

US Whole Grain Regulatory & Policy Framework

International Forum for Whole Grain Foods Development

Hosted by:

*PNDC, Whole Grains Council &
Grains for Health Foundation*

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Overview of Presentation

- Overview of General Mills
- Key US Regulatory Agencies
- US Food Claims Background
- Whole Grain Regulatory Timeline
- Key Whole Grain Nutrition Policies, Regulations & Guidances
- Summary

General Mills Overview

- World's 6th largest food company
- \$14.8 billion in FY10 net sales*
- 28,500 employees
- Marketed in more than 100 countries



* Includes proportionate share of JV sales

Our Mission

nourishinglives®



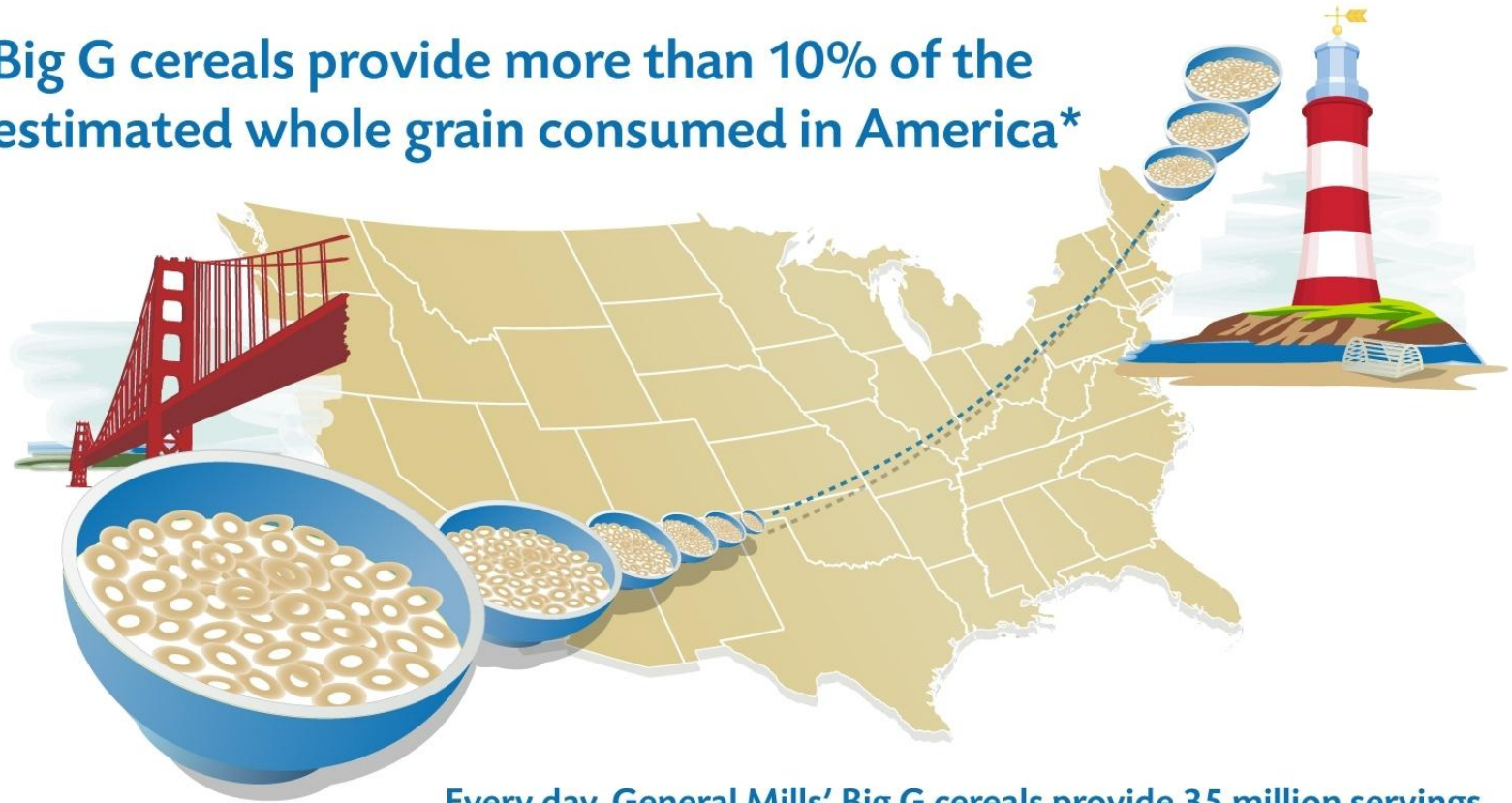
**The Nourishment
We Provide**

**The People
We Serve**

**The Planet
We Share**

General Mills: Whole Grain Leaders

Big G cereals provide more than 10% of the estimated whole grain consumed in America*



Every day, General Mills' Big G cereals provide 35 million servings of whole grain to Americans! If you lined up 35 million cereal bowls end-to-end, they would stretch across the continental United States!

*Based on most recent whole grain consumption figures, NHANES 2003-2004

FDA & USDA: Key US Gov't Food Regulatory Agencies

Responsible for establishing food labeling regulations; both have addressed WGs

FDA



- Leads development of labeling regulations, including format and claims
- Regulates all foods except most meat & poultry products

USDA



- Regulates & administers food programs such as school meals & the Women, Infant & Children (WIC) Supplemental Food Program
- Regulates most meat & poultry products

Nutrition and Health Claims

NLEA Health Claims

- Nutrient/Substance reduces risk of disease based on:
 - **Significant Scientific Agreement (SSA)**
 - Petition process-approx. 2 years
 - Proposal/Public comment
 - Final Rule or deny by FDA

Qualified Health Claim

- Nutrient/Substance reduces risk of disease based on:
 - Weight of scientific evidence
 - Petition process-270 days
 - Public comment
 - Final Rule or deny by FDA

Nutrient Content

- Characterizes the level of a nutrient in the food, e.g., Good, High
- Permitted for nutrients with a Daily Value

