



HEALTH THROUGH HERITAGE

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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Commissioner Gottlieb,

On behalf of Oldways, a 501(c)3 non-profit that inspires people to embrace the healthy joys of the old ways of eating, we fully support FDA's goal of advancing public health by empowering consumers with information and promoting the development of healthier foods. Below, please find our comments on four key elements of the FDA's Nutrition Innovation Strategy: 1) Nutrition Facts Label, 2) Modernizing Standards of Identity, 3) Healthy Icon & Definition, and 4) Whole Grain Label Statements.

Nutrition Facts Label

At Oldways, we interact with a large network of consumers, health professionals, and food professionals seeking more information about the foods they're eating. We applaud FDA for moving forward with the first major overhaul of the Nutrition Facts label in more than 20 years, and urge FDA not to delay implementation any longer. Realistic serving sizes, bolder calorie counts, and listings for added sugar are all common-sense updates that will help families better align their eating habits with the principles of the Dietary Guidelines. Furthermore, we support additional efforts to make formats more readable and understandable to consumers (such as avoiding all caps, or using letter naming for vitamins).

Modernizing Standards of Identity

In a food marketing landscape of increasing confusion and sensationalism, the FDA's standards of identity (SOI) have often served as guardrails to ensure the nutritional integrity of a food. The existing SOI for whole wheat flour, whole wheat bread, and whole wheat macaroni products are extremely useful to help consumers know that the products they're getting are in fact whole wheat, rather than made of refined flour, and we urge FDA to maintain these standards for these products. With regards to standards or claims on other whole grain foods, please see our comments on whole grain label statements, further below in this document.

Though allowing sodium substitutes in the SOI for cheese is a well-intentioned effort to reduce sodium intake among consumers, we fear that unintended consequences that may arise from allowing both artisan and more highly processed cheeses to be deemed equal in the eyes of the consumer.

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Cheesemaking is a craft that dates back centuries in time, and many of the most popular cheeses, such as Parmigiano-Reggiano, or Gruyere, have a time-honored set of production practices and ingredients that go into creating them. While we fully support the innovation of more nutritious products, consumers purchasing a product labeled as “cheese” should not have to question if novel ingredients or methods were used. Rather than water down the current SOI, we propose that FDA create new SOI to reflect innovations such as low-sodium cheeses.

Modernizing Claims: “Healthy” Icon & Definition

We applaud FDA for recognizing that claims should focus on food groups and overall diet, rather than being nutrient-focused. However, a “healthy” claim or icon raises numerous concerns that counteract the emphasis on overall diet.

The release of the 2015-2020 Dietary Guidelines for Americans marked a notable shift in making nutrition recommendations in the context of overall eating patterns, specifically stating that, “people do not eat food groups and nutrients in isolation but rather in combination, and the totality of the diet forms an overall eating pattern.” Reducing the complexity of nutrition and diet into a single icon paves the way for misinterpretation, as the healthfulness of many foods is dependent on both portion size and consumption frequency, as well as the makeup of the rest of the diet. Additionally, because what we consume and what we don’t consume both matter in achieving health outcomes, [leading nutrition researchers](#) “strongly endorse the general principle of specifying practical dietary substitutions – a ‘compared to what’ approach,” which is not possible to capture in a single icon.

Lastly, without knowing where FDA stands on the definition of healthy, it is impossible to express support for a healthy icon. No matter what combination of nutrient criteria FDA might mandate as healthy, it’s inevitable that a reductionist approach will result in efforts to “game” the system with fortified manufactured foods, while some whole, natural foods may fail to qualify. For instance, under the “current thinking” outlined in FDA’s September 2016 guidance, brown rice wouldn’t qualify to be labeled healthy – while the highest fat hamburger meat commonly sold (70% lean/30% fat) would qualify, as would the bun typically eaten with it.

Modernizing Claims: Whole Grain Label Statements

As the creators of the Whole Grain Stamp, a packaging symbol used on more than 12,000 products in 58 countries, we recognize firsthand the importance of using the market to move public health forward, helping both manufacturers and consumers alike.

We are pleased to learn that the FDA is also interested in exploring claims for products that include ingredients from food groups for which American diets typically fall short of recommendations, such as whole grains. In line with our [January 2014 comments on whole grain label statements](#), we urge the agency to address the following two critical issues:

1. FDA should support labeling for three different levels of whole grain foods:

A. 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.

B. Mostly Whole Grain Foods (foods where 50% or more of the grain is whole):

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.

C. 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.

2. FDA should adopt the definition of whole grains that was included in the draft guidance, specifically related to:

- A. Principal components in their same relative proportions.** 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 (doi: 10.3402/fnr.v58.22100), 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, molds, 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.

B. Which grains are included.

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.”

We thank the FDA for the opportunity to share our expertise.

Sincerely,

Handwritten signature of Sara Baer-Sinnott in blue ink.

Sara Baer-Sinnott
President, Oldways

Handwritten signature of Kelly Toups in black ink.

Kelly Toups, MLA, RD, LDN
Director of Nutrition, Oldways