April 2007 Supplement to Prepared Foods www.PreparedFoods.com DEVELOPMENT TRENDS & TECHNOLOGIES FOR FORMULATORS & MARKETERS HEART HEALTH Flax surges ahead in nutrition industry A **bnp** Publication

flax HEART HEALTH

Flax use up as health benefits better realized

By Ann Przybyla Wilkes

lax has been consumed for centuries—both for its good flavor and for its nutritional properties. In recent years, as people have become more concerned about health, demand for flax in food and beverages, functional foods and dietary supplements has risen dramatically both in the U.S. and other countries.

For example, Mintel's Global New Products Database (GNPD) reports that in 2005, 72 new products were launched in the United States that listed flax or flaxseed as an ingredient. In the first 11 months of 2006, there were 75 new products launched in the U.S. that listed flax or flaxseed as an ingredient.

Scientific research has revealed a range of nutritional benefits derived from flax. However, numerous specific benefits are due specifically to its omega-3 fatty acid, lignan and dietary fiber content. Interest in flax and other omega-3-containing foods heightened further in May 2003 when the White House issued a letter to the U.S.

Department of Agriculture (USDA) and the

A typical flax profile is approximately 40% fat, 28% dietary fiber, 21% protein, 4% ash, and 6% carbohydrates. Flax

U.S. Food and Drug Administration (FDA)

of omega-3 fatty acids in the diet.

that asked them to promote the intake

of the most nutritious plant protein compositions—one that is very similar to that of soybean protein. The nutrient composition of flax also includes a number of important essential minerals and minor amounts of water- and fat-soluble vitamins. One tablespoon of milled flax (also known as ground flax or flax meal) contains the same amount of magnesium as a banana (34mg) and the same amount of potassium as a slice of toasted typical pumpernickel bread (66mg). Vitamin E is primarily present as gamma-tocopherol and functions as an antioxidant.

Omega-3 Fatty Acids

As research has expanded our knowledge of the health benefits of omega-3 fatty acids, consumers have increased their consumption of foods rich in omega-3 oils, such as flax. Flax oil has a very healthy fatty-acid profile, with low levels (approximately 9%) of saturated fat, moderate levels (18%) of monounsaturated fat, and high concentrations (73%) of polyunsaturated fatty acids (PUFAs). The PUFA content comprises about 16% omega-6 fatty acids, primarily as linoleic acid (LA), and 57% alpha-linolenic acid (ALA), an omega-3 fatty acids.

Both LA and ALA are essential fatty acids (EFAs) since they cannot be produced by the body and must come from the diet. ALA is converted in the body to eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), omega-3 fatty acids^{1,2}. EPA and DHA are also found in nature, primarily in fish oil. LA is converted in the body to arachidonic acid (AA).

AA and EPA are further metabolized to produce hormonelike substances known as eicosanoids that effect physiological functions such as cell growth and division, inflammatory responses, muscle activity, blood pressure, and immune function. Eicosanoids formed from AA are released in the body in response to injury, infection, stress, or



certain diseases. Conversely, eicosanoids derived from EPA may help protect individuals against heart attacks and strokes, as well as certain inflammatory diseases such as arthritis, lupus and asthma.

Since LA and ALA compete with one another for the enzymes responsible for their conversion to AA and EPA, respectively, it is important to have a proper balance of omega-6 and omega-3 fatty acids in the diet. The ratio of omega-6 to omega-3 fatty acids consumed in today's Western society is estimated to be 20 to 30:1³. For optimal health, many government and public health authorities recommend increasing omega-3 fatty acids. In fact as early as 1990, Health Canada recommended an omega-6:omega-3 fatty acid dietary ratio of 4:1 to 10:1⁴.

The FDA has yet to set an official recommendation for omega-3 fatty acid consumption, although a report on omega-3 fatty acids by the Office of Dietary Supplements, the National Institutes of Health (NIH), notes that most U.S. diets provide more than 10 times as much omega-6 than omega-3 fatty acids, and cautions that individuals should consume more omega-3 and less omega-6 to promote good health. NIH suggests that good sources of ALA are leafy green vegetables, nuts, and vegetable oils such as canola, soy, and especially flax⁵.