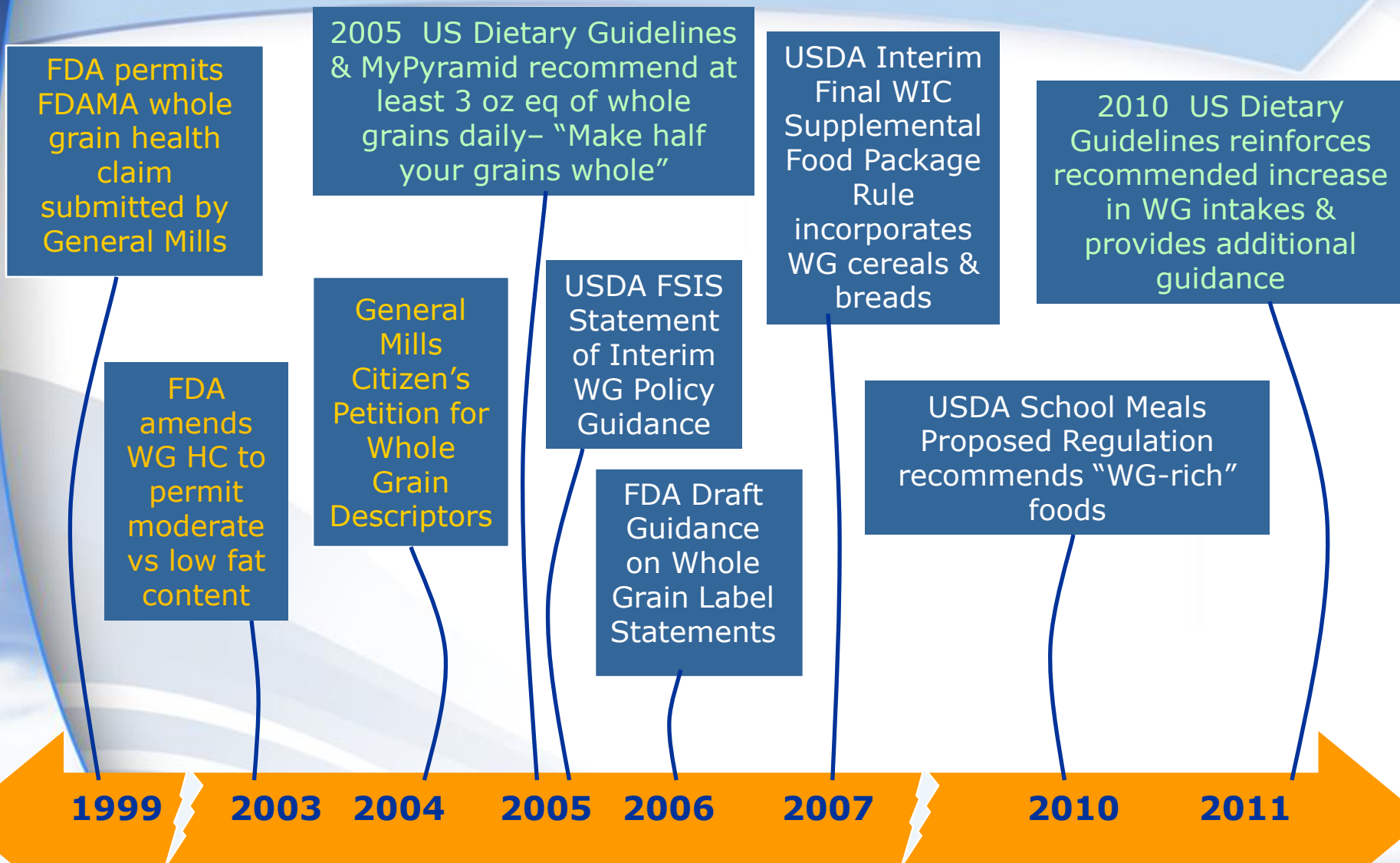
Structure/Function

- Nutrient/Substance has an impact on a body structure or function

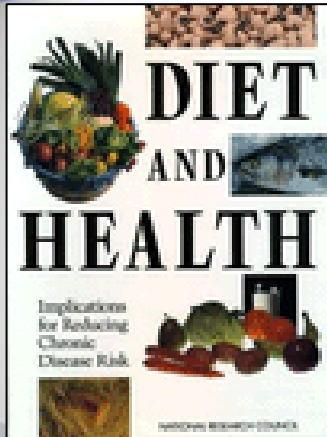
FDAMA Health Claims

- Nutrient/Substance reduces risk of disease based on:
 - **Authoritative statement by a "Recognized Government Health Body"**
 - Submit authoritative statement, proposed claim & rationale
 - Deliberative process; FDA seeks input from NIH & other government agencies
 - FDA Allows or denies (120 days)
 - No proposal or Public comment Required

Whole Grain: Evolution of Policy and Regulations



FDA Affirmed GMI submission for Whole Grain Health claim



“Diets rich in whole grain foods and other plant foods that are low in total fat, saturated fat, and cholesterol may reduce the risks of heart disease and certain cancers”.

Based on authoritative statement from NAS Diet & Health, 1989



Existing epidemiological data reinforced the authoritative statement but was not required for claim affirmation

FDAMA Whole Grain Health Claim Product Requirements

- Food must be 51% or more whole grain by weight per RACC
 - Dietary fiber used as marker for compliance
- Food must be moderate total fat, low saturated fat and low cholesterol

Setting the Criteria for the Whole Grain Health Claim

- Needed a standard for WG content
 - Characterize the level of whole grain in the product
 - Minimum of 51% Whole Grain
 - Not meant for other labeling purposes
- Compliance marker needed as a way to confirm that the product meets the 51% WG definition
 - Fiber marker is for enforcement purposes only, not part of the definition of a WG food
 - Fiber level of whole wheat used as default (predominant grain in the U.S.)
 - 11 grams x 51% x RACC/100

Product Challenges with the Whole Grain Health Claim

- Foods must contain at least 51% whole grain by total weight of ingredients
 - Difficult for products with higher moisture level and a variety of non-grain ingredients
 - Example: whole grain raisin bread
 - 40% of weight is moisture
 - Additional weight from raisins, oil or honey
 - Whole grain flour would be less than 51% of the total weight

Whole Grains Vary in Fiber Content

Fiber marker for enforcement purposes only,
not an indicator of the WG content of a food

