January 24, 2023

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-2335 for "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy.'"

The American Cancer Society (ACS) and the American Cancer Society Cancer Action Network (ACS CAN) appreciate the opportunity to comment on the proposed rule to update the definition for the implied nutrient content claim "healthy" to be consistent with current nutrition science and Federal dietary guidance.

ACS is the leading cancer-fighting organization with a vision to end cancer as we know it, for everyone. For more than 100 years, we have been the only organization improving the lives of people with cancer and their families through advocacy, research, and patient support, to ensure that everyone has an opportunity to prevent, detect, treat, and survive cancer. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden.

Background

Cancer is the second leading cause of death, exceeded only by heart disease, in both men and women in the United States.[1] The burden of cancer extends beyond mortality. Individuals who are affected by a diagnosis of cancer may experience physical suffering, distress, and diminished quality of life associated with disease-related symptoms, diagnostic procedures, cancer therapies, and long-term and late adverse effects of treatment. Moreover, quality of life can also be substantially impacted for family, caregivers, and friends of patients with cancer.

For most Americans who do not use tobacco, the most important cancer risk factors that can be changed are diet, body weight, physical activity, and alcohol intake. Unhealthful diet, excess body

[1] American Cancer Society. Cancer Facts & Figures 2022. Atlanta: American Cancer Society; 2022

weight, alcohol consumption and physical inactivity together account for at least 18.2% of cancer cases and 15.8% of cancer deaths in the U.S., the second highest percentages for any risk factor (after cigarette smoking) in both men and women.[2] Excess body fat causes cancers of the breast (postmenopausal), endometrium, kidney (renal cell), esophagus (adenocarcinoma), colon, rectum, gastric cardia, liver, gallbladder, pancreas, ovary, thyroid, myeloma and meningioma.[3,4] There is some evidence that excess body fat probably increases the risk of advanced, high-grade, or fatal prostate cancer and cancers of the oral cavity, pharynx, and larynx.[5] There is growing evidence that adult weight gain is associated with the risk of several types of cancer, including cancers of the gallbladder, thyroid, pancreas, postmenopausal ovary, postmenopausal endometrium, and postmenopausal breast, as well as multiple myeloma.[6,7,8,9,10] Sustained weight loss, even modest amounts, is associated with lower breast cancer risk among women over 50 years of age.[11]

ACS Guidelines

Poor diet, including the consumption of red and processed meats, refined carbohydrates, and sugary drinks, increases cancer risk both directly and indirectly through excess body weight. In 2020, ACS published an updated *Guideline for Diet and Physical Activity for Cancer Prevention*[12] that reflects the latest evidence, most of which is based on observational epidemiological studies, especially prospective cohort studies, published since the last update in 2012. The guidelines were developed by a national panel of experts in cancer research, prevention, epidemiology, public health, and policy. The ACS guideline emphasizes the importance of an overall healthy dietary pattern, comprised of a variety of vegetables, whole fruit, and whole grains. The guidelines also recommend limiting or eliminating red and processed meat, sugary drinks, refined grains and highly-processed foods, in reducing the risk of cancer and boosting overall health. Consistent with the DGAs 2020-2025 edition, the ACS recommends following a healthy eating pattern at all ages. One exception is that for cancer

