Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
July 25, 2011

Docket Number FDA-2011-N-0320  
Experimental Study on Consumer Responses to  
Whole Grain Labeling Statements on Food Packages

Dear Food and Drug Administration,

Oldways is a 501c3 educational organization that changes the way people eat through practical and positive programs grounded in science, tradition, and delicious foods and drinks. The Whole Grains Council, a non-profit consumer-advocacy group that is part of Oldways, helps consumers find whole grains and understand their benefits, helps manufacturers and restaurants offer more and better whole grain products, and helps the media to write accurate and compelling stories about whole grains.

Oldways and the Whole Grains Council (WGC) appreciate the opportunity to comment on FDA’s proposed Experimental Study on Consumer Responses to Whole Grain Labeling Statements. In our remarks below, we will comment on Topic 1 and Topic 3, as outlined in the Federal Register.

Is this study necessary, and will it be useful?

Topic 1: “Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility.”

While every issue can always be further improved or clarified, we think that this study may not be necessary in a time of budget deadlock and deficit cuts, given FDA’s many pressing responsibilities.

Oldways and the Whole Grains Council share FDA’s belief in “the importance of whole grains in maintaining a healthy diet.” There is strong evidence that the American people agree too, as growth in whole grain products and whole grain consumption is one of the singular successes of nutrition policy and practice in the past half decade. Below are just a few indicators of the strong momentum in whole grains since the 2005 Dietary Guidelines urged Americans to “make at least half their grains whole.”

- **Whole Grain Consumption up 20% from 2005 to 2008**  
  Using methodology designed to complement USDA’s What We Eat In America, NPD Group’s National Eating Trends survey¹ found that whole grain consumption rose 20% from early 2005 to early 2008 – after remaining steady from 1998 to 2005. 18 to 34 year olds, as a group, increased the most, with consumption rising 34% in this three year period.
• **Whole Grain Product Sales up 61% from 2001 to 2006**
  According to USDA’s Economic Research Service, whole grain products were 11.1% of all grain products in 2001. By 2006, they had risen to 17.9% of all grain products – a 61% gain in five years.

• **Whole Grain Bread and Cereal Sales Up Sharply, 2001 to 2007**
  Also according to USDA ERS, whole grain bread sales went from 6% of bread sales in 2001 to 20% in 2007; during the same period, whole grain cereals rose from 20% of cereal sales to 46% of cereal sales, a 130% increase.

• **Consumer Tastes Increasingly Favor Whole Grains**
  In a 2009 survey, Kellogg asked more than a thousand adults to explain their reasons for making an effort to eat more whole grains. 36% of them cited, “I enjoy the taste.” This compares to 13% who cited “better taste” as the primary reason for choosing to eat whole grain products in a 2006 Harris Interactive survey.

FDA, in its Federal Register proposal, cited a European consumer study from 2007 and U.S. studies from 2001 and 2003 (refs. 6 to 8) as references that “consumers may have difficulties in understanding the meaning of whole grains or recognizing whole-grain foods.” While some consumers’ understanding of whole grains is still evolving, we feel that earlier data and overseas references may not be directly applicable to U.S. consumer understanding in 2011.

As the NPD consumption data and ERS sales data above indicate, the simultaneous advent of the 2005 Dietary Guidelines and the Whole Grain Stamp in January of 2005 greatly increased consumers’ ability to understand the benefits of whole grains and to find and purchase them in stores. With the Whole Grain Stamp, we have in place today a whole grain labeling system based on voluntary industry standards, that is working well for most products and for most people.

More than 5,000 products in the U.S. have been reviewed by the Whole Grains Council and approved to use the Whole Grain Stamp, helping consumers find products that contain at least half a serving (8g) of whole grain.

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**Can the Quality, Utility and Clarity of the Study be Improved?**

*Topic 3: Ways to enhance the quality, utility, and clarity of the information to be collected.*

If this study *does* go forward, we would like to suggest several ways that the quality, utility and clarity of the study can be improved.

