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Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products

February 2012

Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch



Canada 

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Introduction

In 1985, the Department of National Health and Welfare adopted the dietary fibre definition developed by its Expert Advisory Committee on Dietary Fibre:

“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 isolated from plants, 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 the non-starch polysaccharides of plant origin would be considered as novel sources of fibre and 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).

During the last decade, a number of countries and scientific bodies have recognized a wide range of substances as dietary fibre based on their chemical nature and their physiological properties, regardless of their origin (American Association of Cereal Chemists (AACC) Report, 2001; Standard 1.2.8 Food Standards Code; Institute of Medicine (IOM), 2001; Agence Française de Sécurité Sanitaire des Aliments (AFSSA), 2002; European Commission, 2008; Codex, 2009; European Food Safety Authority (EFSA), 2010). These products include, for example, the non-digestible oligosaccharides, resistant starch, and other modified and synthetic substances. However, some of these fibre-like products are not considered to be dietary fibre according to the current Canadian definition. The current international trend in defining dietary fibre is to specify the basic chemical features and resistance to digestion in addition to requiring that a fibre have physiological effects. This approach does not typically limit dietary fibre to plant sources.

In light of positions taken on dietary fibre by the U.S. Food and Nutrition Board of the Institute of Medicine and the Codex Alimentarius Commission, and taking into account advances in scientific knowledge about dietary fibre and food industry innovation, Health Canada has developed a revised dietary fibre definition. In addition, Health Canada is adopting a general caloric value of 2 kcal (8 kJ) /g for dietary fibre to replace the previous energy value of 4 kcal (17 kJ) /g. The purpose of these changes is to bring Canada up to date with international standards regarding the definition of dietary fibre.

This report presents Health Canada's policy on the recognition and labelling of food products and ingredients with respect to dietary fibre. The new fibre policy takes into consideration the relevant comments expressed by respondents in the course of the consultation.

1- Consultation

Health Canada posted a consultation document on the revised dietary fibre policy on Health Canada's website that was open to stakeholder feedback between December 9, 2010 and February 7, 2011. In addition to the proposed dietary fibre definition and energy value, the [consultation document](#) included an overview of the most recent dietary fibre definitions and energy values from other jurisdictions along with an analysis of the issues related to those currently used in Canada.

Fifty-one comments were received from industry associations, food companies, consultants, universities and not-for-profit organizations. The comments were analyzed and a summary of stakeholders' feedback on the fibre proposal will be posted on Health Canada's website.

In general, respondents supported the revised fibre definition and the energy value of 2 kcal (8 kJ) /g. However, some respondents made suggestions regarding an expanded list of physiological effects for fibre as well as the implementation of a more flexible pre-market review process.

2- Definition of Dietary Fibre (2012)

“Dietary fibre consists of:

1) carbohydrates with a DP¹ of 3 or more that naturally occur in foods of plant origin and that are not digested and absorbed by the small intestine; and

2) accepted novel fibres.

Novel fibres are ingredients manufactured to be sources of dietary fibre and consist of carbohydrates with a DP of 3 or more that are not digested and absorbed by the small intestine. They are synthetically produced or are obtained from natural sources which have no history of safe use as dietary fibre or which have been processed so as to modify the properties of the fibre contained therein. Accepted novel fibres have at least one physiological effect demonstrated by generally accepted scientific evidence.”

¹ DP: degree of polymerization or number of saccharide units.

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The substances in part 1 of this definition are all edible plant materials that have a history of use as food and have been processed or cooked using conventional processes. They include fruits, vegetables, pulses, seeds, nuts, cereals, legumes, etc.

Some minor substances, such as lignin, waxes, cutin, suberin, phytate, and 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 not separated from 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 isolated and introduced into a food.

Substances in part 2 of the definition include, for example, substances obtained from agricultural crop by-products and from raw plant materials, substances of animal or bacterial origin, chemically modified substances, synthetic products, etc. These substances are not historically used as food fibre sources. The term “novel fibre” is used only during the pre-market review process involving Health Canada, the food industry, and the Canadian Food Inspection Agency. Once a novel fibre source has been accepted by Health Canada, it is labelled as dietary fibre and is known as such.