ALA Improves Heart Health

Cardiovascular disease (CVD) is an area of research where the consumption of ALA appears to show the greatest potential for health benefit, notes Kelley Fitzpatrick, Director of Health and Nutrition with Flax Canada 2015, Winnipeg, Manitoba. This is significant since CVD is the leading cause of death in Canada and the U.S.⁶ Of note is the fact that populations of Japan and Crete have the greatest life expectancy in the industrialized world and also consume the highest levels of ALA in the diet in addition to low intakes of saturated fat⁷.

This certified organic spaghetti from Hodgson Mill boasts 600mg of omega-3 oils per serving. The whole-grain pasta consists of organic durum whole wheat flour and milled flaxseed.

Numerous intervention studies have shown beneficial effects of ALA on cardiac health. For example, in the Health Professionals Follow-up Study,⁸ a 1% increase in ALA intake (expressed as percent of energy) was associated with a 40% reduction in the risk of non-fatal coronary heart disease (CHD). Another major study, the Lyon Diet Heart Study, included participants who had previously survived a myocardial infarction. The experimental group consumed a typical Mediterranean-style diet rich in ALA, whereas the control group consumed a typical Western-type diet low in ALA. Those who consumed the diet rich in ALA had a 75% reduction in non-fatal myocardial infarctions, and a 70% reduction in total death compared to the control group⁹.

A number of studies have focused on the health benefits provided specifically by flax. In one of these studies, women who consumed 50g of milled flax a day for four weeks exhibited total blood and LDL-cholesterol ("bad" cholesterol) level reductions of 9% and 18%, respectively¹⁰. And, a review of studies focusing on flax and ALA⁷ concluded that the fatty acid may reduce ventricular fibrillation.

Two ways by which ALA may protect the heart are through improvements in abnormal heart rhythms and a reduction of blood platelet stickiness (thrombosis)¹¹. More recently, studies have shown that ALA lowers C-reactive protein (CRP)—an inflammatory biomarker. Lowering blood levels of CRP may be as important as reducing LDL or "bad" cholesterol for the prevention of heart attacks and strokes¹². Half of all heart attacks and strokes in Canada and the U.S. occur in people with normal cholesterol levels, and 20% of all

events occur in people with no major risk factors.

In one study, a diet high in ALA dramatically decreased CRP in men and women with high cholesterol levels¹³. Additionally, data from the Nurses Health Study demonstrated an inverse association between ALA intake and plasma concentrations of CRP¹¹.

Epidemiological research has shown cardioprotective effects of ALA despite differences in study populations, length of follow-up, outcomes, and methods of statistically analyzing the study data. Heart protective effects from diets high in ALA come from numerous mechanisms including decreasing lipid and lipoprotein

levels and by eliciting vascular anti-inflammatory effects. This research is leading to a consensus that ALA has very beneficial effects in the prevention of cardiovascular disease^{14,15}.

At the present time, there is no Recommended Dietary Allowance (RDA) for EFAs in the U.S. However, the National Academy of Sciences' Institute of Medicine (IOM) recommends 1.6g/day of ALA for men and 1.1g/day for women⁵. Health Canada has established a Recommended Nutrient Intake (RNI) for EFAs, specifying the minimum daily intake of ALA should be 0.5% of total energy⁴.

Excellent Source of Dietary Fiber

While numerous health benefits are derived from consuming ALA in flax, its dietary fiber content provides additional health benefits. Flax contains approximately 28% dietary fiber. The American Dietetic Association has cited the "significant impact" that fiber can have on the prevention of obesity, cardiovascular disease and type 2 diabetes¹⁶.

Flax has a ratio of soluble to insoluble fiber between 20:80 and 40:60¹⁷. The insoluble dietary fiber fraction of flax plays an important role in the relief of constipation, improves colon health, and may have protective effects against colon cancer¹⁸. The soluble dietary fiber fraction of flax is found primarily as mucilage gums, which have been shown to play a role in lowering serum cholesterol levels¹⁸.