• **Support the 2010 Dietary Guidelines**
  The 2010 Dietary Guidelines suggest three standards for consumers to use in seeking out whole grains (p. 37): look for 100% whole grain products; look for products using the FDA Whole Grain Health Claim; look for products with at least 8g of whole grain. These three standards should be incorporated into the study.
• **Include a Variety of Grains – and Whole Grain Foods**
As drafted, the study centers mostly on wheat and seems lacking in references to a range of common whole grain foods. We would suggest including questions that gauge consumer understanding of whole grain terms that are not wheat-based, and that refer to actual foods, such as “brown rice” and “oatmeal” and “popcorn.”

• **Put Whole Grain Understanding in Context**
Answers would be more useful in the context of consumer understanding of other aspects of a healthy diet. If the study asks consumers about daily recommendations for whole grain consumption, for example, and 50% answer correctly, does that result indicate a major problem related to whole grain understanding? If we also know that, for example, just 10% know the correct recommendations for leafy green vegetables or legumes, a 50% level of understanding about whole grains could in fact indicate that whole grain understanding surpasses other areas, and that FDA’s resources and attention might better be diverted to other areas.

• **Follow the Highest Standards for Survey Design**
As stated by the American Association for Public Opinion Research, “The ideal survey or poll recognizes that planning the questionnaire is one of the most critical stages in the survey development process, and gives careful attention to all phases of questionnaire development and design, including: definition of topics, concepts and content; question wording and order; and questionnaire length and format.

“Beyond their specific content, however, the manner in which questions are asked, as well as the specific response categories provided, can greatly affect the results of a survey. Concepts should be clearly defined and questions unambiguously phrased. Question wording should be carefully examined for special sensitivity or bias. … Ways should be devised to keep respondent mistakes and biases … to a minimum, and to measure those that cannot be eliminated.”

**Comments on the Draft Questionnaire Attached.** FDA is carrying out important work, and we would like to contribute to the success of this work in any way possible.

Oldways / Whole Grains Council staff have made specific suggestions for improvement on the Draft Questionnaire, especially Section B and Section C, and have pooled our comments with those of the AACC International Whole Grains Working Group. We have included a copy of that group’s comments below, to represent our suggestions.

Thank you once again for the opportunity to comment on this important project.

Sara Baer-Sinnott
President

Cynthia Harriman
Director of Food and Nutrition Strategies
References

1  NPD National Eating Trends, as cited by the Whole Grains Council at http://wholegrainscouncil.org/files/3.AreWeThereYet.pdf
Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages
Draft Questionnaire
As of March 2011

Form Approved: OMB No. 0910-xxxx
Expiration Date: xx/xx/201x

PUBLIC Disclosure Burden Statement

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
CFSAN/PRB Comments/HFS-24
5100 Paint Branch Parkway
College Park, MD 20740-3835.

Overall Comments

The AACC Whole Grains Working Group strongly urges FDA to rework this questionnaire using survey methodology that will ensure that questions are clearly written and that they will deliver the insights that FDA seeks about whole grain labeling.

FDA has advised that – once the agency has had a chance to review and respond to initial comments – there will be a further 30-day comment period, during which the visuals for the labels will also be available upon request. During this 30-day comment period, we urge FDA to make both the visuals and the revised, final questions available together, so that they may be considered in their totality. This will enable all interested parties to provide the highest possible level of useful input to FDA. Further we wish to emphasize that labels be completely neutral so that there is no box color or label identifier that might cause a respondent to think of a particular product.