In contrast to Health Canada’s previous position on novel fibre (Health Canada, 1988), fine grinding is not a factor in determining whether a product is a novel fibre source. Health Canada considers that very fine particle size does not represent a risk for human health since toxicological data from humans and animals have provided no evidence of any adverse pathology associated with the intestinal persorption of microcrystalline cellulose of particle size as small as 5 microns (European Commission, 1997; World Health Organization (WHO), 1998). Processed fibre sources have an average particle size much greater than 5 microns. In addition, the data reviewed by Health Canada of various novel fibre sources, as well as literature data (Brodribb and Groves, 1978; Jenkins et al, 1999), support the conclusion that fine particle materials can be effective fecal bulking agents. It has also been shown that reducing particle size improves fibre fermentability (Jenkins et al, 1999; Stewart and Slavin, 2009).

3- Energy Value

In Canada, a caloric value of 4 kcal (17 kJ)/g was previously applied to the fibre portion of a product, unless a specific energy value was available for the fibre source and had been approved by Health Canada. However, advances in scientific knowledge indicate that an energy value of 2 kcal (8 kJ)/g for dietary fibre more accurately reflects its metabolizable energy in mixed diets (Brown, Livesey et al, 1998).

This is supported by experts consulted by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization which held an Expert Consultation on Carbohydrates in Human Nutrition in 1997 (FAO/WHO, 1998), and a Technical Workshop on Food Energy - Methods of Analysis and Conversion Factors in 2002 (FAO, 2003). Both expert consultations recommended that, for nutritional and labelling purposes, the energy value should be set at 2 kcal (8 kJ) /g for carbohydrates that reach the colon. It was also indicated that 70 percent of the fibre in traditional foods can be assumed to be fermentable. The recommended energy value was based on studies published by Livesey (1990) and Livesey and Elia (1995).

Some jurisdictions such as Australia and New Zealand, Japan, and the European Union have adopted the energy value of 2 kcal (8kJ) /g for dietary fibre (Standard 1.2.8, Food Standards Code; Goldring, 2004; European Commission, 2008). However, in the USA, the calorie calculation is different, namely, the amount of insoluble fibre can be subtracted from the total carbohydrate content (Electronic Code of Federal Regulations, Title 21, § 101.9(c)(1)(i)(C)). Therefore, the energy value assigned in the USA to insoluble fibre is 0 kcal/g and the energy value for soluble fibre is 4 kcal (17 kJ) /g (IOM, 2001).

Health Canada considers the energy value for carbohydrate that is not digested in the small intestine, but is fully fermented in the large intestine, is 2 kcal (8 kJ) /g. This will be the general value used for all unavailable carbohydrate, including dietary fibre, in the absence of specific values. This will also apply to inulin for which the previously calculated value was 2.2 kcal (9.2 kJ) /g.

Products with energy values lower than 2 kcal (8kJ) /g, which have already been accepted by Health Canada based on scientific evidence, may carry a label declaration of these specific caloric values. Thus, the energy value of the fibre portion of wheat bran is 0.6 kcal (2.5 kJ) /g and the wheat bran itself has an energy value of 2.4 kcal (10 kJ) /g. Polydextrose, an eligible fibre source under the new definition, has been previously accepted as having an energy value of 1 kcal (4 kJ) /g given that it is only partially fermentable (Auerbach, Craig et al. 2007).

For food manufacturers wishing to declare an energy value lower than 2 kcal (8 kJ)/g, Health Canada requires substantiation with evidence obtained from a properly designed human balance study. Animal experimentations and in vitro fermentation techniques are optional and would be considered as supporting information.

4- Physiological Effects

In the [proposed dietary fibre policy](#) posted in 2010, with respect to defining physiological effects associated with dietary fibre, Health Canada aligned with the position taken by the Institute of Medicine (IOM) panel in charge of proposing a new US dietary fibre definition (IOM, 2001).

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While recognizing the three physiological effects identified by Health Canada in 1997 (improving laxation or regularity, normalization of blood lipid levels, and attenuation of blood glucose responses), the IOM panel did not provide a list of specific effects required to be demonstrated, as it considered that a list would become quickly outdated as new health effects of non-digestible carbohydrates were identified and characterized. The intent was to promulgate definitions that had overall long-term applicability.

However, during the consultation, many stakeholders asked for more explicit guidance on the physiological effects recognized by Health Canada. In response to this request, Health Canada considers that the physiological effects listed below are functions of dietary fibre and are acceptable as a physiological effect of novel fibre sources. However, they are not exclusive and other effects attributable to dietary fibre may be recognized by Health Canada as science evolves.