Quaker expanded its Take Heart line of products to include instant oatmeal with the claims that it supports healthy arteries, removes cholesterol and reduces the risk of high blood pressure. Flaxseed is touted on the back of the box as a "great source of omega-3," as a tool in combating heart disease and as a "rich source of dietary fiber."

Quaker Take Heart may help you:

♥ Remove cholesterol**

Advanced Nutrition for your Heart

OATMEAL

Support healthy arteries

Reduce the risk of high blood pressure*

The Promise of Lignans

Flax is also rich in lignans, phytochemicals that are showing promise for their potential benefits to both men's and women's health. More specifically, flax lignans are phytoestrogens, which have chemical structures similar to the human hormone estrogen. Despite being much

weaker than human estrogens, they can help balance hormone

levels in the body. Flax is one of the richest sources of lignans, providing 75 to 800 times higher levels than other plant sources¹⁹. Lignans and other flax components may also have antioxidant properties and, hence, may reduce the activity of cell-damaging free radicals²⁰.

The major lignan in flax is seicoisolariciresinol diglucoside, commonly referred to as SDG.

Once ingested, SDG is converted in the colon to enterodiol and enterolactone, which have shown promise in reducing growth of cancerous tumors, especially hormone-sensitive ones such as those of the breast, endometrium and prostate²¹. One such study involved 50 women diagnosed with breast cancer²². While waiting for surgery, half the women received muffins containing 25g of milled flax daily while the other half received ordinary muffins. The women who received the flax muffins had slower-growing tumors compared to the other group.

Other benefits of SDG from flax include effectiveness in lowering the onset of both type 1 and 2 forms of diabetes due to its potent antioxidative ability^{20,23} and the ability to lower serum cholesterol²⁴. Research is also examining lignans' positive effect on prostate health, bone health, hair loss and acne²⁵.

Regulatory Status of Flax

Flax is consumed worldwide, and individual countries have their own regulations that govern its use. In the U.S., a food additive petition has not yet been submitted to the Food and Drug Administration (FDA) for flax, nor has a formal review of the GRAS status of whole or milled flax been conducted. However, the Generally Recognized As Safe (GRAS) status of flax has been declared by food manufacturers²⁶ and no objection by the FDA to its use in foods up to 12% has been noted²⁷.

In the spring of 2006, a letter was submitted, in response to the FDA Draft Guidance: Whole Grains Label Statement, requesting that the agency include flax in its definition of whole grains by several Canadian organizations including the Flax Council of Canada. Flax Canada 2015. Saskatchewan Flax Development Commission and led by Pizzey's Milling, Angusville, Manitoba. In support of the request, the letter stated, "whole grain flaxseed is an oilseed that has comparable nutrients to cereal grains listed by the FDA." Supporting this request was AmeriFlax, Mandan, N.D. If the FDA includes whole-grain flax in the definition of "Whole Grains." it would dramatically increase the usage, predicts Kaye Effertz, Executive Director, AmeriFlax.

The regulatory environment for health claims in the U.S. has evolved towards a lowering of regulatory hurdles starting with the 1990 Nutrition Labeling and Education Act (NLEA).

NLEA defines a health claim as a statement that characterizes the relationship of a substance to a disease or health-related condition. Disease-reduction claims for "soy protein and risk of CHD," "dietary fat and cancer," and "dietary saturated fat and cholesterol, and risk of CHD" are three of the twelve claims currently approved by the FDA.

The FDA Modernization Act (FDAMA) became law in November 1997. It allows the FDA to authorize health claims that are based on the published authoritative statements from U.S. Government agencies. One of the two claims currently in use under FDAMA concerns whole-grain foods and risk of heart disease and certain cancers.

