# Global review of whole grain definitions and health claims

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Recommendations to increase whole grain consumption are part of dietary guide-lines around the world. To assist consumers in meeting this recommendation, some countries, and health-promoting organizations, have defined qualifying criteria for a whole grain food for product labeling or health claims. Other countries have not yet developed similar guidelines. Existing whole grain definitions and health claims are reviewed here. While there appears to be increasing consensus for defining a whole grain, significant disparity exists in defining a whole grain food when a product is not 100% whole grain. Moreover, while whole grain health claims have been approved in a few countries, other countries have concluded there is insufficient evidence to substantiate such claims.

#### INTRODUCTION

Dietary guidelines in several countries across the globe currently include recommendations to consume whole grains. 1,2 Although the recommendations vary from general guidance on increasing or selecting whole grains over refined grains, to quantitative guidelines that specify a target daily amount, all underscore the importance of consuming whole grains in maintaining health. Only a few countries have adopted a quantitative recommendation, and variability exists among them. Data on whole grain intake has not been reported in national food consumption surveys in most countries.<sup>3</sup> Among the few that report this type of information, the data suggests a wide gap between recommendations and actual intake, even in countries where the intake of whole grain products is actively promoted.<sup>4</sup> For example, in the United States, the 2015-2020 Dietary Guidelines for Americans recommend a minimum of 3-oz. equivalents (ie, 48 g) of whole grains per day, but the 2009-2010 National Health and Nutrition Survey (NHANES) indicated mean intakes of less than onethird of recommended amounts for all age groups in the US population.<sup>6</sup> Even in Scandinavian countries where whole grains form part of the traditional diet, whole grain intakes fall short of recommended amounts. In Denmark for example, a 2011–2015 Danish national survey reported a mean intake of 55 g/d for whole grains and this was significantly below the recommended amount of 75 g/d per 10 MJ.<sup>7</sup>

Whole grain consumption may be encouraged through a variety of promotional measures that require partnerships between government, food industry, health professionals, and health-promoting organizations. One aspect of active promotion is meaningful food labeling that identifies a whole grain food, as well as evidence-based health claims that communicate the benefits of whole grains. The first step in this process is to define what qualifies as a whole grain food or ingredient. Therefore, the aim of this paper is to compile and review whole grain definitions and health claims from around the world. This article stems from a presentation by Yifang Chu at the symposium on whole grains, dietary fiber, and public health convened in Beijing, China, on May 11, 2018.

#### **CEREAL GRAINS AND PSEUDOCEREALS**

Cereal plants belong to the grass family (*Gramineae* or *Poaceae*), which produce seeds known as kernels or grains. True cereal grains include wheat, oat, rice, wild rice (not included originally, but later amended), corn,

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barley, rye, kamut, triticale, sorghum, Job's tears, fonio, millet, teff, and canary seed. All cereal grains have three anatomical components: the bran, endosperm, and germ. Bran consists primarily of the main outer layers of the grain – the pericarp and aleurone layers – and is rich in dietary fiber, vitamins, minerals, and phytochemicals. The nutritional composition of the bran fraction can vary according to the type of grain and the milling technology used. The endosperm constitutes about 60%–85% of the grain, comprised mainly of carbohydrates in the form of starches with some protein and B vitamins. The germ is the smallest fraction (2.5%–3%) of the grain, containing a high lipid and protein content and some vitamins and minerals.

Amaranth, quinoa, and buckwheat are not part of the grass family, but are considered pseudocereal grains partly owing to their seed-like structure and similar macronutrient composition but also because they are used in the same way cereals are traditionally used. In addition, pseudocereals are included in the cereal category in dietary guidance such as MyPyramid, developed by the United States Department of Agriculture (USDA). Seeds, legumes, and nuts are not considered cereals or pseudocereals owing to differences in their macronutrient content and positioning in the meat and protein food group.

## **DEFINITION OF WHOLE GRAIN**

A definition of whole grains was first put forward by the American Association of Cereal Chemists International (AACCI) in 1999 that described the principal components and composition of whole grains:<sup>10,11</sup>

"Whole grains shall 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."

This definition was adopted by the US Food and Drug Administration (FDA) in their draft guidance document on whole grain label statements for true cereal grains and pseudocereals. Agriculture and Agri-Food Canada also proposed to incorporate this definition into the Canadian Food and Drug Regulations in 2006 for all true cereals and pseudocereals. The Scandinavian countries utilize this definition for wheat, rye, oats, barley, maize (dry seeds), rice, millet, and sorghum, but not for wild rice, quinoa, amaranth, and buckwheat, in food labeling. The AACCI definition with minor variation in wording has been accepted in other European countries, Australia and New Zealand, Mexico, Malaysia, Singapore, Mexico, In Malaysia, Singapore, In and Taiwan.

definition, but the 2016 Chinese Dietary Guidelines use a definition consistent with the AACCI definition.<sup>20</sup> The specific grains that are considered whole grain may vary among countries.

