 84:472-478.

Cummings JH. The effect of dietary fiber on fecal weight and composition. In: Spiller G, ed. Dietary Fiber in Human Nutrition. Boca Raton, FL: CRC Press; 2001:183–252.

Cummings JH, Stephen AM (2007) Review- Carbohydrate terminology and classification. Eur J Clin Nutr, 61, Suppl 1, S5-S18.

de Slegte J (2002) Determination of trans-galactooligosaccharides in selected food products by ion-exchange chromatography: collaborative study. J AOAC Int. 85:417-423.

EFSA (European Food Safety Authority). Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the EC on population reference intakes for carbohydrates and dietary fibre. The EFSA Journal (2009) xxx, 1-80.

EFSA (European Food Safety Authority). Outcome of the Public consultation on the Draft Opinion of the Scientific Panel on Dietetic products, Nutrition, and Allergies (NDA) on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 2010; 8(5):1508.

Englyst H, Wiggins HS, Cummings IH (1982) Determination of the nonstarch polysacchanides in plant foods by gas-liquid chromatography of constituent sugars as alditol acetates. Analyst 107:307-18.

Englyst HN, Kingman SM, Hudson GJ, Cummings JH (1996) Measurement of resistant starch in vitro and in vivo. Br J Nutr 75:749–755

FAO/WHO (1998) Carbohydrates in Human Nutrition. FAO Food and Nutrition Paper 66, Rome.

FAO/WHO (2003) Food Energy – Methods of Analysis and Conversion Factors. FAO Food and Nutrition Paper 77, Rome.

Fuchs CS, Giovannucci EL, Colditz GA, et al. (1999) Dietary fibre and the risk of colorectal cancer and adenoma in women. N Engl J Med 340:169-176.

Goldring JM (2004) Resistant starch: safe intakes and legal status. J AOAC Int. May-Jun;87(3):733-9.

Gordon DT, Okuma K (2002) Determination of total dietary fibre in selected foods containing resistant maltodextrin by enzymatic-gravimetric method and liquid chromatography: collaborative study. J AOAC Int 85:435-444.

Guide to Food Labelling and Advertising, Canadian Food Inspection Agency, Section 6.4. http://www.inspection.gc.ca/english/fssa/labeti/guide/ch6e.shtml

Health and Welfare Canada (1985) Report of the Expert Advisory Committee on Dietary Fibre. Ottawa: Supply and Services Canada.

Health Canada (1988) Guideline concerning the safety and physiological effects of Novel fibre sources and food products containing them. Ottawa: Food Directorate, Health Protection Branch, Health Canada.

Health Canada (1997) Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them. Health Canada's Food Directorate Guideline No. 9. Ottawa, Health Protection Branch, Health Canada. http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/novel_fibre_nouvelle_gui-eng.php

Health Canada and Statistics Canada (2004) Canadian Community Health Survey, Cycle 2.2, Nutrition. Provincial, Regional and National Summary Data Tables.

Health Canada (2006) Guidelines for the Safety Assessment of Novel Foods. Food Directorate, Health Products and Food Branch, Health Canada.

Hodge AM, English DR, O'Dea K, Giles GG (2004) Glycemic Index and Dietary Fibre and the Risk of Type 2 Diabetes. Diabetes Care 27:2701-2706.

Hoebregs H (1997) Fructans in foods and food products, ion-exchange chromatographic method: collaborative study. J AOAC Int 80:1029-1037.

IOM (Institute of Medicine) (2001) Dietary Reference Intakes: Proposed Definition of Dietary Fibre. Panel on the Definition of Dietary Fibre, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board. http://newton.nap.edu/books/0309075645/html (Last accessed on January 31, 2006).

IOM (Institute of Medicine) (2005) Dietary Reference Intakes for energy, carbohydrate, fibre, fat, fatty acids, cholesterol, protein, and amino acids (Macronutrients). Food and Nutrition Board, Institute of Medicine. The National Academies Press, Washington, DC. http://books.nap.edu/openbook.php?record_id=10490&page=R1 (Last accessed on September 9, 2009).

Jacobs ET, Giuliano AR, Roe DJ, Guillen-Rodriguez JM, Alberts DS, Martinez ME (2002) Baseline dietary fibre intake and colorectal adenoma recurrence in the wheat bran fibre randomized trial. J Natl Cancer Inst 94:1620-1625.

Jones JR, Lineback DM, Levine MJ (2006) Dietary reference intakes: implications for fibre labeling and consumption: a summary of the International Life Sciences Institute North America Fibre Workshop, June 1-2, 2004, Washington, DC. Nutr Rev 64:31-38.

Lee SC, Prosky L, DeVries JW (1992) Determination of total, soluble, and insoluble dietary fibre in foods—Enzymatic-gravimetric method, MES-TRIS buffer: Collaborative study. J AOAC Int 75: 395–416.

Lee SC, Rodriguez F, Storey M, Farmakalidis E, Prosky L (1995) Determination of soluble and insoluble dietary fibre in psyllium-containing cereal products. J AOAC Int, 78 (3), 724-729.

Livesey, G. and Elia, M. 1995. Short chain fatty acids as an energy source in the colon: metabolism and clinical implications. Physiological and clinical aspects of short chain fatty acids, (J.H. Cummings, J.L. Rombeau and T. Sakata, eds.) Cambridge University Press, Cambridge, 472-482.

