The Effect of Applying the FDA Definition of Whole Grains to Health Claims for Risk Reduction of Cardiovascular Disease and Diabetes

Michael Falk, Ph.D.
Life Sciences Research Office, Inc.

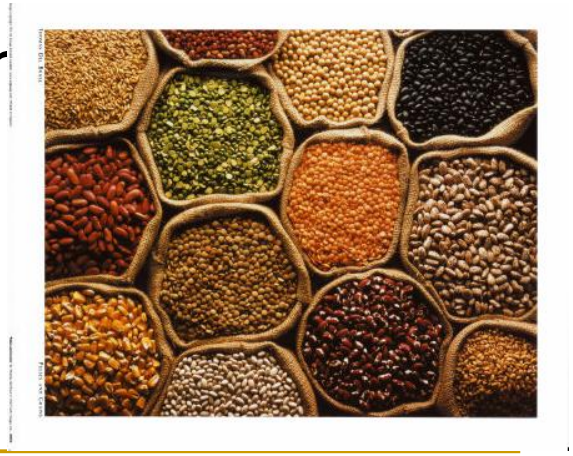
For Whole Grain Global Summit, March 27, 2009

The Process

- Since 1962 LSRO has provided scientific analysis and advice to government and industry
  - Non-profit, independent, impartial
- In conjunction with an external panel of experts
  - Nutrition, cereal chemistry, epidemiology, FDA regulations
- The project was sponsored by Kellogg, Co.
  - Hands-off, no input into the panel selection, design, or outcome

Goals

- Evaluate the “whole grain” literature to see if it supports selected scientific relationships based on AACC/FDA definition of whole grains (CVD and diabetes)
- Expand the analysis to include other grain components such as bran or fiber and studies that do not explicitly use the terr grain”



LSRO

Health Claims in US

- Risk reduction not curing, treating, mitigating disease
- Based on scientific relationship
- First and foremost based on effects in humans
  - Interventional (RCT)
  - Observational
  - Everything else is considered supplementary
- Require significant scientific agreement or qualifying language (NLEA)
- Based on authoritative statement from an appropriate scientific organization (FDAMA)

Current Health Claims

- Three fiber-related NLEA claims
  - Fruits , vegetables, and grain products that contain fiber, particularly soluble fiber and the risk of CHD (also cancer)
  - Soluble fiber from certain foods and risk of CHD
    - 1st whole-oat sources
    - Then psyllium seed husk
    - Hydrolyzed oat flour
    - Barley and barley products

- Two whole grain FDAMA claims

Current FDAMA Health Claims

- "Diets high in plant foods i.e., fruits, vegetables, legumes and whole grain cereals are associated with lower occurrence of CHD…"

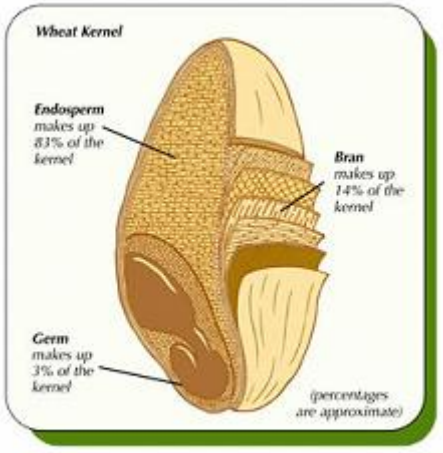
  US National Academy of Sciences

  - Whole grain food must be 51% whole grain ingredients
  - Using FDA definition for whole grain
- Second claim - whole grain food with moderate fat content (refers to the association between low saturated fat and CHD)

AACC/FDA Definition of Whole Grain

- "consist of the intact, ground, cracked or flaked caryopsis, whole principal anatomical components – the starchy endosperm, germ and bran – are present in the same relative proportions as they exist in the intact caryopsis"

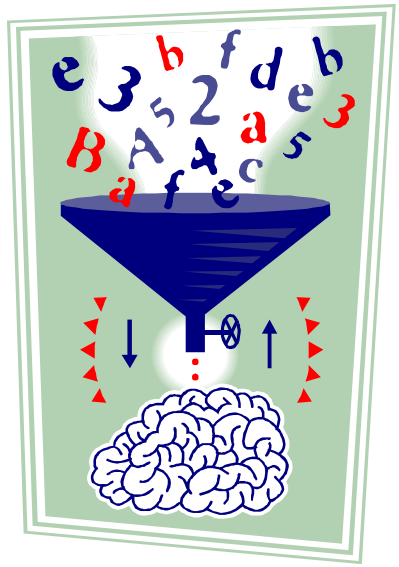
First adopted by AACC (1999) then adopted by FDA in guidance on Whole Grain Label Statements (2006)



