Overview

The US Food and Drug Administration (FDA) authorized use of a health claim for the role of beta-glucan soluble fiber from barley in reducing the risk of coronary heart disease. The FDA amended CFR 101.81, the regulation authorizing a health claim on the relationship between oat beta-glucan soluble fiber and reduced risk of coronary heart disease to include barley as an additional eligible source of beta-glucan soluble fiber. The FDA concluded that, based on the totality of publicly available scientific evidence, in addition to certain oat products, whole grain barley and certain dry milled barley grain products are appropriate sources of beta-glucan soluble fiber for the health claim. An interim final rule was published in the Federal Register on December 23, 2005. The ruling is in response to a petition submitted by the National Barley Foods Council in 2004.

Sample claim

Following is an example of the health claim that may be used:

Soluble fiber from foods such as [name of food], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies [x] grams of the soluble fiber necessary per day to have this effect.

Note: Health claim CFR 101.81 is based on eating 3 grams of beta-glucan soluble fiber daily.

Study results significant

After reviewing the scientific evidence provided in the health claim petition, the FDA noted that five clinical trials testing the impact of consuming whole grain barley and dry milled barley products consistently reported statistically significant lower serum total and LDL cholesterol levels. In the trials, subjects consumed diets in which whole grain barley or dry milled barley product ingredients replaced wheat and rice ingredients. A study published in 2004, for example, reported a 6% and 8% reduction in LDL cholesterol following consumption of diets containing barley with 3 grams and 6 grams of beta-glucan soluble fiber, respectively. For more information on barley clinical trials, visit www.barleyfoods.org.

The barley-fiber advantage

Barley has a distinct advantage over some other grains in that beta-glucan soluble fiber is found throughout the entire barley kernel. In some other grains, the fiber is only found in the outer bran layer. If these grains are processed, the fiber can be easily lost. This is not the case with barley. Since fiber is found throughout the barley kernel, even refined products such as barley flour contain beta-glucan soluble fiber making the grain a versatile and heart-healthy ingredient for commercial food applications.

The NBFC

The National Barley Foods Council is a not-for-profit 501 (a) organization based in Spokane, WA. Established in 1989, the group serves as an information clearinghouse for barley food and health issues to promote awareness and usage of the grain on behalf of the US barley industry. National Barley Foods Council membership is comprised of five state barley producer groups including the Idaho Barley Commission, Montana Wheat and Barley Committee, North Dakota Barley Council, Oregon Grains Commission and the Washington Barley Commission. For more information, call (509) 456-4400 or visit www.barleyfoods.org.
Questions and answers

What barley products qualify as eligible beta-glucan soluble fiber sources?
- whole grain barley
- barley bran
- barley flakes
- barley flour
- barley grits
- barley meal
- pearl barley
- sieved barley meal

Does the FDA specify fiber content of the qualifying barley sources?
Yes. Dehulled and hulless whole grain barley must have a total dietary fiber content of at least 10% on a dry weight basis (dwb) and a beta-glucan soluble fiber content of at least 4% dwb. Barley flakes, barley grits, pearl barley, barley flour and barley meal must have a total dietary fiber content of at least 8% dwb and a beta-glucan soluble fiber content of at least 4% dwb. Barley bran and sieved barley meal must have a total dietary fiber content of at least 15% dwb and a beta-glucan soluble fiber content of at least 5.5% dwb.

Does the FDA include any processing specifications for the qualifying barley beta-glucan soluble fiber sources?
Yes. Qualifying barley products must be produced from clean, sound dehulled or hulless barley using standard dry milling techniques.

Is barley bran made from the malting process or distillers dried grains (DDGs) eligible for the claim?
No. Considerable water is used in the processing and is therefore not considered dry milling, so this product is not currently eligible.

What about barley malt flour? Is it eligible for the claim?
No. The malting process causes beta-glucans to break down, so barley malt flour is not currently eligible for the claim.

How does a food made from eligible barley sources qualify for the claim?
A food made from eligible barley sources must contain at least 0.75 grams of beta-glucan soluble fiber per serving. Health claim CFR 101.81 is based on eating a total of 3 grams of beta-glucan soluble fiber daily.

May companies use the health claim on food labels now even though the current ruling is an interim final ruling?
Yes. Companies may use a health claim on qualifying food labels effective December 23, 2005. In its decision to issue the interim ruling, the FDA noted that allowing manufacturers of qualifying barley food products to use an interim health claim prior to a final ruling may result in a reduction in the risk of heart disease by helping at-risk consumers make healthier food choices now.

Where can I obtain more information about the interim final ruling?
For a full transcript of the FDA’s interim final ruling, see the Federal Register of December 23, 2005 (Volume 70, Number 246, Pages 76150-76162) or go to www.accessdata.fda.gov. Search by Docket No. 2004P-0512.

Can I submit a comment on the FDA’s interim final ruling?
Yes. The FDA has provided for a public comment period that will extend through March 8, 2006. The FDA will address comments and confirm or amend the interim final rule in a final rule. For more information on submitting comments on the interim final rule, go to www.fda.gov/dockets/ecomments.

Where can I get more information on sourcing barley products?
For information on barley processors and suppliers, call the National Barley Foods Council at (509) 456-4400 or e-mail mary@washingtonbarley.org.

How can I learn more about barley?
For more information about the US barley industry, barley nutrition, research and recipes, go to www.barleyfoods.org.