[2] Islami F, Goding Sauer A, Miller KD, et al. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. CA Cancer J Clin. 2018;68: 31-54.
[3] International Agency for Research on Cancer. IARC Handbooks of Cancer Prevention: Weight Control and Physical Activity. Vol 6. World Health Organization/ IARC; 2002
[4] Lauby-Secretan B, Scoccianti C, Loomis D, et al. Body fatness and cancer—viewpoint of the IARC Working Group. N Engl J Med. 2016;375:794-798.
[5] World Cancer Research Fund/American Institute for Cancer Research. Diet, Nutrition, Physical Activity and Cancer: A Global Perspective. Continuous Update Project. The Third Expert Report. American Institute for Cancer Research; 2018. Accessed July 21, 2019. wcrf.org/dietandcancer
[6] Campbell PT, Newton CC, Kitahara CM, et al. Body size indicators and risk of gallbladder cancer: a pooled analysis of individual-level data from 19 prospective cohort studies. Cancer Epidemiol Biomarkers Prev. 2017;26:597-606.
[7] Kitahara CM, McCullough ML, Franceschi S, et al. Anthropometric factors and thyroid cancer risk by histological subtype: pooled analysis of 22 prospective studies. Thyroid. 2016;26:306-318.
[8] Genkinger JM, Kitahara CM, Bernstein L, et al. Central adiposity, obesity during early adulthood, and pancreatic cancer mortality in a pooled analysis of cohort studies. Ann Oncol. 2015;26: 2257-2266
[9] Keum N, Greenwood DC, Lee DH, et al. Adult weight gain and adiposity-related cancers: a dose-response meta-analysis of prospective observational studies. J Natl Cancer Inst. 2015;107:djv088.
[10] Teras LR, Kitahara CM, Birmann BM, et al. Body size and multiple myeloma mortality: a pooled analysis of 20 prospective studies. Br J Haematol. 2014;166: 667-676.
[11] Teras LR, Patel AV, Wang M, et al. Sustained weight loss and risk of breast cancer in women >/=50 years: a pooled analysis of prospective data. J Natl Cancer Inst 2019.
[12] Rock, CL et al. American Cancer Society guideline for diet and physical activity for cancer prevention. CA Cancer J Clin 2020; 0:1-27.

prevention, ACS recommends it is best not to drink alcohol,[13] whereas the DGAs currently suggest limiting alcohol intake. Recent research has found that non-smoking adults who followed the ACS guidelines for weight control, diet, physical activity, and alcohol consumption lived longer and had a lower risk of dying from cancer and cardiovascular disease.[14,15]

Diet, body weight and physical activity are also important factors in the risk of recurrence and mortality among cancer survivors. There are more than 18 million cancer survivors in the U.S.[16] Although advances in cancer diagnosis and treatment have improved clinical outcomes, the inability to maintain a healthy diet because of cancer symptoms and treatment-related side effects is common and can negatively impact overall clinical outcomes. To reduce risk for recurrence and mortality among cancer survivors, the ACS also recently released *Guidelines for Nutrition and Physical Activity Guideline for Cancer Survivors*,[17] which includes nutrition and physical activity recommendations during cancer care and following recovery from treatment. These guidelines provide recommendations for anthropometric parameters, physical activity, diet, and alcohol intake for reducing recurrence and cancer-specific mortality, and overall mortality. To learn how modifiable factors might contribute to cancer recurrence or survival, the basis of these guidelines relied on sources of evidence that included systematic literature reviews, meta-analyses, pooled analyses of cohort studies, and large randomized clinical trials published since 2012. Researchers from the ACS, as well as experts from across the U.S. developed these new evidence-based recommendations for use by health care providers, cancer survivors, and their families.

Recommendations

We support the revision of the criteria for the "healthy" labeling claim in order to better align with the current scientific evidence. Proposed revisions include incorporating food group requirements and also lowering the amounts of added-sugar, sodium, and saturated fat. A "healthy" labeling claim bears the responsibility to have stringent criteria, so that individuals are not steered toward purchasing foods with a "small amount of healthy food," while also containing other less healthy ingredients. A mandatory front-of-package label that ranks foods according to healthfulness would be a superior method to encourage consumers to select foods higher in nutrient density and lower in energy density that are consistent with dietary guidelines; this should be pursued in future FDA efforts. It is important for FDA to consider the limitations of a "healthy" labeling claim, including issues related to serving size and that certain foods tend to be overconsumed.