Please note that the comments below suggest several different alternatives for improving each unclear question. In the interest of being as productive and helpful as possible, the Whole Grains Working Group has included the collective input of its members’ suggestions, rather than distill these suggestions to one possible solution.
AACC International Comments

Section A: Food Label Awareness & Perceptions

A1. Think about shopping for food at the store. On a scale of 1 to 6, where 1 is not important at all and 6 is very important, how important to you is each of the factors listed below? [ROTATE FACTORS]

<table>
<thead>
<tr>
<th>Not important at all</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
</tr>
</tbody>
</table>

Price
Brand
Healthiness or nutritional qualities
Convenience
Taste

A1 Comments
• “Health” or “healthiness” is a very subjective term, that may or may not be related, in some people’s minds, to nutritional qualities. Healthiness or nutritional qualities should be either separated into two responses or respondents should be directed that for this study specifically, healthiness should be defined as nutritional qualities.
• If a person says that he/she does NOT normally consider health or nutrition when purchasing products, is that person disqualified from answering any further questions? Those persons may know nothing about whole grain labeling, as it doesn’t matter to them.
• If the survey is about food labels, does price belong here?
• This question might be simpler if respondents were asked to rank these factors in order, from 1 to 5 (most important to least important).

A2. When you buy a type of food for the first time, how often do you read the label to find out how much it has of things like calories, fat, sodium, or vitamins?

1) Always
2) Most of the time
3) Sometimes
4) Rarely
5) Never
Don’t know

A2 Comments
• Question would be clearer worded simply “When you buy a food for the first time, how often do you read the label?” In its current wording, respondents who (for example) don’t check sodium may answer rarely or never, even though they seek out other label information.
• The choice of “don’t know” may not be appropriate here.
A3. On a 1 to 4 scale, where 1 is strongly disagree and 4 is strongly agree, how much do you agree with each of the following statements? Please select one for each statement.

<table>
<thead>
<tr>
<th>Strongly disagree 1</th>
<th>2</th>
<th>3</th>
<th>Strongly agree 4</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel confident that I know how to use food labels to choose a nutritious diet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The nutrition information on food labels is hard to interpret</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reading food labels takes more time than I can spare</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would like to learn more about how to use food labels to choose a nutritious diet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using food labels to choose foods would be better than just relying on my own knowledge about what is in them</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A3 Comments
- The first and fourth questions are leading questions because of the words “to choose a nutritious diet;” we suggest omitting these words so that the first question reads “I feel confident that I know how to use food labels” and the fourth one reads “I would like to learn more about how to use food labels.”
- The ranking system needs a “neutral position” that is neither agree nor disagree.
- The third question would be more consistent with the others if it were worded as “Reading food labels is too time-consuming.”
Section B: Label and Claim Responses

General Comments on Section B and Section C
• The section on General Knowledge of whole grains (currently Section C) should come first, before questions on specific label examples (currently Section B).
• Questions should be more clearly assigned to the appropriate sections – all general knowledge questions in the first section, and all label-specific questions in the second section.
• Generally, for label examples, include approach of listing whole grain content in grams per serving.
• It’s almost impossible to assess this section without seeing the actual labels. If these “non-branded” labels are “patterned after existing labels” consumers could easily pick up cues despite the lack of branding (e.g., yellow cereal box evokes Cheerios).
• We suggest including more foods than simply the three planned (bread, cereal, breakfast bars) as these three are likely to be high in grain content. Testing consumer reaction to foods low in overall grain content is also important.

[SHOW LABEL 1 ON THE SCREEN]
[PROVIDE A BUTTON FOR INTERESTED PARTICIPANTS TO SEE THE BACK PANEL]

B1. Which of the following best describes the amount of whole grains in this (FOOD)? Please select one.
   1) A lot
   2) More than half
   3) About half
   4) Less than half
   5) None or very little
   Don't know

B1 Comments
• Current question should be deleted because of confusion with the word “half.” Some government standards for whole grain are based on the percent of the total ingredients that are whole grain, while others are based on the percent of grain that is whole grain.
• To gauge consumer understanding of amount without using the word “half,” consider simplifying the question to use a 5pt scale anchored by “none or very low” on one end and “high” on the other end, such as this example:

Which of the following best describes the amount of whole grains in this (FOOD)? Please select one.

<table>
<thead>
<tr>
<th>None or very low</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B2. Which of the following best describes the amount of fiber in this (FOOD)? Please select one.
   1) High
   2) Moderately High
   3) Neither high nor low
   4) Moderately low
   5) Low
   Don't know
B2 Comments

- This question would also be clearer on a continuum the same as the one above, especially if the goal is to explore confusion between whole grain content and fiber content.