The absence of a consensus definition for whole grains in the European Union (EU) led the EU-sponsored HEALTHGRAIN Forum to develop a definition in 2010 that was more comprehensive than current definitions used in most EU countries, and equivalent to definitions outside Europe, notably the AACCI definition, while reflecting current industrial flour manufacturing practices.<sup>4</sup> The following whole grain definition for true cereals and pseudocereals was therefore developed<sup>4</sup>:

"Whole grains shall consist of intact, ground, or flaked kernel after removal of inedible parts, and principal anatomical components—the starchy endosperm, germ and bran—are present in the same relative proportions as they exist in the intact kernel.

Small losses of components—that is, less than 2% of the grain/10% of the bran—that occur through processing methods consistent with safety and quality are allowed."

The inclusion of small losses of components in the HEALTHGRAIN definition was intended to reflect the removal of outer layers, which is a practice widely used in current milling and processing methods.<sup>4</sup> This practice removes mycotoxins, pesticides, and microbial contaminants that are concentrated in the outer layers.<sup>4</sup> Common milling or grain production practices often involve separating grain fractions and recombining them later, as, for example, in the production of wholemeal flour.<sup>4</sup> However, it was noted that that although recombination and grain variety will result in some fluctuations in the ratios of endosperm, bran, and germ, there should be no significant nutritional losses, and differences should not be greater than would be normally found with seasonal changes or between varieties.<sup>4</sup>

# **DEFINITION OF WHOLE GRAIN FOOD**

Discerning what constitutes a whole grain food is relatively simple when a product is 100% rolled oats or brown rice, or when all the flour in a bread is made from 100% whole wheat flour. However, when a food product such as bread, pasta, or breakfast cereal incorporates whole grains as one ingredient along with other ingredients, including refined grains, it is less clear whether the product should be considered a whole grain food. While the whole grain definition focuses on the proportion of the components of whole grain, the definition of a whole grain food focuses on the quantity

of whole grain ingredients that must be incorporated into a food to qualify it as whole grain. Wide variation exists among countries and organizations in relation to the guidelines and codes of practice they use to define whole grain foods (Table 1). <sup>13,14,17,19,21–35</sup> The qualifying criterion is often reported as a percentage of whole grain or as a specific amount of whole grains per serving. There is variability in the quantification of both approaches, as well as whether the criteria are to be applied to total product weight or to dry product weight.

## Percentage whole grain

In some countries, specific whole grain products must consist entirely, or almost entirely, of whole grain. Whole grain bread must consist of 100% whole grain flour in the Netherlands,<sup>30</sup> and a minimum of 90% grain ingredients in Germany.<sup>28</sup> Scandinavian countries (Norway, Denmark, Sweden) require whole grain flour and grain to be 100% whole grain, whereas foods with non-whole grain ingredients must contain more than 50% whole grain ingredients (≥51%) based on dry matter. 14 Although not mandated by the French government, the French biscuit industry provided guidelines for whole grain content for their products based on the total weight of ingredients: 15%-39% whole grain for a "source of whole grain" claim and  $\geq 40\%$  for a "rich in whole grain" claim. 30,32 Currently, there is no legally binding definition for whole grain foods across the EU.3 Owing to the divergence of acceptable definitions throughout the EU, the HEALTHGRAIN Forum attempted to set a threshold that would be meaningful across diverse products and would be acceptable to countries that consume foods that are close to 100% whole grain, as well as to countries where whole grains are not frequently consumed.<sup>30</sup> Hence, the HEALTHGRAIN Forum recommended that a whole grain food should contain a minimum of 30% whole grain ingredients and more whole grain than refined grain ingredients, both on a dry-weight basis.<sup>30</sup> This definition was intended for whole grain content labeling and not for health claims.

Taiwan has authorized whole grain food claims for foods that contain a minimum of 51% whole grain ingredients per total dry weight of product. However, if the whole grain content is less than 51% (dry weight), a claim is also permitted that allows declaration of partial whole grain content. In Indonesia, "whole, broken, or flaked grain, including rice" and "breakfast cereals, including rolled oats" can claim to be whole grain foods if they contain a minimum of 25% whole grain ingredients. In a proposed regulatory document, Malaysia has defined whole grain foods according to specific food types: 100% whole grain ingredients for

wheat flour, rice flour, rice, and grains; 60% whole grain ingredients for bread; and 25% whole grain ingredients or 8 g per serving for other products.<sup>17</sup>

The US FDA has permitted the use of whole grain health claims since 1999. For whole grain foods to qualify for the claim, a minimum of 51% whole grain ingredient(s) by weight per recommended amount customarily consumed (RACC) is required, and such foods must also comply with a dietary fiber stipulation. 21-23 In 2002, the United Kingdom also authorized a whole grain health claim with similar qualifying criteria, but without the dietary fiber caveat.<sup>33</sup> In 2003, Sweden permitted a whole grain health claim for products that contain at least 50% whole grain based on the product's dry weight.<sup>31</sup> Limitations to the US qualifying criteria include the inability of certain whole grain foods with high moisture content to meet the dietary fiber standard, even when the foods consist solely of 100% whole grain ingredients.<sup>36</sup> Hence, the FDA permitted the expansion of the health claim to allow singleingredient whole grain foods (eg, brown rice) to qualify for the claim even if they did not meet the minimum 11% dietary fiber requirement.<sup>23</sup>

