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April 17, 2006

Division of Docket Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA Docket No. 2006D-006. Guidance for Industry and FDA Staff: Whole Grain Label Statements.

To whom it may concern:

On behalf of Archer Daniels Midland Company (Decatur, IL), we are providing the following comments to the U.S. Food and Drug Administration regarding the agency's Draft Guidance on Labeling of Whole Grains (Docket 2006D-0066). ADM is a world leader in processing commodity grains and oilseeds into food ingredients. We appreciate the agency's efforts on this important issue by seeking comments from stakeholders involved in producing America's food.

The Dietary Recommended Intakes for Macronutrients Report from the National Academy of Sciences Institute of Medicine¹ strongly recommends the consumption of fiber and grains for prevention of chronic disease. The Federal government effectively responded to these recommendations in the 2005 Dietary Guidelines for Americans² by encouraging the consumption of enriched and whole grain products at a level relative to an individual's daily caloric requirements with an emphasis on consuming "half your grains from whole grains."

In order to broaden the possibilities to consume whole grains and thus receive their health benefits, we ask the agency to revise and clarify issues surrounding whole grain labeling. First, we believe that the DEFINITION of whole grains should be expanded to include other grains such as grain legumes. Second, we urge the agency to consider technological and food processing limitations encountered when including whole grains in foods by allowing CONTENT CLAIMS in graded amounts. Third, we ask the FDA to allow the

¹ Institute of Medicine. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids, 2002. Washington, D.C.: The National Academies Press.

² U.S. Department of Health and Human Services and U.S. Department of Agriculture. Dietary Guidelines For Americans, 2005. 6th Edition. Washington, DC: U.S. Government Printing Office. January 2005.

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RECONSTITUTION of whole grains from individual components when processing creates technical limitations in using intact whole grains.

THE DEFINITION OF WHOLE GRAIN

We respectfully disagree with the agency's narrow definition of whole grain by exclusively focusing on cereal grains. For example, soybeans are considered grains as established by the United States Grain Standard Act³. Therefore, soybeans are generally recognized as a commodity grain by industry and regulatory agencies. From an anatomical viewpoint, grain legumes contain the same features as cereal grains (Figure 1). Both grains are characterized by a bran/seed coat, endosperm and germ. *Grain legumes can be utilized also in a manner consistent with other grains.* Whole grain legume flour/powder can be used as an ingredient alone or in combination with cereal grains in whole grain soybreads, muffins, cereals, pastas and chips. Thus, grain legume-based or grain legume-containing whole grain foods can contribute to intakes of whole grains encouraged by the 2005 Dietary Guidelines for Americans.

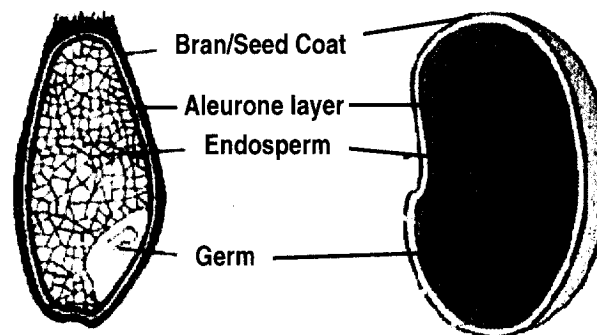


Figure 1. Diagram of Anatomical Features for Cereal Grain (Wheat Kernel; left image) and Grain Legume (Bean Seed; right image). Wheat kernel image from <http://www.correllconcepts.com> and bean seed image from <http://www.virtualsciencefair.org>.

From the health and nutrition viewpoint, consumption of grain legumes is significantly and inversely related to the risk of cardiovascular and coronary heart disease. Legume consumption (≥ 4 times per week compared to ≤ 1 time per week) is associated with a 22% lower risk of

³ 7CFR 810.1601. United States Grain Standard Act.

coronary heart disease (RR = 0.78) and 11% lower risk of cardiovascular disease (RR = 0.89)⁴. Health benefits of soybeans have been amply documented⁵. Most grain legumes are excellent sources of fiber and protein. In addition, grain legumes are important dietary sources for folate, potassium, iron, phosphorus, calcium and magnesium, as well as numerous other micronutrients (Table 1). This nutrient profile, equivalent or in some instances superior to the one in cereal grains, may in part explain why increased grain legume consumption is often associated with health benefits⁶.

