This guideline is designed to help establishments determine:

- Whether a whole grain statement can be made or not;
- The types of statements that may be made; and
- The supporting documentation needed for each type of statement.
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Preface

What is the purpose of this compliance guideline?

The purpose of this compliance guideline is to help industry determine which whole grain statements are permitted on meat and poultry products and the criteria for their use.

The Food Safety and Inspection Service (FSIS) is the agency in the United States Department of Agriculture (USDA) with the responsibility for assuring that the labeling of meat, poultry and egg products is truthful and not misleading.

Labeling bearing any reference to whole grains is a special statement. All labels bearing special statements or claims must be sent to the Agency’s Labeling and Program Delivery Staff (LPDS) for evaluation and approval before use according to the Code of Federal Regulations (CFR) Title 9 Section 412.1. However, once a label with a statement on whole grains is approved, there are many types of changes to the label that do not require submission to the Agency prior to use and can be generically approved (e.g., change in net weight, label color, vignettes, cooking instructions, and the addition of information that is not considered a special statement or claim). The key for making the change “generically” is that the change cannot affect the special statement or claim. Slide 40 of the Generic Label Approval PowerPoint Presentation from the link below provides an example of a special claim. http://www.fsis.usda.gov/wps/wcm/connect/1364c48d-214b-41bf-bab8-6289f951cb31/Generic-Final-Rule-Overview-Industry.pdf?MOD=AJPERES.

Who is this guideline designed for?

This guideline is for establishments that are designing or modifying meat or poultry product labels with statements related to whole grains.

What changes have been made to the guideline from the last version?

FSIS previously issued guideline on whole grains claims in October 2005. This previous version was focused on references to USDA’s MyPyramid. FSIS has updated the guideline to include further details and explanations on the different types of claims and a key-points reference chart.

How can I comment on this guideline?

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the Agency will update the document in response to the comments.

Comments may be submitted by either of the following methods:
Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to: Docket Clerk U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3 1400 Independence Avenue SW, Mailstop 3782, 8-163A Washington, DC 20250-3700.

All items submitted by mail or e-mail must include the Agency name, FSIS, and document title: Food Safety and Inspection Service Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products October 2017. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Although FSIS is requesting comments on the guideline and may update it in response to comments, the guideline reflects FSIS’s current position, and establishments may start using it now.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter FSIS Interim Policy Guide on Whole Grain Claims
Question Field: Enter question with as much detail as possible
Product Field: Select Labeling from the drop-down menu
Category Field: Select Labeling Regulations, Policies & Claims from the drop-down menu
Policy Arena: Select Domestic (U.S.) only from the drop-down menu

When all fields are complete, press Continue.
BACKGROUND
Since a petition was submitted in 2004 to the Food and Drug Administration (FDA) regarding the uses of Whole Grain Descriptive Claims, the use of these statements has increased and diversified. Companies have shown interest in making claims such as: “whole wheat pasta.” For that reason, this guideline aims to help the meat and poultry industry determine which claims are permitted on the labeling of their products.

GENERAL WHOLE GRAIN STATEMENTS
The Agency will allow, with LPDS sketch approval, factual statements and certain whole grain claims provided the statements/claims do not conflict with FSIS regulations and are not false or misleading. Factual statements simply state the level of a grain component in a serving of the product, e.g., 10 grams whole grain per serving. FSIS will also allow certain claims that do not expressly state or imply a specific level of whole grains through sketch approval, e.g., “made with 100% whole grain brown rice” or the label has a product name declaring a whole grain, e.g., “whole wheat pepperoni pizza.”

NOTE: See Label Example 1 for a factual statement representation

The basis for all whole grain factual statements and claims is that the product contains a minimal quantity of the specified whole grain component. FSIS considers these statements to be false or misleading if the product does not contain at least 8 grams of dry whole grain ingredient per labeled serving size of the meat or poultry product as declared in the nutrition facts panel on the label and per the appropriate Reference Amount Customarily Consumed (RACC) for the meat or poultry product (9 CFR 317.312 Table 2 or 381.412 Table 2). Labeling for institutional use products that are exempt from including the nutrition facts panel may make whole grain statements or claims but the labeling application that needs to be submitted to FSIS will still need to show that the product meets the 8 gram minimum requirement per recommended serving size and per the appropriate RACC.

