



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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Re: Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements, Docket No. FDA-2006-D-0298-001 (formerly 2006D-0066)

The Whole Grains Council is a program of Oldways, a 501c3 nonprofit nutrition education organization. The Whole Grains Council has offered education about the benefits of whole grains since 2003, and introduced the Whole Grain Stamp in 2005. The Whole Grain Stamp is now used on more than 9,000 products in 41 countries, to help people identify foods offering a significant amount of whole grains.

Oldways and the Whole Grains Council (WGC) appreciate FDA's ongoing efforts to ensure that consumers seeking whole grains can readily find foods that meet their nutritional needs, through accurate labeling and definitions. As FDA works toward final guidance on whole grain labeling, Oldways and the Whole Grains Council urge the agency to address the following three critical issues summarized directly below. Each of these three critical issues is discussed in greater detail on the following pages.

- A. FDA should support labeling for three different levels of whole grain foods:
 1. 100% Whole Grain Foods
 2. Whole Grain Foods (foods where 50% or more of the grain is whole)
 3. Foods Contributing Whole Grains
- B. FDA should adopt the definition of whole grains that was included in the draft guidance, specifically related to
 1. Principal components in their same relative proportions. To support this basic definition, FDA should also clarify guidelines on how these "same relative proportions" may be achieved, and what (if any) measures are permissible to address safety issues such as stabilization and the removal of mycotoxins.
 2. Which grains are included. All members of the *poaceae* family should be included, plus amaranth, buckwheat and quinoa - without reference to fiber levels. Legumes, oilseeds, nuts and roots shall not be included.
- C. FDA should ensure that any final guidance on whole grain labeling is inclusive of *all* whole grains, and that such guidance avoid the three serious limitations of AACCI's May 2013 whole grain characterization described below.

Details on all of these issues are included on the following pages

A. FDA Should Support Labeling for Three Levels of Whole Grain Foods

In its final guidance document on whole grain statements, Oldways and the Whole Grains Council recommend that FDA should support clear labeling for three different levels of whole grain foods:

1. 100% Whole Grain Foods

FDA should approve the use of terms such as “100% whole grain” or “100% whole wheat” e.g. “100% whole grain crackers” on foods where all the grains are whole grains, and the food contains at least 16g of whole grain per labeled serving.

FDA should clarify any limits on permissible trace levels of release agents or other non whole grain ingredients for foods identified as 100% whole grain (similar to the approach in 21 CFR 136.110 (c) (11) in the Standard of Identity for whole wheat bread).

Such foods should be labeled with the number of grams of whole grain they contain per serving, and should include a statement on minimum daily recommended consumption of whole grain.

2. Mostly Whole Grain Foods

FDA should allow foods to use the term “whole grain” in their name, e.g. “whole grain crackers” when at least half of the grain by weight is whole grain, and the food contains at least 8g of whole grain per labeled serving. This is in line with USDA’s definition of “whole grain-rich foods;” a consistent approach would facilitate consumer education efforts.

Such foods should be labeled with the number of grams of whole grain they contain per serving, and should include a statement on minimum daily recommended consumption of whole grain.

3. Foods Contributing Whole Grains

FDA should allow foods that contribute a significant amount of whole grain (8g or more per labeled serving) to make factual statements about the amount of whole grain per serving, e.g. “14g whole grain per serving.” These foods, however, should not be allowed to use the term “whole grain” or similar terms in their names, as their grains are not primarily whole grains.

Such foods should be labeled with the number of grams of whole grain they contain per serving, and should include a statement on minimum daily recommended consumption of whole grain.

While we expect the market will continue to migrate toward foods that are primarily whole grain as consumers’ palates adjust to the fuller, nuttier taste of whole grain, this third level is important because it helps many people start on the road to enjoying whole grains—and reaping their health benefits. Koh-Banerjee (2004) and Jensen (2004) examined foods containing different levels of whole grain ($\geq 51\%$, $\geq 25\%$, and any amount) and found that risk reduction was associated with overall whole grain consumption but was not significantly affected by the whole grain content of individual foods consumed.

B. FDA Should Finalize Key Points of Whole Grain Definition in its Draft Guidance

The 2006 Draft Guidance defined a whole grain, including examples of accepted whole grains. Key points in this definition should be included in final guidance:

1. As stated in the Draft Guidance, a whole grain shall be defined as a cereal grain where all of the “principal anatomical components” - bran, germ and endosperm - “are present in the same relative proportions” as they exist in the intact kernel.

