

Flax Council of Canada Announces GRAS Status Determined for Flax in U.S.

A panel of experts determined in January 2009 that whole and milled flax seed be given Generally Recognized As Safe (GRAS) status. Expected within three months is a letter of "no objection", finalizing GRAS status for flax by the United States Food and Drug Administration (FDA). Gaining this status expands opportunities for flax use by food manufacturers worldwide.

Increasingly, to be accepted in the mass food industry in the U.S., a 'new' food ingredient needs to be shown to be GRAS, or free of harmful toxins or unsafe side effects. In addition, the FDA will not consider an ingredient for a health claim (substantiated or qualified) if the ingredient has not been demonstrated to be GRAS.

"This ruling marks an important turning point for the flax industry," said Barry Hall, President of the Flax Council of Canada. "Now that GRAS has been established, we hope to develop health claims for flax."

Although flax has long been recognized by several U.S. government agencies, including the U.S. Institute of Medicine and the National Institute of Health (NIH), as an appropriate source of omega-3 fatty acid, FDA 'official' approval of GRAS status of flax has proven elusive due to a lack of a comprehensive safety and toxicological assessment of flax. The industry simply did not have the resources necessary to compile the literature and submit a dossier to the FDA – until recently, and possible only through the support of Agriculture and Agri-Food Canada (AAFC).

Since 2004, Flax Canada 2015 has led the process to develop a data package to submit to the expert panel to obtain GRAS status for flax. Supported work included compilation and assessment of safety and toxicological data and human clinical research outcomes specific to food safety. The package was reviewed and approved by a four person team of Scientific Experts recognized by the FDA for its ability to deem food ingredients as GRAS for designated applications. Some 210 research papers on flax were assessed in the GRAS application.

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"This is a commodity that has been well-studied," noted Barry Hall. (Continued on Page 2) Pursuit of GRAS status for flax has been unanimously supported by the Canadian flax industry as a significant requirement for increased sales leverage in the U.S. and in international markets such as Japan and Korea.

"GRAS will provide the assurance that some companies require in using flaxseed ingredients in new formulations," says Jerry O'Dea, President of Glanbia Nutritionals USA, a global leader in flaxseed sales to the food industry, through its subsidiary, Pizzey's Nutritionals, Manitoba.

"In addition, companies can use the ruling as a springboard for their own applications; it should now be easier to obtain GRAS status for flax oil, flax lignans or flax fibre supplements, based on GRAS having been granted to whole and milled flax," said Barry Hall.

Flax Canada 2015 is a federally chartered not-forprofit corporation, operating as a wholly owned subsidiary of the Flax Council of Canada (FCC). Major five year (2004-2009) funding from AAFC Agricultural Policy Framework Science and Innovation Broker Program has allowed FC2015 to operate its programs which included the GRAS process.



The leading product categories of all new flax products tracked in the United States in 2008 are: baked goods, breakfast cereals, pet foods and snacks, according to Thomas J. Payne Market Development.

Current labelling

Governments regulate the health claims companies can make on product packages. The following list those which you might find on flax products:

- Nutrient content claims. In the United States, the Food and Drug Administration (FDA) has allowed a nutrient content claim for alpha-linolenic acid (ALA), the omega-3 fatty acid in flax, on food product labels. A food product containing added flax qualifies for a "high"-type claim if the product contains 260 mg or more of ALA. A "high"-type and "good source" label claim is accompanied by a statement regarding the Daily Value. For example, the label would read: 'Contains ____%' of the Daily Value for ALA per serving. The Daily Value for ALA is 1.3 g.
- *Structure/Function claims*. Claims about the function of ALA in foods are permitted by the FDA as long as the claims are adequately substantiated by reliable scientific evidence, and don't imply that the food product can diagnose, cure, mitigate, treat, or prevent a disease. Examples for ALA omega-3 include:
 - ALA Omega-3 from flaxseed supports cardiovascular health
 - ALA Omega-3 from flaxseed supports overall health
- *Health claims* regarding ALA omega-3 fatty acids are not permitted on food products in either Canada or the U.S. ■

Flax is featured at Mexican trade show



ANIPRON, a well-established event in Mexico, produced a huge general attendance as it was open to the general public.