## Grams of whole grain per serving

The Oldways Whole Grains Council in the United States has developed a whole grain stamp that food manufacturers can use to help consumers identify whole grain products.<sup>24</sup> To qualify for the "basic whole grain stamp," products must contain a minimum of 8 g whole grain per serving. For the "50% whole grain stamp," products must provide a minimum of 8 g whole grain per serving and at least 50% of the grain ingredients must be whole grain. For the "100% stamp," products must contain a minimum of 16g of whole grain per serving and all grain ingredients must be whole grain. The 8g and 16g minimum levels were based on the latest research on whole grains and the 2010 and 2015 Dietary Guidelines for Americans. The 2005, 2010, and 2015 Dietary Guidelines for Americans noted that at least 3 or more ounce-equivalents of whole grains per day can reduce the risk of chronic diseases, and 1 ounce-equivalent of 100% whole grains provides 16 g of whole grains.<sup>5,37</sup> The whole grain stamp is currently being used in 61 countries, including China.<sup>24</sup> In Canada, there are differences in how the whole grain stamp may be used. The 100% stamp can only be used on Canadian products when 100% of all the ingredients are whole grain, whereas in the United States and most other countries, the 100% stamp can be used when 100% of the grain ingredients are 100% whole grain. 13,27 Similar distinctions are made for the 50%+ stamp,

Table 1 Examples of whole grain food definitions

Region/country	Organization/source	Whole grain qualifying criteria
North America		
USA	FDA Whole Grain Health Claim (1999, 2003, 2008) <sup>21–23</sup>	$\geq$ 51% whole grain by weight per RACC; compliance determined by TDF $\geq$ 11 g $\times$ 51% $\times$ RACC/100 (waived for single-ingredient whole grain foods, eg, brown rice)
	Whole Grain Council Whole Grain Stamp (2005, 2006, 2017) <sup>24</sup>	≥8 g whole grain/serving ("basic stamp") ≥8 g whole grain/serving and at least 50% of <i>grain</i> ingredients must be whole grain ("50%+ stamp")
	A A	≥16 g whole grain/serving and all <i>grain</i> ingredients are whole grain ("100% stamp")
	American Association of Cereal Chemists International (2013) <sup>25</sup>	$\geq$ 8 g whole grain/ 30 g product
	USDA/Food Safety and Inspection Service (FSIS) Interim policy (2017) <sup>26</sup>	Specific for meat/poultry products containing whole grains ≥8 g dry WG ingredient per labeled serving on nutrition label and per RACC, and must meet standard of identity for whole grain products. If this standard is not met, ≥51% of the dry grain components must be WG.
Canada	Whole Grain Council Whole Grain Stamp (2008) <sup>13,27</sup>	≥8 g whole grain/serving ("basic stamp") ≥8 g whole grain/serving and at least 50% of <i>all ingredients</i> must be whole grain ("50%+ stamp") ≥16 g whole grain/serving and <i>all ingredients</i> are whole grain
		("100% stamp")
Europe	Fodoval Ministry of Faced C Assistation	>000/ of final ingradients anout from water mouth a whale week
Germany	Federal Ministry of Food & Agriculture (1999, 2005) <sup>28,29</sup>	≥90% of final ingredients, apart from water, must be whole grai for WG bread 100% of grain ingredients must be whole grain for WG pasta
Netherlands	Secretary of Public Health, Welfare & Sport (1998) <sup>30</sup>	100% of grain ingredients must be whole grain for WG bread (le gal requirement) ≥50% of grain components must be whole grain for WG biscuit:
Sweden	Swedish National Food Agency,	To use keyhole symbol
Norway Denmark	Norwegian Food Safety Authority, Danish Veterinary and Food Administration: Keyhole Symbol (1989,	100% of flours, grains, and flakes must be whole grain (dry matter) ≥50% of ingredients must be whole grain in WG crispbread,
	2009) <sup>14</sup>	pasta, breakfast cereals, and porridge (dry matter)
	Swedish Food Sector Code of Practice Whole Grain Health Claim (2004) <sup>a 31</sup>	≥25% of ingredients must be whole grain in WG soft bread ≥50% of ingredients must be whole grain based on product weight. TDF must be ≤ 4.5 g per 1000 kJ and conditions for fa
France	Charter of Ethics for French Biscuit and Cake Manufacturers (2009) <sup>32</sup>	sugar, salt for keyhole symbol must be met. 15%–39% whole grain ingredients per total weight of product can use "source of whole grain" claim
		>39% whole grain ingredients per total weight of product can use "rich in whole grain" claim Whole grain claims must also contain a minimum of 3 g/100 g
		TDF
United Kingdom	United Kingdom Joint Health Claim Initiative (2002) <sup>a 33</sup>	≥51% of ingredients must be whole grain ingredients by weigh
European Union	HEALTHGRAIN Forum (2017) <sup>30</sup>	≥30% of ingredients must be whole grain ingredients based on total-product (or total ingredients for mixed products) dry weight, and with a greater proportion of whole grain ingredients than refined-grain ingredients
Asia	Taiwan Ministry of Hoalth Food and Drive	> 510% of ingradiants must be whale assis based on total and
Taiwan	Taiwan Ministry of Health Food and Drug Administration Whole Grain Food	≥ 51% of ingredients must be whole grain based on total prod- uct dry weight for a whole grain food claim
	Product claim and Labeling Standards (2010, 2013) <sup>19</sup>	≥ 51% of ingredients must be whole grain based on total product dry weight for a single-grain product 100% of the ingredients must be whole grain for WG powder,
		with no other material or additive < 51% of ingredients must be whole grain based on total dry product weight for a "partial material of product is whole xxx grain" claim or "product contains whole grain partially" claim
Indonesia	National Agency of Drug and Food Control (2016) <sup>34</sup>	<ul> <li>25% of ingredients must be whole grain in order to bear a whole grain claim for whole, broken, or flaked grain, including rice and breakfast cereals, including rolled oats</li> </ul>