[13] Rock, CL et al. American Cancer Society guideline for diet and physical activity for cancer prevention. CA Cancer J Clin 2020; 0:1-27.
[14] Kohler LN, Garcia DO, and Harris RB. Adherence to Diet and Physical Activity Cancer Prevention Guidelines and Cancer Outcomes: A Systematic Review. Cancer Epidemiol Biomarkers Prev 2016; 25(7): 1018-28.
[15] McCullough ML, Patel AV, Kushi LH, et al. Following Cancer Prevention Guidelines Reduces Risk of Cancer, Cardiovascular Disease, and All-Cause Mortality. Cancer Epidemiol Biomarkers Prev 2011; 20(6): 1089-97.
[16] Miller, K.D., Nogueira, L., Devasia, T., Mariotto, A.B., Yabroff, K.R., Jemal, A., Kramer, J. and Siegel, R.L. (2022), Cancer treatment and survivorship statistics, 2022. CA A Cancer J Clin. https://doi.org/10.3322/caac.21731.
[17] Rock, CL, Thomson, CA, Sullivan, KR, Howe, CL, Kushi, LH, Caan, BJ, Neuhouser, ML, Bandera, EV, Wang, Y, Robien, K, Basen-Engquist, KM, Brown, JC, Courneya, KS, Crane, TE, Garcia, DO, Grant, BL, Hamilton, KK, Hartman, SJ, Kenfield, SA, Martinez, ME, Meyerhardt, JA, Nekhlyudov, L, Overholser, L, Patel, AV, Pinto, BM, Platek, ME, Rees-Punia, E, Spees, CK, Gapstur, SM, McCullough, ML. American Cancer Society nutrition and physical activity guideline for cancer survivors. CA Cancer J Clin. 2022. https://doi.org/10.3322/caac.21719.

Ultra-processed foods, as defined by the NOVA classification system, should not be permitted to carry the "healthy" labeling claim. These foods are typically created using industrial techniques and processes to chemically modify the original food product, and include ingredients such as varieties of sugars, modified oils, and processed proteins, as well as additives to enhance color, texture, and to increase palatability. NOVA classifies all foods into four groups.[18] The group classified as ultra-processed foods is made up of snacks, drinks, readymade meals and many other product types formulated mostly or entirely from substances extracted from foods or derived from food constituents. Ultra-processed foods are made possible by use of many types of additives, including those that imitate or enhance the sensory qualities of foods or culinary preparations made from foods.[19] Colors, flavorings, emulsifiers, and other food additives are commonly added to these foods to make them more palatable.[20]

Current evidence suggests that consumption of ultra-processed foods may be associated with weight gain,[21] cardiovascular disease,[22] and cancer risk.[23] Diets rich in ultra-processed foods are higher in energy density and disease-promoting nutrients. Examples of ultra-processed foods include mass-produced cookies, cakes, some breakfast cereals made with refined grains and sugars, chicken "nuggets," powdered and packaged "instant" soups, noodles and desserts, candies and sugary drinks.[24,25]

These specific examples of ultra-processed foods which could fall under individual food products or combination foods frequently contain higher amounts of sugar, saturated fat, and sodium so the proposed rule's limitations on these ingredients may likely prevent them from using the "healthy" labeling claim. However, we are concerned about other ingredients often contained in these foods and overall healthfulness of the products. We are also concerned that food manufacturers may attempt to revise their formulations on these and other kinds of ultra-processed foods to meet the

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[18] Monteiro CA, Cannon G, Moubarac JC, Levy RB, Louzada MLC, Jaime PC. The UN Decade of Nutrition, the NOVA food classification and the trouble with ultra-processing. Public Health Nutr. 2018 Jan;21(1):5-17. doi: 10.1017/S1368980017000234. Epub 2017 Mar 21. PMID: 28322183.

[19] Poti JM, Mendez MA, Ng SW, Popkin BM. Is the degree of food processing and convenience linked with the nutritional quality of foods purchased by US households? Am J Clin Nutr. 2015 Jun;101(6):1251-62. doi: 10.3945/ajcn.114.100925. Epub 2015 May 6. PMID: 25948666; PMCID: PMC4441809.

[20] Monteiro, C.A., Cannon, G., Lawrence, M., Costa Louzada, M.L. and Pereira Machado, P. 2019. Ultra-processed foods, diet quality, and health using the NOVA classification system. Rome, FAO.