FDA STANDARDIZED WHOLE GRAIN PRODUCTS
When a claim specifies the product component that contains the whole grain, for example, “made with whole wheat spaghetti” or “pepperoni pizza made with whole grain crust,” the whole grain component apart from the total meat or poultry product will need to meet an additional requirement which will be determined based on the standards of identity for whole grain products in 21 CFR 139.138. Products that have a whole grain standard of identity in 21 CFR must meet the FDA standard in order to use that product name, for example, in order to make the claim “made with whole wheat spaghetti” the whole wheat spaghetti must meet the FDA standard of identity in 21 CFR 139.138, which requires 100% of the grain used to make the spaghetti be whole wheat.
SPECIFYING THE COMPONENT THAT CONTAINS WHOLE GRAIN

When the component identified in the claim does not have a standard of identity for the whole grain product in 21 CFR, for example, there is no FDA standard for “whole wheat pizza crust” or “whole wheat tortillas,” then FSIS requires that whole grains make up at least 51% of the total dry grain used to formulate the non-standard grain product.

CALCULATION EXAMPLES

In order to obtain label approval, the label application form should provide calculations to support and verify that the product meets the above requirements. The calculations provided will need to correspond to the formula provided for the particular product. Because the calculations will vary depending on the statement or claim made and the nature of the formulation, below are several examples of the calculations that could be acceptable with a label application:

A. Example calculations for a factual statement, such as, “made with whole grains” which needs to show a minimum of 8g whole grain per labeled serving size as provided in the nutrition facts panel, and a minimum of 8 grams whole grains per RACC:

Serving size of meat or poultry product in grams × % dry whole grains in total formula
= grams whole grains per serving (must be 8 grams or higher)

AND

RACC in grams for the meat or poultry product × % dry whole wheat in total formula
= grams whole wheat per RACC (must be 8 grams or higher)

B. Example calculations for a factual statement, such as, “10 grams whole wheat per serving,” which needs to show a minimum of 10 grams of whole wheat per labeled serving size as provided in the nutrition facts panel, and a minimum of 10 grams whole wheat per RACC:

Serving size of meat or poultry product in grams × % dry whole wheat in total formula
= grams whole wheat per serving (must be 10 grams or higher)

AND

RACC in grams for the meat or poultry product × % dry whole wheat in total formula
= grams whole wheat per RACC (must be 10 grams or higher)

C. Example calculations for a “pepperoni pizza made with whole grain crust” that requires 8 grams or more whole grain per labeled serving size as provided in the nutrition facts panel, 8
grams or more whole grain per RACC, and a minimum of 51% dry whole grain in the total dry grain used to make the crust:

Serving size of pizza in grams × % crust × % whole grain in the crust
= grams of whole grain per serving (must be 8 grams or higher)

AND

RACC in grams for the meat or poultry product × % crust × % whole grain in the crust =
grams of whole grain per RACC (must be 8 grams or higher)

AND

\[
\left(\frac{\text{Grams of whole grain in the crust}}{\text{grams of total grain in the crust}}\right) \times 100
\]

= % of whole grain in the grain component (must be 51% or higher)

When the whole grain factual statements and claims meet the outlined requirements above, such statements and claims may be declared on any panel of the labeling of meat and poultry products.

Declaring a whole grain component in the ingredients statement alone is not considered a claim and does not need to meet the 8 grams criteria but it should still meet the 51% criteria (or 100% criteria if there is a FDA standard). For example, if the product name is “pepperoni pizza” and the ingredients statement declares “whole wheat crust” then the crust should be at least 51% whole wheat of the total grain component in the crust. This is because there is no FDA standard for whole wheat crust and the product does not need to meet the 8 grams criteria per labeled serving size or per RACC.

**LEVEL CHARACTERIZATION**

The nutrition labeling regulations in 9 CFR 317.313(b) and 381.413(b) clearly state that claims that, expressly or by implication, characterize the level of a nutrient may not be made on the labeling of a meat or poultry product unless the claim is made in accordance with the nutrition labeling regulations. The FSIS nutrition regulations do not include provisions to make claims about whole grains, whole grain cannot be included within the nutrition facts panel as a nutrient, and there is no regulatory percent Daily Value for whole grains. Therefore, claims such as “good source of whole grains,” and “excellent source of whole grains” are not permitted on meat and poultry product labeling.