Table 1. Comparison of Nutrient Content of Whole Wheat, Edible Beans and Soybeans

Item (per 100 g)	Wheat (Durum)	Wheat (Hard Red Spring)	Black Edible Beans-Raw (Phaseolus vulgaris)	Soybeans-Raw (Glycine max)
Energy (Kcal)	339.0	329.0	341.0	416.0
Protein (g)	13.7	15.4	21.6	36.5
Fat (g)	2.5	2.0	1.4	20.0
Carbohydrate (g)	71.1	68.0	62.4	30.2
Dietary Fiber (g)	-	12.2	15.2	9.3
Riboflavin (mg)	0.12	0.11	0.19	0.87
Pantothenic Acid (mg)	0.94	0.94	0.90	0.79
Folate (µg)	43.0	43.0	444	375.0
Thiamin (mg)	0.42	0.50	0.90	0.87
Niacin (mg)	6.7	5.7	2.0	1.6
Vitamin B ₆ (mg)	0.42	0.34	0.3	0.38
Vitamin E (mg alpha-tocopherol)	-	1.0	0.22	0.85
Iron (mg)	3.5	3.6	5.0	15.7
Phosphorus (mg)	508.0	332.0	352.0	704.0
Selenium (µg)	89.4	70.7	3.2	17.8
Calcium (mg)	34.0	25.0	123.0	277.0
Magnesium (mg)	144.0	124.0	171.0	280.0
Potassium (mg)	431.0	340.0	1,483.0	1,797.0
Sodium (mg)	2.0	2.0	5.0	2.0
Zinc (mg)	4.2	2.8	3.7	4.9
Manganese (mg)	3.0	4.1	1.1	2.5

Source: USDA SR18 (<http://www.nal.usda.gov/fnic/foodcomp/search/>)

⁴ Bazzano, et al. Legume consumption and risk of coronary heart disease in US men and women: NHANES I Epidemiologic Follow-up Study. Arch Intern Med 2001;161:2573-8.

⁵ 21CFR101.82. Health claims: Soy protein and risk of coronary heart disease (CHD).

⁶ Geil and Anderson. Nutrition and health implications of dry beans: a review. J Am Coll Nutr 1994;13:549-58.

In relation to fiber, the dietary advice provided by the Institute of Medicine's DRI Report on Macronutrients and 2005 Dietary Guidelines for Americans focused primarily on the consumption of whole grains due largely to the fiber content. By comparison, grain legumes have higher fiber content than cereal grains (Table 2) while possessing similar or even greater health benefits than whole cereal grains. The inclusion of grain legumes would enhance further the recommendation for the consumption of beans already encouraged in the 2005 Dietary Guidelines for Americans. Therefore, we urge the agency to adopt a definition of whole grains based simply on the anatomical presence of the bran, endosperm and germ components which is not limited to solely cereal grains.

Table 2. Total Dietary Fiber Content of Edible Beans, Bread, Ready-to-Eat Cereal and Cereal Grains.

Description	USDA SR18 NDB No.	Common Measure	Total Dietary Fiber (g)
Beans, black, mature seeds, cooked, boiled, without salt	16015	1 cup	15.0
Beans, great northern, mature seeds, cooked, boiled, without salt	16025	1 cup	12.4
Beans, kidney, red, mature seeds, canned	16034	1 cup	16.4
Beans, navy, mature seeds, cooked, boiled, without salt	16038	1 cup	19.1
Beans, pinto, mature seeds, cooked, boiled, without salt	16043	1 cup	15.4
Beans, white, mature seeds, canned	16051	1 cup	12.6
Chickpeas (garbanzo beans, bengal gram), mature seeds, canned	16058	1 cup	10.6
Cowpeas, common (blackeyes, crowder, southern), mature seeds, canned, plain	16064	1 cup	7.9
Soybeans, mature cooked, boiled, without salt	16109	1 cup	10.3
Bread, cracked-wheat	18025	1 slice	1.4
Bread, mixed-grain (includes whole-grain, 7-grain)	18035	1 slice	1.7
Bread, oatmeal	18039	1 slice	1.1
Bread, pumpernickel	18044	1 slice	2.1
Bread, whole-wheat, commercially prepared	18075	1 slice	1.9
Cereals ready-to-eat, GENERAL MILLS, TOTAL Raisin Bran	08247	1 cup	5.0
Cereals ready-to-eat, wheat, shredded, plain, sugar and salt free	08147	2 biscuits	5.5
Cornmeal, whole-grain, yellow	20020	1 cup	8.9
Wheat, cracked, cooked*	NA	1 cup**	6.0
Wild rice, cooked	20089	1 cup	3.0

Unless otherwise noted, all information obtained from USDA SR18's single nutrient report for total dietary fiber content of selected foods (<http://www.nal.usda.gov/fnic/foodcomp/Data/SR18/nutrlist/sr18a291.pdf>).

* = Value obtained from www.tufts.edu/med/nutrition-infection/hiv/health_fiber.html; ** = Value calculated by doubling original value since provided as 1/2 cup measure.

CONTENT CLAIMS FOR WHOLE GRAINS

For all practical purposes, we believe that whole grains should be categorized as a food ingredient and not a nutrient or food. This classification would allow proposed labeling of various amounts of whole grains in processed foods as established by the presence of qualifying content of whole grains. Graded amount of whole grain, and not necessarily only 100% whole grain, have been shown to elicit significant changes in metabolic responses of humans when prepared as breads (Figure 2).