Which of the following best describes the amount of fiber in this (FOOD)? Please select one.

<table>
<thead>
<tr>
<th>None or very low</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>High</th>
</tr>
</thead>
</table>

- Alternately, consider asking a True / False question such as:
  "Whole grains are always high in fiber. T/F" or
  "If a food contains 8g of whole grain it will also contain 8g of fiber. T/F"

B3. On a six-point scale, where 6 means “definitely” and 1 means “definitely not,” how likely is it that THIS food is organic? Please select one.

1 = definitely not
2
3
4
5
6= definitely
Don't know

B3 Comments

- If the goal is to explore confusion between organic and whole grain, we suggest including organic as a term in question C5 instead of asking this question.

B4

On a scale of 1 to 6, where “1” means "very likely to raise the risk," and “6” means "very likely to lower the risk" how likely is this product to lower or raise the risk of each of these health problems?

<table>
<thead>
<tr>
<th></th>
<th>Very likely to raise the risk</th>
<th>Likely to raise the risk</th>
<th>Somewhat likely to raise the risk</th>
<th>Somewhat likely to lower the risk</th>
<th>Likely to lower the risk</th>
<th>Very likely to lower the risk</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High blood pressure or hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetics or high blood sugar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Obesity or overweight</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis or bone problem</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
B4 Comments

- If this question cannot be improved, it should be removed.
- This question measures knowledge of whole grains (and their benefits) and does not seem to be directly tied to information on the label. If such a question is included, it should be in Section C.
- In Section C, it would be better structured as a question such as “Which of the following benefits do you associate with regular consumption of whole grains?” followed by a list of possible benefits.
- Consumers may be surprised that an FDA questionnaire would ask about the degree to which a food may raise a health risk. They may see it as a trick question – Is this questionnaire trying to tell me something I don’t know about? Please consider an alternative.
- Eating one serving of any food ONCE will not be likely to have any health effects. If this question is asked, it needs to be worded in a way that is more reflective of the science supporting health benefits of whole grains, along the lines of the format below:

“If you eat whole grain foods like this three times or more a day, as recommended in the Dietary Guidelines, how will these foods raise or lower your risk of each of these health problems? Rate each one on a scale of 1 to 5 where “1” means “very likely to raise the risk and “5” means “very likely to lower the risk.”

<table>
<thead>
<tr>
<th></th>
<th>Very likely to raise the risk</th>
<th>Somewhat likely to raise the risk</th>
<th>No effect</th>
<th>Somewhat likely to lower the risk</th>
<th>Very likely to lower the risk</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes or high</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood sugar</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity or overweight</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Osteoporosis or bone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Problems</td>
<td></td>
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</tbody>
</table>

- Although not optimal if the question remains, consider removing the raising health risk portion of the scale and at a minimum add a neutral point anchor to the scale.
- typos need to be fixed. Diabetics should be diabetes; bone problem should be bone problems.

B5. Thinking about the claim you just saw, how would you rate it on the following scales?

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Untrustworthy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Trustworthy</td>
</tr>
<tr>
<td>Unreasonable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Reasonable</td>
</tr>
<tr>
<td>Dishonest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Honest</td>
</tr>
</tbody>
</table>
Not helpful | Helpful
Confusing | Clear
Tries to Sell | Tries to Inform

B5 Comments
• Once again, the scale would benefit from a neutral point that would mean “neither trustworthy nor untrustworthy,” etc.
• Question may be biased / leading, since all the negative terms are first.
• Many of these words are not well matched. We would suggest:
  Confusing / not confusing
  Not informative / informative
  Not believable / believable
• Selling and Informing should not be seen as diametric opposites. The best sales efforts are also informative.
• Product cues – color, graphics, etc. – even on ostensibly non-branded packages may make it difficult to isolate the impact of whole grain claims.