FSIS regulations in 9 CFR 317.313 and 381.143 do not allow statements or claims that imply that the level of whole grains in a product is high, or places significance on a specific level of whole
grains, including, but not limited to: “contains X grams of whole grains,” “more than X grams of whole grains,” “at least X grams whole grains” and “fortified with X grams of whole grains.”

COMPANY NAMES or BRAND NAMES
Trademarked company or brand names that name or imply a level of whole grain in a product cannot be approved when given prominence on the label. One exception is that a company or brand name that includes a whole grain claim or implies a whole grain claim may be part of the signature line as required by 9 CFR 317.2(g) and 381.122 provided that the signature line is normally placed, for example, in normal size font at the bottom of the information panel, and is not given undue prominence which would cause the use of the company name to be a false or misleading claim.

AD-COPY
FSIS needs to review and approve ad-copy as labeling and the above mentioned statements and claims criteria will be applied. Ad-copy may make general statements about whole grains provided it does not make a specific claim or relate to specific health benefits, for example, the statement, “include whole grains as part of your daily life” provides general nutrition advice without making a specific unapproved claim and would be acceptable on labeling through LPDS sketch approval, but a statement such as, “whole grains are chock full of nutrients” is making a claim about whole grains which is undefined and not permitted.

TRADEMARKED SYMBOLS
Trademarked company or brand names, trademarked symbols or phrases, and statements used in ad-copy on labeling that name or imply a level of whole grain in a product cannot be approved. Certain non-specific trademarked symbols may be eligible to include on labeling of meat and poultry products provided the product provides a minimum of 8 grams whole grain (or specific grain) per serving and per RACC for the product and obtains LPDS sketch approval. Trademarked company or brand names, trademarked symbols or phrases, and statements associated with whole grains are evaluated in the context of the label on which it is used. Just because a symbol is trademarked does not mean it can be added to labeling if it creates a false or misleading statement or claim about the product.

USDA’s CHOOSE MY PLATE
The Choose MyPlate:
The USDA MyPyramid program was replaced by USDA’s Choose MyPlate in 2011. Thus, companies referencing MyPyramid on labeling will need to revise such labeling to eliminate the outdated references. USDA’s Center for Nutrition Policy and Promotion (CNPP) provides guidance to companies if they wish to include Choose MyPlate on labeling. Including Choose MyPlate on labeling is a special claim that requires LPDS sketch approval.

Contact CNPP for questions about Choose MyPlate: http://www.choosemyplate.gov/
Choose MyPlate Whole Grain Food Group Statements

Statements declaring the amount of a food group or food sub-group that a product contributes as it relates to the 2015-2020 Dietary Guidelines for Americans (DGA) recommendations are considered special claims that require LPDS sketch approval. In order to make such statements, the product should be in compliance with CNPP, who, on their MyPlate Style Guide and Conditions of Use for the Icon, states that the use of whole grain content calculations based on MyPlate will only be granted on the labeling of meat and poultry products that:

1) Meet the criteria for “healthy” as defined by USDA and FDA in 9 CFR 317.363(d) and 381.463(d), and 21 CFR 101.65(d)(2), respectively; and
2) Contain little or no added sugars.

Statements that FSIS would approve include: “One whole grain ounce equivalent per serving, MyPlate recommends at least 3 one-ounce equivalents of whole grains per day,” and “Whole Grains = 2 one-ounce equivalents* *MyPlate recommends at least 3 one-ounce equivalents of whole grains per day.”

Moreover, in order to not be viewed as misleading, the label that bears the claim must provide an adequate explanation for the consumer, for example, include content calculations, or references, based on a 2,000 calorie diet, and specify that the information is based on MyPlate recommendations. In addition, FSIS asks for the following to be taken into account when making this kind of statements:

1) Ounce equivalents of whole grain may be declared by half or whole numbers and should be declared as “ounce equivalents” in harmony with the language found in MyPlate;
2) Ounce equivalents may not be rounded up to the nearest half or whole ounce, but products should contain at least the amount declared by any claim or information; and
3) Calculations of the amount of whole grain ingredient or ounce equivalent must be provided with the label for sketch approval when statements are made regarding ounce equivalents of whole grains.