Dietary fibre:

- improves laxation or regularity by increasing stool bulk;
- reduces blood total and/or low-density lipoprotein cholesterol levels;
- reduces post-prandial blood glucose and/or insulin levels;
- provides energy-yielding metabolites through colonic fermentation.

In this list, “providing energy-yielding metabolites through colonic fermentation” has been added as a fourth effect to the list of the three well established physiological effects of dietary fibre previously accepted by Health Canada (Health Canada, 1997). Traditionally, the large intestine was seen as an organ responsible for water and electrolyte absorption as well as providing a mechanism for the disposal of waste products of digestion. It is clear now that the large intestine is also a major site of bacterial fermentation not only of non-digestible carbohydrate, but also of protein escaping digestion in the small intestine, sloughed epithelial cells, and mucins. Bacteria are present in the human colon at 10^{10} to 10^{11} colony forming unit/g wet weight with over 400 species identified in human feces (Topping and Clifton, 2001). The major end products of colonic fermentation are the short chain fatty acids (SCFA), primarily acetate, propionate and butyrate. While carbohydrates remain the major source of substrate for colonic SCFA production in a normal western diet, protein can also contribute significantly. Cummings (1997) estimated that 20-60 g of carbohydrate and 5-20 g of protein are available to the colonic microflora on a daily basis.

From the host's view point, this metabolic activity is important given that 95% of SCFA generated in the colon are absorbed and metabolised by the host (Cummings and Macfarlane, 1991; Topping and Clifton, 2001). It is reported that in individuals living on western diets, the energy provided by SCFA is about 5-10% of the basal energy requirement (McNeil, 1984; McBurney and Thompson, 1989; Cummings, 1997).

Short chain fatty acids can be used as an energy source either by colonic mucosal epithelial cells (Scheppach, 1994; Marsman and McBurney, 1995; Clausen and Mortensen, 1995; Scheppach et al, 1996) or when they are absorbed into the circulation (Cummings, 1981; Scheppach et al, 1991). There is evidence that colonocytes are specifically adapted to utilize butyrate (Marsman and McBurney, 1995) and, in cells and tissue sections from normal subjects, as well as *in vivo*, butyrate stimulates cell proliferation (Sakata, 1987; Bartram et al, 1993; Scheppach et al, 1995).

In conclusion, Health Canada considers that dietary fibre acts as a substrate for the bacterial community of the large intestine and, through the action of this community, provides energy-yielding nutrients such as SCFA to the colon epithelial cells as well as to other organs of the body.

The evidence required by Health Canada to support the production of energy-yielding metabolites through the colonic fermentation of dietary fibre would include *in vivo* and *in vitro* studies. Depending on what is known about the physico-chemical characteristics of the product, the types of studies required could include:

- 1) Human or animal studies demonstrating that the product is not digested and absorbed in the small intestine (for example, human breath gas evolution, ileal excreta collected from colectomized animals);
- 2) *In vitro* fermentation studies providing an estimate of SCFA and gas production;
- 3) Human or animal feces analysis showing fibre disappearance.

Health Canada would also consider other applicable methods.

France was the first jurisdiction to recognize the stimulation of colonic fermentation as a physiological property of dietary fibre (AFSSA, 2002). In 2008, this property (fermentability by colonic microflora) was adopted by the European Commission as one of the physiological effects of dietary fibre (European Commission, 2008). In addition, in 2010, the *Panel on Dietetic Products, Nutrition and Allergies* of the European Food Safety Authority identified short-chain fatty acids-production in the colon by undigested oligosaccharides as one of the fibre-like effects (EFSA, 2010).

The U.S. Food and Nutrition Board of the Institute of Medicine considers fermentation to be one of the physiological effects affected by the fibre properties and indicates that butyrate, one of the fermentation end products, is the preferred energy source for colon cells. In addition, they emphasize that foods rich in hemicelluloses and pectins contain more completely fermentable fibre than foods rich in celluloses, whereas resistant starch was identified as being highly fermentable (IOM, 2005).

5- Requirements for Novel Fibre Sources without a History of Safe Use as Food

The safety of a novel fibre source must be established before it may be used as an ingredient in foods. As well, the physiological effect of the novel fibre source must be demonstrated before it may be claimed to be a source of fibre in foods (Section 4 and Subsection 5.1 of the *Food and Drugs Act*). The physiological effects of dietary fibre are identified in Section 4 of this policy and a [guideline](#) is available to assist food manufacturers in preparing a fibre application to Health Canada (Health Canada, 1997).