(continued)

Table 1 Continued

Region/country	Organization/source	Whole grain qualifying criteria
Malaysia	Malaysia Ministry of Health <i>proposed</i> draft (2018) <sup>17</sup>	100% of ingredients must be whole grain for WG wheat flour, rice flour, rice, and grains
		60% of ingredients must be whole grain for WG bread
		25% of ingredients must be whole grain, or 8 g whole grain per serving for other products.
Australia	Grains and Legumes Nutrition Council (GLNC) Code of Practice (2017) <sup>35</sup>	≥8 g whole grain/manufacturer serving for a "contains whole grain" claim
		≥16 g whole grain/manufacturer serving for a "high in whole grain" claim
		$\geq$ 24 g whole grain/manufacturer serving for a "very high in whole grain" claim

<sup>&</sup>lt;sup>a</sup>Approved prior to the EU regulation of health claims in 2007. *Abbreviations*: RACC, recommended amount customarily consumed; TDF, total dietary fiber; WG, whole grain.

whereas use of the basic whole grain stamp is the same for both US and Canadian products. 13,27

The Grains and Legumes Nutrition Council (GLNC), an independent authority on grains and legumes, has developed a code of practice in Australia for manufacturers to use in making whole grain claims on food.<sup>35</sup> Whole grain products can use the following claims per manufacturer serving: "contains whole grain" if the product contains a minimum of 8 g of whole grain; "high in whole grain" if the product contains a minimum of 16 g of whole grain; and "very high in whole grain" if the product contains a minimum of 24 g of whole grain.<sup>35</sup>

In 2013, a whole grain food was characterized by the AACCI as one that must contain a minimum of 8 g of whole grain per 30 g of product (ie, ounce-equivalent or standard serving of most cereal products).<sup>25</sup> This level was chosen to take into account food products that include refined grains and are widely accepted by consumers.<sup>25</sup> However, there have been some concerns regarding this definition because certain foods, for example those with a high moisture content, mixed meals, and heat-and-serve grains, would not qualify as whole grain foods even when the food contains more than 8 g of whole grain per serving, or when all or most of the grain ingredients are whole grain.<sup>38</sup> Moist foods such as breads and bagels would be required to contain a much higher proportion of their grain as whole grain than dry foods such as dry breakfast cereals, pasta, or crackers.<sup>38</sup> In addition, some foods would be labeled whole grain even if they contained more refined ingredients than whole grain ingredients.<sup>38</sup> To date, the AACCI definition has not been adopted by any governmental agency, although the USDA/Food Safety and Inspection Service has specified a definition for a whole grain food in the meat and poultry category that incorporates several criteria including those specified by the AACCI. In this case, to be considered whole grain,

foods must contain a minimum of 8 g dry whole grain ingredient(s) per labeled serving and per RACC and must meet the standard of identity for whole grain products, and if they do not meet the standard of identity, they must contain a minimum of 51% dry whole grain ingredients.<sup>26</sup>

# WHOLE GRAIN HEALTH CLAIMS

A few countries have authorized health claims for whole grains (Table 2). 21-23,31,33,39,40 The United States was the first country to authorize a whole grain health claim in 1999 based on a notification submitted by General Mills on the relationship between diets rich in whole grain foods, and low in total fat, saturated fat, and cholesterol, and the reduced risk of heart disease and certain cancers.<sup>21</sup> This claim was based on the Food and Drug Administration Modernization Act of 1997 (FDAMA), which allowed a food manufacturer to submit a notification of a health claim based on an authoritative statement from a federal agency or the National Academy of Sciences.<sup>21</sup> The notification cited the statement from the National Academy of Sciences 1989 report, "Diet and Health: Implications of Reducing Chronic Disease Risk." In 2003, the FDA authorized a variation of this claim based on a notification submitted by Kraft Foods from the same report on the association between diets rich in whole grain foods, and low in saturated fat and cholesterol, and the reduced risk of heart disease.<sup>22</sup> The removal of the term "low in total fat" permitted whole grain foods with moderate fat content to make the claim based on evidence total fat intake per se is not associated with high blood cholesterol levels and coronary heart disease.<sup>22</sup> Whole grain foods were defined as foods that contained a minimum of 51% whole grain ingredient(s) by weight per RACC in both health claims, in addition to other nutrient-qualifying criteria. 21,22