[21] Cordova R, Kliemann N, Huybrechts I, Rauber F, Vamos EP, Levy RB, Wagner KH, Viallon V, Casagrande C, Nicolas G, Dahm CC, Zhang J, Halkjær J, Tjønneland A, Boutron-Ruault MC, Mancini FR, Laouali N, Katzke V, Srour B, Jannasch F, Schulze MB, Masala G, Grioni S, Panico S, van der Schouw YT, Derksen JWG, Rylander C, Skeie G, Jakszyn P, Rodriguez-Barranco M, Huerta JM, Barricarte A, Brunkwall L, Ramne S, Bodén S, Perez-Cornago A, Heath AK, Vineis P, Weiderpass E, Monteiro CA, Gunter MJ, Millett C, Freisling H. Consumption of ultra-processed foods associated with weight gain and obesity in adults: A multi-national cohort study. Clin Nutr. 2021 Sep;40(9):5079-5088. doi: 10.1016/j.clnu.2021.08.009. Epub 2021 Aug 21. PMID: 34455267.

[22] Srour B, Fezeu LK, Kesse-Guyot E, Allès B, Méjean C, Andrianasolo RM, Chazelas E, Deschasaux M, Hercberg S, Galan P, Monteiro CA, Julia C, Touvier M. Ultra-processed food intake and risk of cardiovascular disease: prospective cohort study (NutriNet-Santé). BMJ. 2019 May 29;365:l1451. doi: 10.1136/bmj.l1451. PMID: 31142457; PMCID: PMC6538975.

[23] Fiolet T, Srour B, Sellem L, Kesse-Guyot E, Allès B, Méjean C, Deschasaux M, Fassier P, Latino-Martel P, Beslay M, Hercberg S, Lavalette C, Monteiro CA, Julia C, Touvier M. Consumption of ultra-processed foods and cancer risk: results from NutriNet-Santé prospective cohort. BMJ. 2018 Feb 14;360:k322. doi: 10.1136/bmj.k322. PMID: 29444771; PMCID: PMC5811844.

[24] Monteiro C, Cannon G, Lawrence M, Louzada ML, Machado P. FAO. Ultra-processed foods, diet quality, and health using the NOVA classification system. 2019.

[25] Poti JM, Mendez MA, Ng SW, Popkin BM. Is the degree of food processing and convenience linked with the nutritional quality of foods purchased by US households? *Am J Clin Nutr 2015*;101(6):1251-62 doi 10.3945/ajcn.114.100925.

proposed rule's criteria and to be able to promote these types of foods as "healthy." For example, other individual food products containing vegetable and fruit powders, grains, oil-based spreads or oil-based dressings and combination foods can also contain ultra-processed foods. We urge FDA to take steps to prevent loopholes that may result in ultra-processed foods being eligible to use the "healthy" labeling claim. Some of these ultra-processed foods may meet the proposed rule's limits for added sugar, sodium, and saturated fat, but still contain refined grains, artificial sweeteners, and other additives. Specific comments follow.

Raw, Whole Fruits and Vegetables

We agree that whole fruits and vegetables should automatically qualify for the use of the claim, as they are rich in fiber, vitamins, minerals, and other phytochemicals. ACS recommends consuming a variety of vegetables—dark green, red and orange, fiber-rich legumes (beans and peas), and others; as well as fruits, especially whole fruits with a variety of colors. The evidence that non-starchy vegetables lower the risk of aerodigestive cancers (mouth, pharynx, larynx, nasopharynx, esophagus, lung, stomach and colorectal) is "probable." Carotenoid-rich vegetables and fruit are associated with lower risk of harder-to-treat estrogen receptor-negative breast tumors.[26,27] In addition, fruits and vegetables contribute to healthy dietary patterns associated with lower cancer risk and mortality.