B6 Imagine that you are in a grocery store and thinking about getting some (FOOD) for yourself. Assume the (FOOD) you see here is comparable to other (FOOD)s on the shelf in terms of price, taste, flavor, and nutritional values. On a six-point scale, where 6 means “definitely would consider buying” and 1 means “definitely would not consider buying,” how likely or unlikely would you be to consider buying THIS (FOOD) rather than another (FOOD)? Please select one.

6 Definitely would consider buying
5
4
3
2
1 Definitely would not consider buying
Don't know

B6 Comments
We recommend simplifying this question to one that asks,
How does [this claim] affect your decision to buy this product?
1 Makes me more likely to buy this product
2 Does not change my likelihood of buying this product
3 Makes me less likely to buy this product

This question as currently worded raises a number of significant issues.

- First, the question and methodology assume that consumers make rational purchase decisions and can explain their thinking to others through a series of questions. It is questionable whether consumers can realistically disregard major factors like price, taste and nutrition and still answer a question about purchase considerations for a food item. (What is driving the purchase decision if all normal considerations have been equalized?) It is also unclear why a question should ask consumers to disregard nutritional value when it could be a perception driving label message motivation.

How and why consumers make choices is often assessed using choice methodology, which asks consumers to make choices among a set of products but derives the “why” analytically by
identifying choice motivators. This sort of approach would allow for expansion to include price, flavors, and other variables to help understand the relative importance of all potential drivers. As currently written, however, the questionnaire task is confusing for consumers to perform. This confusion may lead to a high variance in response and less discrimination across all variables.

• Second, if altering the study design to choice methodology is not a consideration, then a better approach would be to focus on just the label claims. The question sequence could be altered to include believability, relevance (i.e., tells the consumer something she cares about) as well as purchase motivation based on specific message language. This approach is already in place in B5 and could be supplemented by adding “would motivate me to buy/would not motivate me to buy.” As a result, the survey is not asking about buying considerations for the food and then trying to get them to tell you why they made the choice. This more direct questioning specific to message language is a task that consumers can more easily understand and do.

• Third, there is a concern about order bias. Questions that come before Q6 bias a respondent to more deeply consider many aspects of that label that they would not necessarily consider otherwise. Typically questions of purchase motivation are of priority and need to be withheld from any education the questionnaire is providing along the way.

• Fourth, there is a need to remove/screen out non-category buyers or add ‘I do not purchase this type of food’ to question B6.

• What is the second food they are asking to compare to here? Are they being shown a second label? Is it identical to the first one EXCEPT for the specific whole grain statement?

• If a consumer answers “definitely would not consider buying it” how do we know if this is because of an allergy to oats, adherence to a low-carb diet, or some other reason unrelated to the label?

B7. Which part or parts of the label did you use to decide your answer? Please select all that apply.
1) Claim on the Front panel
2) Nutrition Facts Panel
3) Amount of nutrient
4) % Daily value
5) Ingredient list
6) Other (please specify)
   Don't know

Comments on B7
We recommend rewording this question to ask something like,
“When deciding to buy a product, which of the following affects your decision? Please rank in order, with the most important factor first.” (List of factors follows.)

This question as written is confusing and may not yield the desired data.
• The list is not all-inclusive; there are likely to be other factors that affect the buying decision.
• At a minimum, need to add “did not use parts of the food label” as a response.
• List includes “Nutrition Facts Panel” as one choice, followed by “amount of nutrient” and “% daily value” – which are also part of the NFP. Unclear: if a consumer selects % daily value, does that imply he also used the NFP?
B8. Overall, on a six-point scale, where 6 means “very helpful” and 1 means “not helpful,” how helpful would you say the claim on the label is in helping you decide whether to buy THIS Food? Please select one.
1 = not helpful
2
3
4
5
6= very helpful
Don't know

Comments on B8
• This question is redundant. Question B5 already asked if the claim was helpful or not helpful.

REPEAT THE EIGHT QUESTIONS ABOVE FOR LABEL 2]
Section C: General Knowledge about Whole Grain and Food Labeling

General Comments on Section C
• As stated in the General Comments on Section B, the section on General Knowledge of whole grains (currently Section C) should come first, before questions on specific label examples (currently Section B).

