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November 8, 2019

Admiral Brett P. Giroir, MD  
Acting Commissioner  
U.S. Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: FDA-2018-N-2381; Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments**

Dear Admiral Giroir:

The American Institute for Cancer Research (AICR) appreciates the opportunity to provide input to inform the Food and Drug Administration's (FDA's) effort to modernize food standards of identity (SOI). AICR is part of the World Cancer Research Fund (WCRF) network and the leading U.S. authority on the links between diet, weight, physical activity and cancer prevention and survival. Our mission is to champion the latest and most authoritative scientific research from around the world on cancer prevention and survival, relevant to these lifestyle factors, to help people make informed choices to reduce their cancer risk.

AICR supports FDA using its authority to improve diet and address chronic disease through its Nutrition Innovation Strategy. Poor diet is the leading cause of preventable death and disease in the U.S.,<sup>1</sup> and after tobacco use, the leading cancer risk factor.<sup>2</sup> In fact, overweight and obesity increase the risk for 12 types of cancer.<sup>3</sup> Obesity costs the U.S. health care system at least \$147 billion in health care costs,<sup>4</sup> contributing substantially to the unsustainable high costs of health care.

AICR also supports FDA's intent to modernize SOI to promote the availability of healthier food choices. Changes in the marketplace that increase the availability of healthier options, and make it easier for consumers to choose healthier products, are important for promoting dietary improvements across the population. Unlike many consumer-targeted policies, horizontal changes to SOI that improve the healthfulness of the food supply will support all consumers eating a healthier diet, without some of them even realizing it. The goals of FDA's Nutrition Innovation Strategy and SOI modernization are aligned with AICR's mission of using the latest, best available research and evidence on healthy nutrition to prevent cancer and support long-term survivorship.

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<sup>1</sup> GBD 2017 Diet Collaborators. Health effects of dietary risks in 195 countries, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *The Lancet* 2019; 393 (10184): 1958-1972.

<sup>2</sup> WCRF/AICR. *Diet Nutrition, Physical Activity and Cancer: A Global Perspective*. Continuous Update Project Expert Report 2018. Available at [www.wcrf.org/dietandcancer](http://www.wcrf.org/dietandcancer)

<sup>3</sup> WCRF/AICR, 2018.

<sup>4</sup> Finkelstein EA1, Trogon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer- and service-specific estimates. *Health Aff (Millwood)*. 2009 Sep-Oct;28(5):w822-31. doi: 10.1377/hlthaff.28.5.w822.

We agree with FDA that horizontal modernization of SOI is more efficient than separate rulemaking to update each of the more than 200 SOI as they become out of date. Updates are needed to align SOI with current nutrition science and to help FDA address the increasing rates of obesity and related chronic disease burden. Horizontal updates will also allow FDA to more effectively update the regulations as new research becomes available because a smaller number of updates would be needed.

The remainder of our comment letter provides high-level recommendations for the principles that FDA should utilize when considering horizontal changes to modernize SOI and specific recommendations for changes to the SOI for grain-based products.

## General Principles for Modernizing SOI

**To promote improved nutrition and health, AICR recommends that any changes to the SOI, and particularly horizontal changes, align with AICR’s [Cancer Prevention Recommendations](#)<sup>5</sup> and the most recent edition of the *Dietary Guidelines for Americans* (DGA).<sup>6</sup>**

AICR’s Cancer Prevention Recommendations are based on comprehensive analyses and syntheses of the global scientific research on the roles of diet, weight, and physical activity in cancer risk and outcomes. AICR, and its umbrella organization WCRF International, publish these analyses and evidence syntheses as Continuous Update Project (CUP) Reports and Expert Reports, including a series on specific cancer sites that we have published over the past 10 years.<sup>7</sup> Most recently, AICR/WCRF published its Third Expert Report in May 2018, *Diet, Nutrition, Physical Activity and Cancer: A Global Perspective*.<sup>8</sup> The evidence for each exposure was rigorously assessed through systematic literature reviews, meta-analyses, and deliberation by an expert panel. AICR’s diet-related Cancer Prevention Recommendations include:

- Be a healthy weight.
- Eat a diet rich in whole grains, vegetables, fruit, and beans.
- Limit consumption of “fast foods” and other processed foods high in fat, starches, or sugars.
- Limit consumption of red and processed meat.
- Limit consumption of sugar-sweetened drinks.
- Do not use supplements for cancer prevention.
- For mothers: breastfeed your baby, if you can.

In addition to the specific recommendations above, AICR’s research supports consuming minimally-processed foods and beverages that are nutrient-dense.<sup>9</sup> Therefore, any changes to the SOI should incentivize production of less-processed and more nutrient-dense versions of the food or beverage. For example, horizontal changes to SOI should encourage manufacturers to produce whole grain bakery

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<sup>5</sup> AICR. Cancer Prevention Recommendations. 2018. Available at <https://www.aicr.org/reduce-your-cancer-risk/recommendations-for-cancer-prevention/index.html>.

<sup>6</sup> U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA). *2015-2020 Dietary Guidelines for Americans*. 8<sup>th</sup> Edition. December 2015. Available at <https://health.gov/dietaryguidelines/2015/guidelines/>.