To calculate whole grain ounce equivalents: http://www.choosemyplate.gov/grains

MULTI-GRAIN

Because the claim “multi-grain” is not specifically a “whole grain” claim, FSIS permits the use of “multi-grain” when the product includes more than one grain source without the need to submit the label for review and approval prior to its use. For example, if the label declared a product name as “multi-grain pepperoni pizza” and the ingredients statement showed that the crust was made with two or more different grains (whole grain or not whole grain when derived
from different grains), then no further documentation is needed to support the claim “multi-grain.”

GRAINS CONSIDERED WHOLE GRAINS
Examples of grains that are commonly considered a whole grain by the Whole Grains Council or FDA can be found below.

- Amaranth
- Unhulled barley
- Buckwheat
- Whole kernel corn (including popcorn)
- Millet
- Oats (including rolled, quick and steel cut varieties)
- Quinoa
- Brown rice (including wild varieties)
- Sorghum
- Teff
- Triticale
- Whole wheat (including Kamut and other varieties)

Legumes and oilseeds such as: soy, chickpeas, flax seeds, chia and sunflower seeds are not are not considered whole grains.

Lastly, any labeling sketches granted approval with references to whole grains that are not in compliance with this policy should be brought into compliance with this policy. Consistent with the Agency’s regulations about generic label approval, labels bearing special statements, such as those described above, must be submitted to LPDS for evaluation and approval before use for compliance with 9 CFR 412.1. However, once a label is approved with a whole grains statement or claim, additional changes may be made to the label such as to the brand name, net weight, handling statement, ad copy, and label design. These types of changes to the previously approved label are generically approved under 9 CFR 412.2 because they do not affect the special statement or claim.

For additional information about FSIS labeling policies and programs, review the FSIS website for labeling at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/ or contact the LPDS at (301) 504-0878 or (301) 504-0879.
FULLY COOKED
Chicken Nuggets
WHOLE GRAIN BREADED STAR SHAPED
CHICKEN BREAST WITH RIB MEAT

KEEP FROZEN
NET WT. 5 LBS (2.26kg)

FRONT EXAMPLE

BACK EXAMPLE

Nutrition Facts

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>Calories 230</th>
<th>Calories from Fat 120</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Fat 13g</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Saturated Fat 3g</td>
<td>16%</td>
<td></td>
</tr>
<tr>
<td>Trans Fat 0g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol 40mg</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Sodium 460mg</td>
<td>20%</td>
<td></td>
</tr>
<tr>
<td>Potassium 0mg</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Total Carbohydrate 14g</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Dietary Fiber 3g</td>
<td>16%</td>
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</tr>
<tr>
<td>Sugars 0g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protein 12g</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>Vitamin A 0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin C 0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium 0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron 4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INGREDIENTS: Chicken breast with rib meat, water, whole wheat flour, contains 2% or less of the following: dried garlic, corn flour, salt, spices, natural flavoring.

Breeding set in vegetable oil.

CONTAINS: Wheat.

Distributed by:
Tolreck Inc.
St. 765 Jolosk,
Mayam Blo, GA 00612

[Back to reading]
<table>
<thead>
<tr>
<th>Claim Type</th>
<th>Permitted</th>
<th>Examples</th>
<th>Criteria and Requirements ¹ for Approval</th>
</tr>
</thead>
</table>
| GENERAL STATEMENTS                               | Yes (requires FSIS approval under 9 CFR 412.1) | - “Whole Wheat Pepperoni Pizza”  
- “X grams of whole grain per serving” | 1) A minimum of 8 grams of dry whole grain per both labeled serving size and Reference Amount Customarily Consumed (RACC) for the product;  
2) Demonstrate that “X” grams per serving size is accurate when specifying the amount; plus  
3) Provide calculations for points 1 and/or 2 according to claim. |
| FDA STANDARDIZED WHOLE WHEAT PRODUCTS           | Yes (requires FSIS approval under 9 CFR 412.1) | - “Whole Wheat Spaghetti and Meatballs” | 1) A minimum of 8 grams of dry whole grain per both, labeled serving size and RACC for the product;  
2) Grain portion of the product needs to be 100% whole wheat; plus  
3) Provide calculations for points 1 and 2 (based on 21 CFR 139.138). |
| SPECIFYING THE COMPONENT THAT CONTAINS WHOLE GRAIN | Yes (requires FSIS approval under 9 CFR 412.1) | - “Pepperoni Pizza with Whole Grain Crust”  
- “Whole Grain Breaded Chicken Patty”  
- “Made with Whole Grain Brown Rice” | 1) A minimum of 8 grams of dry whole grain per both labeled serving size and RACC for the product;  
2) At least 51% of the grain components are whole grain; plus  
3) Provide calculations for points 1 and 2. |
| LEVEL CHARACTERIZATION                          | No                         | - “Good Source of Whole Grains” | These statements are not permitted because there are  |

