Defining Whole Grains: Challenges and Regulatory Implications

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For Fiber: The heart of whole grain IFT 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 term “whole grain”

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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…"

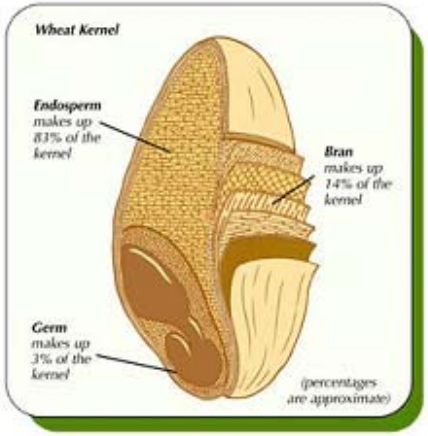
  US National Academy of Sciences

  - 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"

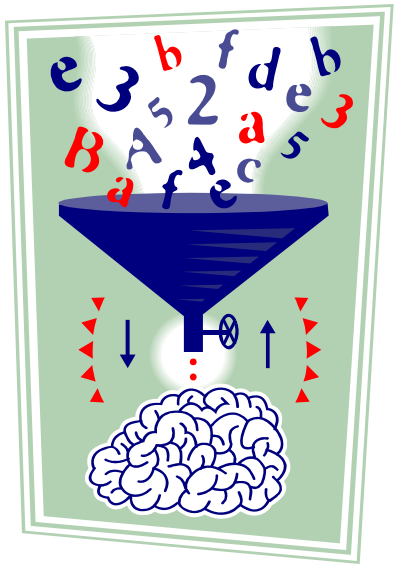
First adopted by AACC (1999) then adopted by FDA in guidance on Whole Grain Label Statements (2006)



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



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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
- Restricted Analysis - meets FDA definition only
- Expanded Analysis - broader 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

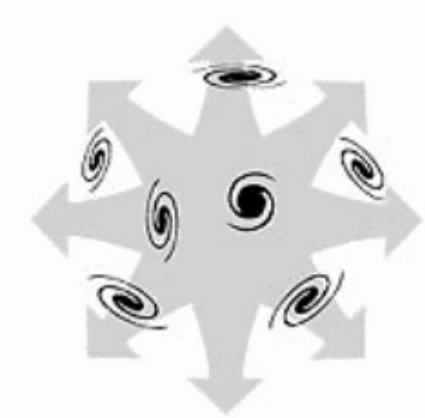
Results: CVD Using FDA Definition

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)

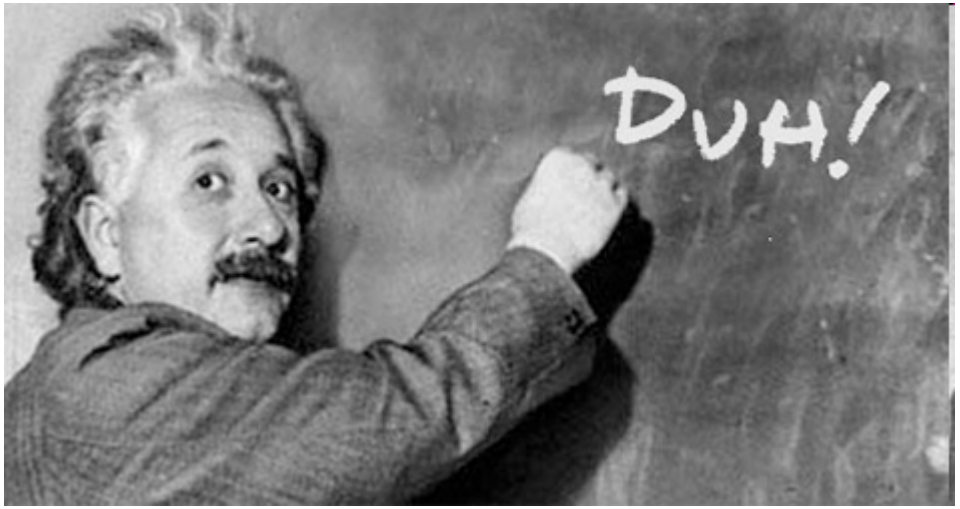
Results: Expanded Analysis



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

A Common Definition Does Not Make Them Equal

- All grains are not equal



- A focus on whole grains may distract from fiber recommendations

Selected Nutrient Content (per 100g) of a Variety of Grains

Nutrient	Barley hulled	Brown Rice	Bulgur	Corn Yellow	Oats	Rye	Sorghum	Wheat	Wild Rice
Energy (Kcal)	354	362	342	365	389	335	339	327	357
Carbohydrate (g)	73.5	76.2	75.9	74.3	66.3	69.8	74.6	71.2	74.9
Fiber, total dietary (g)	17.3	3.4	18.3	7.3	10.6	14.6	6.3	12.2	6.2

USDA National Nutrient Database for Standard reference, Release 20

Dietary Fiber Content of Cereal Grains

Dietary Fiber	Barley	Oat	Rye	Wheat
Soluble fraction				
Glucose	69	87	27	11
Xylose	15	4	41	48
Arabinose	12	5	24	30
Mannose	2	2	3	4
Insoluble fraction				
Glucose	39	44	29	28
Xylose	37	34	40	42
Arabinose	19	18	23	29
Mannose	4	2	4	trace
β-Glucan	4.4	3.4	1.9	0.7

Adapted from Marlett (1991)

Phytochemical Content of Cereal Grains

Phytochemicals	*Barley*	*Oat*	*Rye*	*Wheat*
Lignan (µg/100g)	58.0	13.7	112.0	35.5
Isoflavonoids (µg/100g)	21.7	-	-	-
Phenolic acids (µg/g,dw)	478.0	9.4	1,210.0	640.0
Alkylresorcinols (µg/g)	45.0	-	734.0	583.0
Sterols (mg/100g,wb)	67.8	33.5	88.7	66.4

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
  - Will it encourage or discourage fiber intake?
- 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

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Nutrition Facts
Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving
Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

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Thank you for your consideration

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