<sup>7</sup> More information about AICR/WCRF’s research methodology, systematic literature reviews, and reports is available at [www.wcrf.org/dietandcancer](http://www.wcrf.org/dietandcancer).

<sup>8</sup> WCRF/AICR, 2018.

<sup>9</sup> WCRF/AICR, 2018.

products, cereal flours, and macaroni and noodle products in place of those made with refined grains, which have healthful components removed during processing.

While AICR’s Cancer Prevention Recommendations focus specifically on strategies to prevent cancer, they are largely consistent with the 2015-2020 DGA, which provide dietary recommendations for promoting overall health across the population. The DGA are also intended to serve as the basis of all federal policies, programs, and communications related to diet and health, including those of FDA.

Cancer is the second leading cause of death in the U.S.,<sup>10</sup> and poor diet, physical inactivity, and excess weight are the leading cancer risk factors for Americans who do not use tobacco products.<sup>11</sup> Therefore, policies that support adherence to AICR’s guidelines are likely to promote overall health. Indeed, research has shown that following AICR’s guidelines for diet, weight, and physical activity reduces cancer risk<sup>12,13,14,15</sup> and overall mortality.<sup>16,17,18</sup>

FDA should consider whether changes to SOI contribute to public health goals and will support Americans eating a diet that is consistent with the most recent DGA and AICR’s recommendations.

**Changes to SOI should align with and build on other FDA initiatives that support the availability of healthier foods in the marketplace and consumers making healthier choices, including updates to the “healthy” claim and to the Nutrition Facts label.**

To promote consistency across the regulatory landscape, FDA should align updates to SOI with other related FDA initiatives. For example, FDA has expressed its intention to update the criteria for the “healthy” claim to align with current nutrition science and federal dietary guidelines. The agency has also finalized rulemaking for the updated Nutrition Facts label, and the new label must be on most food packages by January 2020. AICR is helping to educate consumers and health professionals about the

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<sup>10</sup> Murphy SL, Xu J, Kochanek KD, and Arias E. *Mortality in the United States, 2017*. NCHS Data Brief No. 328. November 2018. Available at <https://www.cdc.gov/nchs/products/databriefs/db328.htm#Summary>.

<sup>11</sup> WCRF/AICR, 2018.

<sup>12</sup> Romaguera D, Vergnaud AC, Peeters PH et al. Is concordance with World Cancer Research Fund/American Institute for Cancer Research guidelines for cancer prevention related to subsequent risk of cancer? Results from the EPIC study. *Am. J. Clin. Nutr.* 2012; 96(1):150–163.

<sup>13</sup> Romaguera D, Gracia-Lavedan E, Molinuevo A et al. Adherence to nutrition-based cancer prevention guidelines and breast, prostate and colorectal cancer risk in the MCC-Spain case-control study. *Int. J. Cancer* 2017; 141(1):83–93.

<sup>14</sup> Makarem N, Lin Y, Bandera E V et al. Concordance with World Cancer Research Fund/American Institute for Cancer Research (WCRF/AICR) guidelines for cancer prevention and obesity-related cancer risk in the Framingham Offspring cohort (1991-2008). *Cancer Causes Control* 2015; 26(2):277–86.

<sup>15</sup> Lavalette C, Adjibade M, Srouf B et al. Cancer-Specific and General Nutritional Scores and Cancer Risk: Results from the Prospective NutriNet-Sante Cohort. *Cancer Res.* 2018; 78(15):4427–4435.

<sup>16</sup> Vergnaud A-C, Romaguera D, Peeters PH et al. Adherence to the World Cancer Research Fund/American Institute for Cancer Research guidelines and risk of death in Europe: results from the European Prospective Investigation into Nutrition and Cancer cohort study. *Am. J. Clin. Nutr.* 2013; 97(5):1107–20.

<sup>17</sup> Hastert TA, Beresford SAA, Sheppard L, White E. Adherence to the WCRF/AICR cancer prevention recommendations and cancer-specific mortality: results from the Vitamins and Lifestyle (VITAL) Study. *Cancer Causes Control* 2014; 25(5):541–552.

<sup>18</sup> Lohse T, Faeh D, Bopp M, Rohrmann S. Adherence to the cancer prevention recommendations of the World Cancer Research Fund/American Institute for Cancer Research and mortality: a census-linked cohort. *Am. J. Clin. Nutr.* 2016; 104(3):678–685.

updated label. To promote consistency in requirements for manufacturers and messaging for consumers, horizontal changes to SOI should align with other nutrient content and labeling requirements.

### **FDA should consider potential unintended consequences of changes to SOI.**

While AICR supports FDA's goal of changing SOI to promote the production of healthier products, it will be important for the agency to consider potential unintended consequences of horizontal updates. For example, changes to the SOI for grain-based products could promote the addition of whole grains (currently under-consumed by Americans) to primarily refined grain-based products. However, these changes could have the unintended consequence of encouraging consumers to purchase grain-based products that include only a small proportion of whole grain instead of 100% whole grain breads and cereals. As another example, allowing the use of sodium and sugar substitutes in highly-processed foods could lead to increased consumption of highly-processed foods high in fats, starches, and/or calories that consumers erroneously perceive to be healthful. Increased consumption of these foods and beverages could take the place of less-processed and truly healthy foods such as fruits, vegetables, and whole grains. FDA should fully consider how horizontal changes to SOI could have broader effects on food in the marketplace and consumer diets both within and across food categories.

