



A consortium of industry, scientists, chefs and Oldways to increase consumption of whole grains to provide better health for all consumers

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October 12, 2005

Re: Docket 2004P-0223

Dear Sir or Madam,

On May 11, 2004, the FDA received a "Whole Grain Descriptive Claims Citizen Petition" from General Mills asking that the descriptors "good source of whole grain" and "excellent source of whole grain" be recognized as 8-15 grams of whole grain (good source) and 16 grams and above (excellent source).

Since September of 2004, these descriptors have rapidly become established as an industry standard. Leading companies including General Mills, Kellogg, Kraft and Pepperidge Farm (Campbell Soup) have standardized on the 8g/good source and 16g/excellent levels in their packaging and advertising. The Whole Grains Council, a consortium of industry, scientists and culinary professionals including 93 of America's important grains companies, has also standardized on these same levels.

Consumers have benefited from this unprecedented industry-wide harmony. At a time when the 2005 Dietary Guidelines call for all Americans to consume at least three servings a day of whole grains, many people have been unsure how to find whole grains on the grocery shelves. Now, industry has given consumers an easy tool: To get three whole grains, just eat three Excellent Source servings or six Good Source servings.

ConAgra Foods, in a letter dated June 15, 2005, submitted comments on this standard, in a document filed at the FDA as C19 in Docket 2004P-0223. ConAgra asks that the rapidly-established standard of 8g and 16g for Good Source and Excellent Source be reduced to 5g and 10g respectively.

The Whole Grains Council urges the FDA to recognize the industry standard of 8g and 16g, and reject ConAgra's efforts to weaken this prevailing, appropriate standard. In this letter, the Council takes issue with several points raised in ConAgra's letter, and reiterates its whole-hearted support for General Mills' original petition.

A. 8g and 16g support the 2005 Dietary Guidelines and meet existing criteria for "Good Source" and "Excellent Source."

According to cfsan.fda.gov, the FDA says Good Source "means that one serving of a food contains 10 to 19 percent of the Daily Value for a particular nutrient" and that for Excellent Source "the food must contain 20 percent or more of the Daily Value for that nutrient in a serving."

There is no established DV for whole grains, but the Dietary Guidelines recommend three servings of 16g each, for a total of 48g - a figure that is widely used as the "DV" for whole grain. At 8g and 16g, the industry standard is in line with these established criteria and in fact exceeds them: 8g is 17% of 48g, and 16g is 33%.

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ConAgra's proposal for 5g and 10g – although technically meeting the bare minimum allowable for Good Source and Excellent Source – would encourage unhealthy overeating and would not be in line with the Dietary Guidelines.

The minimum levels (10% as Good Source and 20% as Excellent Source) may be appropriate for nutrients like calcium, as consumers can choose ten different foods, from milk and cheese to leafy greens and almonds, to reach 100% of their calcium needs while still eating a balanced and healthy diet. Whole grains come only from whole grain foods, however. Under the Dietary Guidelines, most adult women are advised to eat a total of 5-6 grain servings, with men at 6-8 servings. It would be irresponsible of manufacturers to tout a product with 5g of whole grains as a Good Source, if someone would have to eat 10 servings of such foods to meet their whole grain needs of 48g (the Dietary Guidelines minimum "DV.")

Using the 5g and 10g levels would also engender further confusion among consumers. Consumers focused on the Guidelines advice of three whole grain servings can easily learn that "one Excellent Source equals one serving." If Excellent Source were to be set at 10g, consumers would not easily reach the goal of three whole grains, as they would need to count with measures like "one Excellent Source equals 5/8 of a serving."

B. A wide range of products can easily meet the 8g and 16g levels.

It is *not* difficult to incorporate 8g or 16g of whole grain ingredients in a serving of a product. In fact, 8g is equivalent to a rounded tablespoon of whole wheat flour, or about 2 teaspoons of uncooked brown rice; 16g is twice these amounts.