This section has many challenges that seem likely to confuse respondents.
• Consumers do not understand ounces and ounce-equivalents. We strongly recommend that these terms not be used if FDA’s goal is to gain insights into whole grain consumption patterns.
• If ounces / ounce-equivalents must be used they should be explained (and examples of them) given upfront. Example:
   The following constitute a “serving” or a “one ounce-equivalent” of whole grain:
   1 slice of 100% whole grain/whole wheat bread
   1 cup of 100% whole grain ready-to-eat cereal
   ½ cup of cooked brown rice, 100% whole wheat pasta or oatmeal
   in the following survey, these will simply be referred to as “ounces”

• We recommend questioning about grams of whole grain, the approach to whole grain labeling specifically endorsed / recommended by FDA in its 2006 Draft Guidance.
• Survey should tie into the three approaches endorsed in the 2010 Dietary Guidelines (see p. 37 of DG):
  100% wg foods
  foods qualifying for the WG Health Claim
  foods with at least 8g of whole grain content.
• Include question about knowledge of grams of whole grain per day (48g) which is the focus of industry communications vs “servings” or “ounce-equivalents.”
• Many questions are grammatically awkward / incorrect, which adds extra elements of confusion. We have suggested alternate wording in several of the questions, if these questions are retained.

C1. How often do you eat foods made from whole grains?
  1) Everyday [Every day]
  2) 2-3 times a week
  3) Once a week
  4) Once a month or longer [Once a month or less]
  5) Never

Comments on C1
• Data will not be useful unless “foods made from whole grains” is defined.
• Add a “don’t know” choice, for consumers who may not know if the foods they are eating are whole grains.

C2. How much whole grains do you usually eat every day? [How much whole grain food…]
  1) Never or almost never [I never or almost never eat whole grain foods]
  2) less than 1 ounce (Examples of a one-ounce equivalent include 1 regular slice of 100% whole-grain bread or ½ cup cooked oatmeal) [Less than one serving (examples of a serving include…]
  3) 1-3 ounces [1-3 servings]
  4) More than 3 ounces [more than three servings]
Comments on C2

- Consumers do not understand ounces and ounce-equivalents. We strongly recommend that these terms not be used if FDA’s goal is to gain insights into whole grain consumption patterns.
- Data will not be useful unless “whole grains” is defined.
- As written, it’s unlikely that most consumers will be able to answer.
- Make this a follow-up question, only for those who answered “every day” in C1.
- If FDA is interested in consumption data, it would be better to get a more comprehensive picture from 2008 What We Eat in America (WWEIA)/NHANES data.
- To avoid the awkwardness of ounce-equivalents, and to ask a question more in line with a purchasing survey, consider asking something such as:

What best describes your habits in choosing grain foods?
1) I always choose whole grains
2) I mostly choose whole grains
3) I occasionally choose whole grains
4) I never choose whole grains
5) I rarely consume grain foods

C3. How much whole-grain foods should a person eat daily according to the Dietary Guidelines for Americans? [How much whole grain food should an average adult…]

1) At least 1 ounce (Examples of a one-ounce equivalent include 1 regular slice of 100% whole-grain bread or ½ cup cooked oatmeal) [At least 1 serving… (Examples of a serving include…]
2) At least 2 ounces [At least 2 servings]
3) At least 3 ounces [At least 3 servings]
4) At least 4 ounces [At least 4 servings]
5) At least 5 ounces [At least 5 servings]

Don’t know

Comments on C3

- Consumers do not understand ounces and ounce-equivalents. We strongly recommend that these terms not be used if FDA’s goal is to gain insights into whole grain consumption patterns.
- Data will not be useful unless “whole grain food” is defined.
- Consider reframing question around definitions on page 37 of the Dietary Guidelines, which advises on several different ways in which one can “make at least half your grains whole.”
- Consider showing graphic on page 37 of the Dietary Guidelines, and asking respondents to mark which choices would provide the recommended daily amount of whole grains.
- Include choices such as “half or more of all grains…”
- Consider framing this question in relation to MyPlate. “How much of my plate should be filled with grains? How much of these grains should be whole grains?”

