

Comments from the American Institute for Cancer Research
Re: FDA-1995-N-0062; Food Standards; General Principles and Food Standards
Modernization; Reopening of the Comment Period
July 20, 2020

The American Institute for Cancer Research (AICR) is grateful for the opportunity to provide input on the Food and Drug Administration's (FDA's) effort to modernize food standards of identity (SOI). We previously [submitted comments](#) on this topic in November 2019 to express our support for FDA's role in setting principles for food standards and to share our research and recommendations on this topic. We would like to reiterate the key points included in those comments as well as respond directly to some of the questions outlined in the request for public comments.

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 continues to support FDA's Nutrition Innovation Strategy (NIS) and the opportunity that it provides to reduce and prevent chronic disease through diet. Modernizing SOI is a particularly important component of the strategy and could help to increase the availability of healthful food options, promote transparency and consumer protection, and encourage healthier food purchases. Given that poor diet is the leading cause of preventable death and disease in the U.S.,¹ and after tobacco use, the leading cancer risk factor,² improving diet quality among Americans is vital.

AICR asks that FDA align the proposed rule with the latest nutrition science and with the current *Dietary Guidelines for Americans (DGA)*. Additionally, the rule should incentivize food manufacturers to produce minimally processed, nutrient-rich foods to assist consumers in achieving a healthy diet.

In addition, given the link between whole grain consumption and the decreased risk of colorectal cancer,³ we ask that FDA amend SOI for grain products in a way that ensures products make clear the amount of whole grains as a percentage of total grains that a product contains. Some food companies have added artificial ingredients and colors, such as caramel coloring, to have products appear as though they contain a substantial amount of whole grains. Additionally, labels and nutrition information should indicate the amount of whole grains helping consumers

¹ 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.

² WCRF/AICR. *Diet Nutrition, Physical Activity and Cancer: A Global Perspective*. Continuous Update Project Expert Report 2018. Available at www.wcrf.org/dietandcancer.

³ WCRF/AICR, 2018.

identify a true 100% whole grain product versus a product containing mostly refined grains. Research has shown that consumers are often confused about the whole grain content of grain products and unable to discern the relative healthfulness of grain products given nutrition information and product labels.⁴ Providing this information in a clear and simple manner may promote whole grain consumption, which is recommended by the Dietary Guidelines.

In addition to sharing our research and general comments of support for modernizing SOI, we address some of the specific questions that FDA has included in the request for public comments.

Should FDA finalize the proposed rule? Why or why not?

AICR requests that FDA finalize and implement the proposed rule as soon as possible in a way that increases healthy food options and benefits public health. We also ask that consumer education be a part of the implementation plan and that nongovernmental consumer education and advocacy organizations be included in the dissemination of information to consumers. As stated previously, finalizing the rule will help consumers make more informed food purchasing decisions and possibly lead them to choose healthier food items.

Are there general FDA principles that should be added, eliminated, revised, or retained?

We recommend that FDA aim to make the identity of foods more clear and understandable to consumers. Terms that assist consumers in discerning potential health benefits should also be made clear to consumers. For example, the word “grain” or “wheat” may appear on a food label for a product made of mostly refined grains. However, the full nutritional benefits of these ingredients are only achieved when the grain component of the food contains 100% whole grains or whole wheat.

Principle 4 could be revised and strengthened to ensure that if there are changes to food standards, they do not decrease the nutritional quality of the food supply. Additionally, principles should direct food manufacturers to use truthful nutrition claims and labels to limit consumer confusion.

What specific revisions should FDA make to the proposed rule's principles or framework to better reflect our modernization goals of:

Providing flexibility to produce more healthful foods?

It is imperative that the principles promote transparency and good nutrition. Food manufacturers should be provided reasonable flexibility and encouraged to produce more healthful foods and beverage items. Principle 4 states that, with respect to nutrition, “food does not appear to be better or of a greater value than it is.” This principle should be utilized to improve the nutritional quality of food items, promoting a more healthful diet. Declarations of the amounts of certain healthful ingredients such as whole grains, fruits, or vegetables would provide for more transparency and information to drive consumer purchasing decisions.

⁴ Wilde P, Pomeranz JL, Lizewski LJ, and Zhang FF. Consumer Confusion about Whole Grain Content and Healthfulness in Product Labels: A Discrete Choice Experiment and Comprehension Assessment. *Public Health Nutrition*. In press.

How should FDA weigh the general principles?

The proposed rule stated that the first four principles were the most fundamental to addressing consumer economic protection and therefore, FDA would consider eliminating a food standard if it is inconsistent with any of these four principles.

Please explain whether you agree with this framework.

If you do not agree, what principles should FDA consider when deciding whether to eliminate a food standard?

In addition to the first four principles, we ask that you also incorporate principles 12 and 13 as fundamental principles. Principle 12 speaks directly to protecting consumers and ensuring consumers are not misled by food or labeling terms. Principle 13 ensures that ingredients and functional uses of foods are consistent with other food standards. Incorporating these principles as fundamental will protect consumers and ensure appropriate claims based on ingredients and their functional uses.

What explanation is needed to provide more clarity, certainty, or context regarding: How FDA will consider the principles when evaluating whether to eliminate, revise, or establish a new food standard?

As noted previously, SOI should protect consumers' rights to transparent information about the foods they choose to feed themselves and their families. This principle, above all else, should be at the heart of any effort to eliminate, revise, or establish a new food standard.

What additional information should FDA consider when evaluating the costs, benefits, and estimates of the annual reporting burden of the proposed rule?

First and foremost, as a consumer protection agency, FDA should consider the health benefits and potential cost savings for society and the overall health care system of finalizing and implementing the proposed rule. Poor diet has a profound impact on the quality of life of Americans as well as a heavy cost burden. Obesity costs the U.S. health care system at least \$147 billion per year,⁵ contributing substantially to the unsustainable high costs of health care. The benefit of improving the health of Americans outweighs the cost.

Conclusion

While we encourage FDA to finalize and implement the proposed rule regarding modernizing SOI, we ask that the final rule be well aligned with public health and nutrition priorities. We also ask that FDA provide adequate oversight and guidance to the food industry to comply with the regulations. As with any changes to the food marketplace, consumer education will be an integral part of implementation. Improving and updating SOIs has the potential to be an impactful nutrition policy to improve the health of consumers. It is an integral part of the overall NIS and we encourage FDA to provide the necessary attention and resources to this topic along with the other components of the strategy.

If we can provide any additional information, please contact Deirdre McGinley-Gieser, AICR's Senior Vice President of Programs and Strategic Planning, at d.mcginley-gieser@aicr.org or 703-237-0159.

⁵ Finkelstein EA, 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.