Dietary Guidance Statements
An Industry Perspective

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Outline

- Consumer Understanding
- Claims on Food Packaging
- Dietary Guidance
Food and Health Information
Consumer Attitudes 2008

As in 2007, this year more than 80 percent of all Americans say they are currently consuming or would be interested in consuming foods or beverages for benefits. Very few Americans indicated that they are not interested in consuming foods or beverages for all of the stated benefits. Of the benefits explored in the survey, Americans are most apt to be currently consuming foods or beverages for an “overall health and wellness” benefit or for a “heart health” benefit.

2008 Food & Health Survey: Consumer Attitudes toward Food, Nutrition & Health; IFIC
Consumers Are Interested in Food and Health Information *AND*... Are Searching for Consistent and/or Positive Messages.

Reading or hearing about the relationship between food and health is of interest to me*

<table>
<thead>
<tr>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>24%</td>
<td>67%</td>
</tr>
</tbody>
</table>

I feel that food and health information is confusing and conflicting

<table>
<thead>
<tr>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>29%</td>
<td>29%</td>
<td>42%</td>
</tr>
</tbody>
</table>

I am more interested in hearing about what TO eat, rather than what NOT to eat

<table>
<thead>
<tr>
<th>Disagree</th>
<th>Neither</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>13%</td>
<td>31%</td>
<td>56%</td>
</tr>
</tbody>
</table>

*Total does not add to 100 percent due to rounding

▲ / ▼ Significant increase/decrease from year indicated

2009 Food & Health Survey
What three sources of information do you use most often to guide your food, nutrition, and food safety practices? Select three. (n=1064)

NOTE: Responses less than five percent not shown
Claims on Food and Beverage Packaging

- Nutrient Content Claims
- Structure Function Claims
- Health Claims
- Dietary Guidance Statements
Content Claims

• A quantitative statement of the amount of a food component can be made.
  - Examples:
    • 180 mg flavonoids per serving
    • 1.2 g Linoleic Acid per serving
    • 100 mg DHA/EPA per serving.
## FDA Authorized Nutrient Content Claims

<table>
<thead>
<tr>
<th>NUTRIENT</th>
<th>CLAIM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fat (Total)</td>
<td>Fat Free, Low Fat, Reduced/Less/Lower Fat, % Fat Free, Light</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>Saturated Fat Free, Low Saturated Fat, Reduced/Less/Lower Saturated Fat</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>Cholesterol Free, Low Cholesterol, Reduced/Less/Lower Cholesterol</td>
</tr>
<tr>
<td>Sodium</td>
<td>Sodium Free, Salt Free, Low Sodium, Very Low Sodium, Reduced/Less/Lower Sodium, Unsalted, Light, Light in Sodium, Lightly Salted, No Salt Added</td>
</tr>
<tr>
<td>Calories/Sugar</td>
<td>Calorie Free, Low Calorie, Less/Fewer/Reduced Calorie, Light, Diet, Sugar Free, No Sugar Added, Reduced/Less/Lower Sugar</td>
</tr>
<tr>
<td>Relative Claims</td>
<td>Less, Fewer, Light, Reduced</td>
</tr>
<tr>
<td>and Other Claims</td>
<td>Healthy, Lean, Extra Lean</td>
</tr>
</tbody>
</table>

) covers nutrients ) listed above) covers vitamins, minerals and other substances, including fiber, with a DV
Structure-Function Claims

- Helps Maintain Cholesterol Levels That Are Already Within The Normal Range
- Use As Part Of Your Diet To Help Maintain A Healthy Heart
- Helps Maintain Cardiovascular Health
- Calcium Helps Build Strong Bones
- Flavonoids Help Maintain Blood Vessel Function
FDA Qualified Health Claims
Disqualifying Nutrient Levels

FDA

fat: 13 g
saturated fat: 4 g
cholesterol: 60 mg
sodium: 480 mg

[Trans not technically required, but should be considered]

If the food falls below on a per RACC and per serving basis (and per 50 g for foods with RACCs of 30 g or 2 tbsp or less):

ADDITIONAL, MORE RIGOROUS CRITERIA FOR SPECIFIC CLAIMS
Main Components of FDA Health Claims

- **Message:** Describes the relationship between a food or ingredient and disease.
  
  “Diets low in saturated fat and cholesterol fat may reduce the risk of heart disease. Heart disease is dependent upon many factors.”

- **Substantiation:** “Significant scientific agreement” among qualified experts, based on totality of evidence
  
  - Clinical trials of the substance that is the subject of the claim, not the exact product on which the claim appears
  
  - If the product is not tested, the claim may need to refer to the substance rather than the product
  
  - Requires a strong, relevant, consistent body of evidence that is not likely to be reversed by new and evolving science

- **FDA Authorization:** Petition or Authoritative Statement Notification
FDA Unqualified Heart Disease Claims

WHOLE GRAIN FOODS LOW IN SATURATED FAT AND CHOLESTEROL, INCLUDING THOSE WITH MODERATE TOTAL FAT CONTENT
- 51% or more whole grain ingredients by weight

“Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease.”

SOLUBLE FIBER FROM OAT SOURCES (E.G., OAT BRAN, ROLLED OATS, WHOLE OAT FLOUR, OATRIM) AND PSYLLIUM HUSK
- at least 0.75 g soluble fiber per RACC from oat products, or 1.7 g from Psyllium

“Soluble fiber from foods such as [FIBER SOURCE], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [FOOD] supplies [X] grams of the [Y] grams soluble fiber from [FIBER SOURCE] necessary per day to have this effect.”