FDA should also clarify guidelines on how these “same relative proportions” may be achieved, and what (if any) measures are permissible to address safety issues such as stabilization and the removal of mycotoxins.

In doing so, FDA may find it useful to reference a European definition of whole grain, developed by the Healthgrain Forum (see http://www.healthgrain.org/webfm_send/601), which starts with the same basic definition above, but includes the following clarifying points:

- *Whole grain foods are almost universally processed to make them edible and safe for human consumption.*
- *Whole grain includes grains that have been subjected to processing but only if, after processing, the germ, endosperm and bran are present in the same, or virtually the same, proportions as in the original grain.*
- *Temporary separation of whole grain constituents during processing for later recombination is acceptable, provided the proportions of the germ, endosperm and bran are the same or virtually the same as in the original grain.*
- *Recombination of bran, germ and endosperm from the same type and variant of grain in which a component (bran, germ or endosperm) has been stabilized is allowed, provided that the three components are in the correct proportions.*
- *Removal of the very outer bran layer - up to 10% of the bran or 2% of the grain - is acceptable for minimizing levels of undesirable substances such as bacteria, moulds, agrochemicals and heavy metals.*
- *Recombination of the endosperm, bran and germ takes into account that there are variations in the ratio of endosperm, bran and germ between kernels in one ear and between varieties of one type of grain. Recombination per grain and per variety will result in some fluctuations in the ratios of endosperm, bran and germ between batches of flour and products. There should, however, be no significant nutritional losses, and differences should be not greater than normally found from season to season or between varieties.*

2. As stated in the Draft Guidance, foods considered to be whole grain shall include amaranth, barley, buckwheat, corn, millet, quinoa, rice, rye, oats, sorghum, teff, triticale, wheat and wild rice. Other foods such as legumes, oilseeds, and roots shall not be considered whole grains.

While the 2006 Draft Guidance lists examples of cereal grains (III.2), the list is not comprehensive. Since other grains from the same botanical family (such as Job’s Tears, Canary Seed, Fonio) are beginning to be available in our food supply, it would be useful to simply clarify that all grains in the *poaceae* family may be considered whole grains, along with the “pseudocereals” amaranth, buckwheat and quinoa, which are of similar macronutrient composition *and* have similar culinary uses.

These grains should all be included without reference to fiber content, as it is widely accepted that different whole grains vary in fiber content, and, as FDA has stated publicly, “scientific evidence suggests that the health benefits of whole grains are based on more than their fiber content.”

C. FDA Should Avoid the Limitations of the AACCI Characterization

Definitions established by AACC International have often served as the basis for regulatory decisions, both in the US and elsewhere. For example, the definition of a whole grain in FDA's 2006 Draft Guidance is based on AACCI's 1999 definition of a whole grain.

In May 2013, AACCI characterized a whole grain *food* as one containing "8 grams or more of whole grain per 30 grams of product." This move represents a helpful preliminary step toward standardizing the definition of a whole grain food, especially for research purposes. However, the AACCI characterization has three important and serious limitations that – if it were used as a standard for whole grain labeling – could be misleading, and would have negative consequences for consumers, for health, and for whole grain momentum. These three limitations are:

1. Foods in four categories - foods naturally high in water weight, heat-and-serve grains, mixed meals, and commonly accepted grain foods with low grain content - would likely be ineligible to be considered as whole grain foods, even when most or all of their grains are whole grains and when the foods contain more than 8 grams of whole grain.
2. Many foods containing more refined grain than whole grain would easily qualify as "whole grain foods," which could be considered misleading.
3. Moist foods, such as bread and bagels, would be required to contain a much higher percentage of their grain as whole grain than dry foods, such as crackers, pasta, and RTE breakfast cereals.

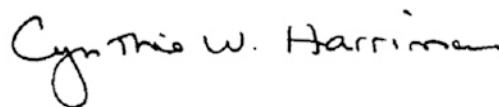
Oldways and the Whole Grains Council have detailed these three limitations in Appendix A. We urge FDA to make sure that a definition of a whole grain food (if any) avoid the limitations of the AACCI characterization. The ideal definition of a whole grain food will

- Include *all* foods containing more whole grain than refined grain, while excluding foods that contain mostly refined grains.
- Encourage manufacturers to make whole grain options available in *all* categories.
- Help consumers increase whole grain consumption from *all* sources and categories.