The Flax Council of Canada exhibited in February, 2009 at Asociación Nacional de Industriales de Productos Naturales (ANIPRON), the annual event of the National Association of the Natural Products Industry, Mexico City.

Interest in flax (linaza in Spanish) is still very high and several Canadian companies sell flax and blended flax products in Mexico. As part of its ongoing marketing efforts, the Flax Council distributed 16,000 flyers and nutritional kits on flax health at the show, providing information about alpha-linolenic fatty acid in the omega-3 family, dietary fibre and lignans found in flax and flax products. With support from Agriculture and Agri-Food Canada, the Council has worked with Mexican food processors to inform Mexicans about the benefits of Canadian flax and to emphasize the safety of flax from Canada.

Mexicans seek high fibre for weight management

A February 2009 report by Caroline Scott-Thomas in Navigation Navigator reports Mexicans are becoming more interested in healthy foods and dietary fibre, opening up new opportunities for food and beverage companies to launch high fibre products, according to research from Tate & Lyle.

Nearly half of Mexico's 110 million people are overweight, and the Mexican government has recently launched a number of health campaigns to try and tackle the nation's obesity problem. Last year, it introduced "Vamos Por un Million de Kilos" (Let's Lose a Million Kilos), in an effort to collectively shed about two million pounds. It reached its goal in just four months, and has now launched the less specific "Vamos Por Mas Kilos" (Let's Lose More Kilos).

Tate & Lyle's research – conducted by market research organization Illuminas – was based on a sample of 1,399 adults in Mexico, and showed weight management was the top health concern for Mexicans.

by Dr. Diane H. Morris

at issue

How do **fish** fare in terms of sustainability, safety and affordability?

Current North American intakes of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), the long-chain omega-3 fatty acids found mainly in fatty fish, are about 100 to 200 mg/day. Achieving recommended higher intakes of 500 mg to 1 g of EPA + DHA daily will be challenging on several fronts. Any increase in consumers' fish intake is likely to place additional pressures on North American and global fish stocks, many of which are overfished. In addition, concerns about the contamination of fish with methylmercury, dioxins, pesticides and other chemicals have led to federal advisories in both Canada and the United States. Finally, many low-income and middle-class families may not be able to afford to buy fatty fish, the main source of EPA + DHA.

Compared with seafood, plant-based sources of the essential omega-3 fatty acid alpha-linolenic acid (ALA) are a sustainable, renewable and relatively inexpensive source of essential omega-3 fat. Many consumers may find it easier, more convenient and more environmentally friendly to add a little ground flax or flax oil to the diet than to learn to cook or enjoy the taste of fatty fish.

Fish and shellfish are widely valued for their healthy fat profile, high-quality protein, and vitamins and minerals.¹ Even so, there are serious concerns about the long-term sustainability of fish stocks and the safety and affordability of seafood.

Sustainability of fish stocks

In 2006, the latest year for which data are available, 80% of the world's wild fish stocks were reported as fully exploited or overexploited, leading the Food and Agriculture Organization to conclude that the maximum potential for wild fisheries in the world's oceans has probably been reached.² Furthermore, commercial fishing over the past half-century has seriously depleted the biomass of the topmost fish in aquatic food chains.^{3,4}

The Northwest Atlantic, the Western Indian Ocean and the Northwest Pacific are the areas showing the highest proportions of fully-exploited stocks.² Indeed, a report released in December 2008 by the U.S. National Marine Fisheries Service identified the following species as being overfished: Atlantic cod, Atlantic halibut, haddock, flounder, black sea bass, red snapper, bluefin tuna and Atlantic salmon.^{5,6}

Safety of fish and fish oil supplements

Contamination of fish and fish oil with chemicals and heavy metals is a growing concern, as some of these pollutants are toxic to the nervous system or cause cancer. Moreover, the issue of seafood contamination is not likely to disappear, as water pollution occurs as a by-product of agriculture, transportation, manufacturing and industrial processes. In the Great Lakes region, for example, the number of "zero consumption" fish advisories increased between 2005 and 2007,⁷ indicating increased water pollution in an area where efforts are being made to reduce pollution emissions.

