



Novel Fibers in Canada: Regulatory Developments



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No one can argue that the ultimate goal of any government legislation related to food should be consumer safety and protection, but when sound research predates regulatory action by an extended period, the issue becomes more than a little frustrating for both the industry and consumers. At what point does red tape hinder rather than help? For Canadian and international companies interested in marketing novel fiber sources in Canada, regulatory barriers have been overwhelming to the point that many simply choose to ignore the Canadian market altogether.

The Canadian Food and Drugs Act and Regulations were passed into law in 1953. The definition of food under the Food and Drugs Act includes "... any article manufactured, sold, or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever." Drugs are defined as "...any substance or mixture of substances manufactured, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or its symptoms, restoring, correcting, or modifying organic function."

Through its definitions of "food" and "drug," this legislation currently restricts health-related claims for foods and food ingredients and limits the government's ability to deal with new ingredients, even those submitted without claims. Since 1953, these products have been considered as either foods or drugs depending on the type and concentration of the "active ingredient" and whether claims are made.

The regulatory environment in Canada is believed to have stifled innovation, competition, and investment in the food industry. Ten years ago, it was stated that Canada had among the least favorable regulatory environments for allowing the sale of novel food products and that Canadian regulations have led to significant lost opportunities and sales for the food and food ingredient industries (7). Since this report was released, regulatory developments for dietary supplements, known as natural health products in Canada, have progressed significantly and new legislation came into effect on January 4, 2004. However, "functional" food regulatory initiatives have been less than speedy.

With regard to dietary fibers, while the need for higher levels in North American diets has been widely publicized, Canada has historically blocked the use of ingredients that could bring more fiber to foods in an appealing way to consumers. Industry has denounced Health Canada's definition of dietary fiber, and their regulations of such, as restricting innovation in new fiber ingredients.

Novel Fiber Regulation in Canada

In 2001, Wendy Dahl, then a researcher at the University of Saskatchewan, presented research indicating that finely processed pea hull fiber can be incorporated into a variety of pureed foods for use in elder care facilities, thus benefiting residents by significantly increasing their daily fiber intake (3).

In June of 2006, a full 5 years later, the Canadian Food Inspection Agency (CFIA) released modifications to its most recent publication, the 2003 Guide to Food Labeling and Advertising (2). Included is a regulatory change approved by Health Canada allowing Best Cooking Pulses (BCP), a western Canadian agri-food company active in the international pulse trade since 1936, to have its yellow pea fiber recognized as a novel fiber and listed on nutritional labels in Canada. Is a lag time of 5 years between research and regulation acceptable? Many would argue no.

Manufacturers outside of Canada either seeking to source Canadian novel fiber sources or to market their fibers in Canada may be surprised to find that ingredients that have been recognized as dietary fibers by health agencies in other countries for many years have yet to receive approval in Canada.

In Canada, dietary fibers are defined as "the endogenous components of plant material in the diet that are resistant to digestion by enzymes produced by humans. They are predominantly non-starch polysaccharides and lignin and may include, in addition, associated substances." Within the definition, there are two types of fiber: soluble, which will dissolve in water, and insoluble, which will not dissolve in water. The total fiber content of most plant foods consists of both types in varying amounts (5).

Some sources of insoluble fiber include wheat bran, some vegetables, and whole grains. Some sources of soluble fiber include oats, barley, nuts, seeds, beans, lentils, and some fruits and vegetables.

A novel fiber (or a novel fiber source) is a food that has been manufactured to be a source of dietary fiber and/or

- has not traditionally been used for human consumption to any significant extent.
- has been chemically processed (e.g., oxidized) or physically processed (e.g., very finely ground) so as to modify the properties of the fiber.
- has been highly concentrated from its plant source (2).

Some examples of novel fibers not currently recognized in Canada as food ingredients or fiber sources include (2):

- fiber that has not traditionally been used for human consumption to any significant extent, such as cane sugar stalks, cocoa bean hulls, oat hulls, mucopolysaccharides (e.g., chitin) from shells of shellfish, and wheat straw.
- fiber that has been chemically processed, (e.g., oxidized), or physically processed (e.g., very finely ground), so as to modify the properties of the fiber, such as bleached oat hulls, finely ground wheat bran, bleached pea hulls (seed coats), and bleached wheat straw.

- fiber that has been highly concentrated from its plant source, such as beta-glucans from barley and oats.

