



June 5, 2017

Dr. Ruth Lunn  
Director, Office of Report on Carcinogens, NTP  
National Institute for Environmental Health Sciences  
P.O. Box 12233  
Mail Drop K2-14  
Research Triangle Park, NC 27709

Dr. Andrew A. Rooney  
Office of Health Assessment and Translation, NTP  
National Institute for Environmental Health Sciences  
P.O. Box 12233  
Mail Drop K2-04  
Research Triangle Park, NC 27709

Re: Nomination of Meat-Related Exposures to the National Toxicology Program for the Report on Carcinogens

Dear Dr. Lunn and Dr. Rooney,

The Center for Science in the Public Interest (CSPI) supports the inclusion of meat-related exposures in the Report on Carcinogens. CSPI is a non-profit consumer education and advocacy organization that since 1971 has been working to improve the public's health through better nutrition and food safety. The organization's work is supported primarily by the 600,000 subscribers to its *Nutrition Action Healthletter*, the nation's largest-circulation health newsletter. CSPI is an independent organization that does not accept government or corporate funding. CSPI has advocated for decades to ensure that dietary advice for red and processed meat reflects the best available science.

Cancer of the colon or the rectum (colorectal cancer) is the second-leading cause of cancer deaths in the United States, and is expected to cause about 50,260 deaths in 2017.<sup>1</sup> The American Cancer Society, the International Agency for Research on Cancer (IARC), and the World Cancer Research Fund all cite research that found about an 18 percent increased risk of colorectal cancer for every 50 grams of processed meat consumed daily.<sup>2,3</sup>

In December, CSPI called on the U.S. Department of Agriculture to require a warning label on packages of bacon, ham, hot dogs, and other processed meat and poultry products to inform consumers that eating those foods is associated with an increased risk of colorectal cancer.<sup>4</sup> Citing the findings of IARC, which concluded in 2015 that processed meat is

---

<sup>1</sup> American Cancer Society. (2017). Estimated deaths, 2017. By cancer type, both sexes combined. Available at <https://cancerstatisticscenter.cancer.org/module/vg6E0ZLc>.

<sup>2</sup> Chan DS, Lau R, Aune D, et al. (2011). Red and processed meat and colorectal cancer incidence: Meta-analysis of prospective studies. *PLoS One*, 6(6): e20456.

<sup>3</sup> Kushi LH, Doyle C, McCullough M, et al. (2012). American Cancer Society Guidelines on nutrition and physical activity for cancer prevention. *CA: A Cancer Journal for Clinicians*, 62(1):30-67.

<sup>4</sup> Center for Science in the Public Interest. (2016). Petition for a label on processed meat and poultry products warning the public that frequent consumption may increase the risk of colorectal cancer. Available at <https://cspinet.org/sites/default/files/attachment/Processed%20Meat%20Petition-CSPI%20120116.pdf>.

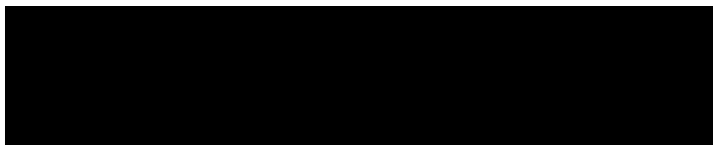
“carcinogenic to humans,”<sup>5</sup> the petition urges the USDA’s Food Safety and Inspection Service to require the industry to inform consumers about the risk of consuming processed meats.

In a letter to outgoing Secretary of Agriculture Tom Vilsack, eleven leading nutrition and epidemiology experts endorsed the idea of a warning label on processed meats.<sup>6</sup> “People want clear and accurate information about potential health hazards in the foods they eat to help them make wise choices at the grocery store and restaurants,” the scientists wrote. The level of risk posed by processed meats may have contributed to as many as 5,000 colorectal cancer deaths in 2015 alone, they wrote, citing estimates by the Institute for Health Metrics and Evaluation.<sup>7</sup>

In comments to the 2015 Scientific Report of the Dietary Guidelines Advisory Committee, CSPI noted the clear, consistent, and still-mounting evidence of the link between regular consumption of red and processed meats and certain types of cancer. In 2011, American Institute for Cancer Research and World Cancer Research Fund published a Continuous Update Project report on colorectal cancer. The expert panel concluded that both red and processed meats are a “convincing cause” of colorectal cancer, supported by plausible mechanisms operating in humans and by dose-response relationships in cohort studies.<sup>8</sup>

The evidence that diets high in red meat (beef, pork, lamb, veal) and processed meats (hot dogs, bacon, sausage, deli meats, etc.) increase the risk of colorectal cancer is convincing. CSPI strongly recommends that the National Toxicology Program include exposure to meats in the Report on Carcinogens. Attached please find CSPI’s 2016 petition to the USDA and comments to the 2015 Scientific Report of the Dietary Guidelines Advisory Committee.

Sincerely,

A large black rectangular redaction box covering the signature area.

Michael F. Jacobson, PhD  
President  
Center for Science in the Public Interest

---

<sup>5</sup> Bouvard V, Loomis D, Guyton KZ, et al. (2015). Carcinogenicity of consumption of red and processed meat. *The Lancet Oncology*, 16(16): 1599-600.

<sup>6</sup> Center for Science in the Public Interest. (2016). Scientist letter supporting processed meat petition to Secretary Tom Vilsack. Available at <https://cspinet.org/resource/scientist-letter-supporting-processed-meat-petition>.

<sup>7</sup> Institute for Health Metrics and Evaluation. (2017). Global burden of disease compare: Global, both sexes, all ages, 2015, DALYs. *University of Washington*. Available at <https://vizhub.healthdata.org/gbd-compare/>.

<sup>8</sup> World Cancer Research Fund/American Institute for Cancer Research. (2011). Colorectal cancer 2011 report: Food, nutrition, physical activity, and the prevention of colorectal cancer. Available at <http://www.wcrf.org/sites/default/files/Colorectal-Cancer-2011-Report.pdf>.

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE

Petition for a Label on Processed Meat )  
and Poultry Products Warning the Public ) Docket No. \_\_\_\_\_  
that Frequent Consumption May Increase )  
the Risk of Colorectal Cancer )  
)

CITIZEN PETITION

Submitted by:

Center for Science in the Public Interest

December 1, 2016

FSIS Docket Clerk  
Department of Agriculture  
Food Safety and Inspection Service  
Room 2534 South Building  
1400 Independence Avenue, S.W.  
Washington, DC 20250-3700

## INTRODUCTION

Americans eat considerable amounts of fresh and processed meat and poultry. In 2013, the average American consumed 71 pounds of red meat and 55 pounds of poultry,<sup>1</sup> with processed meat constituting at least 22 percent of total meat and poultry consumption.<sup>2</sup> In recent years, scientific research has led to the conclusion that processed meat and poultry increases the risk of colorectal cancer,<sup>3</sup> which is the second-leading cause of cancer deaths in the United States, and expected to account for 49,190 deaths in 2016.<sup>4</sup> The Food Safety and Inspection Service (“FSIS”) is responsible for safeguarding the public by ensuring that the labels on meat and poultry products provide consumers with information about nutrition, ingredients, and health risks. In this petition we request that FSIS require a label on processed meat and poultry products informing the public that their frequent consumption may increase the risk of colorectal cancer.

## CITIZEN’S PETITION

### ACTION REQUESTED

Pursuant to 5 U.S.C. § 553(e), 9 C.F.R. § 392, and 7 C.F.R. § 1.28, petitioners request that the Food Safety and Inspection Service issue a regulation amending 9 C.F.R. §§ 317 and 381 to require a label on packages of processed meat and poultry as follows:

#### **§ 317.2 Labels; definition; required features.**

\* \* \* \* \*

( ) (1) All meat products that are preserved by smoking, curing, salting, and/or the addition of chemical preservatives shall bear the labeling statement:

**USDA WARNING:** Frequent consumption of processed meat products may increase your risk of developing cancer of

---

<sup>1</sup> USDA Econ. Research Serv., Red Meat: Per Capita Consumption Adjusted for Loss.

<sup>2</sup> Carrie R. Daniel, et al., *Trends in Meat Consumption in the United States*, 14 Public Health Nutrition 575 (2011). (The 22 percent estimate is low because the study left out certain cured meats, such as bacon and ham, from its definition of processed meat.)

<sup>3</sup> The studies are discussed in the Factual Basis section of this petition.

<sup>4</sup> Am. Cancer Society, Key Statistics for Colorectal Cancer, (2016) at <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-key-statistics> (Last Accessed Nov. 4, 2016).

the colon and rectum. To protect your health, limit your consumption of such products.

(2) The warning statement shall be prominently placed with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) The words “USDA WARNING” shall be capitalized and shall appear in bold type.

(4) The warning statement shall be set off in a box by the use of hairlines.

### **§ 381.125 Special handling label requirements.**

\* \* \* \* \*

( \_ )(1) All poultry products that are preserved by smoking, curing, salting, and/or the addition of chemical preservatives shall bear the labeling statement:

**USDA WARNING:** Frequent consumption of processed poultry products may increase your risk of developing cancer of the colon and rectum. To protect your health, limit your consumption of such products.

(2) The warning statement shall be prominently placed with such conspicuousness as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(3) The words “USDA WARNING” shall be capitalized and shall appear in bold type.

(4) The warning statement shall be set off in a box by the use of hairlines.

## **ABOUT THE PETITIONER**

The Center for Science in the Public Interest (“CSPI”), founded in 1971 and located in Washington, D.C., is a nonprofit, non-governmental, consumer-advocacy organization focused primarily on nutrition, health, and food safety issues.

## **FACTUAL BASIS**

Processed meat is produced by smoking, curing, salting, and/or the addition of chemical substances such as nitrate and nitrite to preserve the meat and enhance its flavor.<sup>5</sup> Nitrite used in the curing process performs an additional function of inhibiting the

---

<sup>5</sup> This definition is consistent with others for the term processed meat. *Compare* “Processed meat refers to meat that has been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavour or improve preservation. Most processed meats contain pork or beef, but might also contain other red meats, poultry, offal (e.g., liver), or meat byproducts such as blood.” Véronique Bouvard, et al., *Carcinogenicity of Consumption of Red and Processed Meat*, 16 *The Lancet Oncology* 1599 (2015); “Processed meat [and] processed poultry [are] products preserved by smoking, curing, salting, and/or the addition of

growth of *Clostridium botulinum* spores. Processed meat has been included in the human diet since antiquity and its preparation was the principal method for preserving meat before the 20<sup>th</sup> century. Examples of processed meats include bacon, hot dogs, ham, sausages, and deli or luncheon meats. For purposes of this petition, the term “processed meat” refers to any processed meat or poultry product.

CSPI is submitting this petition because convincing scientific evidence demonstrates that frequent consumption of processed meat carries a recognized and avoidable risk to public health to which consumers should be alerted. The most recent review of the evidence was conducted by the International Agency for Research on Cancer (“IARC”) which announced on October 26, 2015, that processed meat is “carcinogenic to humans.”<sup>6</sup> The IARC is an agency of the World Health Organization that is charged with coordinating and conducting research on the causes of human cancer. Its monograph is the latest in a series of reports concluding that consumption of processed meat increases the risk of colorectal cancer. The World Cancer Research Fund International (“WCRF”) in association with its affiliate the American Institute for Cancer Research (“AICR”) and the Imperial College London reported in 2011 that processed meat is a convincing cause of colorectal cancer.<sup>7</sup> The American Cancer Society (“ACS”) advises the public to “minimize consumption of processed meats such as bacon, sausage, luncheon meats, and hot dogs” based on evidence that the risk of colorectal cancer increases by 15 to 20 percent for every 50 grams consumed daily.<sup>8</sup> Researchers estimate that in 2015, roughly 5,000 deaths from colorectal cancers in the United States were attributable to diets high in processed meat.<sup>9</sup> In spite of firm conclusions reached by WCRF, AICR and others, public awareness of the cancer risk due to processed meats is low. A 2015 poll by the AICR found that only about one in three Americans knew that consumption of processed meat is a significant factor in developing cancer.<sup>10</sup>

The evidence that processed meat causes cancer in humans comes largely from epidemiological studies. That evidence is supported by mechanistic evidence from studies

---

chemical preservatives. Processed meats and poultry include all types of meat or poultry sausages (bologna, frankfurters, luncheon meats and loaves, sandwich spreads, viennas, chorizo, kielbasa, pepperoni, salami, and summer sausages), bacon, smoked or cured ham or pork shoulder, corned beef, pastrami, pig’s feet, beef jerky, marinated chicken breasts, and smoked turkey products.” U.S. Dept. of Health and Human Serv. and USDA, 2015-2020 Dietary Guidelines for Americans, (8<sup>th</sup> Ed., 2015); and “[The] common thread is [that] processed meats are fresh products that have been changed from their original state.” and “Processed meats are commonly made from beef, pork, chicken and turkey...” Am. Meat Inst., *Processed Meats: Convenience, Nutrition, Taste: American Traditions and Iconic Foods* (undated).

