

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

WINNIPEG, Manitoba, March 16 (SEND2PRESS NEWSWIRE) – The Flax Council of Canada announced that a panel of experts determined in January 2009 that whole and milled flax seed be given Generally Recognized As Safe (GRAS) status. Expected within six 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.

“This is a commodity that has been well-studied,” noted Barry Hall.

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 lignan 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-for-profit 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. FC2015 is also funded through cash and in-kind contributions from the Flax Council of Canada, the Saskatchewan Flax Development Commission; the provinces of Alberta, Saskatchewan and Manitoba and through the flax industry.

Canada leads the world in flax production and exports, producing a range of about 700,000 to one million tonnes of flax annually in the western provinces. Flax production is concentrated in Saskatchewan and Manitoba, where hot summer days and cooler evenings develop excellent quality flax with high oil content.

More information: [www.flaxcouncil.ca](http://www.flaxcouncil.ca).

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