Mercury contamination. Evidence of the contamination of seafood with methylmercury, a toxic metal that accumulates in the muscles of all fish,⁸ led Canadian and U.S. federal health agencies to issue an advisory, which is still in effect, for women who might become pregnant, for women who are pregnant, for nursing mothers and for young children. Health Canada advises these groups to limit their consumption of fresh and frozen tuna, shark, swordfish, marlin, orange roughy and escolar.⁹ The U.S. Food and Drug Administration advises these populations to avoid eating shark, swordfish, King mackerel or tilefish because these fish contain high levels of mercury. King mackerel is a major source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), the long-chain omega-3 fatty acids found mainly in fatty fish and fish oil. Salmon is low in mercury.10

Other contaminants. Even though salmon is low in mercury,¹⁰ farm-raised salmon contains higher levels of polychlorinated biphenyls (PCBs), dioxin and some pesticides than wild salmon.¹¹ A risk-benefit analysis found that consuming the recommended intake of 1 g of EPA + DHA/day, proposed by the American Heart Association for people with diagnosed heart disease,

cannot be achieved solely from farmed or wild salmon while maintaining an acceptable level of cancer risk.¹² In addition, the purity of fish oil supplements is not regulated by federal health agencies.¹³ Consumers must check with the supplement manufacturer to confirm that environmental contaminants found naturally in fish oil have been removed.

Affordability of fish versus plants

Low-income or even middle-class families may not be able to afford to buy fatty fish, the main source of EPA and DHA. Some sample costs of omega-3-containing foods are:

- A single 4-oz serving of **smoked salmon** or **salmon fillet** costs between \$5.00 and \$8.00, depending upon the region and supermarket.
- A 2 ½-lb bag of milled flax (roughly 1,134 g or 142 servings) can be purchased on the Internet for \$10.00, giving a per-serving cost of \$0.07.
- A bottle of **flax oil** can be purchased on the Internet for \$10.24 (24 servings), giving a per-serving cost of \$0.43.

The cost of one salmon fillet is about 70 times greater than the cost of one serving of milled flax. A recommendation to consume 1-2 tbsp of ground flax, flax oil or canola oil daily will substantially increase the intake of alpha-linolenic acid (ALA) and the proportion of adults who comply with the recommended ALA intake,¹⁴ with a minimal effect on a household's budget.

Conclusion

Experts generally agree that most North Americans stand to benefit from consuming more omega-3 fats, and they recommend obtaining them from fatty fish or fish oil supplements. Many consumers, however, may not find this recommendation practical for reasons of taste, cost and concerns about fish contamination. In the long-term, choosing fish or fish oil supplements may not be sustainable, given current pressures on global fish stocks.¹⁵ Compared with seafood, plant-based sources of ALA are a sustainable, renewable and relatively inexpensive source of essential omega-3 fat. Many consumers may find it easier, more convenient and more environmentally friendly to add a little ground flax or flax oil to the diet than to learn to cook or enjoy the taste of fatty fish.

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For more information on this topic, see *The truth about ALA*, page 7.

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A big boost for bioproduct research and development

by Les Rankin

Flax Canada 2015 will manage, as lead recipient reporting to Agriculture and Agri-Food Canada, approximately \$9.6 million research funds over the next two and a half years.