<sup>6</sup> Press Release, Internat’l Agency for Research on Cancer, IARC Monographs Evaluate Consumption of Red Meat and Processed Meat (Oct. 26, 2015) available at [https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr240\\_E.pdf](https://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr240_E.pdf) (Last Accessed Oct. 14, 2016).

<sup>7</sup> World Cancer Research Fund/Am. Inst. for Cancer Research, Continuous Update Project Report: Food, Nutrition, Physical Activity, and the Prevention of Colorectal Cancer (2011).

<sup>8</sup> Lawrence H. Kushi, et al., *American Cancer Society Guidelines on Nutrition and Physical Activity for Cancer Prevention*, 62 CA Cancer J. Clin. 30, 40, 2012.

<sup>9</sup> Global Burden of Disease Inst. for Health Metrics and Evaluation, GBD Compare | Viz Hub display of deaths from colon and rectum cancer attributable to diets high in processed meat for both sexes and all ages in 2015, available at <http://vizhub.healthdata.org/gbd-compare/> (Last Accessed Nov. 4, 2016).

<sup>10</sup> Am. Inst. for Cancer Research, The AICR 2015 Cancer Risk Awareness Survey Report.

on humans and animals.<sup>11</sup> (Randomized clinical trials testing the impact of processed meats on colorectal cancer risk would not be feasible or ethical.)

An IARC working group of 22 scientists from 10 countries concluded that the consumption of processed meat is “carcinogenic to humans (Group 1) on the basis of sufficient evidence for colorectal cancer.”<sup>12</sup> According to IARC, a majority of the highest-quality cohort studies, including studies from the United States, reported that the consumption of processed meat is associated with an increased risk of colorectal cancer.<sup>13</sup> Furthermore, a meta-analysis of nine cohort studies reported a statistically significant 18 percent increased risk of colorectal cancer for every 50 grams of processed meat consumed daily.<sup>14</sup> To put the increased risk into perspective, a typical serving of ham, sausage, bologna, or hot dog weighs 55 grams.<sup>15</sup> The IARC concluded that the “large amount of data and the consistent associations of colorectal cancer with consumption of processed meat across studies in different populations [make] chance, bias, and confounding unlikely as explanations” for the consistent association between processed meat and colorectal cancer, leading the working group to conclude that “there is sufficient evidence in human beings for the carcinogenicity of the consumption of processed meat.”<sup>16</sup>

Similarly, the 2011 WCRF report concluded that “processed meat is a convincing cause of colorectal cancer.”<sup>17</sup> The report’s meta-analysis of 13 studies found an 18 percent increased risk for colorectal cancer for every 50 grams of processed meat consumed per day.<sup>18</sup> The results are similar to those from a 2009 meta-analysis which found a 19 percent increased risk for that cancer in people who consumed the highest versus the lowest amount of processed meat.<sup>19</sup> According to the WCRF report, a substantial amount of evidence, with a dose-response relationship apparent from cohort studies, and strong

---

<sup>11</sup> Bouvard, *supra* note 5.

<sup>12</sup> *Id.* The current estimated publication date for the full IARC monograph is the summer of 2017. Email from Helene Lorenzen, Assistant for IARC Monographs Section, to Michael Farr, CSPI Food Law and Regulatory Policy intern (June 1, 2016)(on file with CSPI).

<sup>13</sup> Teresa Norat, et al., *Meat, Fish, and Colorectal Cancer Risk: the European Prospective Investigation into Cancer and Nutrition*, 97 *J. Nat’l Cancer Inst.* 906 (2005); Shino Oba, et al., *The Relationship Between the Consumption of Meat, Fat, and Coffee and the Risk of Colon Cancer: a Prospective Study in Japan*, 244 *Cancer Letter* 260 (2006); Adam M. Bernstein, et al., *Processed and Unprocessed Red Meat and Risk of Colorectal Cancer: Analysis by Tumor Location and Modification by Time*, 10 *PLoS One* e0135959 (2015); Amanda J. Cross, et al., *A Large Prospective Study of Meat Consumption and Colorectal Cancer Risk: An Investigation of Potential Mechanisms Underlying this Association*, 70 *Cancer Research* 2406 (2010); Ann Chao, et al., *Meat Consumption and Risk of Colorectal Cancer*, 293 *JAMA* 172 (2005).

<sup>14</sup> Doris S.M. Chan, et al., *Red and Processed Meat and Colorectal Cancer Incidence: Meta-Analysis of Prospective Studies*. 6 *PLoS One* e20456 (2011).

<sup>15</sup> Table 2—Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply, 9 C.F.R. § 317.312 (2016)

<sup>16</sup> Bouvard, *supra* note 5.

<sup>17</sup> World Cancer Research Fund, *supra* note 7.

<sup>18</sup> *Id.*

<sup>19</sup> Rachel R. Huxley, et al., *The Impact of Dietary and Lifestyle Risk Factors on Risk of Colorectal Cancer: A Quantitative Overview of the Epidemiological Evidence*. 125 *Internat’l J. Cancer* 171 (2009).

evidence for plausible mechanisms operating in humans is consistent with the conclusion that processed meat is a convincing cause of colorectal cancer.<sup>20</sup>

The exact mechanism by which processed meat increases the risk of colorectal cancer is unknown. However, multiple meat components provide “substantial supporting mechanistic evidence,” according to the IARC.<sup>21</sup> For example, “meat processing, such as curing and smoking, can result in formation of carcinogenic chemicals, including N-nitroso-compounds (NOC) and polycyclic aromatic hydrocarbons (PAH). Furthermore, studies have demonstrated that the consumption of processed meat leads to the formation of NOC in the gastrointestinal tract.<sup>22</sup>

The meat industry has challenged efforts to regulate substances added to processed meat based on the mechanistic evidence. That has happened most recently with the California Environmental Protection Agency proposal to list nitrite in combination with amines or amides as a carcinogen under the state’s Safe Drinking Water and Toxic Enforcement Act (Proposition 65).<sup>23</sup> The meat industry cites studies finding uncertainty about the role of nitrite in its opposition to the proposal.<sup>24</sup> Such studies are not relevant to this petition, however, because its arguments are based not on the mechanism, but on the strength of the epidemiological evidence, which is sufficient to establish risk and obligate USDA to require the industry to inform consumers about the risk of consuming processed meats.

FSIS already employs this approach with regard to other risks that may be difficult to control at the processing level and, therefore, must be managed by the consumer. For instance, processed meat that was cured without using nitrate or nitrite must be labeled as “Uncured” and include the statements “No Nitrate or Nitrite Added” and “Not Preserved – Keep Refrigerated Below 40° F. At All Times” on its packaging to inform consumers how to manage the risk from *Clostridium botulinum*.<sup>25</sup> FSIS requires safe-handling instructions on raw meat and poultry products to warn the public about the risk of bacterial pathogens on

---

<sup>20</sup> World Cancer Research Fund, *supra* note 7.

<sup>21</sup> Bouvard, *supra* note 5.

<sup>22</sup> J.C. Lunn, et al. *The Effect of Haem in Red and Processed Meat on the Endogenous Formation of N-nitroso Compounds in the Upper Gastrointestinal Tract*, 28 *Carcinogenesis* 685 (2007); Annemiek M.C.P. Joosen, et al., *Effect of Processed and Red Meat on Endogenous Nitrosation and DNA Damage*, 30 *Carcinogenesis* 1402

<sup>23</sup> Calif. Environmental Protection Agency, Notice of Intent to List: Nitrite in Combination with Amines or Amides, (2014) available at <http://oehha.ca.gov/proposition-65/crn/notice-intent-list-nitrite-combination-amines-or-amides> (Last Accessed Nov. 7, 2016).

<sup>24</sup> Letter to Cynthia Oshita, OEHHA, from Betsy Booren, vice president, scientific affairs, American Meat Inst. (May 8, 2014) available at <http://oehha.ca.gov/media/downloads/proposition-65/crn/comments/0515144aminoinitrite.pdf> (Last Accessed Nov. 7, 2016); and Letter to Cynthia Oshita, OEHHA, from Barry Carpenter, CEO of the North Am. Meat Ass’n (May 8, 2014) available at <http://oehha.ca.gov/media/downloads/proposition-65/crn/comments/0515147namanitrite.pdf> (Last Accessed Nov. 7, 2016).

<sup>25</sup> See, Nitrates and Nitrites: Proposed Rule, 43 Fed. Reg. 18193 (Apr. 28, 1978) (Final rule codified at 9 C.F.R. §§ 316.10(d) & 317.17 (2016)).



mishandled or improperly cooked product.<sup>26</sup> Mechanically tenderized beef must be labeled to inform consumers that the meat presents a greater risk that pathogenic bacteria may survive normal cooking than would be the true for intact cuts of meat.<sup>27</sup>

The mechanically tenderized meat label is particularly relevant to this petition. FSIS reasoned in its rulemaking that mechanically tenderized meat is indistinguishable from intact cuts, and therefore misbranded if not labeled.<sup>28</sup> FSIS has on other occasions required processors to label food with material facts that would not be evident to consumers in the absence of labeling.<sup>29</sup> For example, the source of natural sausage casings must be labeled if they are derived from a different type of meat or poultry than is encased in the sausage. The purpose of the requirement is to keep consumers from being misled into eating food that, whether for health, religious, or other reasons, they would not want to consume.<sup>30</sup> The same reasoning applies to the request made by this petition, which asks FSIS to address a matter of serious public health concern (indeed, greater than the several examples just given) by following its well-established practice of requiring meat and poultry to be labeled with information material to protecting public health.

## LEGAL BASIS

The Federal Meat Inspection Act (“FMIA”), 21 U.S.C. § 601, et seq., and Poultry Products Protection Act (“PPIA”), 21 U.S.C. § 451, et seq., provide FSIS with authority to undertake the action requested in this petition. Under §§ 602 and 451, FSIS is charged with regulating the meat and poultry industry to protect the health and welfare of consumers by assuring that meat and poultry is wholesome, not adulterated, and properly marked, labeled, and packaged. Food is misbranded under §§ 601(n)(1) and 453(h)(1) “if its labeling is false or misleading in any particular.” FSIS has the authority to make “rules and regulations as are necessary for the efficient execution of the provisions” of the FMIA and PPIA under §§ 621 and 463(b). This has been described as broad authority to enact regulations and require other information to carry out its responsibility.<sup>31</sup>

The authority listed above directs the agency to give favorable consideration to the request made by this petition. Under the agency’s interpretation of §§ 601(n) and 453(h) processed meat is misbranded if its label fails to reveal material facts “with respect to consequences which may result from the use of the food... under conditions of use as are customary or usual.”<sup>32</sup> Materiality looks at “inherent characteristics of the food itself,”<sup>33</sup>

---

<sup>26</sup> Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products, 59 Fed. Reg. 14528 (March 28, 1994).

<sup>27</sup> Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products, 80 Fed. Reg. 28153, 28155 (May 18, 2015).

<sup>28</sup> *Id.*

<sup>29</sup> *See*, Irradiation of Meat Food Products, 64 Fed. Reg. 72150, 72157 (Dec. 23, 1999).

<sup>30</sup> Labeling of Natural or Regenerated Collagen Sausage Casings, 66 Fed. Reg. 40843 (Aug. 6, 2001).

<sup>31</sup> *Nat’l Pork Producers v. Bergland*, 931 F.2d 1353, 1362 (8<sup>th</sup> Cir., 1980).