Respectfully submitted,



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Appendix A: Limitations of the AACCI Characterization of a Whole Grain Food

Limitation #1: Excludes Foods in Four Categories

The WGC analyzed 7615 products registered to use the Whole Grain Stamp as of January 2013. We found that 12% of foods we reviewed contained significant amounts of whole grain and yet would likely be unfairly excluded by the current draft of the AACCI Characterization of a Whole Grain Food. These foods fall into four major categories. We have included examples for each category below, to illustrate changes necessary to be inclusive of all food categories.

1. Foods naturally very high in water weight, such as brown rice milk or soups.

Examples:

- (1) Brown rice milk with 16g whole grain per 250g serving; contains no refined grains.
- (2) Chicken Noodle Soup with 38g whole grain per 312g serving; traces of rice starch are the only refined grain ingredient.

2. Foods that qualify in dry form, but not when sold in cooked “heat-and-serve” form because of the weight of added water.

Examples:

- (1) Heat & serve steel-cut oatmeal with 41g of whole grain per 284g serving; contains no refined grains.
- (2) Heat & serve black pearl sticky rice with 37g of whole grain per 180g serving; contains no refined grains.

3. Mixed meals or dishes where grains are just one component of the serving size, because the other ingredients weigh so much.

Examples:

- (1) Chicken and vegetable pasta with 40g of whole grain per 255g serving; 0.54g cornstarch is the only refined grain ingredient.
- (2) Vegetable egg rolls with 19g of whole grain per 85g serving; wrapper is primarily whole grain.
- (3) Dry whole grains and beans soup mix with 17g of whole grain per 128g serving; contains no refined grains.
- (4) Whole wheat pizza with 51g of whole grain per 213g serving; crust is primarily whole grain.
- (5) Shrimp breaded with whole grain, with 16g of whole grain per 85g serving; breading is primarily whole grain.
- (6) Whole wheat ham sandwich with 27g of whole grain per 120g serving; bread contains only whole wheat flour and a small amount of wheat gluten as grain ingredients.

4. Foods that typically contain less than 26.7% (8/30) grain overall.

Some foods normally considered as “grain foods” typically contain lower amounts of grains, such that they would not reach the 8/30 threshold even if *all* of their grain is whole grain. Marquart et al., in *Cereal Foods World*, May-June 2006, vol 5 no 3, listed the overall grain content of a range of foods, including brownies and cookies (20% flour), muffins (25% flour), and cake (24% flour).

Examples:

- (1) 100% whole grain brownie with 9g of whole grain per 40g serving; contains no refined grains.
- (2) Whole grain carrot cake with 8g of whole grain per 80g serving; only refined grain is cornstarch in the cream cheese icing.
- (3) Whole grain cranberry nut muffin with 10g whole grain per 59g serving; contains no refined grains.

Limitation #2: Includes Some Foods Primarily Made with Refined Grains

Some dry foods such as crackers, breakfast cereals and pasta contain more than 16 grams of grain in each 30 grams of product. Ready To Eat cereals contain an average of 21 grams of grain in each 30 grams; crackers 25.5 grams grain in each 30 grams; and pasta generally 30 grams of grain in each 30 grams.

When these foods contain only the minimum 8 grams of whole grain with the balance as refined grain, the foods would be made primarily with refined grains. The cereal and crackers could contain around twice as much refined grain as whole grain and still qualify for the AACCI characterization, while the pasta could contain almost three parts refined grain for each part of whole grain. While these foods may contribute positively to whole grain consumption, labeling such foods “whole grain foods” seems at odds with common sense.

Limitation #3: Puts Moist Foods at a Disadvantage

The ideal definition would treat all food categories equally. However, because the AACCI approach is based on a percentage of total weight, food groups with a higher water content must meet a higher standard than drier foods. The table below illustrates the problem:

Food category	% flour overall	Flour in 30g	% wg to qualify
Bread	51%	15.3g	52.3%
Bagel	50%	15.0g	53.3%
RTE Cereal	70%	21.0g	38.1%
Crackers	85%	25.5g	31.4%
Pasta	100%	30.0g	26.7%

Source: Marquart et al, Cereal Foods World, May-June 2006, vol 5 no 3

This “bias to the dry” not only unfairly includes dry foods like crackers even when they’re made mostly with refined grains (as explained previously) but also unfairly sets a higher standard for moist foods like breads and bagels.