Table 2 Whole grain health claims

Country	Model health claim	Qualifying criteria
USA <sup>21–23,39</sup>	Diets rich in whole grain foods and other plant foods, and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.	≥51% of ingredients must be whole grain by weight per RACC; compliance determined by TDF ≥11 g/100 g whole wheat × 51% × RACC/100 (waived for single-ingredient whole grain foods, eg, brown rice).  Low fat, low saturated fat, low cholesterol
	Diets rich in whole grain foods and other plant foods, and low in saturated fat and choles- terol, may help reduce the risk of heart disease.	≥51% of ingredients must be whole grain by weight per RACC; compliance determined by TDF ≥11 g/100 g whole wheat x 51% x RACC/100 (waived for single-ingredient whole grain foods, eg, brown rice).  Low saturated fat, low cholesterol <6.5 g total fat and 0.5 g trans-fat per RACC
	Whole grains may reduce the risk of type 2 dia- betes, although the FDA has concluded that there is very limited scientific evidence for this claim.	Does not specify minimum amount of whole grains needed to make claim owing to limited evidence
United Kingdom <sup>a 33</sup>	Whole grain may help to maintain a healthy heart when eaten as part of a low-fat diet and healthy lifestyle.	$\geq$ 51% of ingredients must be whole grain ingredients by weight
Sweden <sup>a 31</sup>	A healthy lifestyle and well-balanced diet high in wholegrain products reduces the risk of (coronary) heart disease. Product XXX has a high wholegrain content (Y% wholegrain).	$\geq$ 50% of ingredients must be whole grain based on product weight. TDF must be $\geq$ 4.5 g per 1000 kJ and conditions for fat, sugar, salt for keyhole symbol must be met
Singapore <sup>40</sup>	A healthy diet rich in whole grains, fruits, and vegetables, which contain dietary fiber, may reduce the risk of heart disease. (Name of food) is low/free of fat and high in dietary fiber.	A product from the following food groups: whole grains, fruit vegetables, or fiber-fortified foods and Low in fat or fat free high in dietary fiber ( $\geq$ 3 g per 100 kcal or $\geq$ 6 g per 100 g c 100 mL) and $\geq$ 25% of the dietary fiber comprising soluble fiber
		Whole grain is defined as the "intact grain or the dehulled, ground, milled, cracked, or flaked grain where the endosperm, germ, and bran are present in proportions that represent the typical ratio of these constituents occurring in the whole cereal and includes wholemeal. Product cannot be labeled as wholegrain unless it complies with the definition and the term "wholegrain" is qualified immediately indicating the percentage of whole grain ingredients used.
	A healthy diet rich in fiber-containing foods such as whole grains, fruits, and vegetables may reduce the risk of some types of cancers.	A product from the following food groups: whole grains, fruit, vegetables, or fiber-fortified foods and low in fat or fat free, high in dietary fiber (≥3 g per 100 kcal or ≥6 g per 100 g or 100 mL), and reference quantity of the food product should not contain sodium in an amount exceeding 25% of sodium RDA (2000 mg).  amount customarily consumed; RDA, recommended dietary

Abbreviations: FDA, Food and Drug Administration; RACC, recommended amount customarily consumed; RDA, recommended dietary allowance; TDF, total dietary fiber.

In the United States, a qualified health claim for the association between whole grains and the reduced risk of type 2 diabetes was permitted in 2013.<sup>39</sup> The food manufacturer can petition the FDA to exercise enforcement discretion for the use of a qualified health claim that is supported by scientific evidence but does not meet the "significant scientific agreement" standard for an authorized health claim. If the petition has credible evidence, the FDA issues a letter of enforcement discretion with specific claim wording that reflects the supporting scientific evidence, as follows: "The FDA has concluded that there is very limited scientific evidence for this claim. Due to the very limited scientific evidence available for this qualified health claim, the FDA did not specify a qualifying minimum level of whole grain for the use of the claim."<sup>39</sup>

The Joint Health Claim Initiative in the United Kingdom approved a health claim between whole grain foods and a healthy heart in 2002,<sup>33</sup> and the Swedish Code of Practice approved a health claim for whole grains and a reduced risk of heart disease in 2003,<sup>14,31</sup> prior to the European Commission's regulation on health claims in 2007. In the United Kingdom, the qualifying criteria were for wheat, rice, maize, and oat foods that contained 51% or more whole grain ingredients by weight per serving.<sup>33</sup> In Sweden, a food with at least 50% whole grain ingredients from wheat, rye, oats, or barley could qualify for the same claim.<sup>31</sup>