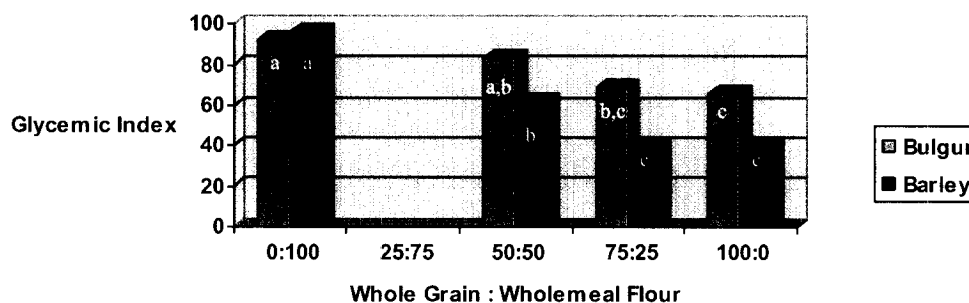


Figure 2. Mean Glycemic Index for Different Bulgur and Barley Test Meals [Adapted from Table II in Jenkins et al.⁷]. Note: The authors indicate that “breads made from 100% wholemeal flour (wheat or barley) resulted in glycaemic responses that were not significantly different from those for white bread.”

The following proposed ingredient content claims for food labeling of whole grains (Table 3) would not be in conflict with any current content claim guidelines while aiming to be compatible in supporting consumption of whole grains as encouraged in the 2005 Dietary Guidelines for Americans.

⁷ Jenkins, et al. Wholemeal versus wholegrain breads: proportion of whole or cracked grain and the glycaemic response. Br Med J 1988;297:958-60.

Table 3. Proposed ingredient content claims for food labeling of whole grains

Qualifying Level of Whole Grain (expressed as % of total grain content)	Proposed Label Claim
25 – 50	Contains whole grains
51 – 75	Made with whole grains
76 – 99	Whole grain
100	100% Whole Grain

Using an ingredient approach, grain legumes, like cereal grains, can be made into and used as whole grain legume powders. From a nutritional approach based on fiber as previously described, whole grain legume powders contain a greater amount of total dietary fiber among whole grain and vegetable-based ingredients which would be used in a similar manner to displace more highly refined flours (Table 4).

Table 4. Caloric Content (per 100g) and Total Dietary Fiber (per 100g) for Select Ingredients Derived from Whole Cereal Grains, Grain Legumes and Potato.

Description	USDA SR18		Total Dietary
	NDB No.	Calories	Fiber (g)
Wheat flour, whole-grain	20080	340	12.2
Cornmeal, degermed, enriched, yellow	20022	366	7.4
Cornmasa	NA	362	7.3
Potato, dehydrated, flakes	NA	354	6.9
Rice flour	NA	366	2.4
Soybean, whole, pre-cooked, powdered	NA	400	17.0
Pinto bean, whole, pre-cooked, powdered	NA	292	23.0
Black bean, whole, pre-cooked, powdered	NA	321	22.2
Navy bean, whole, pre-cooked, powdered	NA	367	27.7
Great Northern bean, whole, pre-cooked, powdered	NA	325	22.3
Kidney bean, light red, whole, pre-cooked, powdered	NA	356	23.8

NA = Not available. Calories and Total Dietary Fiber values determined by calculation and analysis, respectively, for items not available in USDA SR18 NDB.

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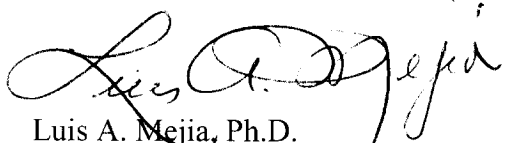
RECONSTITUTION OF WHOLE GRAINS

For technological reasons, certain foods prepared using large scale continuous manufacturing systems may not be able to utilize intact whole grains, and the processing of grains to separate the main grain components may be required. But, foods with the same proportion of bran, germ and endosperm as the original intact whole grain can then be made if the bran and germ components are reconstituted later in the manufacturing process. Without this reconstitution approach, fewer whole grain products would be available in the marketplace for consumers to choose in order to meet target consumption goals. In this manner, the consumer will receive the same benefits arising from the whole grain components while preserving function, color, taste and price of the more familiar products. Furthermore, preparation of grains has been suggested to have a potential beneficial effect with regard to improving the digestibility of certain nutrients and phytochemicals⁸. This approach would be compatible with the definition of whole grain and the desired health and nutrition purposes for which whole grain consumption is encouraged.

In summary, we encourage the agency to issue whole grain labeling regulations that

- Expand the DEFINITION of whole grains to include other grains such as grain legumes
- Allow CONTENT CLAIMS for graded amounts of whole grains
- Allow RECONSTITUTION of whole grains from individual components when processing creates technical limitations in using intact whole grains.

Respectfully yours,



Luis A. Mejia, Ph.D.
Director of Regulatory and Scientific Affairs

cc: M. Empie

⁸ Slavin, et al. Grain processing and nutrition. Crit Rev Food Sci Nutr 2000;40:309-26.