C4. What kinds of food can be considered whole grains? [What kinds of foods…]

1) Grains that consist of three parts: the bran, the germ, and the inner most part of the kernel. [... and the endosperm, or innermost part of the kernel]
2) Grains that is naturally rich in fiber [Grains that are…]
3) Any food made of unbleached flour
4) Any food with the whole grain stamp
Comments on C4
• This question should be eliminated and the terms being tested for here should be incorporated into question C5.
As is, the question is unclear.
• What is meant by “considered whole grains?” This could be confusing, as there are many different and competing official definitions of a whole grain food (e.g., WIC, FDA Health Claim, USDA/FSIS, Healthier US School Challenge, Dietary Guidelines, etc.)
• Some of the answers concern the definition of a whole grain ingredient and others concern the definition of a whole grain food, making the question especially confusing.
• Are multiple correct answers allowed? Using Dietary Guideline standards, both answer 1 and answer 4 could be considered correct; in some instances, answer 2 may also be correct.

C5. In this question, please rate the meaning of each pair of terms on a six-point scale where 1 means "They mean totally different things to me" and 6 means "They mean exactly the same thing to me."

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Whole Grain&quot; and</td>
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<td>&quot;100% Whole Wheat&quot;</td>
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<td>&quot;Whole Grain&quot; and &quot;12</td>
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<td>&quot;Made with Whole</td>
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<td>Whole Wheat&quot;</td>
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<td>&quot;Enriched Grain&quot; and</td>
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<td>&quot;Whole Grain&quot;</td>
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<td>&quot;Multi-Grain&quot; and</td>
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</table>

Comments on C5
• 6pt scale is not easily interpreted for same/different. Consider 3pts – same, different, don’t know. You could add a followup for different responses to ask…a lot different or a little different.
• As written, question C5 is extremely confusing and should be deleted. Similar to asking “Are a carrot and a vegetable the same or different?” A carrot is a vegetable but a vegetable is not necessarily a carrot – so are they the same or different?
• If the goal is to gauge how consumers try to get three or more servings a day, consider this approach:
C5. When you choose a product labeled with the following, do you know you are getting at least half a serving of whole grain?

<table>
<thead>
<tr>
<th>Term</th>
<th>Probably not</th>
<th>Possibly</th>
<th>Very likely</th>
<th>Always</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>“whole grain”</td>
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<td>“whole wheat”</td>
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<tr>
<td>“100% whole grain”</td>
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<tr>
<td>“100% whole wheat”</td>
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<tr>
<td>“12 grain”</td>
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<tr>
<td>“Made with whole grain”</td>
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<tr>
<td>“Made with whole wheat”</td>
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<tr>
<td>“Enriched grain”</td>
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<tr>
<td>“Multigrain”</td>
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<td>“High fiber”</td>
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<tr>
<td>“Unbleached flour”</td>
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<tr>
<td>“whole grain stamp”</td>
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</tbody>
</table>

- If the goal is to differentiate between claims that clearly represent whole grains and claims that may be misleading, consider this approach:

C5. In this question, please rate the meaning of each term on a three-point scale where 1 means “this is always whole grain” 2 means “this may or may not be whole grain” and 3 means “this is never whole grain.”

<table>
<thead>
<tr>
<th>Term</th>
<th>Always a whole grain</th>
<th>May or may not be a whole grain</th>
<th>Never a whole grain</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% Whole Wheat</td>
<td>1</td>
<td></td>
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<td>Whole Wheat</td>
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<td>Wheat</td>
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<tr>
<td>12 Grain</td>
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<td></td>
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<tr>
<td>Enriched flour</td>
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<td></td>
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<tr>
<td>Multi-grain</td>
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<td></td>
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<tr>
<td>Oat Bran</td>
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<tr>
<td>Wheat Germ</td>
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<td></td>
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<tr>
<td>Brown rice</td>
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<tr>
<td>Oatmeal</td>
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<td></td>
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<tr>
<td>Stoneground flour</td>
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<tr>
<td>Organic</td>
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<td>Made with whole grain</td>
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<td>High fiber</td>
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<td>Has the WG Stamp</td>
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<td>Does not have the</td>
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<tr>
<td>Whole Grain Stamp</td>
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</tbody>
</table>
Section D: Nutrition Facts Panel Literacy