Individual Food Products

Vegetable and Fruit Food Products

Fresh, frozen, canned and dried intact vegetables and fruit, and 100% vegetable juices that meet the sugar, sodium and saturated fat limit should be able to carry the "healthy" labeling claim. However, we do not support the "healthy" labeling claim being applied to 100% fruit juice as it may imply "more is better," or "unlimited is OK," which is not the case. While 100% fruit juice in small amounts may offer a way for people to obtain important nutrients and contribute to dietary recommendations for fruit intake, 100% fruit juice is likely to be overconsumed, considering its high palatability and accessibility. In addition, the liquid form of 100% juice does not elicit the same satiety response compared eating whole fruit. Given that consumers are more likely to choose products that have a nutrition-related claim on the packaging, the presence of a "healthy" labeling claim may promote excess consumption of 100% fruit juice, which could contribute large amounts of unnecessary calories and sugar to the diet. Furthermore, it is possible that labeling 100% fruit juice as "healthy" may cause it to replace fruit in the diet. Whole fruit is the preferred way to meet the recommendation for fruit intake.

Similarly, fruit puree and fruit paste, such as that added to yogurts, jams, and bakery items should not carry the "healthy" labeling claim as they are seldom consumed independently. We agree with the exclusion of vegetable and fruit powders, which are often used to create ultra-processed snack foods such as vegetable sticks, puffs and other snack foods high in fat and salt, and low in dietary fiber. In contrast, whole fruit and vegetables, whole grains, nuts and seeds are rich in dietary fiber. In addition,

[26] Eliassen AH, Liao X, Rosner B, Tamimi RM, Tworoger SS, Hankinson SE. Plasma carotenoids and risk of breast cancer over 20 y of follow-up. *Am J Clin Nutr*. 2015;101(6):1197-1205.

[27] Bakker MF, Peeters PH, Klaasen VM, et al. Plasma carotenoids, vitamin C, tocopherols, and retinol and the risk of breast cancer in the European Prospective Investigation into Cancer and Nutrition cohort. *Am J Clin Nutr*. 2016;103(2):454-464.

these foods are associated with a lower risk of weight gain, overweight, or obesity.[28] Approximately 10% of deaths from colorectal cancer are estimated to be attributed to a diet low in dietary fiber.[29]

Grain Products

For grain products to qualify for the "healthy" labeling claim, they should be required to be nearly 100% whole grain and minimally processed. The proposed ¾ ounce whole grain equivalent must not be a minimum.

In addition, whole grains are under-consumed in the population, potentially in part due to confusing labeling of grain foods. Many whole grain products that tout their whole grain content list white flour as the first ingredient and contain little whole grain. Misleading advertising is confusing to the public. We therefore strongly encourage the FDA to improve labeling of whole grains to improve transparency for consumers, and also promote healthful reformulation of grain-containing foods. Whole grain products that meet the criteria for the "healthy" labeling claim should be required to prominently and uniformly disclose the percentage of both whole grains and refined grains.

Protein Foods

For beans, peas and soy products, we recommend excluding powders derived from these protein rich vegetables as they are typically used to create ultra-processed foods. We support the decision to include nuts and seeds under the "healthy" labeling claim and support the proposed rule including the provision that the saturated fat content of nuts and seeds does not contribute toward the overall saturated fat limit for nut and seed products.

Oils

We only support including 100% oils to qualify for the "healthy" labeling claim that meet the adjusted oil criteria to encourage their use during the cooking process instead of saturated fats. We do not support oil-based spreads and oil-based dressings using the "healthy" labeling claim as we have concerns that many of these products contain ultra-processed or highly-processed oil or other ingredients.

Combination Foods

We recommend the agency consider the potential unintended consequences of allowing combination foods that typically also include less healthy ingredients to bear the "healthy" labeling claim. We have concerns that some combination foods that meet the limits for added sugar, sodium, and saturated fat, but still contain refined grains, artificial sweeteners, and other additives, will result in some ultra -processed foods being eligible to carry the "healthy" labeling claim.

Combination foods containing whole fruit and vegetables should be emphasized over highly-processed mixed products, main dish products, and meal products. For combination food products containing whole grains to qualify for the "healthy" labeling claim, they should be required to be

[28] World Cancer Research Fund/American Institute for Cancer Research. *Diet, nutrition, physical activity and cancer: a global perspective. Continuous update project expert report 2018.* 2018.