If a proposed fibre source is a “Novel Food,” subject to notification under Division 28 of the *Food and Drug Regulations*, a novel food application must be completed and submitted to Health Canada preceding or concurrent with a novel fibre application.

If a novel fibre source has been reviewed by Health Canada and found acceptable as a dietary fibre source (safety and physiological effect demonstrated), the manufacturer will receive a “letter of no objection”. These letters of no objection are specific to the brand of the fibre source that was reviewed, unless otherwise specified.

6- Requirements for Products Recognized as Dietary Fibre Sources in Other Countries

Health Canada recognizes that under the fibre policy developed in 1985/1988 and revised in 1997 (Health Canada, 1997), many products were not eligible to be reviewed as fibre in Canada due to the restriction to plant origin and non-starch polysaccharides (although they were considered to be fibre in other jurisdictions). Such products include, for example:

- starch derived products (high amylose maize starch (RS2); retrograded starch (RS3) and chemically modified starch (RS4));
- oligosaccharides (fructo-oligosaccharides, galacto-oligosaccharides, etc.)
- synthetic products (polydextrose, etc.)

Another category of products not yet approved as fibre in Canada includes a large variety of plant derived products considered novel fibres, some of them chemically modified or highly concentrated such as various gums and mucilages, cellulose and modified cellulose, extracted beta-glucan, for which either no or inadequate data have been received by Health Canada.

For the products already recognized as fibre sources in other countries and available on the Canadian market as safe food ingredients, Health Canada will assess the scientific evidence substantiating the physiological effect in accordance with the new fibre policy in order to develop a positive list of dietary fibres. This list will be posted on the Health Canada website and regularly updated. Concurrently, Health Canada will consider requests from petitioners to

sell and label products as fibre sources based on submitted systematic literature reviews and opinions issued by regulatory or scientific organizations with standards of evidence that are similar to those of Health Canada. Petitioners will also have the option to submit the results of their own clinical data obtained according to the [Health Canada guideline](#) (1997).

7- Labelling and Claims

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 dietary fibre naturally occurring in foods and the amount of dietary fibre from accepted novel fibre sources are both included as part of the total dietary fibre declaration in the Nutrition Facts table as per the new definition and using methodologies identified in Section 8 – Methods of analysis. 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). The energy value of 2 kcal (8 kJ)/g must be included in the caloric declaration.

Health Canada no longer requires a product accepted as a fibre source based on evidence obtained in one food matrix to have the effect demonstrated in another matrix; it will be permitted to be labelled as dietary fibre in any food matrix.

The existing rules for nutrient content claims are maintained. 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). Comparative claims about amount of dietary fibre may be made under the conditions described in item 44 of the previously mentioned table. “More fibre” claims are not restricted to fibre from the same source. Claims comparing the qualities of one fibre-containing food to another should not be made because of the substantial differences in chemical nature and physiological effects among dietary fibres.

In contrast, a health claim that is made about a beneficial effect of a specific dietary fibre source requires substantiation on a case-by-case basis and is subject to conditions of use. Generally, a health claim about a specific food ingredient must be supported by the totality of relevant evidence related to that food ingredient.

Information on the substantiation of health claims can be found in the [Guidance Document for Preparing a Submission for Food Health Claims](#). This guidance is also applicable to documenting the scientific evidence in support of health claims associated with dietary fibres or sources of dietary fibre.

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8- Methods of Analysis

In consultation with the Canadian Food Inspection Agency (CFIA), Health Canada proposes a list of appropriate analytical methods for dietary fibre in Tables 1 (general methods) and 2 (specific methods). These methods as well as other equivalent and validated methods are considered acceptable to quantify fibre.

The amount of dietary fibre from novel fibre sources used as ingredients but not yet accepted by Health Canada as fibre sources must not be included as part of the total dietary fibre declaration in the Nutrition Facts table.