<sup>32</sup> Letter to Pamela Geller, executive director of SIOA, from Daniel Engeljohn, assistant administrator of the Office of Policy and Program Development, FSIS (Sept. 9, 2016).

<sup>33</sup> *Id.*

and whether that characteristic would affect consumer actions. FSIS applied this interpretation to find that the source of sausage casing is material because consumers could be misled into eating a food they consider unhealthy if that information is missing.<sup>34</sup> Under that reasoning, processed meat should be labeled because of the risk of colorectal cancer resulting from its frequent consumption. Such information about an inherent characteristic of the food would be a factor in a consumer's decision to eat unhealthy amounts of processed meat and is, therefore, material.<sup>35</sup>

Labeling requirements that might discourage people from buying a product have been questioned in the past as violating First Amendment protections.<sup>36</sup> Concern that the label may constitute prohibited compelled speech under the Constitution does not pose a barrier to FSIS granting this petition. The label requested serves a substantial governmental interest in protecting public health, directly advances that interest, and is no more intrusive than necessary to achieve that interest.<sup>37</sup> It provides consumers with information that is factual and uncontroversial in that the link between consumption of processed meat and colorectal cancer is well supported by the evidence.<sup>38</sup>

## CONCLUSION

In light of the strong scientific evidence that the frequent consumption of processed meat increases the risk of colorectal cancer, the agency must act decisively to require a label on processed meat stating that frequent consumption may increase the risk of colon and rectal cancer. We urge the agency to grant this petition.

---

<sup>34</sup> Labeling of Natural or Regenerated Collagen Sausage Casings, *supra* note 30.

<sup>35</sup> Market research in the United Kingdom found a 15.7 percent drop in sales of pre-packaged sausage and a 17 percent drop in sales of pre-packaged bacon in the two weeks following the IARC announcement, demonstrating that consumers value and use information about cancer risks in making purchasing decisions. Jeremy Gerrard, *UK Processed Meat Sales Slide after WHO Cancer Report*, Food Engineering Mag. (Dec. 2, 2015), available at <http://www.foodengineeringmag.com/articles/94903-uk-processed-meat-sales-slide-after-who-cancer-report> (Last Accessed Nov. 18, 2016).

<sup>36</sup> See, *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014); *Irradiation of Meat and Food Products*, 64 Fed. Reg. at 72158.

<sup>37</sup> *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 563 (1980).

<sup>38</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Am. Meat Inst.*, 760 F.3d 18.


**CERTIFICATION**

The undersigned certify that to the best of their knowledge and belief this petition includes all information and views on which the petition relies and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,



Michael F. Jacobson, Ph.D.  
President  
Center for Science in the Public Interest



David Plunkett, JD, JM  
Senior Staff Attorney  
Center for Science in the Public Interest

May 8, 2015

Richard D. Olson, M.D., M.P.H.  
Designated Federal Officer, 2015 Dietary Guidelines Advisory Committee  
Office of Disease Prevention and Health Promotion  
Office of the Assistant Secretary for Health  
U.S. Department of Health and Human Services  
1101 Wootton Parkway, Suite LL100  
Tower Building  
Rockville, MD 20852

Kellie Casavale, Ph.D., R.D.  
Deputy Designated Federal Officer, 2015 Dietary Guidelines Advisory Committee  
Nutrition Advisor; Office of Disease Prevention and Health Promotion  
Office of the Assistant Secretary for Health  
U.S. Department of Health and Human Services  
1101 Wootton Parkway, Suite LL100  
Tower Building  
Rockville, MD 20852

Colette I. Rihane, M.S., R.D.  
Lead USDA Co-Executive  
Secretary, 2015 Dietary Guidelines Advisory Committee  
Director, Office of Nutrition Guidance and Analysis  
Center for Nutrition Policy and Promotion  
U.S. Department of Agriculture  
3101 Park Center Drive, Room 1034  
Alexandria, VA 22302

Shanthy A. Bowman, Ph.D.  
USDA Co-Executive Secretary  
Nutritionist, Food Surveys Research Group  
Beltsville Human Nutrition Research Center  
Agricultural Research Service  
U.S. Department of Agriculture  
10300 Baltimore Avenue  
BARC-West Bldg 005, Room 125  
Beltsville, MD 20705-2350

**Re: The Dietary Guidelines for Americans, 2015**

Dear Dr. Olson, Dr. Casavale, Ms. Rihane, and Dr. Bowman:

The Center for Science in the Public Interest (CSPI) presents these comments on the expert report prepared for the eighth edition of the *Dietary Guidelines for Americans*

(DGA) by the Dietary Guidelines for Americans Committee (DGAC). Overall, we strongly support the conclusions and policy recommendations in the report.

CSPI is a non-profit consumer education and advocacy organization that since 1971 has been working to improve the public's health through better nutrition and food safety policies. CSPI's work is supported primarily by its 900,000 subscribers to its *Nutrition Action Healthletter*, the nation's largest-circulation health newsletter. CSPI is an independent organization that does not accept any government or corporate funding.

Specifically, we make the following points:

- A) We strongly support the DGAC's focus on the broad range of factors, including policy and environmental approaches, that influence people's diet and weight-related behaviors. The final DGA report should continue to reflect these sensible and science-based changes to our food environment and public policies to support and facilitate Americans making healthier food and beverage choices across the lifespan.
- B) We commend the DGAC's attention to a variety of healthy dietary patterns and the continued emphasis that healthy diets should meet nutrient needs with whole foods.
- C) We have specific views with regard to the following nutrients and food sources:
  - a. We unequivocally support the DGAC's recommendations to reduce consumption of added sugars, including the need for a line on added sugars on the Nutrition Facts label that includes a percentage of a Daily Value based on 10 percent of calories or less in a 2,000-calorie diet, and for amounts expressed in teaspoons as well as grams to maximize consumer understanding.
  - b. The DGAC should strongly recommend reducing daily sodium intake to 2,300 milligrams (mg) per day for the general population and to 1,500 mg per day for at-risk subgroups.
  - c. We support the DGAC Scientific Report's conclusion that the Guidelines should include a recommendation to "lower red and processed meat."
  - d. The DGA should continue to advise Americans to replace foods rich in saturated fat with ones higher in monounsaturated or polyunsaturated fats.
  - e. The final Dietary Guidelines should advise Americans to limit their consumption of cholesterol-rich foods (primarily whole eggs and egg yolks) to lower their risk of heart disease and type 2 diabetes.
  - f. We concur with the DGAC report that additional measures are needed to encourage consumption of fruits and vegetables as part of a healthy diet.
  - g. We support the Report's emphasis on whole grains as part of a healthful diet and encourage USDA and HHS to provide clear recommendations to help people translate this advice into healthier consumption patterns.
- D) We support the development of policies, as the DGAC recommends, to promote water as the primary beverage of choice. We also support public education and policy changes to encourage access to clean water, including a symbol for water as part of the graphics for MyPlate.

- E) We endorse the DGAC's recognition of sustainability—or food security—as an essential component of federal dietary guidance.

We strongly urge those tasked with finalizing the Dietary Guidelines to maintain the emphasis in the DGAC's report on changing the food environment to improve the nutritional quality of foods and beverages that are widely available and consumed.

### ***Introduction***

As the DGAC's expert report recognizes, achieving a healthy overall dietary pattern is more important than any specific food or nutrient. A variety of dietary patterns are linked to reduced risk of chronic diseases, including cancer and heart disease, and those diets share many of the same characteristics, including higher intakes of fruits, vegetables, low- and non-fat dairy foods, fish, poultry, legumes, whole grains, healthy oils, and lower intakes of added sugars, saturated fat, sodium, and red and processed meat. We also applaud the report's continued recommendation that nutrients in the diet should come from whole foods rather than fortified, processed foods, or supplements.

Moreover, we want to underscore the significance of the report's recommendations for policies and environments that support and improve public health. Despite public reports to the contrary, the basic nutrition advice in the Guidelines has been largely unchanged for years; what has not yet been altered is the public's under-consumption of fruits, vegetables, and whole grains, and the over-promotion and consequent over-consumption of unhealthful foods. To translate the unbiased science in the expert report into action is not merely a good idea—it is a necessary and critical corollary to the scientific examination of the evidence in the DGAC's report and belongs in the final Guidelines.

Contrary to some criticism, both concern with policy implementation and a broader view of health is consistent with past Guidelines and reports. In its 2010 report, the DGAC stated that “all segments of society—from parents to policy makers and everyone else in between—must now take responsibility and play a leadership role in creating gradual and steady change to help current and future generations live healthy and productive lives.”<sup>1</sup> To that end, in this comment in the discussion of added sugars, as

---

<sup>1</sup> In fact, many substantial matters of policy have been addressed in past Guidelines and Committee reports. These include, in no particular order: the need for physical activity (DG 1980-2010, DGAC 1995-2010); alcohol consumption, warnings against use of driving or machinery (DG 1980-2010, DGAC 1995-2010); reducing healthcare costs through diet (DGAC 1995); poverty as a barrier to nutritional implementation (DGAC 1995, DGAC/DG 2010); racial health disparities (DGAC 2005, DGAC/DG 2010); the cost and availability of fruits and vegetables (DGAC 2005, DGAC/DG 2010); the geographic distribution of fast food and convenience store versus grocery stores (DGAC/DG 2010); opportunities for safe and enjoyable outdoor activities (DGAC 2005, DGAC/DG 2010); benefits of plant-based diets (DGAC/DG, 1995, 2000, 2005, 2010); the need to reduce screen time for children (*i.e.*, television, video games, computer use (DGAC/DG 2010); policies impacting sustainable agriculture and aquaculture (DGAC/DG 2010); land use policy and zoning policy (DGAC 2010); food safety and technology (hand sanitation, kitchen cleanliness, temperature control) (DGAC/DG 2000-2010);

below, we provide new information on a compelling recent consumer survey we conducted regarding the inclusion of added sugars on the Nutrition Facts Panel and for measurements of added sugars in teaspoons as well as grams. The Dietary Guidelines is a living document that must be given meaning by its impact on policies including the labeling of foods.

Next, we comment on several specific food groups, foods, and nutrients, including added sugars, sodium, red and processed meats, saturated fat, fruits and vegetables, and whole grains. Last in this section, our comments address water as a primary beverage and sustainability—or, as it might better be understood—food security.

In addition to the critical matters discussed above, we raise five additional discrete points of concern. In each of these matters, we believe the Committee’s findings did not reflect a careful reading of the current body of scientific evidence and incorporating the Committee’s findings in the DGA would be harmful for consumers. We urge that the final Guidelines more accurately reflect current science on these questions, and ensure that consumers are aware of risks and potential risks to their health in these areas.

In particular, for aspartame, methyl mercury exposures, and caffeine, the Committee’s conclusions reflect a lack of concern for risks to pregnant women and prenatal exposures. In addition, the Committee’s neglect of the science on the harm from artificial food dyes to susceptible children should be corrected in the final Guidelines. The potential for serious and lasting health impacts in these areas impacting highly vulnerable sub-populations warrants a considerably clearer and more protective approach.

The areas in which we think the Guidelines should provide advice different from that recommended by the expert report, based on the evidence, include:

- 1) We support the DGAC’s recommendation for increasing fish consumption, but disagree with its blanket assessment that the health benefits outweigh the risks from methylmercury, particularly as concerns the risks of consuming albacore tuna. Far clearer messages are required to enable consumers—especially pregnant women—to maximize the benefits of consuming fish while minimizing risks.
- 2) The Dietary Guidelines should not state that aspartame is safe, as such a conclusion is not supported by the evidence, and other scientific authorities are

---

economic incentives for food manufacturers as barrier for health (DGAC 2010); the need to increase comprehensive education for health, nutrition and physical education (DGAC 2010 in-depth; and included in prior years); improving public/private partnerships for health (DGAC/DG 2010); developing legislation and policies in diverse sectors (public health, retail, transportation, etc.) (DGAC/DG 2010); and the advisability of limiting food and beverage marketing to children (DGAC/DG 2010).