General Comments on Section D.
• This entire section should be titled ‘Label literacy’ not ‘Health literacy’ – It would be difficult to know if an inaccurate response means that someone needs health education or math education.
• Some questions do not seem to be related to label literacy, and overall this question seems unrelated to whole grains.

Please look at this label as long as you like. The next six questions will be about this label.

D1. If you eat the entire container, how many calories will you eat?
______ calories
Don’t know

D2. If you are allowed to eat 60 g of carbohydrates as a snack, how much of this product could you have?
__ cup(s) (or container, or serving) Don’t know

D3. [Your] doctor advises you to reduce the amount of saturated fat in your diet and you usually have 42 g of saturated fat each day, including 1 serving of this product. If you stop eating this product (but make no other changes in your diet), how many grams of saturated fat would you be consuming each day?
______ grams Don’t know

D4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving of this product?
D5. Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings. Is it safe for you to eat this product?

Yes  
No  
Don’t know

[ASK IF ANSWER TO “IS IT SAFE FOR YOU TO EAT …” WAS NO.] Why is it not safe for you to eat this product?

___________ [OPEN-END; RECORD VERBATIM ANSWERS]

Missing section: Protocol auxiliary measures states plans for capturing information about participants consumption, purchase of the categories studied but I did not see that in the questionnaire. This is critical to do this.

It could be helpful to add health and nutrition attitude questions about each category that would allow for some hypotheses if results differ by category.
Section E: Health Status & Demographics
The next few questions may seem a bit personal, but we need this information because this survey is about nutrition and health.

E1. [ALL PARTICIPANTS] Would you say your health in general is ….

   excellent
   very good
   good
   fair
   poor
   Don’t know
   Prefer not to answer

E2. [ALL PARTICIPANTS] Are these health problems of concern to you? Please select an answer for each of the health problems. [ROTATE HEALTH PROBLEMS]

   Yes      No      Don’t know      Prefer not to answer

   Cancer
   Diabetes
   Heart disease
   Hypertension or high blood pressure
   High cholesterol
   Obesity or overweight
   Osteoporosis or bone problem
   Stroke

E3. [ALL PARTICIPANTS] How tall are you without shoes? Please enter a number in both “feet” and “inches” or select “prefer not to answer.”

   Feet _ [ONE SPACE]   Inches _ _ [TWO SPACES]
   Prefer not to answer


   Pounds _ _ _ [THREE SPACES]
   Prefer not to answer

E5. [ALL PARTICIPANTS] Do you consider yourself to be overweight, underweight, or about the right weight?
Overweight
Underweight
About the right weight
Don’t know
Prefer not to answer

E6. [ALL PARTICIPANTS] What is the highest grade or level of school you have completed or the highest degree you have received? Please select one.

0 - 11 years or grades
12 years, high school graduate, or GED
1 to 3 years of college or associate degree
4 years of college or college graduate
Postgraduate, masters, doctorate, law degree, MD

E7. [ALL PARTICIPANTS] What year were you born?

19 _ _ [TWO SPACES]

E8. [ALL PARTICIPANTS] Are you …. (please select one)

Female
Male

E9. [ALL PARTICIPANTS] Are you of Hispanic or Latino origin? Please select one.

Yes
No

E10 [ALL PARTICIPANTS] What is your race? You may choose one or more categories as they apply.

White
Black or African American
Asian
Native Hawaiian or other Pacific Islander
American Indian or Alaska Native
Some other race

Thank you. These are all the questions in this survey. We hope you have enjoyed your participation in the survey.

END