Type of grain (100g)	Fiber
Whole wheat	12.2g
Whole oats	10.3g
Whole corn meal	7.3g
Brown rice	3.4g



Food*	Serving	Fiber
Brown rice, cooked	140g	2.5g
Whole wheat bread	50g	3-4g
Corn chips	30g	1g
Whole grain cereal	30g	3g
	55g	4-5g

Source: USDA National Nutrient Database
for Standard Reference

*100% of grain in food is whole grain

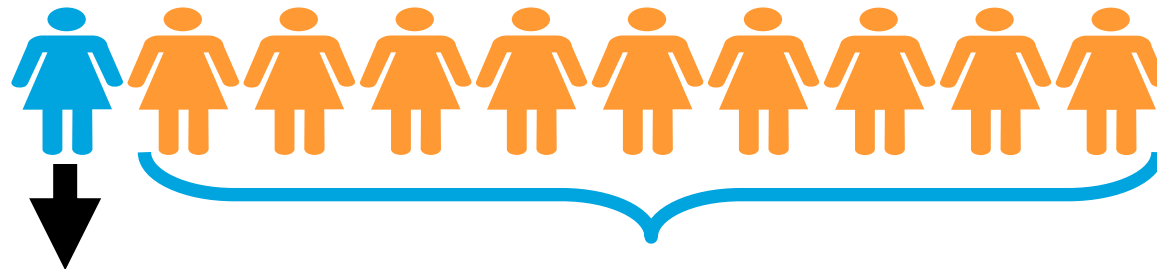
- FDA (2008) ruled that single-ingredient whole grain foods don't need to meet the fiber compliance marker
- Still a challenge for multi-ingredient products

Policy: First WG Recos in 2005 Dietary Guidelines

- US Dietary Guidelines are the cornerstone of nutrition policy and regulations
- The first set of US Dietary Guidelines were issued in 1980
 - Required by law to be updated every 5 years
- 2005 Dietary Guidelines were the first to include a Whole Grain recommendation:
 - Make half your grains whole
 - Get at least 3 oz eq of whole grains daily
 - Replace some 'refined' grain servings with whole grains

Whole Grain Consumption Gap

9 out of 10 Americans (adults and children) are **NOT** getting the recommended 3 servings of whole grains each day!



Getting the Recommended 3 Servings of Whole Grain/Day

Not Getting Enough Whole Grain

Foods making a substantial Whole Grain contribution can help consumers bridge the gap

USDA FSIS* Statement of Interim Policy Guidance re: Whole Grains

- Foods can be considered whole grain that meet:
 - 51% of the grain as whole grain, or
 - 51% of the product by weight, or
 - Contain at least ½ ounce equivalent or 8g dry whole grain ingredient
 - Products that meet FDA standards of identity or that contain at least ½ ounce equivalent or 8g WG can be described as 'made with whole grains'

*FSIS= Food Safety & Inspection Service

FDA Draft Guidance: WG Label Statements

- Defines whole grains as:
 - Cereal grains that consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact caryopsis
 - Adopted from the American Association of Cereal Chemists International (AACCI) definition of whole grain
- Provides examples of whole grains
 - Amaranth, barley, buckwheat, bulgur, corn (including popcorn), millet, quinoa, rice, rye, oats (including rolled oats), sorghum, teff, triticale, wheat, and wild rice
- <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059088.htm>

FDA Draft Guidance: WG Label Statements

- Allows factual statements about WG content of products, e.g.:
 - 100% whole grains or 100% whole grain wheat
 - 10 grams of whole grains
 - ½ ounce whole grains
- Restates the FDAMA WG health claim as a permitted statement
 - Product must meet the requirements outlined in the health claim
- Allows for the WGC Stamp Program



WIC Program Regulations include Whole Grain Cereals & Breads

- WIC is a government supplemental feeding program targeting women, infants and children under age 5
- Selected foods are provided, including cereals that meet specific nutritional criteria & whole grain breads
 - Half of the cereals offered through the WIC must be whole grain