- undertaking more thorough reviews of the safety of aspartame. We are concerned that aspartame is a carcinogen and also that aspartame may affect reproduction.
- 3) For clarity of message and to protect public health, we strongly urge that the 2015 Guidelines maintain the definition of “moderate drinking” as a maximum of one drink a day for women and two drinks a day for men as was recommended in the 2010 Dietary Guidelines.
  - 4) The Committee’s advice to pregnant women on caffeine is incorrect. Even moderate intake of caffeine during pregnancy appears to be associated with serious risks, including low birth weight. Moreover, the committee failed to consider the evidence linking coffee consumption by pregnant women to childhood leukemia. The advice should be to avoid caffeine in coffee or other non-*de-minimis* forms during pregnancy.
  - 5) The Committee failed to consider the safety of artificial food dyes. Yet artificial food dyes have been demonstrated to negatively impact behavior in susceptible children and in Europe are generally used only with warning labels. The final Guidelines should call for individuals and institutions to phase food dyes out of the diets of children and to emphasize the health value from a rainbow of real fruits and vegetables instead.

The following sections focus on the major issues raised by the Committee report; our five specific concerns are addressed in the final sections of the comment.

#### **A) Policy and Environmental Approaches**

**We strongly support the DGAC’s focus on the broad range of factors, including policy and environmental approaches, that influence people’s diet and weight-related behaviors. The final DGA report should continue to reflect these sensible and science-based changes to our food environment and public policies to support and facilitate Americans making healthier food and beverage choices across the lifespan.**

A change to healthier dietary patterns on a broad scale requires a comprehensive, coordinated system-wide approach that engages all levels of the socio-ecological model. In particular, policy, environmental, and systems changes must make healthy foods and beverages more accessible, affordable, and desirable, while making less healthy foods less accessible, affordable, and desirable, particularly for at-risk populations. This approach to improving diet, promoting health, and reducing diet-related chronic disease through changing the policies and environments where youth and adults spend the majority of their time has been promoted by numerous public health authorities, including the Centers for Disease Control and Prevention,<sup>2</sup> Community Preventive

---

<sup>2</sup> Keener, D., Goodman, K., Lowry, A., Zaro, S., & Khan, L. K. (2009). Recommended Community Strategies and Measurements to Prevent Obesity in the United States: Implementation and Measurement Guide. *Centers for Disease Control and Prevention*.



Services Task Force,<sup>3</sup> Institute of Medicine,<sup>4</sup> President’s Cancer Panel,<sup>5</sup> and now the 2015 DGAC.

In addition, education and promotion campaigns and initiatives should be considered as important complements to policy and environmental changes. Such “wrap around” efforts increase the likelihood that policy, systems, and environmental changes will result in positive habits. However, educational interventions by themselves are less likely to be successful if the surrounding environment does not easily enable the behavior change. Policy, systems, and environmental changes can also be used to influence physical activity opportunities and choices and reduce sedentary behavior.

We support the DGAC’s use of the socio-ecological model and recognition that individual diet, physical activity, and weight management behaviors are influenced by individual biological, household, community, societal, and cultural factors, as well as public and private policies, systems, and environments. We are pleased that the DGAC found at least promising, and many times much stronger, evidence that multi-component obesity prevention approaches in child care settings, schools, and worksites improve weight-related outcomes and that the committee found moderate-to-strong evidence that school and worksite policies improve diet outcomes. The fact that the DGAC found that multi-component interventions that addressed both diet and physical activity and used a variety of strategies were most likely to be successful in preventing obesity points to the need for a multi-component, collaborative, and sustainable approach.

### ***Specific Policy and Environmental Change Recommendations***

We strongly support many of the actions for communities and populations recommended by the DGAC and urge the DGA to include and expand upon these recommendations. We recommend that the DGA states the following recommendations:

- Make healthy lifestyles and chronic disease prevention a national and local priority, and incentivize collaborations by multiple sectors of influence at all levels that promote individual healthy lifestyle behavior change and create a “culture of health;”
- Integrate prevention within the health care system and provide incentives and support for preventive lifestyle screening, referral, interventions, and services;
- Model prevention and create cultures of health within health care settings;

---

<sup>3</sup> Community Preventive Services Task Force. (2014). Obesity Prevention and Control: Interventions in Community Settings. *The Guide to Community Preventive Services*. Available at <http://www.thecommunityguide.org/obesity/communitysettings.html>. Accessed March 11, 2015.

<sup>4</sup> Sanchez, E., Burns, A. C., & Parker, L. (Eds.). (2009). *Local government actions to prevent childhood obesity*. National Academies Press.

<sup>5</sup> Reuben, S.H. & The President’s Cancer Panel. (August 2007). Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk. Available at <http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp07rpt/pcp07rpt.pdf>. Accessed March 11, 2015.

- Make healthy foods accessible and affordable;
- Limit access to high-calorie, nutrient-poor foods and sugar-sweetened beverages in public places;
- Encourage healthy eating and physical activity in child care and education settings;
- Within schools, maintain comprehensive school meal guidelines that increase intake of vegetables without added salt, fruits without added sugars, and whole grains and limit sodium, added sugars, saturated fat, and trans fats; make drinking water freely available throughout the day; prohibit marketing of unhealthy foods; eliminate all sugar-sweetened beverages, including mid-calorie drinks;
- Implement Nutrition Facts and Front-of-Package labels that help consumers make healthy choices and, on the Nutrition Facts label, provide added sugar amounts in grams and teaspoons as well as a percentage daily value;
- Align nutrition policies, agriculture policies, and food assistance programs with the DGA and transform the food system to promote population health;
- Reduce added sugars through measures like pricing/taxes of sugar drinks, and reduce sodium content in foods through regulatory limits;
- Expand access to and use of healthy built environments and make physical activity accessible, affordable, and safe;
- Promote a sustainable and safe food supply to ensure long-term food security;
- Encourage consumer behavior consistent with food safety principles to prevent foodborne illness.

### *A Call to Action*

We strongly recommend that the DGA prominently feature the DGAC's recommendations for policies and environments that support and promote healthy diets and lifestyles. The DGA should emphasize the important role that the food environment and public policies play in the ability of Americans to follow the DGA's recommendations. The DGA should include a call to action for a wide range of stakeholders—including policy-makers at all levels of government, public health experts, the food and beverage industry, restaurants and food retailers, media companies, schools, businesses, community-based organizations, and others—to make healthy lifestyles and disease prevention top priorities.

Those and other sectors all have a role to play in promoting healthy behaviors and creating environments that promote a healthy way of life. The key stakeholders must become champions for a healthy diet and lifestyle and work in partnership across sectors to change policies and environments that make eating healthy foods and beverages and maintaining a healthy weight not just easier, but the cultural norm. Many of the recommended population-level strategies involve changes in federal policies, and the federal government must move forward with making evidence-based changes in policies

and practices. The federal government should also encourage and incentivize policy changes at other levels of government and in the private sector that promote healthy environments and behaviors.

## **B) Dietary Patterns**

**We commend the DGAC’s recognition of a variety of healthy dietary patterns and the continued emphasis that healthy diets meet nutrient needs with whole foods.**

We applaud the DGAC’s focus on overall dietary patterns and the common characteristics of healthy diets. We further support the DGAC’s assessment that the overall body of evidence identifies a healthy dietary pattern as one that is:

- higher in fruits, vegetables, whole grains, low or non-fat dairy, seafood, legumes, and nuts;
- moderate in alcohol, among those who choose to drink, except for children and other individuals for whom alcohol consumption is not recommended;
- lower in red and processed meats; and
- low in sugar-sweetened foods and drinks and refined grains.

Because individuals may have difficulty piecing together individual aspects of dietary recommendations, and may find certain diets easier to follow than others, the new guidelines should include several dietary patterns<sup>6</sup> as acceptable models of healthy dietary behavior. The 2015 DGA should include these findings in the recommendations and emphasize the importance of consuming an overall healthy dietary pattern, because the combination of healthy dietary habits has more impact on lowering disease risk than any one specific nutrient or food.

Research participants randomized to healthy diet patterns had a lowering of blood pressure,<sup>7</sup> and a lower number of cardiovascular events,<sup>8</sup> compared to participants following standard diets. Additionally, individuals in prospective cohort studies with higher diet scores representing healthy diet patterns are less likely to be overweight or obese,<sup>9</sup> have lower risk of major chronic diseases, including diabetes, cardiovascular

---

<sup>6</sup> Healthy Eating Index (HEI)-2005), an “alternate” HEI-2010 based on the Harvard Food Pyramid, the Dietary Approaches to Stop Hypertension (DASH) diet, and the Mediterranean diet (and alternative scores adapted for non-Mediterranean countries).

<sup>7</sup> Appel, L. J., Moore, T. J., Obarzanek, E., Vollmer, W. M., Svetkey, L. P., Sacks, F. M., et al. (1997). A clinical trial of the effects of dietary patterns on blood pressure. *New England Journal of Medicine*, 336 (16), 1117-1124.

<sup>8</sup> Estruch, R., Ros, E., Salas-Salvadó, J., Covas, M. I., Corella, D., Arós, F., et al. (2013). Primary prevention of cardiovascular disease with a Mediterranean diet. *New England Journal of Medicine*, 368 (14), 1279-1290.

<sup>9</sup> Vergnaud, A. C., Romaguera, D., Peeters, P. H., van Gils, C. H., Chan, D. S., Romieu, I., et al. (2013). 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

disease, and cancer,<sup>10</sup> and have a lower risk of premature death.<sup>11</sup> The patterns most well-studied include those recommended by the 2005 Dietary Guidelines for Americans: Healthy Eating Index (HEI)-2005; an “alternate” HEI-2010 based on the Harvard Food Pyramid; the Dietary Approaches to Stop Hypertension (DASH) diet; and the Mediterranean diet (and alternative scores adapted for non-Mediterranean countries). Furthermore, clinical trials have demonstrated that the DASH and OmniHeart diets lower blood pressure and LDL (“bad”) cholesterol.<sup>12</sup>

Each of the recommended dietary patterns shares many of the same core elements identified by the DGAC, namely higher intakes of fruits, vegetables, low-fat dairy foods, fish, poultry, beans, nuts, whole grains, healthy oils (providing more monounsaturated and polyunsaturated fats), and lower intakes of added sugars, sodium, and red and processed meats.

---

Nutrition and Cancer cohort study. *The American Journal of Clinical Nutrition*, 97 (5), 1107-1120; Boggs, D. A., Rosenberg, L., Rodríguez-Bernal, C. L., & Palmer, J. R. (2013). Long-term diet quality is associated with lower obesity risk in young African American women with normal BMI at baseline. *The Journal of Nutrition*, 143 (10), 1636-1641; Romaguera, D., Norat, T., Vergnaud, A. C., Mouw, T., May, A. M., Agudo, A., et al. (2010). Mediterranean dietary patterns and prospective weight change in participants of the EPIC-PANACEA project. *The American Journal of Clinical Nutrition*, 92 (4), 912-921.

<sup>10</sup>World Cancer Research Fund/American Institute for Cancer Research. (2007). *Food, Nutrition, Physical Activity, and the Prevention of Cancer: a Global Perspective*. Washington DC: AICR; Thomson, C. A., McCullough, M. L., Wertheim, B. C., Chlebowski, R. T., Martinez, M. E., Stefanick, M. L., et al. (2014). Nutrition and physical activity cancer prevention guidelines, cancer risk, and mortality in the women's health initiative. *Cancer Prevention Research*, 7 (1), 42-53; Kabat, G. C., Matthews, C. E., Kamensky, V., Hollenbeck, A. R., & Rohan, T. E. (2015). Adherence to cancer prevention guidelines and cancer incidence, cancer mortality, and total mortality: a prospective cohort study. *The American Journal of Clinical Nutrition*, ajcn-094854; Chiuve, S. E., Fung, T. T., Rimm, E. B., Hu, F. B., McCullough, M. L., Wang, M., et al. (2012). Alternative dietary indices both strongly predict risk of chronic disease. *The Journal of Nutrition*, jn-111; Sofi, F., Abbate, R., Gensini, G. F., & Casini, A. (2010). Accruing evidence on benefits of adherence to the Mediterranean diet on health: an updated systematic review and meta-analysis. *The American Journal of Clinical Nutrition*, 92 (5), 1189-1196.