In December 2003, the FDA's Consumer Health Information for Better Nutrition Initiative allowed qualified health claims for both foods and supplements. This allows the use of qualified health claims when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In September 2004, the FDA approved a qualified health claim for reduced risk of CHD on conventional foods that contain EPA and DHA omega-3 fatty acids. It does not, however, extend to ALA.

Structure/Function Claims for food products describe the effect that a food product has on the normal structure or function of the body. These need not be pre-approved by the FDA,

but they must be true and not misleading to the consumer. Products containing flax qualify for Structure/ Function Claims. During the summer of 2006, Quaker Oats, Chicago, Ill., launched an instant hot cereal containing flax under its "Take Heart" brand that includes a Structure/Function claim on its packaging that reads "Now with Omega-3 ALA to Help Support a Healthy Heart!"

When asked about the reasoning behind enhancing Quaker's Take Heart whole-grain oatmeal with whole flax meal, Candace Mueller, spokesperson for Quaker, a unit of PepsiCo Beverages and Foods, explained that since the product already had multiple heart health benefits, offering the benefits of flax was a

logical step in the product's evolution.



Barilla's line of PLUS pastas are multi-grain with the package label touting that it is a good source of protein and ALA omega-3.
Flax is a key source of the omega-3 lipids.

Formulating with Flax

Whole and milled flax are both rich in dietary fiber, lignans, protein and the essential fatty acid, ALA. For best use, the seeds need to be ground for people to gain the full health benefits, points out Dr. Linda Malcolmson, Director of Special Crops, Oilseeds and Pulses, Canadian International Grains Institute.

Flax seeds are available in brown and yellow varieties and both contain the same nutritional benefits in terms of ALA, lignan, protein and dietary fiber content. While brown flax is more common, some consumers prefer yellow flax for baking, beverages and in juices.



Breakfast just got tastier with Van's Hearty
Oats Berry Boost waffles, which feature
1,000mg of omega-3, 4g of fiber, 4g of protein
and no cholesterol or trans fat. The product
claims to be an "excellent source" of whole
grains and contains flaxseed.

Effingham, IL-based Hodgson Mill, which has an extensive line of products containing flax, prefers brown seeds. The company purchases flax from a Canadian supplier that uses a three-step selection process that also involves assuring that the seeds are evenly colored and mature. Hodgson Mill's Executive Vice President Paul Kirby explains that immature seeds turn rancid more quickly. The company's whole wheat pasta with flax was selected by ABC's food editor Sara Moulton to be featured on "Good Morning America" as part of the coverage of the 2004 New York Fancy Food Show.

There are two types of flax oil available—conventional and organic. They differ in the way in which the seeds are grown and in how the oil is extracted. Flax oil results from pressing the oil from the seed, either by mechanical means or extraction with organic solvents. Flax oil provides more ALA (approximately 55-58%) on a per weight basis in comparison to whole or milled seed (approximately 15-18%).

The use of flax oil for frying is not recommended. Once the oil is extracted from the seed, the polyunsaturated fatty acids may undergo thermal oxidation when exposed to high temperatures used in food preparation²⁸. This oxidation will give off-flavors and odors to the finished product.

Novel refining techniques are available that produce flax oils which can be added to a range of foods without affecting the flavor profile of the product, explains Fitzpatrick. These techniques include spray-drying flax oil mixed with other ingredients to protect ALA against oxidation, or microencapsulating flax oil.

Whole and milled flax are added to a variety of food products, including rolls, bagels, multi-grain breads, muffins, cereals, pasta, energy bars and dry mixes for pancakes, muffins and waffles. Studies have shown that both the ALA and lignans in flax remain stable under common baking temperatures of 350°F (178°C)²⁹. In baking, milled flax can be substituted for the fat used in recipes at a ratio of 3:1.

Milled flax also can replace some of the flour in baked goods, although the amount of flour that can be replaced is determined by the desired textural characteristics of the finished product, Malcolmson suggests.

One advantage of flax oil, notes Jennifer Cooper, President, Lead Point Solutions—an American Fork, Utah-based company that provides product development, market research and regulatory assistance for health and functional foods—is flax oil has a pleasant taste. She suggests that flax oil can be used in salad dressings and feels fish oil would not be a good choice.