Expanded WG Recos in 2010 Dietary Guidelines

2010 Dietary Guidelines build on 2005 by outlining what constitutes 'substantial' amounts of WG in a food:

- Make half your grains whole
 - Get at least 3 oz eq of whole grains daily
 - Replace some 'refined' grain servings with whole grains
- Partly whole-grain products can contribute substantially to whole-grain intake
 - Minimum of 8g WG/ serving
 - 51% WG by weight of product
 - WG 1st ingredient

Reinforces the minimum daily intake goal of 48g/day



Proposed School Meal Regulation Targets Increasing WG

- Several options suggested to meet “whole grain-rich” definition:
 - 8g per serving
 - 1st ingredient WG
 - 51% whole grain by weight (health claim)
 - 51% of the grain content must be whole grain (based on Healthier US School Challenge)
- Includes a target that all grains be ‘whole grain rich’ two years after implementing the regulation.

Summary

- Dietary Guidelines are the cornerstone for US nutrition policy and regulations
 - 2005 & 2010 Editions provide WG intake recommendations for the US population
 - Partial WG content foods are recognized as contributors to WG intake
 - \geq 8g per oz equivalent
 - 51% of the product by weight
 - WG 1st ingredient
 - Increasing whole grain intake is supported
 - Scientific evidence
 - Public policy

Summary

- Both FDA & USDA have oversight of regulations in the US
 - Both have addressed whole grains but gaps exist
 - Updating would be helpful and valuable for both the food industry & consumers
 - US Regulations are supposed to align with the Dietary Guidelines
 - Most recently developed or updated regulations and guidances encompass whole grain requirements or recommendations
- The proposed School Meals regulation and WIC program both include WG requirements
 - Provides significant incentive for companies to develop new or reformulate existing products to meet the requirements

Summary

- The Whole Grain Health claim is a FDAMA Health Claim
 - It is a simplified health claim notification process
 - Represents scientific consensus through a deliberative process by a government body
- The Whole Grain Health Claim provides incentive to promote whole grain health benefits to consumers
 - Links WG to reduced risk of heart disease & certain cancers
- The WGC WG Stamp program helps consumers identify products with substantial WG content

Thank-you!!



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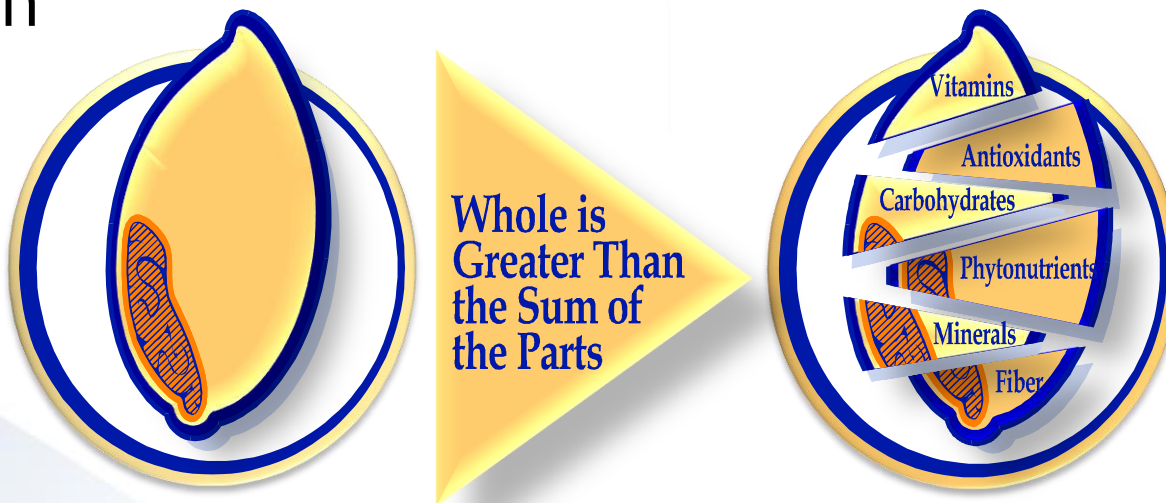
BACKUP SLIDES



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Whole Grain Synergy and Benefits

- Whole grain health benefits come from the entire grain



- Evidence of whole grain benefits is consistent regardless of criteria