FRUITS, VEGETABLES AND GRAIN PRODUCTS THAT CONTAIN FIBER, PARTICULARLY SOLUBLE FIBER
- food must be or contain a fruit, vegetable, or grain, with at least 0.6 g soluble fiber per RACC

“Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.”
Other Unqualified Health Claims

**Dietary SUGAR ALCOHOLS may reduce the risk of DENTAL CARIES**
- Sugar-free foods containing sugar alcohol(s)
  “Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.”

**CALCIUM may reduce the risk of OSTEOPOROSIS**
- 200 mg or more bioavailable calcium per RACC; phosphorus cannot exceed calcium
  “Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.”

**LOW-SODIUM diets may reduce the risk of HYPERTENSION**
- 140 mg or less sodium per RACC
  “Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.”

**FOLATE may reduce the risk of NEURAL TUBE BIRTH DEFECTS**
- 40 mcg folate per serving (without fortification)
  “Healthful diets with adequate folate may reduce a woman’s risk of having a child with a brain or spinal cord defect.”

**Diets containing foods that are good sources of POTASSIUM AND LOW IN SODIUM may reduce the risk of HIGH BLOOD PRESSURE AND STROKE**
- 150 mg or more potassium per RACC; low in sodium, total fat, saturated fat, and cholesterol
  “Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”
FDA Qualified Healthy Claims

• Message: Describes the relationship between a food or ingredient and disease
  AND indicates the limitations of the scientific support.

• Substantiation:
  - Evidence is ranked as:
    • MODERATE/GOOD
    • LOW
    • VERY LOW (below this level, no claim is permitted)
  - For higher rankings, need good clinical trials and other reliable studies
    • randomized, controlled intervention trials and prospective observational cohort studies
  - For lower rankings, can use less rigorous studies
    • at least nonrandomized intervention trials with concurrent or historical controls and/or case-control studies
  - In general, meta-analyses and animal data may not be used as primary evidence, but may be supportive

• FDA Authorization: Petition
Examples of FDA Authorized Qualified Health Claims

- “Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [such as name of specific nut] as part of a diet low in saturated fat and cholesterol MAY REDUCE THE RISK OF HEART DISEASE. See nutrition information for fat content.”

- “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids MAY REDUCE THE RISK OF CORONARY HEART DISEASE. One serving of [FOOD] provides [ ] gram of EPA and DHA omega-3 fatty acids.”

- “Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, MAY REDUCE THE RISK OF HEART DISEASE. See nutrition information for fat content.”

- Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily MAY REDUCE THE RISK OF CORONARY HEART DISEASE due to the monounsaturated fat in olive oil. To achieve this possible benefit, OLIVE OIL is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] g olive oil.”
Dietary Guidance Statements
Examples of Dietary Guidance Statements

• FDA encourages information for consumers that provides general dietary guidance consistent with authoritative recommendations.

• 2005 Dietary Guidelines say:
  - “FATS AND OILS ARE PART OF A HEALTHFUL DIET, BUT THE TYPE OF FAT MAKES A DIFFERENCE TO HEART HEALTH … KEEP TOTAL FAT INTAKE BETWEEN 20 TO 35 PERCENT OF CALORIES, WITH MOST FATS COMING FROM SOURCES OF POLYUNSATURATED AND MONOUNSATURATED FATTY ACIDS SUCH AS … NUTS AND VEGETABLE OILS.”
  - “INCREASED INTAKES OF FRUITS, VEGETABLES, WHOLE GRAINS, AND FAT-FREE OR LOW-FAT DAIRY PRODUCTS ARE LIKELY TO HAVE IMPORTANT HEALTH BENEFITS FOR MOST AMERICANS.”

• Authoritative public health organizations such as AHA are one source of consensus statements that substantiate dietary guidance statements.

- Cocoa/Tea: Flavonoids (Catechins, Proanthocyanins)
- Broccoli, Cabbage, Kale: Isothiocyanates, Indol-3-Carbinol
- Tomato, Carrots, Spinach: Alpha-Carotene, Beta-Carotene, Beta-Cryptoxanthin, Lycopene, Lutein, and Zeaxanthin
- Fish: DHA/EPA
- Garlic: Allylcysteine sulfoxide
Benefits of Dietary Guidance

- Consumers are interested in positive health messaging.
- They want to be told what to eat and why rather than what not to eat.
- Many are interested in overall health and wellness rather than disease prevention.
- Industry can leverages these types of messages as part of branded communication and packaging claims.
Development of Dietary Guidance for Non-Essential Nutrients in Foods

• Should Dietary Guidance be for foods, non-essential nutrients in foods or both?
  – “Vegetables containing isothiocyanates such as broccoli and Kale should be included as part of a healthy diet”
  – “Tea, Chocolate and Cocoa all contain flavonoids compounds that should be included as part of a healthy balanced diet”

• What levels of non-essential nutrients are needed in foods with dietary guidance messages?

• Should foods having Dietary Guidance Messages need to meet specific nutritional criteria (disqualifying levels of SAFA, TFA, Cholesterol, Sodium, Sugars for example)

• What types of evidence should used to substantiate Dietary Guidance statements?