<sup>11</sup> Liese, A. D., Krebs-Smith, S. M., Subar, A. F., George, S. M., Harmon, B. E., Neuhauser, M. L., et al. (2015). The Dietary Patterns Methods Project: Synthesis of Findings across Cohorts and Relevance to Dietary Guidance. *The Journal of Nutrition*, jn-114; McCullough, M. L., Patel, A. V., Kushi, L. H., Patel, R., Willett, W. C., Doyle, C., et al. (2011). Following cancer prevention guidelines reduces risk of cancer, cardiovascular disease, and all-cause mortality. *Cancer Epidemiology Biomarkers & Prevention*, 20 (6), 1089-1097; Liese, A. D., Krebs-Smith, S. M., Subar, A. F., George, S. M., Harmon, B. E., Neuhauser, M. L., et al. (2015). The Dietary Patterns Methods Project: Synthesis of Findings across Cohorts and Relevance to Dietary Guidance. *The Journal of Nutrition*, jn-114.

<sup>12</sup> Appel, L. J., Sacks, F. M., Carey, V. J., Obarzanek, E., Swain, J. F., Miller, E. R., et al. (2005). Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: results of the OmniHeart randomized trial. *JAMA*, 294 (19), 2455-2464; Appel et al, 1997.

Both the American Institute for Cancer Research (AICR)'s Recommendations for Cancer Prevention<sup>13</sup> and the American Cancer Society's guidelines on nutrition and physical activity for cancer prevention<sup>14</sup> call for consuming an overall healthy diet with an emphasis on plant foods, and overlap considerably with the DGAC recommendations and the other diet patterns highlighted above. That overall pattern specifically focuses on vegetables, fruits, whole grains, limiting processed and red meat consumption, limiting sugar-sweetened beverages, and choosing foods and beverages in amounts to help achieve and maintain a healthy body weight. Both organizations' guidelines have been examined in relation to cancer incidence<sup>15</sup> and mortality;<sup>16</sup> significant reductions in risk were observed with greater adherence to all of the guidelines (diet, alcohol, physical activity, obesity) as well as the diet pattern, specifically. Research has confirmed that nonsmoking (former and never smoker) adult men and women whose lifestyles were most consistent with American Cancer Society (ACS) cancer prevention guidelines for weight control, diet, physical activity, and alcohol had a significantly lower risk of dying from cancer, cardiovascular disease, or any cause.<sup>17</sup>

We agree with the DGAC report that the DGA should continue to recommend that nutrient needs be met primarily by consuming nutrient-dense, whole foods as part of an overall healthy dietary pattern. This approach is consistent with recommendations from the Institute of Medicine,<sup>18</sup> American Cancer Society,<sup>19</sup> American Institute for Cancer Research,<sup>20</sup> and others, and research showing that the nutrient density and overall healthfulness of fruits, vegetables, whole grains, and low-fat dairy products cannot be duplicated by simply adding vitamins or minerals to nutrient-poor foods. The American Cancer Society's Nutrition and Physical Activity Guidelines for Cancer Prevention notes, "it is likely that foods and nutrients have additive or synergistic effects on health and interact in complex ways that are difficult to study and are poorly understood."<sup>21</sup> Similarly, the American Institute for Cancer Research's Recommendations for Cancer Prevention are "base[d]...on foods and whole diets rather than specific nutrients...The recommendations contribute to whole diets and overall level of physical activity most likely to prevent cancer. This does not imply one particular diet, or a specific form of

---

<sup>13</sup> WCRF/AICR, 2007.

<sup>14</sup> Kushi, L. H., Doyle, C., McCullough, M., Rock, C. L., Demark-Wahnefried, W., Bandera, E. V., et al. (2012). American Cancer Society guidelines on nutrition and physical activity for cancer prevention. *CA: A Cancer Journal for Clinicians*, 62 (1), 30-67.

<sup>15</sup> Vergnaud et al., 2014; Thomson, 2014; Kabat, G. C., Matthews, C. E., Kamensky, V., Hollenbeck, A. R., & Rohan, T. E. (2015). Adherence to cancer prevention guidelines and cancer incidence, cancer mortality, and total mortality: a prospective cohort study. *The American Journal of Clinical Nutrition*, ajcn-094854.

<sup>16</sup> Romaguera et al., 2010; Thomson, 2014; McCullough et al., 2011.

<sup>17</sup> McCullough et al., 2011.

<sup>18</sup> Stallings, V. A., & Yaktine, A. L. (Eds.). (2007). *Nutrition standards for foods in schools: leading the way toward healthier youth*. National Academies Press.

<sup>19</sup> Kushi et al., 2012.

<sup>20</sup> WCRF/AICR, 2007.

<sup>21</sup> Kushi et al., 2012.

physical activity, but rather key elements designed to be incorporated into existing and traditional diets.”<sup>22</sup>

We support the DGAC’s recommendations that most Americans should rely on healthy diets, not vitamin or mineral supplements, to lower their risk of cancer, heart disease, and other illness. Clinical trials have found that folic acid can lower the risk of neural tube birth defects,<sup>23</sup> calcium supplements lower the risk of recurrent colorectal adenomas,<sup>24</sup> a low-dose multivitamin and mineral supplement may lower the risk of all cancers combined in men,<sup>25</sup> and folic acid can lower the risk of stroke in China, where grains are not fortified with folic acid.<sup>26</sup> However, other clinical trials have found that several nutrients, including beta-carotene, selenium, and vitamin E, do not lower, and may even increase, cancer risk.<sup>27</sup> The majority of the evidence does not suggest that individuals should take single or combined dietary supplements for prevention of cancer or cardiovascular disease.<sup>28</sup>

Another benefit of a focus in the DGA on overall healthy dietary patterns is that it allows individuals to consume a wide range of foods and beverages and meet nutrient needs in a variety of ways. This makes it easier for individuals to consume a healthful diet that is tailored to their individual physical needs and social and cultural preferences but still meets the overarching recommendations for a healthy dietary pattern. The DGA should provide several examples of specific diets that meet the overarching healthy diet pattern recommendations.

---

<sup>22</sup> WCRF/AICR, 2007.

<sup>23</sup> Williams, J., Mai, C. T., Mulinare, J., Isenburg, J., Flood, T. J., Ethen, M., et al. (2015). Updated Estimates of Neural Tube Defects Prevented by Mandatory Folic Acid Fortification—United States, 1995–2011. *MMWR. Morbidity and mortality weekly report*, 64 (1), 1-5.

<sup>24</sup> Grau, M. V., Baron, J. A., Sandler, R. S., Wallace, K., Haile, R. W., Church, T. R., et al. (2007). Prolonged effect of calcium supplementation on risk of colorectal adenomas in a randomized trial. *Journal of the National Cancer Institute*, 99 (2), 129-136.

<sup>25</sup> Gaziano, J. M., Sesso, H. D., Christen, W. G., Bubes, V., Smith, J. P., MacFadyen, J., et al. (2012). Multivitamins in the prevention of cancer in men: the Physicians' Health Study II randomized controlled trial. *JAMA*, 308 (18), 1871-1880.

<sup>26</sup> Huo, Y., Li, J., Qin, X., Huang, Y., Wang, X., Gottesman, R. F., et al. (2015). Efficacy of folic acid therapy in primary prevention of stroke among adults with hypertension in China: the CSPPT randomized clinical trial. *JAMA*, 313(13), 1325-1335.

<sup>27</sup> Kushi et al., 2012; Bjelakovic, G., Nikolova, D., Gluud, L. L., Simonetti, R. G., & Gluud, C. (2012). Antioxidant supplements for prevention of mortality in healthy participants and patients with various diseases. *The Cochrane Library*; Klein, E. A., Thompson, I. M., Tangen, C. M., Crowley, J. J., Lucia, M. S., Goodman, P. J., et al. (2011). Vitamin E and the risk of prostate cancer: the Selenium and Vitamin E Cancer Prevention Trial (SELECT). *JAMA*, 306 (14), 1549-1556.

<sup>28</sup> Fortmann, S. P., Burda, B. U., Senger, C. A., Lin, J. S., Beil, T. L., O'Connor, E., & Whitlock, E. P. (2013). Vitamin, mineral, and multivitamin supplements for the primary prevention of cardiovascular disease and cancer: A systematic evidence review for the US preventive services task force. *Evidence Syntheses* (108).

**C) We have specific views with regard to the following components of the diet: added sugars, sodium, red and processed meats, saturated fat, fruits and vegetables, and whole grains.**

**a. Added Sugars**

**We unequivocally support the DGAC’s recommendations to reduce consumption of added sugars, including the need for a line on added sugars on the Nutrition Facts label that includes a percentage of a Daily Value based on 10 percent of calories or less in a 2,000-calorie diet, and for amounts expressed in teaspoons as well as grams to maximize consumer understanding.**

First, we concur that the scientific evidence underscoring concerns with added sugars in the diet is strong. With regard to high consumption of added sugars, the DGAC concluded that there was “strong evidence” for an increased risk of excess body weight, obesity, and type 2 diabetes and “moderate evidence” for an increased risk of hypertension, stroke, coronary heart disease, high blood pressure, serum triglycerides, and dental caries. After reviewing the evidence, the Committee found that “strong evidence supports reducing added sugars intake to reduce health risks” and that a limit on “added sugars to a maximum of 10 percent of total daily caloric intake” was supported by the food pattern modeling analysis and the scientific evidence review on added sugar and chronic disease risk.<sup>29</sup> By that 10 percent standard, an individual who consumes a 2,000-calorie diet could consume up to 200 calories’ worth (50 grams, 12 teaspoons) of added sugars.<sup>30</sup>

Convincing evidence from randomized trials suggests that drinking sugar-sweetened beverages, the largest source of added sugars in Americans’ diets, leads to weight gain in both children and adults.<sup>31</sup> Sugar-sweetened beverages are also associated with cardiovascular disease, type 2 diabetes, the metabolic syndrome, gout, and dental caries.<sup>32</sup> Recent clinical studies have found that high intakes of fructose-containing

---

<sup>29</sup> Science Based Chapter, Cross-cutting Topics of Public Health Importance, 2015 DGAC slides. See also Scientific Report of the Dietary Guidelines Advisory Committee, 2015, Part D. Chapter 6, at 20.

<sup>30</sup> World Health Organization. (2003). Diet, nutrition and the prevention of chronic diseases. *WHO technical report series* (916) 1-60.

<sup>31</sup> Te Morenga, L., Mallard, S., & Mann, J. (2013). Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. *BMJ*, 346, e7492; de Ruyter, J. C., Olthof, M. R., Seidell, J. C., & Katan, M. B. (2012). A trial of sugar-free or sugar-sweetened beverages and body weight in children. *New England Journal of Medicine*, 367 (15), 1397-1406.

<sup>32</sup> Malik, V. S., Popkin, B. M., Bray, G. A., Després, J. P., & Hu, F. B. (2010). Sugar-sweetened beverages, obesity, type 2 diabetes mellitus, and cardiovascular disease risk. *Circulation*, 121 (11), 1356-1364; Malik, V. S., Popkin, B. M., Bray, G. A., Després, J. P., Willett, W. C., & Hu, F. B. (2010). Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes A meta-analysis. *Diabetes care*, 33 (11), 2477-2483; Choi, H. K., & Curhan, G. (2008). Soft drinks,

sugars raise levels of triglycerides, visceral fat, liver fat, blood glucose, insulin, and small, dense LDL-cholesterol.<sup>33</sup> Moreover, the higher diets are in added sugars (with no apparent threshold), the lower they are in a variety of vitamins and minerals.<sup>34</sup>

A recent prospective study of more than 11,000 people in the National Health and Nutrition Examination Survey (NHANES) III—a nationally representative sample of Americans—followed for 15 years found higher risks of cardiovascular mortality with increasing added-sugars consumption. Those who consumed at least 10 percent but less than 25 percent of their calories from added sugars had a 30 percent higher risk of dying of a heart attack, stroke, or other cardiovascular event than those who consumed less than 10 percent of their calories from added sugars. The risk was nearly three times higher for those who consumed at least 25 percent of their calories from added sugars (more than 10 percent of the study population).<sup>35</sup>

A recent clinical study provides further support for these findings. Researchers fed 85 adults aged 18 to 40 beverages sweetened with enough high-fructose corn syrup to supply 0, 10, 17.5, or 25 percent of their calories for two weeks. (On average, adults aged 20 to 60 get about 14 percent of their calories from HFCS, table sugar, and other added sugars.) The higher the dose, the higher the subjects' fasting LDL cholesterol, after-meal triglycerides, and uric acid levels. (High uric acid levels are linked to a higher risk of gout.) “The dose-dependent increases of these risk factors for CVD, which were shown to be statistically independent of body weight gain, provide a plausible

---

fructose consumption, and the risk of gout in men: prospective cohort study. *BMJ*, 336 (7639), 309-312; Touger-Decker, R., & Van Loveren, C. (2003). Sugars and dental caries. *The American Journal of Clinical Nutrition*, 78 (4), 881S-892S.