Numerous research projects involving flax and also hemp will be carried out with the aim being to provide results and data that will lead to commercialization potential for fibre and the products extracted or derived from the fibre in flax and hemp straw. This is the most significant single financial shot in the arm that this sector of research has ever received.

A federal government program under Agriculture and Agri-Food Canada (AAFC) that was announced in December of 2006, is now about to bear fruit. The Agricultural Bioproducts Innovation Program (ABIP) was designed to provide cross-sector support for research networks conducting scientific research and development related to the advancement of a Canadian bio-based economy.

Eighteen different research participants from outside the federal government located in seven provinces will work in a network that also encompasses Canadian federal research facilities.

A combination of commercial companies, independent researchers, university

researchers, Agriculture Canada researchers and National Research Council of Canada researchers are working together in a coordinated network called Natural Fibres for a Green Economy (NAFGEN). NAFGEN has been in operation for over a year and a half as proposals and budgets were developed and submitted to Agriculture and Agri-Food Canada. NAFGEN is one of only nine of the original one hundred submissions that was selected and allocated funding to proceed.

Flax Canada 2015 has both the mandate and a strategy to improve Canadian health, wellness and environmental sustainability to position flax as one of the main drivers of the Canadian bio-economy.



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The truth about ALA

by Kelley Fitzpatrick

Food manufacturers increasingly seek to improve the nutrient value of their products through the inclusion of omega-3 fatty acids from flax oil and fish oil. Flax contains the omega-3 fatty acid α -linolenic acid (ALA). Fish oils are sources of the longer-chain omega-3s eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

Along with the positive attributes expounded for the category, and omega-3s' increasing presence in the marketplace, there is confusing messaging around the health effects of the specific omega-3s, in particular the physiological significance of ALA vs. fish-based EPA and DHA. Recent headlines have warned consumers not to 'confuse' the benefits of these omega-3s and have downplayed the significance of ALA for health. However, ALA has an important role in reducing chronic disease through conversion to EPA and DHA, as well as through its own unique metabolic activities. Additionally, what many fail to understand is the critical need for both plant-and fish-based omega-3s, especially considering the increasing predominance of omega-6 fatty acids in the diet.

ALA and its counterpart omega-6 essential fatty acid, linoleic acid (LA), are converted to longer-chain fatty acids by a series of alternating desaturations and elongations. Conversion is dependent upon a number of factors. Estimates of the amount of ALA converted to EPA range from 0.2% to 8% (Burdge, GC, Calder PC. 2005. Reprod Nutr Dev. 45:581-97) with young women showing a conversion rate as high as 21% (Burdge, G.C., and Wootton, S.A. 2002. 88: 411-420). Conversion of ALA to DHA appears to be limited in humans, with most studies showing a conversion rate of about 0.05%, although one study reported a figure of 4%; and, a conversion rate of 9% was reported in young women (Burdge and Wootton, 2002). The large differences in the rates of ALA conversion reflect major differences in study methodologies.

The impact that LA has on reducing ALA's health benefits is often overlooked. Diets rich in LA can reduce the conversion of ALA to EPA and DHA. For example, in a study of 22 healthy men funded in part by Flax Canada 2015, an LA-rich diet reduced the EPA content of plasma phospholipids significantly after four weeks compared with a low-LA diet, even though both diets contained the same amount of ALA (Liou, YA, et al. 2007. J. Nutr. 137:945-952). The absolute amounts of ALA and LA in the diet also effect ALA conversion. Decreasing the intake of LA has been found to increase the proportion of dietary ALA converted into EPA, while increasing ALA intake can increase the absolute amount of DHA synthesized (Goyens, PLL, et al. 2006. Am. J. Clin. Nutr. 84:44-53).