Health Canada controls the sale of novel fibers for use as ingredients in Canadian foods through a mandatory premarket notification conducted by its Health Products and Food Branch. Manufacturers or importers are required to submit information to Health Canada regarding the product in question so that a determination can be made with respect to the product's safety prior to sale.

The safety criteria for the assessment of novel fibers was developed from internationally established scientific principles and guidelines developed through the work of the Organization for Economic Cooperation and Development (OECD), Food and Agriculture Organization (FAO), World Health Organization (WHO), and the Codex Alimentarius Commission. Companies are required to submit comprehensive data on toxicology, quality, history of use, and estimated levels of consumption.

The physiological efficacy of novel fiber sources as dietary fiber must also be established before they may be claimed to be a source of dietary fiber in foods. If the novel fiber source has not been tested (and proven) for efficacy, it is considered an unproven novel fiber. If safe, it may be used in foods but it cannot be claimed to be a source of dietary fiber.

When a novel fiber source has been reviewed by the Health Products and Food Branch and found acceptable, either as an ingredient only (where its safety has been demonstrated) or as a dietary fiber source (where both its safety and efficacy have been demonstrated), the manufacturer will receive a "letter of no objection". The letter will indicate any restriction on the use of the novel fiber source.

This system is unique in that Health Canada approves applications on a case-by-case basis, granting approvals to individual companies to use their particular brands of a fiber as ingredients, as opposed to approving the ingredient itself. Because each company must seek approval for its own brand of fiber, the system is slower than in countries where the ingredient itself is approved, as opposed to the individual brand.

BCP had been exporting its high fiber (90%) yellow pea hull based "Best Pea Fiber" into the United States for 10 years before receiving Canadian regulatory approval. The approval paid off. "The day of the CFIA announcement, we received a flurry of inquiries from Canadian companies wanting to produce high-fiber bakery products," says Margaret Hughes, head of BCP's sales and marketing. "They wanted a fiber that was functional, economical, and that could be used to make dietary fiber claims. Best Pea Fiber meets all of these needs. This approval will also allow us to build on our American reputation as the fiber of choice."

The Science

During the time that the Canadian market was closed for business, clinical research undertaken by Canadian scientists was demonstrating the benefits of novel fiber from pea hulls.

It has been well established that fortifying foods with fiber offers a preventative strategy that is a less invasive alternative to laxatives and enemas in the management of constipation in elderly individuals. Residents often do not consume enough fiber, and as a result, upward of 70% are prescribed laxatives and enemas. People who have few bowel movements don't feel well. They are bloated, feel uncomfortable, and don't want to eat anything, which can lead to further health problems.

Adding a moderate amount of ground pea hull fiber (1–3 g per serving) to 3–4 foods each day provided a beneficial laxative effect and increased bowel frequency in institutionalized elderly individuals over a 6-week intervention period (4).

This same group of researchers from the University of Saskatchewan has also studied with success the effect of adding pea hull fiber to pureed foods for home-care residents who experience dysphagia (difficulty chewing and swallowing).

"Often patients don't have enough oral control to manipulate food particles," says lead scientist Wendy Dahl. "Large pieces can be pocketed in the cheeks, causing dental problems and an aspiration risk." Ground pea hull appears to be one fortification tool in the quest to increase fiber intake.

Dahl believes that the best way to increase fiber is through baked goods. "Most people eat two or three slices of bread per day so if baked goods or even bread alone was fiber-enhanced it could increase fiber intake by several grams" (6).

Other Fibers to Come?

In July 2006, Health Canada approved Orafit Active Food Ingredients' proprietary inulin as a dietary fiber, making it the first and only inulin ingredient recognized as a source of dietary fiber in Canada. Derived from chicory root, Beneo inulin is a mixture of oligo- and polysaccharides.

Including ground pea hull fiber and inulin under the umbrella of dietary fiber could help bridge the consumption gap in fiber within the population. Health Canada recommends at least 25 g of dietary fiber per day. However, dietary fiber intakes continue to be at less-than-recommended in the Canadian population, with usual intakes averaging only 15 to 19 g per day (1).

These approvals represent a ray of hope for other fiber ingredient suppliers awaiting approval in Canada, as well as a potential increase in sales associated with these. However, as more Canadians desire to make health-conscious changes to their diets and the industry continues to innovate, it is incumbent on Health Canada to keep pace with the rest of the world with regard to its regulatory approval process.

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