Luo J, Van Yperselle M, Rizkalla SW, Rossi F, Bornet F, Slama G (2000) Chronic consumption of short-chain fructooligosaccharides does not affect basal hepatic glucose production or insulin resistance in type 2 diabetics. J Nutr 130:1572-1577.

Manley C (2006) Japan: A leader in innovation (2006 NAFFS yearbook). http://naffs.mytradeassociation.org/3/3_10/japan-leader-innovation-2.shtml. March issue.

McBurney MI, Sauer WC (1993) Fiber and large bowel energy absorption: validation of the integrated ileostomy-fermentation model using pigs. The Journal of Nutrition, 123(4):721-7.

McCleary BV, Codd R (1991) Measurement of (1-3) (1-4)-β-D-glucan in barley and oats: a streamlined enzymic procedure. J Sci Food Agric 55:303-312.

McCleary BV, Murphy A, Mugford DC (2000) Measurement of total fructan in foods by enzymatic/spectrophotometric method: collaborative study. J AOAC Int 83:356-364.

McCleary BV, Monaghan DA (2002) Measurement of resistant starch. J AOAC Int 85:665-675.

McCleary BV, DeVries JW, Rader JI., Cohen G, Prosky L., Mugford DC., Champ M., Okuma K (2010) Determination of total dietary fiber (CODEX definition) by enzymatic-gravimetric method and liquid chromatography: collaborative study, J.AOAC Int. Jan-Feb;93(1):221-33.

Michaelides J, Cooper K (2005) Dietary Fibre, Part 2. http://www.FoodinCanada.com, March.

Mongeau R, Brassard R (1993) Enzymatic gravimetric determination in foods of dietary fibre as the sum of insoluble and soluble fractions : summary of collaborative study. J AOAC Int 76:923-925.

Nakajima K (2004) Regulation Nation. Functional Foods & Nutraceuticals. January, http://www.ffnmag.com/NH/ASP/strArticleID/347/strSite/FFNSite/articleDisplay.asp Nordic Nutrition Recommendations NNR 2004 - integrating nutrition and physical activity. Nord 2004:013, ISBN 92-893-1062-6 (cited in Danish Food Composition Databank, ed 7.01, http://www.foodcomp.dk/v7/fcdb_aboutfooddata_proximates.asp, Accessed December 22, 2009)

Prosky L, Asp NG, Furda I, DeVries JW, Schweizer TF, Harland BF (1985) Determination of total dietary fibre in foods and food products: collaborative study. J AOAC 68:677-679.

Prosky L, Asp N-G, Schweizer TF, DeVries JW, Furda I (1992) Determination of insoluble and soluble dietary fibre in foods and food products: Collaborative study. J AOAC Int 75:360–367.

Prosky L, Asp N-G, Schweizer TF, DeVries JW, Furda I, Lee SC (1994) Determination of soluble dietary fibre in foods and food products: Collaborative study. J AOAC Int 77:690–694.

Roberfroid, M., Gibson, G.R. and Delzenne, N. 1993. The biochemistry of oligofructose, a non-digestible fibre: an approach to calculate its caloric value. Nutrition Reviews, 51:137-146.

Ruderman B, (2005) Ask the expert. What's in a name? http://www.FoodinCanada.com, October, p34.

Salmeron J, Manson JE, Stampfer MJ, Colditz GA, Wing AL, Willett WC (1997) Dietary fibre, glycemic load, and risk of non-insulin-dependent diabetes mellitus in women. JAMA 277:472-477.

Standard 1.2.8, Food Standards Code, FSANZ, Issue 103. http://www.foodstandards.gov.au/_srcfiles/Standard_1_2_8_Nutrition_Info_v113.pdf (Accessed December 22, 2009)

Theander O, Aman P, Westerlund E, Andersson R, Pettersson D. (1995) Total dietary fiber determined as neutral sugar residues, uronic acid residues, and Klason lignin (the Uppsala method): collaborative study. J AOAC Int.;78(4):1030-44.

Trowell H (1972) Ischemic heart disease and dietary fibre. Am J Clin Nutr 25:926-932.

Tungland BC, Meyer D. Nondigestible Oligo- and Polysaccharides (Dietary Fiber): Their Physiology and Role in Human Health and Food. COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY, Vol. 1, 2002, p73.

Woo KS, Seib PA (2002) Cross-linked resistant starch: preparation and properties. Cereal Chem 79:819–825.

Ylönen K, Saloranta C, Kronberg-Kippilä C, Groop L, Aro A, Virtanen SM, the Botnia Research Group (2003) Associations of Dietary Fibre With Glucose Metabolism in Nondiabetic Relatives of Subjects With Type 2 Diabetes - The Botnia Dietary Study. Diabetes Care 26:1979-1985.

Zygmunt LC, Paisley SD. Enzymatic method for determination of (1-3)(1-4)-β-glucans in grains and cereals: collaborative study. J. AOAC Int. 76, 1069-1082, 1993 (in AOAC 17th edition 2000).

72 Fed. Reg. 62,149, November 2, 2007. Federal Register Advance Notice of Proposed Rulemaking (Food Labeling): Revision of Reference Values and Mandatory Nutrients; US FDA, http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/RegulationsFederalRegisterDocuments/ucm073531.htm