Two whole grain health claims have been authorized by the Agri-Food and Veterinary Authority in Singapore – one linking diets rich in whole grains,

<sup>&</sup>lt;sup>a</sup>Approved prior to the EU regulation of health claims in 2007.

fruits, and vegetables that contain dietary fiber with a reduced risk of heart disease, and the other linking such diets with a reduced risk of certain types of cancers. <sup>40</sup> Under the regulations, whole grain has a definition similar to the AACCI definition and cannot be labeled whole grain unless the word "wholegrain" is qualified immediately by words indicating the percentage of wholegrain ingredients used. <sup>18,40</sup> Additional qualifying nutrient criteria are also specified.

Despite the approval of these whole grain health claims, other jurisdictions have not found adequate evidence to authorize similar claims. In 2007, FSANZ (Food Standards Australia New Zealand) concluded that a review of the relationship between a higher intake of whole grains and a reduction in heart disease had not been adequately substantiated. 41 The evidence was considered unconvincing chiefly because the definition of whole grain in the studies was inconsistent: some of the studies measured fiber intake instead of whole grain and, therefore, may have included intake from nonwhole grain sources, and an insufficient number and range of studies had examined the type of whole grains typically consumed in Australia and New Zealand (eg, wheat). Similarly, the European Food Safety Authority (EFSA) noted in 2010 that a cause and effect relationship could not be established between whole grain and specific health effects because the randomized controlled trials submitted to substantiate this association used varying definitions of whole grain, and, therefore, whole grains were not adequately characterized.<sup>42</sup>

Health Canada has recognized the AACCI definition of whole grain and in 2012 conducted a systematic review of the scientific evidence of the relationship between whole grains and heart disease involving only studies that included grain products that met this definition.<sup>43</sup> On the basis of the systematic review, Health Canada concluded that "the evidence to date from clinical trials and prospective cohort studies was not sufficient to support a whole grains and coronary heart disease risk reduction claim in Canada."43 Six prospective cohort studies met the criteria for inclusion but were limited by potential biases from confounding factors and poor applicability to the Canadian population.43 While 26 controlled clinical trials met the inclusion criteria, and pooled results demonstrated whole grain foods lowered total and LDL-cholesterol, the effect was largely attributed to whole grains high in beta-glucan fiber and the trials assessed to be of poor quality. 43 Health Canada indicated that the cholesterollowering effects of grains high in beta-glucan fiber cannot be generalized to other grains, including wheat, which is the primary grain consumed in Canada. Hence, the agency stated a claim that accepts a relationship between whole grains and the reduced risk of coronary heart disease would be misleading if applied to grains that are not high in beta-glucan fiber, and Health Canada has already approved a health claim for oat products and blood cholesterol lowering. Although the current evidence did not support a health claim for whole grains and the reduced risk of coronary heart disease, Health Canada noted that general health claims referring to Canada's Food Guide recommendation for making at least half of your grain products whole grain each day are permitted, a since whole grains are a source of many nutrients important for health, including fiber, vitamins, minerals, and trace elements.

#### CONCLUSION

Many countries have accepted the basic AACCI definition of whole grains: that whole grains consist of intact, ground, cracked, or flaked grain with the endosperm, germ, and bran present in the same proportions as they are in the intact grain. The EU-sponsored HEALTHGRAIN Forum accepted this definition and expanded it to account for small losses of components that naturally occur with common processing methods. While it is relatively simple to define a whole grain food when it consists of 100% whole grain ingredients, it is more complicated when a food contains additional non-whole grain ingredients. There is wide variation in the definition of whole grain foods. Both percentages and grams of whole grain or a combination of the two have been utilized by different jurisdictions and/or health-promoting organizations. A minimum of 51% or 8 g of whole grain has been frequently cited as a minimum qualifying level per serving; however, some bodies report the qualifying criteria based on dry weight, while others report it based on total weight. Currently, there is no consensus on which approach is best. To encourage greater uniformity, it may be useful if international food standards for whole grain labeling were to be developed through a Codex Alimentarius committee, as occurred for dietary fiber. A few countries have authorized whole grain health claims for the reduced risk of heart disease and certain cancers, while others have concluded that at present there is inadequate scientific evidence to support a whole grain health claim. Reasons include variability in whole grain definitions and insufficient data to support grains other than beta-glucan containing grains.