### **Changes to SOI for Whole Grains**

#### **FDA should consider changes to SOI for grain products to promote increased consumption of whole grains and reduce consumer confusion regarding the whole grain content of grain-based foods.**

As noted previously, AICR's Cancer Prevention Recommendations call for increased consumption of whole grains.<sup>19</sup> The Dietary Guidelines also recommend substituting whole grains for some refined grains and making half of one's grain intake whole grains.<sup>20</sup> AICR's research has shown that whole grains decrease the risk of colorectal cancer.<sup>21</sup>

Despite these health benefits, Americans of all ages are consuming too few whole grains and too many refined grains.<sup>22</sup> Consumer surveys suggest that lack of whole grain products in the marketplace and consumer confusion about which products are whole grain may be contributing to the low levels of consumption. A nationally representative survey of 1,500 consumers conducted in 2018 by the Oldways Whole Grain Council found that 64% of consumers say they are making at least half of their grains whole and nearly half of this number say they are almost always choosing whole grains.<sup>23</sup> The stark contrast between the number of consumers who say they choose grains compared with what Americans are actually eating suggests that confusion exists about whether products are comprised of whole grains or

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<sup>19</sup> AICR, 2018.

<sup>20</sup> HHS and USDA, 2015.

<sup>21</sup> WCRF/AICR, 2018.

<sup>22</sup> HHS and USDA. Figure 2-5. Average Whole & Refined Grain Intakes in Ounce-Equivalents per Day by Age-Sex Groups, Compared to Ranges of Recommended Daily Intake for Whole Grains & Limits for Refined Grains. *2015-2020 Dietary Guidelines for Americans*. 8<sup>th</sup> Edition. December 2015. Available at <https://health.gov/dietaryguidelines/2015/guidelines/>.

<sup>23</sup> Oldways Whole Grain Council. Our 2018 Consumer Survey Results Are Here... And the Momentum Toward Whole Grains is Stronger Than Ever. September 2018. Available at <https://wholegrainscouncil.org/blog/2018/09/our-2018-consumer-survey-results-are-here-and-momentum-toward-whole-grains-stronger>.

only partially so. Currently, for products that are made with both whole grains and refined grains, there is no way for the consumer to know what percentage of the product is whole versus refined grain, and consumers may inadvertently be misled by claims such as “made with whole grain” or labeling that indicates a product is made with wheat flour or is multi-grain or the product or its packaging is brown in color. Forthcoming research from researchers at Tufts University is further exploring concepts such as these.

**To reduce consumer confusion and encourage production of grain-based products with whole grains, FDA should require that products that makes a whole grain claim on the label state the percent whole grain that is in the product.**

This would likely incentivize the inclusion of increased amounts of whole grains in products that contain a mix of whole and refined grains. Any other changes to the SOI for bakery products, cereal flours and related products, and macaroni and noodle products should focus on increasing consumption of 100% whole grain products, increasing the proportion of grain that is whole grain in products that contain both whole and refined grains, and reducing consumer confusion regarding which products are and are not whole grain.

## **Consumer Education**

**Consumer education should accompany any changes to SOI.**

Consumers should have a right to know, and many are interested to learn,<sup>24</sup> what is in their food. Also, being “creatures of habit”, consumers may purchase the same product repeatedly without closely examining the package to see if the product has changed since their last purchase. Therefore, consumer education both on and off the label about changes to the food are important to ensure consumers are aware of any changes to the product and how the revised product may benefit them.

As noted previously, AICR is supporting FDA in educating consumers and health professionals about the updates to the Nutrition Facts label. AICR would be pleased to work with FDA to educate these stakeholders about any changes to the grain standards that increase whole grain consumption and other changes that promote consuming a diet more closely aligned with AICR’s Cancer Prevention Recommendations.

## **Conclusion**

In conclusion, we appreciate the opportunity to submit comments to inform FDA’s efforts to modernize food standards of identity. As the pressing diet-related issues of the day shift from food adulteration to risk of chronic disease, we hope that FDA will continue to consider how it can use its authority to promote the production of foods that increase healthy options in the marketplace and support consumers in making more informed and more healthful choices.

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<sup>24</sup> Nielsen. What Food-Related Causes Do U.S. Consumers Care About Today? *Insights*. March 2019. Available at <https://www.nielsen.com/us/en/insights/article/2019/what-food-related-causes-do-us-consumers-care-about-today/>.

If we can provide any additional information, please contact Deirdre McGinley-Gieser, AICR's Senior Vice President of Programs, at [d.mcginley-gieser@aicr.org](mailto:d.mcginley-gieser@aicr.org) or 703-237-0159.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Kelly B. Browning', with a long horizontal flourish extending to the right.

Kelly B. Browning  
Chief Executive Officer  
American Institute for Cancer Research