<sup>33</sup> Stanhope, K. L., Schwarz, J. M., Keim, N. L., Griffen, S. C., Bremer, A. A., Graham, J. L., et al. (2009). Consuming fructose-sweetened, not glucose-sweetened, beverages increases visceral adiposity and lipids and decreases insulin sensitivity in overweight/obese humans. *The Journal of Clinical Investigation*, 119 (5), 1322; Stanhope, K. L., Bremer, A. A., Medici, V., Nakajima, K., Ito, Y., Nakano, T., et al. (2011). Consumption of fructose and high fructose corn syrup increase postprandial triglycerides, LDL-cholesterol, and apolipoprotein-B in young men and women. *The Journal of Clinical Endocrinology & Metabolism*, 96 (10), E1596-E1605; Maersk, M., Belza, A., Stødkilde-Jørgensen, H., Ringgaard, S., Chabanova, E., Thomsen, H., et al. (2012). Sucrose-sweetened beverages increase fat storage in the liver, muscle, and visceral fat depot: a 6-mo randomized intervention study. *The American Journal of Clinical Nutrition*, 95 (2), 283-289.

<sup>34</sup> Marriott, B. P., Olsho, L., Hadden, L., & Connor, P. (2010). Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003–2006. *Critical Reviews in Food Science and Nutrition*, 50 (3), 228-258.

<sup>35</sup> Yang, Q., Zhang, Z., Gregg, E. W., Flanders, W. D., Merritt, R., & Hu, F. B. (2014). Added sugar intake and cardiovascular diseases mortality among US adults. *JAMA Internal Medicine*, 174 (4), 516-524. (We note that the findings were remarkably robust, as they were “largely consistent across age group, sex, race/ethnicity (except among non-Hispanic blacks), educational attainment, physical activity, health eating index, and body mass index.”).



mechanistic support for the recent epidemiologic findings that there is increased risk of CVD mortality with increased intake of added sugar across quintiles,” note the authors.<sup>36</sup>

In 2003–2006, added sugars (sugar, high-fructose corn syrup, etc.) provided about 14 percent of total calories for the average American, and 25 percent or more of calories for over 36 million Americans.<sup>37</sup> According to data from the National Health and Nutrition Examination Survey (NHANES) 2007–2008 and the U.S. Department of Agriculture’s (USDA) average per-capita loss-adjusted food availability data for 2012, Americans consumed between 18 and 23 teaspoons (about 300 to 390 calories worth) of added sugars per day, though consumption has declined modestly (about 15 percent) in the last 15 years.<sup>38</sup> Consuming foods high in added sugars makes it more difficult to meet nutrient needs and stay within calorie limits. In contrast, foods high in natural sugars, such as fruits and dairy products, are often high in other nutrients.

While we support the DGAC’s recommendation for consuming no more than 10 percent of calories from added sugars, and believe that that could form an adequate basis for FDA to include a percent DV for added sugars on the labels of packaged foods, we believe that a lower recommendation would also be appropriate. Specifically, Americans should get no more than five to ten percent of their calories from added sugars. That recommendation would align the DGA with recommendations from the World Health Organization and the American Heart Association (AHA).<sup>39</sup> Such science-based recommendations and guidelines to reduce added sugar intake have existed for years:

- In 1999, the Center for Science in the Public Interest (CSPI), along with leading health experts and organizations, petitioned the FDA to adopt a DV of 10 teaspoons, or 42 grams, for added sugars (168 calories or about 8 percent of a

---

<sup>36</sup> Stanhope, K. L., Medici, V., Bremer, A. A., Lee, V., Lam, H. D., Nunez, M. V., et al. (2015). A dose-response study of consuming high-fructose corn syrup-sweetened beverages on lipid/lipoprotein risk factors for cardiovascular disease in young adults. *The American journal of clinical nutrition*, ajcn100461. These results may differ from those of other studies or meta-analyses (often funded by industry) because some studies used sucrose as a control, did not measure postprandial triglycerides at their peak (after dinner), restricted calories, or for other reasons that are described in the Supplemental Discussion in the “Supplemental data” link in the online article.

<sup>37</sup> Marriott et al., 2010.

<sup>38</sup> Welsh, J. A., Sharma, A. J., Grellinger, L., & Vos, M. B. (2011). Consumption of added sugars is decreasing in the United States. *The American Journal of Clinical Nutrition*, 94 (3), 726-734; U.S. Department of Agriculture, Economic Research Service. (2014). Food Availability (Per Capita) Data System. Available at <http://www.ers.usda.gov/data-products/food-availability-%28per-capita%29-data-system.aspx>. Accessed March 20, 2015.

<sup>39</sup> World Health Organization. (2015). Guideline: Sugars intake for adults and children. Geneva; Johnson, R. K., Appel, L. J., Brands, M., Howard, B. V., Lefevre, M., Lustig, R. H., et al. (2009). Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. *Circulation*, 120 (11), 1011-1020.

- 2,000-calorie diet).<sup>40</sup> That was based on the U.S. Department of Agriculture's (USDA) recommendation that people consuming a 2,000-calorie diet limit their consumption of added sugars to 10 teaspoons per day (8.4 percent of calories).<sup>41</sup>
- In 2003, the World Health Organization (WHO) recommended that individuals consume less than 10 percent of their calories from “free” sugars. That includes added sugars and the “free” sugars in fruit juices, honey, and syrups, so the percentage of calories from added sugars would be less than 10 percent.
  - In 2005, the DGA recommended quantitative limits for added sugars combined with solid fats based on the discretionary calorie allowance for each level of calorie intake.<sup>42</sup> For example, after lower-calorie, nutrient-dense foods in each food group were selected, someone consuming a 2,000-calorie diet would have up to 267 discretionary calories to expend on solid fats and added sugars (assuming no alcohol, which is not the case for many U.S. adults). Dividing those calories equally between solid fats and added sugars, a reasonable and realistic recommendation, would mean that no more than 133 calories (33 grams or 8 teaspoons) per day should come from added sugars. That would amount to 6 percent of calories in a 2,000-calorie diet.
  - In 2009, the American Heart Association (AHA) recommended that women and men consume no more than 100 calories (25 grams) or 150 calories (37.5 grams) per day from added sugars, respectively. That is equivalent to roughly 6 percent of total calories (based on intakes of 1,800 calories for women and 2,200 for men).<sup>43</sup> The AHA recommendation was based on amounts of discretionary calories for added sugars and solid fats detailed in the appendices of previous versions of the DGA.
  - In 2015, the WHO, following a comprehensive review of the science, published an evidence-informed guideline that provides two strong recommendations: 1) “a reduced intake of free sugars throughout the life course;” 2) “reducing intake of free sugars to less than 10 percent of total energy intake.”<sup>44</sup> The WHO also made

---

<sup>40</sup> Center for Science in the Public Interest. (August 3, 1999). Petition to the FDA to Require Better Sugar Labeling on Foods. Available at [www.cspinet.org/reports/sugar/sugarpet1.pdf](http://www.cspinet.org/reports/sugar/sugarpet1.pdf). Accessed April 23, 2015.

<sup>41</sup> U.S. Department of Agriculture, Center for Nutrition Policy and Promotion. (1996). The Food Guide Pyramid. *Home and Garden Bulletin*, 252. Available at [http://www.cnpp.usda.gov/sites/default/files/archived\\_projects/FGPPamphlet.pdf](http://www.cnpp.usda.gov/sites/default/files/archived_projects/FGPPamphlet.pdf). Accessed March 20, 2015.

<sup>42</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2005). Dietary Guidelines for Americans, 2005. 6<sup>th</sup> Edition, Washington, DC.

<sup>43</sup> Johnson, R. K., Appel, L. J., Brands, M., Howard, B. V., Lefevre, M., Lustig, R. H., et al. (2009). Dietary sugars intake and cardiovascular health a scientific statement from the American Heart Association. *Circulation*, 120 (11), 1011-1020.

<sup>44</sup> World Health Organization. (2015). Guideline: Sugars intake for adults and children. Geneva.

a conditional recommendation for an even lower sugar intake, to “below 5 percent.”

A quantitative recommendation for added sugars must be included in the main body (and not just an appendix) of the DGA, as it has important implications for national programs and policies, including school meals, snacks and drinks in schools, and food labeling.

### ***Policy Recommendations to Reduce Added Sugars Consumption***

We also support the policy implications of the DGAC’s conclusions on the need for policies that address over-consumption of added sugars. They are on-point and sorely needed. Specifically, we agree that the DGA should endorse policies that would discourage excessive consumption of added sugars, and reduce consumption of sugar-sweetened beverages, including the following:

- Revising the Nutrition Facts label to have a line for added sugars, with amounts expressed in both grams and teaspoons, along with a percent DV;
- Economic and pricing approaches, including incentives and disincentives;
- Continued efforts to reduce added sugars in foods and beverages in school meals and snacks;
- Limiting the presence and advertising of foods and beverages high in added sugars to young children, youth, and adolescents;
- Health promotion efforts and policies to reduce the availability of sugar-sweetened beverages in post-secondary institutions and worksites;
- Public education campaigns to raise public awareness of health harms of and alternatives to added sugars.

All of those policies are an appropriate response to decades of food marketing and promotion, lobbying, and attempted influence over health research findings by sugar interests.<sup>45</sup> Connecting dietary advice to consumption patterns is critical to achieving public health improvements.

### ***The Risks of Consuming Sugar-Sweetened Beverages Also Should Be Addressed***

Sugar-sweetened beverages, including soda pop, fruit drinks, energy drinks, sports drinks, juices and sweet teas, are the largest source of calories in Americans’

---

<sup>45</sup> See, e.g., Union of Concerned Scientists. (June 2014). Added Sugar, Subtracted Science; Union of Concerned Scientists. (May 2014). Sugar-Coating Science.

diets.<sup>46</sup> Although consumption has slowly been declining,<sup>47</sup> Americans are still consuming far more sugar drinks than is healthy. The National Health and Nutrition Examination Survey (NHANES) 2005–2008 found that about half the U.S. population consumes sugar drinks on any given day. Males and females aged 12 to 19 consume an average of 273 and 171 total calories per day from sugar drinks, respectively.<sup>48</sup> That is more than any other age group.

Soft drinks are the *only* beverage/food that has been directly linked to obesity, in large part due to the large volumes consumed, the large amounts of added sugars, and the liquid form. Randomized controlled trials have provided convincing evidence that drinking sugar-sweetened beverages can lead to weight gain.<sup>49</sup> Evidence from intervention studies shows that calories consumed in liquid form are less satiating than the same number of calories consumed from food.<sup>50</sup> That can lead people to overeat and eventually gain weight.

Sugar-sweetened beverages provide calories with few nutrients, which makes it difficult for consumers to meet nutritional needs and stay within calorie requirements. Given that sugar-sweetened beverages make a unique direct contribution to obesity and other non-communicable diseases, the DGA should emphasize strongly that Americans should consume these beverages only rarely, comparing the amount in typical servings to the recommended maximum daily intake and that public policies should be developed that encourage consumption of healthier beverages, including water, and discourage the availability of sugar drinks.

Furthermore, the FDA, as a department within HHS, should align its updates to the Nutrition Facts label by including a percent DV for added sugars on the labels of all

---

<sup>46</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. (December, 2010). Table 2-2. Top 25 sources of calories among Americans ages 2 years and older, NHANES 2005–2006. *Dietary Guidelines for Americans, 2010*. 7<sup>th</sup> Edition, Washington, DC: U.S. Government Printing Office. Page 12.