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## REFERENCES

- Slavin J, Tucker M, Harriman C, et al. Whole grains: definition, dietary recommendation and health benefits. Cereal Foods World. 2013;58:191–198.
- Seal CJ, Nugent AP, Tee ES, et al. Whole-grain dietary recommendations: the need for a unified global approach. Br J Nutr. 2016;115:2031–2038.
- EU Whole Grain. Available at: https://ec.europa.eu/jrc/en/health-knowledge-gateway/promotion-prevention/nutrition/whole-grain. Accessed March 29, 2019.
- van der Kamp JW, Poutanen K, Seal CJ, et al. The HEALTHGRAIN definition of "whole grain." Food Nutr Res. 2014;58:22100.
- US Department of Health and Human Services and US Department of Agriculture. 2015–2020 Dietary Guidelines for Americans, 8th ed. Available at: http://health. gov/dietaryguidelines/2015/guidelines/. Published December 2015. Accessed March 29, 2019.
- McGill CR, Fulgoni VL 3rd, Devareddy L. Ten-year trends in fiber and wholegrain intakes and food sources for the United States population: National Health and Nutrition Examination Survey 2001-2010. Nutrients. 2015;7:1119–1130.
- Mejborn H, Ygil KH, Fagt S, et al. Wholegrain intake of Danes 2011-2012. DTU Fødevareinstituttet. 2:1–5.
- 8. Frølich W, Aman P. Whole grain for whom and why? Food Nutr Res. 2010;54:5056.
- AACCI (American Association of Cereal Chemists International). AACCI submits comments to FDA regarding whole grains label statements [Letter]. Available at: http://www.aaccnet.org/initiatives/definitions/pages/wholegrain.aspx. Published April 2006. Accessed March 29, 2019.
- Jones JM. Regulatory aspects of whole grain and whole grain foods: definitions and labeling. Cereal Chem. 2010;87:150–154.
- AACCI (American Association of Cereal Chemists International). Whole grain definition. Cereal Foods World. 1999;45:79.
- FDA (US Food and Drug Administration). Draft guidance for industry and FDA staff: Whole grain label statements. Available at: https://www.fda.gov/Food/

- GuidanceRegulation/ucm059088.htm. Published January 17, 2006. Accessed April 9, 2019.
- Agriculture and Agri-Food Canada. Whole grain claims in the marketplace. Available at: http://www.agr.gc.ca/eng/industry-markets-and-trade/canadian-agri-food-sector-intelligence/processed-food-and-beverages/trends-and-market-op-portunities-for-the-food-processing-sector/whole-grain-claims-in-the-market-place? id=1329944262611. Published December 2015. Accessed April 9, 2019.
- Frølich W, Aman P, Tetens I. Whole grain foods and health—a Scandinavian perspective. Food Nutr Res. 2013;57:18503.
- FSANZ (Food Standards Australia New Zealand). Food Standards (Proposal P1025-Code Revision) Variation. Standard 2.2.1 Cereal and Cereal Products. Available at: https://www.legislation.gov.au/Details/F2015L00420. Accessed March 10, 2019.
- CNDH (Comisión Nacional de los Devechos Humano-Mexico). Official Mexican Standard NOM-043-SSA2-2012. Basic Services of Health, Promotion and Education for Health in Alimentary Matters. Criteria to Provide Orientation [in Spanish]. January 22, 2013. Available at: http://www.cndh.org.mx/DocTR/2016/JUR/A70/01/ JUR-20170331-NOR37.pdf. Published January 22, 2013. Accessed March 10, 2019.
- Ministry of Health (Malaysia) Proposed Regulation 2018. Available at: http://fsq. moh.gov.my/v5/wp-content/uploads/2018/02/ONLINE-PUBLIC-ENGAGEMENT-NO-1.2018.pdf. Accessed April 10. 2018.
- Singapore Government. Part IV. Standards and Particular Labelling Requirements for Food. Wholegrain 40A. Available at: https://sso.agc.gov.sg/SL/SFA1973-RG1#pr40A-. Accessed April 10, 2019.
- Taiwan Food and Drug Administration. FDA Letter No. 0991302590, September 10, 2010. Amendment to FDA Letter No. 1021301154, April 30, 2013 [in Taiwanese].
- Chinese Nutrition Society. 2016 Chinese dietary guidelines [in Chinese]. Available at: http://dg.cnsoc.org/article/04/8a2389fd5520b4f30155be01beb82724.html. Published September 10, 2010. Accessed April 10, 2019.
- FDA (US Food and Drug Administration). Health Claim Notification for Whole Grain Foods. Available at: https://www.fda.gov/food/labelingnutrition/ ucm073639.htm. Published July 1999. Accessed April 8, 2019.
- FDA (US Food and Drug Administration). Health Claim Notification for Whole Grain Foods with Moderate Fat Content. Available at: https://www.fda.gov/Food/ LabelingNutrition/ucm073634.htm. Published December 9, 2003. Accessed April 8, 2019.
- FDA (US Food and Drug Administration). Letter from FDA Center for Food Safety and Applied Nutrition to Johnson Nutrition Solutions, LLC. Available at: https:// www.regulations.gov/document? D=FDA-2008-Q-0270-0010. Published May 22, 2008. Accessed April 8, 2019.
- Oldways Whole Grains Council. Whole grain stamp. Available at: https://whole-grainscouncil.org/whole-grain-stamp. Accessed April 8, 2019.
- AACCI (American Association of Cereal Chemists International). AACCI's Whole Grains Working Group unveils whole grain products characterization. Available at: http://www.aaccnet.org/about/newsreleases/Pages/
  - WholeGrainProductCharacterization.aspx. Published May 21, 2013. Accessed April 9, 2019.
- FSIS/USDA. Food Safety and Inspection Service guideline on whole grain statements on the labeling of meat and poultry products. Available at: https://www.fsis.usda.gov/wps/wcm/connect/6ea06856-e04d-46d7-befd-5b9287c55640/Food\_Guide\_MYPyramid\_Policy.pdf? MOD=AJPERES. Published October 2017. Accessed April 9, 2019.
- Oldways Whole Grains Council. Canadian stamp. Available at: https://wholegrainscouncil.org/whole-grain-stamp/canadian-stamp. Accessed April 9, 2019.
- Germany Federal Ministry of Food and Agriculture. Guidelines for bread and biscuits [in German]. 2005. Available at: https://www.bmel.de/SharedDocs/ Downloads/Ernaehrung/Lebensmittelbuch/LeitsaetzeBrot.html. Accessed April 9, 2019.
- Germany Federal Ministry of Food and Agriculture. Guidelines for pasta [in German]. 1999. Available at: https://www.bmel.de/SharedDocs/Downloads/ Ernaehrung/Lebensmittelbuch/LeitsaetzeTeigwaren.html. Accessed April 9, 2019.
- Ross AB, van der Kamp JW, King R, Healthgrain Forum, et al. Perspective: a definition for whole-grain food products recommendations from the Healthgrain Forum. Adv Nutr. 2017;8:525–531.
- Asp N-G, Health BS. Claims and marketing of food products. Scand J Food Nutr. 2007;51:107–126.
- Les Fabricants de biscuits de gateâux de France. Charter of ethics for French biscuit and cake manufacturers [in French]. 2009. Available at: http://www.alliance7. com/wp-content/themes/alliance7/pdf/charte\_de\_deontologie/charte\_de\_deontologie biscuiterie.pdf. Accessed April 9. 2019.
- Richardson DP. Wholegrain health claims in Europe. Proc Nutr Soc. 2003;62:161–169.
- Brownlee IA, Durukan E, Masset G, et al. An overview of whole grain regulations, recommendations and research across Southeast Asia. Nutrients. 2018;10:752.
- Grains and Legumes Nutrition Council. Whole grain ingredient content claims. Available at: https://www.glnc.org.au/codeofpractice/whole-grain-ingredient-content-claims/. Accessed April 9, 2019.