Table 1. General methods for quantifying dietary fibre

Method (Reference)	Components measured	Procedure Type	Comments
Association of Official Analytical Chemists (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 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.
AOAC 2009.01 (Mc Cleary et al, 2010)	Total, insoluble and soluble dietary fibre, lignin, RS, and oligosaccharides.	Enzymatic-gravimetric-high pressure liquid chromatographic	

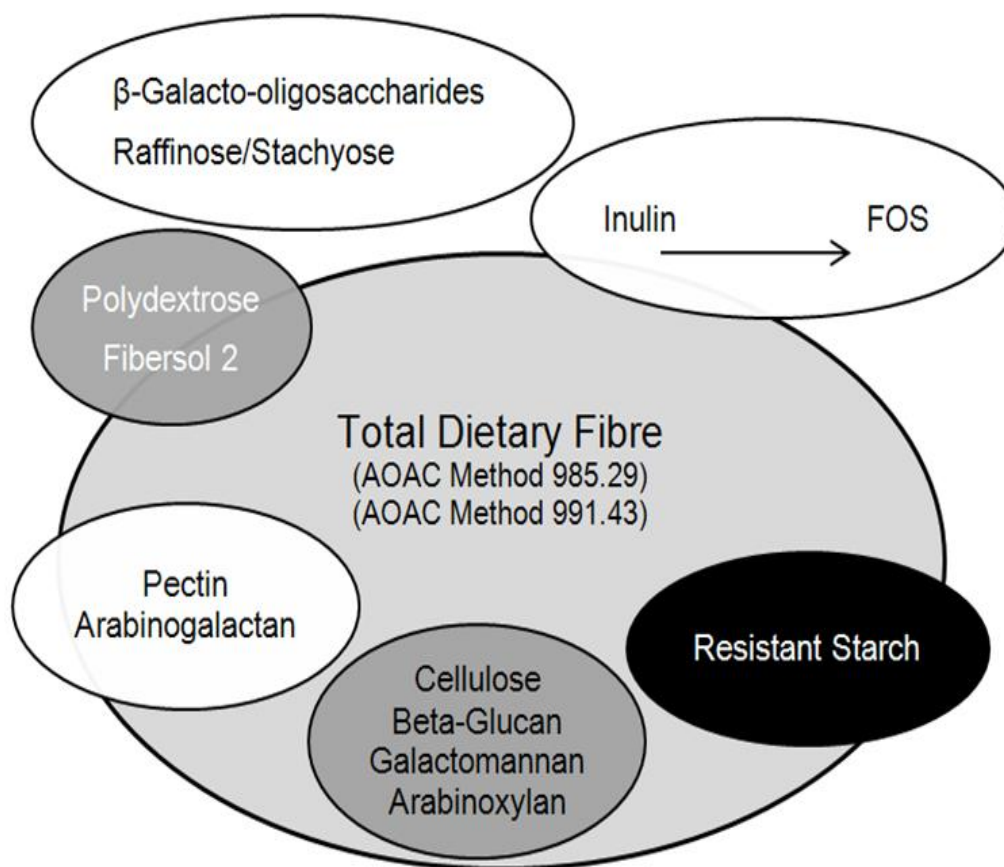
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Table 2. Methods for quantifying specific dietary fibre components

Method (Reference)	Components measured	Procedure Type	Comments
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.

For assuring compliance, CFIA will use the AOAC 2009.01 method. This method is seen as effective for measuring the total dietary fibre content of a food, regardless of the fibre chemical structure. In spite of some concerns expressed by stakeholders during the fibre consultation, Health Canada and the CFIA consider that the variability of the AOAC 2009.01 method is similar to that of other dietary fibre analytical procedures. Furthermore, this method eliminates issues of double accounting when certain potential fibre fractions such as resistant starch, polydextrose and inulin are partially and completely measured by a combination of general and specific methods (Figure 1).

Figure 1- Schematic representation of dietary fibre components measured, and not measured, by AOAC Official Methods 985.29 and 991.43. Also depicted are the problems of partial measurement of RS, Polydextrose and resistant maltodextrins by current AOAC total dietary fibre methods. Most of the low-molecular-weight soluble dietary fibre (galactooligosaccharides, fructooligosaccharides etc) are not measured. The current integrated total dietary fiber procedure measures all components shown, with no possibility of double counting. (Copyright McCleary et al, 2010. Used with permission.)



9- Submission to Health Canada

Submissions for novel fibre sources as well as submissions for health claims for dietary fibre (See Section 7) made on food sold in Canada should be sent to the Submission Management and Information Unit (SMIU) within Health Canada's Food Directorate. Pre-submission consultation is encouraged.

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The SMIU can be reached at:

Submission Management and Information Unit
Food Directorate, Health Products and Food Branch, Health Canada

251, Sir Frederick Banting Driveway
Postal Locator 2202E, Room E224
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