[29] Islami F, Goding Sauer A, Miller KD, Siegel RL, Fedewa SA, Jacobs EJ, McCullough ML, Patel AV, Ma J, Soerjomataram I, Flanders WD, Brawley OW, Gapstur SM, Jemal A. Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. CA Cancer J Clin. 2018 Jan;68(1):31-54. doi: 10.3322/caac.21440. Epub 2017 Nov 21. PMID: 29160902.

nearly 100% whole grain and minimally processed. As previously noted, the proposed ¾ ounce whole grain equivalent must not be a minimum for combination foods that contain whole grains and want to qualify to use the "healthy" labeling claim. In other words, these foods should not additionally contain refined grains.

Lastly, it is worth reiterating that individuals choosing to eat combination foods would benefit more from a mandatory front-of-package label that ranks foods according to healthfulness to select foods higher in nutrient density and lower in energy density that are consistent with dietary guidelines, than a voluntary "healthy" labeling claim.

Synonymous Terms with "Healthy" To Consider

We recommend that "nutritious" could be an additional term synonymous for foods that meet the "healthy" labeling claim criteria.

Need for Rule Requirements to Remain Relevant with Science and Future DGAs

For individuals to make healthful food and beverage choices, the "healthy" labeling claim needs to stay accurate and reflect the current scientific evidence. The existing definitions and requirements of the nutrient content claim "healthy" were originally established in 1994 and based on nutritional science at that time. The scientific evidence has significantly evolved over the past 28 years and resulted in the current criteria for "healthy" to be an unreliable implied food labeling claim. While we support the revised expanded criteria for "healthy" to be updated to align with the current scientific evidence by incorporating food group requirements and also limiting the amounts of added-sugar, sodium, and saturated fat, we urge the FDA to consider ways for the rule requirements to remain relevant over time.

For instance, food manufacturers may replace sugar with artificial sweeteners in order to meet the "healthy" labeling claim. This is concerning because while once considered physiologically inert, accumulating evidence demonstrates that artificial sweeteners are metabolically active and may exacerbate risk factors for chronic disease. For example, recent studies in humans have demonstrated that prolonged consumption of artificial sweeteners, such as sucralose, impair glucose tolerance and reduce insulin sensitivity, both risk factors for development of type 2 diabetes.[30] Furthermore, positive associations between consumption of artificial sweeteners and development of various diet-related chronic diseases are reported in epidemiologic studies.[31] The criteria for use of the "healthy" labeling claim should therefore be updated frequently enough to take into account evolving evidence on other widely consumed food constituents.

We urge the FDA to include language in the proposed rule that requires the agency to review and revise the rule, at least every five years after the date of the final rule's publication in the Federal Register, to ensure the criteria used for the "healthy" labeling claim continues to be based on the current scientific evidence and latest published edition of the DGAs. Regularly aligning the rule requirements to be consistent with federal dietary recommendations is the only way to ensure that

[30] Sylvetsky AC, Rother KI. Nonnutritive Sweeteners in Weight Management and Chronic Disease: A Review. Obesity (Silver Spring). 2018 Apr;26(4):635-640. DOI: 10.1002/oby.22139. PMID: 29570245.

[31] Meng Y, Li S, Khan J, et al. Sugar- and Artificially Sweetened Beverages Consumption Linked to Type 2 Diabetes, Cardiovascular Diseases, and All-Cause Mortality: A Systematic Review and Dose-Response Meta-Analysis of Prospective Cohort Studies. Nutrients 2021; 13 2021/08/28. DOI: 10.3390/nu13082636.

the criteria for the food branded using the “healthy” implied food labeling claim are complete, accurate, and includes up-to-date information. In addition, regularly reviewing and updating the rule requirements should better protect the consumer confidence in the “healthy” labeling claim as a reliable tool consumers can reasonably use to better identify foods with the nutrient content that may help them maintain healthy dietary practices.

Conclusion

Thank you for the opportunity to provide input on this important topic. If we can provide additional information, please contact Christy Cushing, MPP, Senior Analyst, Prevention & Health Equity, at ACS CAN at 801-844-1848 or christy.cushing@cancer.org. Thank you.