- Oldways Whole Grains Council. Government guidance. Available at: https://wholegrainscouncil.org/resources/government-guidance. Accessed April 9, 2019.
- Oldways Whole Grains Council. US dietary guidelines and whole grains. Available at: https://wholegrainscouncil.org/whole-grains-101/how-much-enough/us-dietary-guidelines-and-wg. Accessed April 9, 2019.
- Oldways Whole Grains Council. Re: Draft guidance for industry and FDA staff: Whole grain label statements, Docket No. FDA-2006-D-0298-001 (formerly 2006D-0066). Available at: https://wholegrainscouncil.org/sites/default/files/atoms/files/WGCtoFDAJan2014.pdf. Published January 17, 2014. Accessed April 9, 2019.
- FDA (US Food and Drug Administration). Enforcement discretion letter 2013. Petition for a qualified health claim for whole grains and reduced risk of diabetes mellitus type 2 (Docket No. FDA-2012-Q-0242). Available at: http://wayback.archive-it.org/7993/20171115122041/https://www.fda.gov/downloads/Food/ IngredientsPackagingLabeling/LabelingNutrition/UCM368051.pdf. Accessed April 9. 2010.
- Agri-Food and Veterinary Authority, Singapore. A guide to food labelling and advertisements. 2019. Available at: https://www.sfa.gov.sg/docs/default-source/

- tools-and-resources/resources-for-businesses/aguidetofoodlabellingandadvertise-mentsversionjuly2.pdf. Accessed April 9, 2019.
- FSANZ (Food Standards Australia New Zealand). Wholegrains and coronary heart disease: FSANZ consideration of a commissioned review. 2007. Available at: http://www.foodstandards.gov.au/consumer/labelling/nutrition/documents/ FSANZ%20consideration%20of%20Wholegrains%20and%20coronary%20heart %20disease%20\_2\_.pdf. Accessed April 9, 2019.
- EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific opinion on the substantiation of a health claim related to whole grain (ID 831, 832, 833, 1126, 1268, 1269, 1270, 1271, 1431) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA J. 2010;8:1766.
- 43. Health Canada. Summary of Health Canada's assessment of a health claim about whole grains and coronary heart disease. Available at: https://www.canada.ca/en/ health-canada/services/food-nutrition/food-labelling/health-claims/assessments/ assessment-health-claim-about-whole-grains-coronary-heart-disease.html. Published July 2012. Accessed April 9, 2019.