¹ The basis for all whole grain factual statements and claims is that there should be a significant amount of the specified whole grain component in the product. FSIS considers these statements to be false or misleading if the product does not contain at least 8 grams of dry whole grain ingredient per labeled serving size of the meat or poultry product as declared in the nutrition facts panel on the label and per the appropriate Reference Amount Customarily Consumed (RACC)
<table>
<thead>
<tr>
<th>COMPANY/BRAND NAMES</th>
<th>Yes (in signature line only; requires FSIS approval under 9 CFR 412.1)</th>
<th>“Whole Grain Company”</th>
<th>The name of the packer, manufacturer, or distributor (i.e., the signature line) is normally placed at bottom of information panel; not given undue prominence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD COPY and TRADEMARKED SYMBOLS</td>
<td>Yes (requires FSIS approval under 9 CFR 412.1)</td>
<td>“Include whole grains as part of your daily life”</td>
<td>Evaluated on a case by case basis; documentation would be required if found to be a claim.</td>
</tr>
<tr>
<td>WHOLE GRAIN COUNCIL</td>
<td>Yes (requires FSIS approval under 9 CFR 412.1)</td>
<td>-</td>
<td>1) A minimum of 8 grams of dry whole grain per both labeled serving size and RACC for the product; 2) Demonstrate that “X” grams per serving size is accurate when specifying an amount different from 8 grams; 3) Cannot state “or more,” because it implies level characterization; 4) Cannot state “eat 48 grams or more whole grain daily,” because there is no Daily Reference Value in the nutrition regulation for whole grains; plus; 5) Provide calculations for points 1 and/or 2.</td>
</tr>
<tr>
<td>USDA’s CHOOSE MY</td>
<td>Yes (requires</td>
<td>- Including the</td>
<td>1) Not to be used with what</td>
</tr>
<tr>
<td>PLATE</td>
<td>FSIS approval under <a href="#">9 CFR 412.1</a></td>
<td>USDA Choose MyPlate on label [image]</td>
<td>or how much to eat, <em>plus</em> 2) Use with “Learn about healthy eating at <a href="#">ChooseMyPlate.gov</a>”</td>
</tr>
<tr>
<td>-------</td>
<td>---------------------------------</td>
<td>-----------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>MY PLATE WHOLE GRAIN FOOD GROUP STATEMENTS</td>
<td>Yes (requires FSIS approval under <a href="#">9 CFR 412.1</a>)</td>
<td>- “One whole grain ounce equivalent per serving, MyPlate recommends at least 3-one ounce equivalents of whole grain per day”</td>
<td>1) Meets “healthy”; 2) Contains little or no added sugars; 3) Keep separate from Choose MyPlate; <em>plus</em> 4) Calculations for whole grain ounce equivalents (contact CNPP for methodology)</td>
</tr>
</tbody>
</table>
SMALL PLANT HELP DESK
A resource for small and very small plants
Est. 12-17-2010
Knowledgeable, USDA-FSIS specialists from the Outreach and Partnership Division are available weekdays 8:00 AM to 4:00 PM EST to give you personal assistance on matters relating to the regulation of meat, poultry, and processed egg products. We can also be reached by email at faqsources@fsis.usda.gov.

Call Toll-Free 1-877-374-7435

askFSIS
a policy-related question

http://askfsis.custhelp.com/

FSIS/USDA
www.fsis.usda.gov
2017