



**WHOLE GRAIN INTAKE AND CARDIOVASCULAR  
DISEASE AND WHOLE GRAIN INTAKE AND DIABETES  
A REVIEW**

**EXECUTIVE SUMMARY**

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This is a brief summary of the review by LSRO. It is not a complete document and should be considered within the context of the full report, which can be obtained at [WWW.LSRO.ORG](http://WWW.LSRO.ORG)

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## **EXECUTIVE SUMMARY**

Cardiovascular disease (CVD) and diabetes are significant causes of morbidity and mortality. Heart disease and stroke are the first and third leading causes of death, respectively, accounting for approximately 40% of deaths in the US annually (American Heart Association & American Stroke Association, 2008). In addition, approximately 21 million children and adults, 8% of the US population, have diabetes (American Diabetes Association, 2008). In the last decade, epidemiological studies have reported a reduction in the risk of CVD and Type 2 diabetes among habitual consumers of whole grains compared to those who rarely eat whole grains (Jacobs, Jr. et al., 1998; Meyer et al., 2000).

However, it wasn't until 1999 that a standard definition of whole grains was recommended on the basis of a consensus among an ad hoc committee of experts from the former American Association for Cereal Chemists (AACC). In 2006, the AACC whole grains definition was adopted by the US Food and Drug Administration (FDA) in the document "Whole Grain Label Statements" to provide guidance to the industry about what the agency considers to be whole grain and to assist manufacturers in labeling their products. In that document whole grains are defined as consisting of the intact, ground, cracked or flaked fruit of the grains whose principal components—the starchy endosperm, germ and bran—are present in the same relative proportions as they exist in the intact grain (U.S. Food and Drug Administration, 2006). Throughout this review, the whole grains definition was referred to as the FDA's definition of whole grains.

In this context, the Kellogg Company requested that the Life Sciences Research Office, Inc. (LSRO) conduct an independent review of the scientific literature to evaluate the effect of applying the FDA definition of whole grains on the strength of scientific evidence in support of whole-grains health claims for risk reduction of CVD and diabetes. This report was undertaken in consultation with an independent Expert Panel that was composed of scientific experts in the fields of cereal chemistry, nutrition, epidemiology and food regulation (Appendix I).

### **Health Claim Regulations in the United States**

Health claims for food labels are authorized in the United States by two amendments to the Federal Food, Drug and Cosmetic Act: the Nutrition Labeling and Education Act of 1990 (NLEA) and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Under the NLEA, a health claim is a food label statement that characterizes a relationship between a food substance or specific food and a disease. These health claims must be authorized and published as regulations by the FDA to be used in food labels (U.S. Congress, 1990). FDAMA health claims are based on an authoritative statement from an appropriate federal agency or the National Academy of Sciences (NAS) (U.S. Congress, 1997). Manufacturers may submit to FDA a notification of a FDAMA health claim and if FDA does not prohibit or modify it within 120 days of receipt of

the notification, the claim may be used. Therefore, the health claim provisions in FDAMA were intended to expedite the process by which the use of food label health claims are authorized (U.S. Food and Drug Administration, 1998a).

Currently, three NLEA health claims have been approved for grain products (not whole grains), one related to cancer and two related to coronary heart disease (CHD). All health claims for grain products refer to a specific substance – one to total dietary fiber, the others to soluble dietary fiber – and a disease component. The FDAMA health claim addressing whole grains is based on the following authoritative statement “diets high in plant foods—i.e., fruits, vegetables, legumes, and *whole grain cereals*—are associated with lower occurrence of CHD and cancers of the lung, colon, esophagus, and stomach” extracted from the NAS report. At present there are no health claims that relate grain products to diabetes.