<sup>47</sup> Beverage Digest. (2014). U.S. beverage results for 2014. Available at [http://beverage-digest.com/pdf/top-10\\_2014.pdf](http://beverage-digest.com/pdf/top-10_2014.pdf). Accessed May 7, 2015.

<sup>48</sup> Ogden, C. L. (2011). *Consumption of sugar drinks in the United States, 2005-2008* (p. 71). US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics.

<sup>49</sup> Te Morenga, L., Mallard, S., & Mann, J. (2013). Dietary sugars and body weight: systematic review and meta-analyses of randomised controlled trials and cohort studies. *BMJ*, 346, e7492; de Ruyter, J. C., Olthof, M. R., Seidell, J. C., & Katan, M. B. (2012). A trial of sugar-free or sugar-sweetened beverages and body weight in children. *New England Journal of Medicine*, 367 (15), 1397-1406.

<sup>50</sup> DiMaggio, D. P., & Mattes, R. D. (2000). Liquid versus solid carbohydrate: effects on food intake and body weight. *International journal of obesity*, 24 (6), 794-800; Mourao, D. M., Bressan, J., Campbell, W. W., & Mattes, R. D. (2007). Effects of food form on appetite and energy intake in lean and obese young adults. *International Journal of Obesity*, 31 (11), 1688-1695.

processed foods, as the DGA recommended.<sup>51</sup> In addition, added sugars should be indicated on labels in teaspoons to ease consumer understanding. Few Americans are familiar with the metric measures used for total sugars (and other nutrients), because they are unrelated to their common experiences, such as measuring sugar into coffee or tea. They do, however, instantly understand measurements such as teaspoons, tablespoons, and cups, which are commonly used in cooking and baking and used on the Nutrition Facts label to indicate serving sizes.<sup>52</sup>

***CSPI's Studies on Consumer Understanding of Labels Underscores Need for a Line for Added Sugars, a Daily Value for Added Sugars, and for Measurements in Teaspoons on the Nutrition Facts Panel, as the DGAC Recommended***

CSPI has been conducting surveys on labeling of added sugars for years. Prior results were compelling, but a recent survey adds further evidence that underscores the public's desire for additional and clearer information on sugars.

A 2010 national telephone survey commissioned by CSPI found that 72 percent of respondents favored listing teaspoons of added sugars on the label (38 percent preferred listing only teaspoons, while 34 percent preferred both teaspoons and grams). Just 20 percent of respondents preferred listing sugar amounts in grams only.<sup>53</sup>

There is also ample reason to provide a daily value (DV) for added sugars to facilitate consumer understanding. In a survey we commissioned in July 2014 of 1,045 consumers, 78 percent indicated that they either could not tell (58 percent) or did not know (another 20 percent) the “recommended daily limit of added sugars” from a version

---

<sup>51</sup> Percentage Daily Values (DVVs) are an essential tool for consumer comprehension and use of nutrition information. In its proposal, FDA notes: “Section 2(b)(1)(A) of the 1990 amendments mandated that FDA regulations implementing section 403(q) of the FD&C Act require that nutrition labeling must be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet. In particular, the percent DV of a nutrient present in food is declared on food labels to help consumers understand the relative significance of nutrition information in the context of a total daily diet, compare the nutritional values of food products, and to plan general diets. We also noted that the percent DV information advises the consumer how much of a recommended intake of that nutrient is provided by the food.” See 79 F.R. 11880, 11887.

<sup>52</sup> A 2010 nationally representative telephone survey conducted by Center for Science in the Public Interest (CSPI) found that 72 percent of respondents thought that including teaspoons as a measurement for sugar on food labels would be of assistance: 38 percent preferred listing *only* teaspoons of added sugars on the label, while 34 percent of respondents preferred both teaspoons and grams. Just 20 percent of those polled preferred listing sugar only in grams. Center for Science in the Public Interest. (August 2, 2011). Unrealistic serving sizes understate calories, sodium, saturated fat, says CSPI. *Press Release*. Available at <http://cspinet.org/new/201108021.html>. Accessed April 23, 2015.

<sup>53</sup> Center for Science in the Public Interest. (August 2, 2011). Unrealistic serving sizes understate calories, sodium, saturated fat, says CSPI. *Press Release*. Available at <http://cspinet.org/new/201108021.html>. Accessed April 23, 2015.

of a label displaying a line for added sugars but not a percentage DV for added sugars.<sup>54</sup> In contrast, when shown a label including the percentage DV, 66 percent of consumers correctly identified the information.

In April 2015, we commissioned a new survey that focused on added-sugars labeling with April 2015, of 1,011 consumers.<sup>55</sup> The results were instructive:

- Only 18 percent of consumers correctly identified the number of teaspoons of sugar in one gram of sugar, while 53 percent indicated outright that they “didn’t know” the amount. That is, Americans simply don’t understand grams.
- When informed that a beverage contained 40 grams of sugar per serving, and asked to convert the number to teaspoons of sugar, 40 percent of consumers indicated they did not know the answer, and only about 25 percent came *within five teaspoons* of the correct answer—9½ teaspoons. It is clear that Americans cannot convert grams into the more familiar measurement of teaspoons.
- Next, we asked respondents to review two nutrition labels, one with the sugar expressed only as grams, the other only as teaspoons. When asked which label “more clearly conveys to you the amount of sugar in a 20-ounce bottle,” 61 percent of respondents preferred teaspoons while only 28 percent preferred the current measurement of grams. A second question asked consumers to review three labels with differences in the line for sugars, showing: grams alone, teaspoons alone and both teaspoons and grams. A majority – 61 percent – preferred grams and teaspoons together, while 18 percent wanted only teaspoons and 14 percent only grams. In sum, 79 percent identified a desire for measurements in teaspoons, while a mere 14 percent preferred listing grams alone (which is even lower than the 20 percent of those surveyed who indicated a preference for grams in CSPI’s 2010 survey).
- Last, we asked whether inclusion of a percentage DV for added sugars would be helpful in figuring out how many servings of either a high-sugar muffin or soft drink would fit into a healthy daily diet. For the soft drink, we provided two identical labels, one with, and one without, a DV for sugars. A stunning 80 percent of consumers identified the label including the DV as the one that would “make it easier” for them “to determine whether drinking one bottle would fit into a healthy daily diet.” The results to the same question (with the label order switched) with regard to a hypothetical muffin were similar: 84 percent of respondents identified the label with the DV as more helpful.

---

<sup>54</sup> Center for Science in the Public Interest. (July 10-13, 2014). *Food Label Study of 1,045 Consumers by Online Caravan*.

<sup>55</sup> Center for Science in the Public Interest. (April 23-26, 2014). *Sugar Nutrition Facts Label Survey of 1011 Consumers by Online Caravan*. We would be pleased to provide the Departments with a copy of the survey.

For all of those questions, there were no significant differences in the answers given by men and women, across socio-economic classes, more- or less-well-educated consumers, or among racial and ethnic groups.

## b) Sodium

**The DGAC should strongly recommend reducing daily sodium intake to 2,300 milligrams (mg) per day for the general population and to 1,500 mg per day for at-risk subgroups.**

We applaud the DGAC for emphasizing sodium reduction in its Scientific Report. Sodium continues to be a major public health problem, with Americans consuming an average of roughly 3,500 mg per day—far more than the recommended amount. Excess sodium consumption is linked to the development and worsening of high blood pressure and an increased risk of heart disease, stroke, kidney failure, gastric cancer, and osteoporosis. As the DGAC noted, despite the methodological flaws and limitations that plague many studies, it is clear that higher sodium intakes are associated with a higher risk of cardiovascular disease.

Reports of increased risks among people with low intakes are likely to be due to reverse causation, residual confounding, or errors in sodium assessment.<sup>56</sup> For example, a recent observational study (PURE) of roughly 101,000 people in 17 countries reported that “an estimated sodium intake” between 3,000 and 6,000 mg per day and 6 g per day was associated with a lower risk of death and cardiovascular events.<sup>57</sup> However, this study has several serious limitations:

- **Illness may have caused low sodium intakes.** The people in this study who consumed the least sodium also had the most illness, suggesting that it was illness that caused their low sodium intake rather than low sodium intake that caused their illness (a methodological problem known as reverse causation). As a letter in the *New England Journal of Medicine* notes, “the group in which urinary sodium levels were less than 3.00 g (making up 10.6% of the total study population) included persons with the highest rates of cardiovascular disease, diabetes mellitus, current alcohol use, and diuretic use.”<sup>58</sup> Although it is possible to control for these factors, it is difficult to *adequately* control for all of them and for others that the authors failed to measure or failed to measure well. O’Donnell et al. acknowledge that “reverse causation cannot be completely ruled out and

---

<sup>56</sup> Cobb, L. K., Anderson, C. A., Elliott, P., Hu, F. B., Liu, K., Neaton, J. D., et al. (2014). Methodological Issues in Cohort Studies That Relate Sodium Intake to Cardiovascular Disease Outcomes: A Science Advisory from the American Heart Association. *Circulation*, 129 (10), 1173-1186.

<sup>57</sup> O’Donnell, M., Mentz, A., Rangarajan, S., McQueen, M. J., Wang, X., Liu, L., et al. (2014). Urinary sodium and potassium excretion, mortality, and cardiovascular events. *New England Journal of Medicine*, 371(7), 612-623 .

<sup>58</sup> Batuman, V. (2014). Sodium and cardiovascular disease. *N Engl J Med*, 371(22), 2134-2135.

may account in part for the increased risk observed in the group of participants with a low estimated sodium excretion.”

- **Sodium intake measures were unreliable.** As another letter to the Journal noted, “a single morning urine sample is an inaccurate measure of usual sodium intake, ignoring day-to-day variability in sodium intake, diurnal variation in sodium excretion, and the effects of medication.”<sup>59</sup> Furthermore, the Kawasaki formula (which was used to estimate 24-hour urine levels from a spot urine) also overestimates sodium exposure in non-Asian populations. In addition, the study inflated the validity of using a spot urine sample to estimate long-term sodium intake.<sup>60</sup>
- **Results may not apply to Americans.** Only about 14 percent of the participants in the PURE study came from high-income countries like the United States. Roughly 60 percent came from China, India, and other lower-income countries where other factors might have altered sodium intakes and the risk of dying. Nor is there any evidence that the PURE subjects who consumed the least sodium were doing so to protect their health. As the O’Donnell paper notes, “our findings should not be interpreted as evidence that the intentional reduction of sodium intake would alter the risk of death or cardiovascular disease.”

In contrast, lower sodium intakes are linked to a *lower* cardiovascular risk in studies with fewer flaws. In the Trials of Hypertension Prevention (TOHP), the researchers used three to seven 24-hour urine samples taken over 1 to 4 years to get a reliable estimate of each person’s typical sodium intake. TOHP found a higher risk of cardiovascular events at higher sodium intakes and no indication of an increased risk at lower sodium intakes (down to below 1,500 mg per day).<sup>61</sup>

To help Americans achieve a healthier sodium intake, the Committee has recommended that the general population limit sodium to less than 2,300 mg or the age-

---

<sup>59</sup> Cook, N. R., O’Donnell, M., Mente, A., & Rangarajan, S. (2014). Sodium and cardiovascular disease. *N Engl J Med*, 371, 2134.

<sup>60</sup> O’Donnell et al. cites an accompanying study by Mente et al., which cites an earlier validation study that “showed an intraclass correlation coefficient of 0.71 (95% confidence interval [CI], 0.65 to 0.76) for the Kawasaki estimate versus measured 24-hour sodium excretion.” However, Mente et al. calculated the intraclass correlation of 0.71 after excluding roughly half of the subjects, whose 24-hour urine samples were judged incomplete. The ICC based on the full sample was only 0.59. Mente, A., O’Donnell, M. J., Rangarajan, S., McQueen, M. J., Poirier, P., Wielgosz, A., et al. (2014). Association of urinary sodium and potassium excretion with blood pressure. *New England Journal of Medicine*, 371(7), 601-611; Mente, A., O’Donnell, M. J., Dagenais, G., Wielgosz, A., Lear, S. A., McQueen, M. J., et al. (2014). Validation and comparison of three formulae to estimate sodium and potassium excretion from a single morning fasting urine compared to 24-h measures in 11 countries. *Journal of hypertension*, 32(5), 1005-1015.