Credit www.grainsessential.ca

Literature Search

- Whole Grains and Heart Disease (CVD, heart, CHD, stroke, blood pressure, myocardial infarction..)
- Whole Grains and Diabetes
- 634 potentially relevant articles
- Excluded
  - Reviews, meta-analyses, editorials
  - Animal and *in vitro* studies
- 204 selected for further evaluation



LSRO

Literature Search (continued)

- Included (FDA definition)
  - Human intervention and observational studies
  - Validated endpoints or surrogate endpoint for CVD and/or diabetes
  - Study populations representative of US
  - Healthy populations
- First analysis - meets FDA definition only
- Second analysis expanded definition
  - Included bran, germ or fiber (the use of products with 25% bran content was commonly included in definition of whole grain in observational studies)
  - Did not explicitly use the term “whole grains” but used whole grains in the study

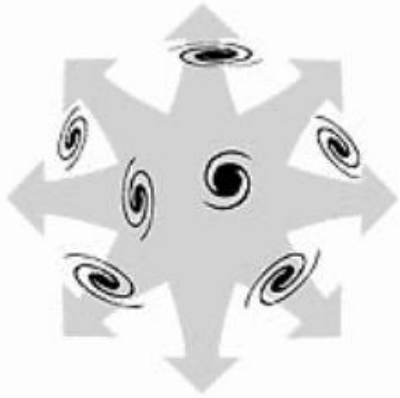
Results: CVD Using FDA Definition

Reference	Study Design	Country	N (Len)	Outcome
Andersson et al. 2007	Randomized Crossover	US	30 (6 wk)	CVD (no significant change)
Rave et al. 2007	Randomized Crossover	Germany	31 (4 wk)	CVD (no significant change)
Jensen et al. 2004 (HPFS)	Prospective Cohort	US	42,850	CVD (RR=0.82, p=0.01, intake 42.2 vs 3.5 g/d)
Jensen et al. 2006	Cross-sectional	US	938	CVD (Total cholesterol: -0.16 mmol/L, p=0.02, intake 43.8 vs 8.2 g/d)

Results: Diabetes Using FDA Definition

Reference	Study Design	Country	N (Len)	Outcome
Andersson et al. 2007	Randomized Crossover	US	30 (6 wk)	Diabetes (no significant change)
Rave et al. 2007	Randomized Crossover	Germany	31 (4 wk)	Diabetes (improved insulin and HOMA-IR)
De Munter et al, 2007 (NHS)	Prospective Cohort	US	73,327	Diabetes (RR=0.63, p<0.001, intake 31.2 vs 3.7 g/d)
			88,410	Diabetes (RR=0.68, p<0.001, intake 39.9 vs 6.2 g/d)

Results: Expanded Analysis



Outcome	Design	FDA only	Expanded	Expanded Analysis
CVD	Intervention	2	15	Beneficial effect
	Observational	2	14	Consistent protective effect
Diabetes	Intervention	2	10	Suggestive but inconclusive
	Observational	1	11	Suggestive but inconclusive

LSRO

Report Conclusions

- Using FDA definition as a selection criterion is limiting
  - Historically whole grain definitions have been inconsistent
  - Scientific evidence is “confounded” with fiber/bran (e.g. observational research historically included products with 25% bran content as whole grain)
- Expanded analysis converts conclusions for CVD from inconclusive to strongly positive
- Diabetes is inconclusive for either analysis
- Because of nutrient variability among whole grains, the beneficial health effects of one whole grain may not be the same for other whole grains

Study participants

- LSRO
  - Fabiana DeMoura, Ph.D.
  - Kara Lewis, Ph.D.
  - Michael Falk, Ph.D.
- Expert Panel
  - James Hoadley, Ph.D.
  - Julie Mares, M.S.P.H, Ph.D
  - Judith Marlett, R.D., Ph.D.
  - Harry Sapirstein, Ph.D.

The LSRO Report and Beyond

- Implications for national nutrition advisory bodies
  - US Dietary Guidelines Advisory Committee
- Implications for health claims
  - Accuracy
  - Applicability to all grains
  - Difficulty in quantification of ingredients
  - Reconsideration of FDAMA whole grain claims to include fiber/bran/germ components
  - Considerations by EFSA for Article 14 claims

MyPyramid.gov
STEPS TO A HEALTHIER YOU

efsa
European Food Safety Authority

LSRO

Thank you for your consideration

Michael Falk, Ph.D.
301-634-7030
301-634-7876 (fax)
Falkm@LSRO.org