### **Whole Grains Composition**

A whole cereal grain is the fruit (also known as the seed, caryopsis, or kernel) of plants belonging to the *Poaceae* (or *Gramineae*) family also known as grasses. Some examples of cereal grains are wheat, rice, barley, corn, rye, oats, millets, sorghum, teff, triticale, canary seed, Job’s tears, fonio, and wild rice. The seed is composed of three parts: the endosperm which comprises approximately 80-90% of the grain, the bran which is the outer layers of the whole grain and the germ or embryo that is located at the base of the grain. Although all grains contain the three anatomical parts there is a great variability among the various whole grains in their content of macronutrients, micronutrients and bioactive components, including components thought to have a role in disease prevention, such as, fiber, folate, phenolic compounds, lignan, and sterols. For example, the total fiber content of bulgur and barley is approximately 5-fold higher than that of brown rice. Rye contains the highest amount of lignan and sterols (other than phenolic acids and phenolic lipids) compared to wheat, oats, and barley. Furthermore, some nutrients are absent in some grains, but present in high amounts in other grains as in the case of vitamin A,  $\beta$ -carotene, lutein and zeaxanthin that are present in high levels in corn but absent in brown rice, oats, and sorghum.

### **LSRO Study Approach**

LSRO conducted a comprehensive search of the literature by searching MEDLINE for articles published through February, 2008. The following search strategy was used to identify relevant articles: (whole grain OR whole grains) AND (cardiovascular disease OR heart OR coronary heart disease OR stroke OR blood pressure OR myocardial infarction OR health OR diabetes). LSRO considered only human intervention and observational studies, because according to FDA, these studies can provide evidence from which scientific conclusions can be drawn about substance and disease relationships in humans (U.S. Food and Drug Administration, 2007). In addition, only studies that

measured a validated endpoint or a surrogate endpoint for CVD and/or diabetes in a healthy US population and population's representative of the US were considered.

In order to evaluate the effect of applying the FDA definition of whole grains on the strength of scientific evidence, LSRO first analyzed only studies that explicitly described or defined whole grains according to the FDA definition of whole grains. Later LSRO expanded the analysis, to include studies with a broader definition of whole grains, studies that considered added bran and germ as whole grains or studies that did not explicitly use the term "whole grains" but were, in fact, conducted with individual whole grains (e.g. studies with oats or barley). Five studies were included in the analysis when considering only studies that met the FDA definition. The expanded approach included additional human studies for a total of 29 (15 intervention and 14 observational) studies for the association between whole grains and CVD, and 21 (10 intervention and 11 observational) studies for the association between whole grains and diabetes. Thirty-eight studies were excluded that evaluated the association between whole grains and CVD or whole grains and diabetes but did not meet one or more of our inclusion criteria.

## Conclusions

A consistent definition of whole grains has not been applied in existing research that investigates the health benefits of consuming whole grains. As such, drawing specific conclusions on benefits of "whole grains" in general from the body of scientific evidence is confounded, typically with bran/dietary fiber. Using the FDA definition for whole grains as a selection criterion is limiting because the vast majority of existing studies often use a broader meaning to categorize a grain product as whole grain. Applying the FDA definition of whole grains excludes the majority of observational studies, because they include the intake of bran and germ to evaluate the health effect of whole grains, and a great number of intervention studies that use individual grains, because they do not explicitly state that the endosperm, bran and germ are present in the same proportion.

LSRO concluded that the scientific evidence on the relationship of whole grain consumption and CVD can be evaluated two ways. First, there is no consistent scientific evidence to support a whole grain and CVD risk health claim if only whole grain studies that conform to the FDA whole grain definition are considered. In contrast, a whole grain and CVD health claim is supported using a broader concept of whole grain, typically used in the literature that includes whole-grain foods containing principal components such as bran. A health claim for the relationship between soluble fiber from oats and barley and risk of CHD has been approved by the FDA (U.S. Food and Drug Administration, 2008a).

LSRO concluded that the scientific evidence on the relationship of whole grain consumption and diabetes is suggestive but inconclusive whether the analysis

was restricted to studies that defined whole grain according to the FDA definition, or included studies using a wider classification of whole grains.

Finally, LSRO concluded that the health benefits observed from consumption of one whole grain do not necessarily reflect the same type or the same magnitude of benefit from other whole grains. This is because of the diversity among whole grains in terms of macronutrient, micronutrient, and bioactive components.

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