ConAgra claims that "only a few products [will be able to] make [the] content claim." In fact, industry already markets hundreds of products that meet this level. The Whole Grains Council licenses a packaging symbol – the Whole Grain Stamp – to its members for use on qualifying products meeting the industry standard of 8g (Good Source) or 16g (Excellent Source) of whole grain content per serving. As of October 1, 2005, the Council had qualified over 360 products ranging from soups to cereals, breads to brownie mixes, and cookies to crackers. 299 of the 362 registered products qualified for the Excellent Source level, including breads from a range of leading manufacturers. Some companies, like Nature's Path, are using the Whole Grain Stamp throughout their product lines. Consequently, this standard does *not* create an "unequal playing field."

C. The 8g and 16g descriptor claims complement existing health claims.

The existing FDA-approved health claims for whole grains are laudable, and are very useful in helping consumers find products that are made solely, or almost entirely, with whole grains. The new 8g and 16g "Good Source" and "Excellent Source" descriptor claims, however, allow consumers to reliably locate foods that, while they may not contain *only* whole grains, contribute heavily to increasing Americans' consumption of whole grains.

Just as most consumers did not switch overnight from whole milk to skim milk, but instead retrained their palates with 2% milk and 1% milk, Americans need transition foods to help them move from refined grains to whole grains at their own pace. Previously, with the FDA whole-grain health claims as the only marker for "real" whole grain products, consumers had an "all or nothing" choice. Now, with the Good Source and Excellent Source descriptors on packages, consumers can find foods with a dietarily and nutritionally significant amount of whole grains – a half or a full serving – and still enjoy foods that they find palatable.

D. Changing an emerging standard would lead to consumer confusion.

In the last year, many leading companies, including the 93 members of the Whole Grains Council, have been working to educate consumers that "Good Source of Whole Grain" denotes a half-serving of whole grains under the Dietary Guidelines, and that "Excellent Source" denotes a full serving. As

industry has coalesced around this standard, consumers have learned about the Whole Grain Stamps and about this standard through such wide-reaching media vehicles as The Washington Post (February and September 2005) The Today Show (March 2005), the Oprah Winfrey Show (May 2005), *Prevention*, *Time*, and *Cooking Light* magazines (October 2005) and *Parade* magazine (scheduled for November 2005). Several leading companies, including Kraft and Quaker, have also published promotional materials based on this standard. Supporting a different standard now would engender confusion.

In summary, the Whole Grains Council believes that the emerging industry standard of 8g as "Good Source" and 16g as "Excellent Source" is consistent with labeling standards and precedents, is easily attainable by manufacturers, and is the best way to help Americans easily find and enjoy whole grains for better health, as recommended by the 2005 Dietary Guidelines.

Federal Law supports the Whole Grains Council's position. US Code, Title 7, sec. 5341 states the "Dietary Guidelines for Americans" shall be published "at least every five years" and "shall be based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared." It further requires that these Guidelines "shall contain nutritional and dietary information and guidelines for the general public, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program."

As the FDA is a federal agency, and its labeling regulation activities are Federal food, nutrition and health programs, it follows that the FDA should promote the Dietary Guidelines by supporting a standard (8g and 16g) that will most readily result in Americans eating 3 or more servings of whole grains per day.

The Whole Grains Council has determined that the "8g/Good Source, 16g/Excellent Source" standard best harmonizes the Dietary Guidelines, the scientific report of the Dietary Guidelines Advisory Committee, the USDA, and the FDA. Most important, this standard promotes the public health of adults and children alike, unlike least-common-denominator approach that could result from ConAgra's letter.

We urge the FDA to disregard ConAgra's letter, as it risks diluting and undermining industry-wide efforts to present a united health message to consumers.

On behalf of the Whole Grains Council, very truly yours,



Jeff Dahlberg
National Grain Sorghum Producers
Chairman, the Whole Grains Council



K. Dun Gifford
President
Oldways Preservation Trust

Sent electronically to fdadockets@oc.fda.gov and by hard copy on this date.