Increasingly, research indicates that ALA consumption may reduce the risk of heart disease and other inflammatory diseases by reducing inflammatory compounds called cytokines and eicosanoids. LA is converted to longer-chain omega-6 fatty acids, in particular, arachidonic acid (AA). AA is the precursor of eicosanoids, several of which promote blood platelet aggregation, the clotting of blood within blood vessels (thrombosis) and inflammatory reactions. ALA dampens inflammation by blocking the formation of the compounds that promote it. Inflammation is a feature of many chronic diseases such as heart disease, type 2 diabetes, metabolic syndrome, obesity, cancer and Alzheimer's disease. Secondly, ALA interferes with the conversion of LA to AA – acting as a 'nutritional brake' to block further synthesis of AA to its pro-inflammatory eicosanoids.

For example, in a study of healthy men who consumed 1.75 tbsp of flax oil daily for four weeks, the TXB2 (an inactive metabolite of TXA2) concentration in immune cells decreased by 30% (Caughey, GE, et al. 1996. Am. J. Clin. Nutr. 63:116-22). TXA2 is one of the most potent promoters of both inflammation and platelet aggregation known. Similarly, concentrations of the pro-inflammatory cytokines TNF- α and IL-1 β in immune cells decreased 26% and 28%, respectively.

Another study, (Zhao, G, et al. 2007. Am. J. Clin. *Nutr.* 85:385 – 91) in which serum levels of TNF- α decreased by 43% and the production by immune cells of TNF- α and IL-1 β , decreased between 18% and 22% in 23 people with high cholesterol levels who consumed a diet rich in ALA compared with the average American diet, supports the anti-inflammatory aspects of ALA.

Epidemiological studies and, increasingly, clinical work is supportive of beneficial effects of ALA in minimizing the risk of heart disease and for anti-inflammatory effects. ALA is the main, if not only, omega-3 in the diet of at least one billion vegetarians worldwide - despite not consuming fish, vegetarians do not have a higher prevalence of chronic diseases than nonvegetarians.

There is no doubt that EPA and DHA are beneficial – these fatty acids have been the subjects of thousands of clinical trials. In September 2004, the United States Food and Drug Administration (FDA) approved a qualified health claim (QHC) for reduced risk of coronary heart disease on conventional foods that contain EPA and DHA. This claim, however, does not extend to ALA, because ALA was not a part of the petition process. The FDA has never assessed nor denied a QHC for ALA.

It is unfortunate that in the "omega-3 debate", there are those that choose to downplay the importance of ALA in the diet and simply ignore the omega-6 side of the metabolic equation. The typical North American diet is "deficient" in omega-3 fatty acids and overly rich in omega-6 fatty acids. The omega-6/omega-3 (n-6/n-3) ratio may be as high as 17:1 in some Western diets. In the Women's Health Study, some women ate diets with a ratio of 33:1 (Miljanović, et al. 2005. Am. J. Clin. Nutr. 82: 887-893). The n-6/n-3 ratio recommended by international nutrition agencies ranges from 4:1 to 10:1 (Gebauer, et al., 2006. Am. J. Clin. Nutr. 2006. 83: 1526S-1535S). Improving one's n-6/n-3 ratio can be achieved by decreasing the intake of omega-6 fats, increasing the intake of omega-3 fats or, most importantly, doing both.

The current intakes of ALA, EPA and DHA in North America are well below the levels recognized for optimal health. To bridge this "nutritional gap" will require increasing the intakes of all the omega-3s-ALA, EPA and DHA-in whole foods, flax, fortified foods and supplements, and decreasing the intakes of omega-6s.

To obtain referenced articles, please contact Kelley Fitzpatrick, fc2015@fc2015.ca

For more information, please contact John Oliver, Chair, Flax Canada 2015 Inc. at (905) 706-1405; Les Rankin, Co-ordinator, and Director, Industrial and Fibre Uses; Kelley Fitzpatrick, Director, Health and Nutrition at the Flax Canada 2015 Inc. office at (204) 982-2115, or email: fc2015@fc2015.ca



www.fc2015.ca

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