"As today's active consumers continue to look for foods that have health benefits, you will see more flax in convenient dosage forms, such as bars—especially if flax is granted whole-grain status," Cooper predicts. "There is a real potential for growth of flax usage in this area," she adds.

Consumers Want Nutrition and Taste

Consumers want to eat healthy, but they do not want to sacrifice taste. This desire to eat good-tasting, healthy food is the reason behind the success of Barilla PLUS, explains Weizhi Chen, Vice President of R&D for Barilla USA. Barilla PLUS is a premium, multi-grain pasta that includes flax. It offers consumers balanced nutrition.

The target market for this pasta is people who want to eat healthy. "If our purpose is to really help people become healthier, we need to provide good-tasting products," Chen stresses. The first priority is taste, then nutrition, he adds.

A new product launch starts with a concept, such as a nutritionally-balanced food product that tastes just as good as the same item without the added nutritional ingredients, Chen says. When the concept for Barilla's flax products was tested, it scored extremely well. Then, when consumers tested the actual flax products, 80% said they would purchase them. Fifty percent or higher is considered good, Chen explains.

Quaker's Take Heart oatmeal with omega-3 is also well-received by consumers. Mueller points out that it is one of the leading heart-health foods on the market. Quaker decided to introduce an oatmeal cereal with flax after data indicated that a segment of the more health-conscious consumers already enhanced their oatmeal at home by the addition of flax.

"Importantly, we are using whole flax meal in Quaker Take Heart Instant Oatmeal so that the nutrients of the flaxseed are available for digestion and absorption," Mueller adds.

Another reason for the success of foods and supplements offering health benefits provided by flax was provided by Datamonitor. In its report, "Ten Trends to Watch in Packaged Goods in 2006"³⁰ Datamonitor suggested the demise of the low-carbohydrate fad has left a wide open market for other health and wellness-related trends to surface. This new product development trend for 2006 was good news for the flax industry.

Flax's popularity has resulted in its use in a wide range of products. In the report³¹, "The U.S. Market for Flax Ingredients and Competitive Products," published in spring 2006, TJP Market Development reviewed the categories where flax is making an impact. The report points out that the bakery segment was the first sector to embrace the use of flax in the U.S. and continues to offer the greatest demand. If FDA approves the request to allow flax to be labeled as a whole grain, the category will see enormous growth, suggests the report. Currently, this category is estimated to account for 20.6% of total flaxseed sales into the U.S.

Another category that will see long-term positive sales growth if flax is recognized as a whole grain is the cereal category, which currently accounts for between 8-10% of all flaxseed sales in the U.S., according to TJP Market Development.

While flax is not currently used to a large extent in the dairy sector, given the trend towards using dairy products as "health delivery vehicles," it seems quite likely that flax will continue to make inroads in this category, notes TJP Market Development. One dairy product incorporating flax is Smart Balance® Light Buttery Spread with Flax Oil. This product provides 300mg of omega-3 per serving to achieve a 4:1 ratio of omega-6 to omega-3. In the prepared foods category, flax is found in new products, such as pasta and breakfast cereals.

As the science continues to expand our knowledge of the benefits of flax, sales of products containing it will continue to rise. Flax is a source of ALA omega-3, a source of dietary fiber, protein, antioxidants, and lignans, some of which offer synergistic health benefits. Flax also has almost no digestible or glycemic carbohydrates.

"In all respects, flax offers a model for whole grains or seeds and underscores the recognition given to the nutritional value of "whole grains", "whole seeds" and "whole foods," says Fitzpatrick.

Research into some of flax's health benefits is still in its infancy but it is very promising, suggests Cooper. She predicts that as more clinical research is conducted, we will uncover increased health benefits from flax. These benefits will be discovered as consumers' interest in health continues to rise. People are linking food to wellness more and more, making flax and the benefits it offers a compelling story.

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