<sup>61</sup> Cook, N. R., Appel, L. J., & Whelton, P. K. (2014). Lower levels of sodium intake and reduced cardiovascular risk. *Circulation*, 129, 981-989.



appropriate Dietary Reference Intake (DRI) amount.<sup>62</sup> Although we believe the ultimate target intake should be even lower (1,500 mg per day), 2,300 mg or less can be viewed as an interim recommendation based on current consumption levels and the amount of sodium in the food supply. Reducing sodium consumption to less than 2,300 mg or less per day would be a good first step. We also agree with the Committee’s conclusion that adults who would benefit from blood pressure lowering—namely people with prehypertension or hypertension, which includes two-thirds of the adult population—should reduce their sodium intake ideally to 1,500 mg per day.

Confusingly, the DGAC also recommended that people with hypertension or prehypertension should consume no more than 2,400 mg of sodium per day. We recognize that 2,400 mg was recommended because that was the estimated average urinary sodium excretion when subjects in the DASH sodium trial were assigned to a 2,300 mg diet. However, recommending less than 2,300 mg for the general population and no more than 2,400 mg for adults who would benefit from blood pressure lowering would result in confusion.

We urge HHS and USDA to simplify the messaging in the final policy document and recommend less than 2,300 mg for the general population. At-risk subgroups should be advised that a greater reduction to 1,500 mg would be desirable, and that if they cannot immediately reach either target level, that reducing sodium by at least 1,000 mg per day—and more to reach the 1,500 mg/day level—would be beneficial.

To help individuals lower their sodium intake, the Committee has recommended that a “primary emphasis be placed on policies and population-based strategies for sodium reduction while at the same time paying attention to consumer education.” We strongly agree. Despite decades of dietary guidance advising Americans to reduce their sodium consumption, high intakes have persisted. It is clear that relying on individual behavior change alone is not enough. With nearly 80 percent of the sodium we eat coming from packaged and restaurants foods, Americans will continue to have difficulty reducing their sodium intake unless there are changes to the food supply (or people are encouraged to switch to diets based to a much greater extent on low-sodium natural foods, such as fruits and vegetables, as we urge below). As the Committee advised, HHS and USDA should work with the food and restaurant industry to lower the amount of sodium in the food supply. The DGAC also said that it could be achieved by implementing the recommendations contained in the 2010 IOM report “Strategies to Reduce Sodium Intake in the United States,” including modifying the GRAS status of salt and establishing sodium limits for foods.

The Agencies should also continue to move forward with existing efforts to reduce sodium intake in children. As the DGAC’s Scientific Report discusses, the

---

<sup>62</sup> We recommend that the final policy document specify the amount of sodium that corresponds to the DRI amount for each age group so that policies can be set accordingly. Per the 2006 IOM DRIs for sodium, the Upper Levels (mg/day) are: Age 1-3: 1,500; Age 4-8: 1,900; Age 9-13: 2,200; Age 14-18: 2,300. Hellwig, J. P., Otten, J. J., & Meyers, L. D. (Eds.). (2006). *Dietary Reference Intakes: The Essential Guide to Nutrient Requirements*. National Academies Press.

concern over excess sodium consumption and negative health effects is not just limited to adults. American children are also at risk of developing heart disease and elevated blood pressure at an earlier age, because about 90 percent of them consume too much sodium.<sup>63</sup> The prevalence of elevated blood pressure in children is already on the rise, and blood pressure rises with age. The evidence shows that in children, just like in adults, blood pressure decreases as sodium intake goes down. In addition, lowering sodium intake can significantly blunt the age-associated rise in blood pressure. Accordingly, federal efforts are needed to lower sodium intake in children, such as continuing the tiered reduction in the School Meals program.

For children and adults, there is consensus that the U.S. population has to reduce sodium intake. A target of 2,300 mg is reasonable for the general population, with a second recommendation to reduce intake ideally to 1,500 mg in people with pre-hypertension or hypertension. Achieving these targets will not happen without a significant commitment from industry to reduce sodium in packaged and restaurant foods and for industry and consumers to reduce portion sizes. Additionally, reducing sodium in the foods purchased or made available through schools, government feeding programs, and workplaces is essential to achieving the enormous health benefits of sodium reduction across the population.

### **c) Red and Processed Meats**

#### **We support the DGAC Report's recommendation to consume a diet that is "lower in red and processed meats."**

We applaud the DGAC for its proposal to alter the current Dietary Guidelines language regarding meat intake from "choose lean meat and poultry" to "consume dietary patterns that are...lower in red and processed meats." That is an important and necessary change, supported by clear, consistent, and still-mounting evidence of the link between regular consumption of red and processed meats and certain types of cancer.

Studies report that both red and processed meats are significantly associated with an increased risk of total mortality, cardiovascular disease mortality, and cancer mortality.<sup>64</sup> In cohorts of roughly 37,700 men and 83,600 women, researchers estimated that 8 to 9 percent of deaths could have been prevented over a period of 22 to 28 years if all participants had consumed less than ½ serving (about 1½ oz.) per day of red meat. We are pleased that the DGAC also acknowledged that diet and weight status affect the risk of breast and colorectal cancers, two of the most common types. We urge that the

---

<sup>63</sup> Centers for Disease Control and Prevention. (2014). CDC Vital Signs: Reducing Sodium in Children's Diets. Available at <http://www.cdc.gov/VitalSigns/pdf/2014-09-vitalsigns.pdf>. Accessed May 7, 2015.

<sup>64</sup> Pan, A., Sun, Q., Bernstein, A.M., et al. (2012). Red meat consumption and mortality: results from 2 prospective cohort studies. *Arch Intern Med*, 172(7), 555-563; Kushi et al., 2012; WCRF/AICR, 2007; Sinha, R., Cross, A. J., Graubard, B. I., Leitzmann, M. F., & Schatzkin, A. (2009). Meat intake and mortality: A prospective study of over half a million people. *Archives of Internal Medicine*, 169 (6), 562-571.

2015 DGA include a recommendation to lower consumers' red and processed meat intake.

We also applaud the DGAC for recommending increased consumption of healthier protein sources, including plant protein sources. In particular, the DGA should recommend that people replace red and processed meats with seafood, nuts, legumes, and lean poultry. Major health organizations already support these recommendations for protein foods. For example, the American Cancer Society recommends consuming a healthy diet with an emphasis on plant foods.<sup>65</sup> The American Heart Association recommends that the general population eat a variety of (preferably fatty) fish at least twice a week and include oils and foods rich in alpha-linolenic acid (flaxseed, canola, and soybean oils; flaxseed and walnuts).<sup>66</sup> It is essential that the DGA contain clear, consistent, and actionable guidance for consumers regarding the types of protein foods that should and should not be a regular part of their diet.

### ***Clear Evidence Links Regular Consumption of Red and Processed Meats to Some Cancers***

There is clear, consistent, and still-mounting evidence of the link between regular consumption of red and processed meats and certain types of cancer. The evidence that diets high in red meat (beef, pork, lamb) and processed meats (hot dogs, bacon, sausage, deli meats, etc.) increase the risk of colorectal cancer is convincing.<sup>67</sup>

Evidence indicates approximately a 15 to 20 percent increased risk of cancers of the colon and/or rectum per 100 grams (g) of red meat or 50 g of processed meats consumed per day.<sup>68</sup> For this reason, the American Cancer Society has recommended limiting the consumption of both red and processed meats for more than a decade.<sup>69</sup>

Since the 2010 Dietary Guidelines for Americans were issued, the evidence supporting the link between red meat and processed meat consumption and colorectal cancer has increased. In 2011, AICR and WCRF published a Continuous Update Project report on colorectal cancer, in which new evidence was added to the existing evidence base. The expert panel concluded that both red and processed meats are a “convincing cause” of colorectal cancer:

---

<sup>65</sup> Kushi et al., 2012.

<sup>66</sup> American Heart Association. (2015). Fish 101. Available at [http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/Fish-101\\_UCM\\_305986\\_Article.jsp](http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/Fish-101_UCM_305986_Article.jsp). Accessed May 1, 2015.

<sup>67</sup> World Cancer Research Fund/American Institute for Cancer Research. (2011). Continuous Update Project Report. Food, Nutrition, Physical Activity, and the Prevention of Colorectal Cancer.

<sup>68</sup> WCRF/AICR, 2007; Chan, D. S., Lau, R., Aune, D., Vieira, R., Greenwood, D. C., Kampman, E., & Norat, T. (2011). Red and processed meat and colorectal cancer incidence: meta-analysis of prospective studies. *PLoS One*, 6 (6), e20456; WCRF/AICR, 2011.

<sup>69</sup> Kushi et al., 2012.

- A substantial amount of data from cohort studies showed a dose-response relationship, supported by evidence for plausible mechanisms operating in humans...red meat is a convincing cause of colorectal cancer.
- There is a substantial amount of evidence, with a dose-response relationship apparent from cohort studies. There is strong evidence for plausible mechanisms operating in humans...processed meat is a convincing cause of colorectal cancer.<sup>70</sup>

### ***Higher Intakes of Red Meat Are Also Associated with a Higher Risk of Cardiovascular Disease***

Studies report a higher risk of heart disease and stroke among people who consume higher intakes of red meat.<sup>71</sup> Red meat is likely to raise those risks in part because it is one of the largest sources of saturated fat in the average American's diet.<sup>72</sup> The American Heart Association and American College of Cardiology recommend that adults with high cholesterol levels lower their saturated fat intake to 5-6 percent of calories to lower their risk of cardiovascular disease. That conclusion was based on the highest quality evidence.<sup>73</sup>

Moreover, a pooled analysis of 11 cohort studies on roughly 345,000 people reported that the risk of coronary events falls by 13 percent and the risk of coronary deaths drops by 26 percent for every 5 percent of calories from saturated fat that is replaced by polyunsaturated fat.<sup>74</sup> In addition, evidence suggests that the heme iron in red meat and the sodium in processed meats may also raise the risk of cardiovascular disease, indicating that a healthy dietary pattern should be low even in lean red meat.<sup>75</sup>

Last, research on carnitine and its impact on gut microbes may describe a convincing mechanism linking red meat consumption to heart disease. This research is further outlined in the attachment to this comment, a 2013 cover story from our *Nutrition Action* newsletter detailing six reasons to lower meat consumption, including the risk of heart disease as well as the carcinogenic heterocyclic amines created in common cooking processes for meats.

---

<sup>70</sup> WCRF/AICR, 2011.

<sup>71</sup> Bernstein, A. M., Pan, A., Rexrode, K. M., Stampfer, M., Hu, F. B., Mozaffarian, D., & Willett, W. C. (2012). Dietary protein sources and the risk of stroke in men and women. *Stroke*, 43(3), 637-644.

<sup>72</sup> National Cancer Institute. (2013). Table 1. Top Food Sources of Saturated Fat Among US Population, 2005-2006 NHANES. Available at [http://appliedresearch.cancer.gov/diet/foodsources/sat\\_fat/sf.html](http://appliedresearch.cancer.gov/diet/foodsources/sat_fat/sf.html). Accessed May 1, 2015.

<sup>73</sup> Eckel, R. H., Jakicic, J. M., Ard, J. D., de Jesus, J. M., Miller, N. H., Hubbard, V. S., et al. (2014). 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology*, 63(25\_PA), 2960-2984.

<sup>74</sup> Jakobsen, M. U., O'Reilly, E. J., Heitmann, B. L., Pereira, M. A., Bälter, K., Fraser, G. E., et al. (2009). Major types of dietary fat and risk of coronary heart disease: a pooled analysis of 11 cohort studies. *The American journal of clinical nutrition*, 89(5), 1425-1432.

<sup>75</sup> Pan et al., 2012.

## ***Higher Intakes of Red and Processed Meat Increase the Risk of Type 2 Diabetes***

The DGAC reported that “moderate evidence indicates that healthy dietary patterns ... lower in red and processed meats ... reduce the risk of developing type 2 diabetes.” We concur. Meta-analyses of multiple cohorts have consistently reported an increased risk of type 2 diabetes among people who consume more red or processed meat.<sup>76</sup>

Researchers suggest that a variety of constituents of red meat—including saturated fat, sodium, advanced glycation end products, nitrates or nitrites, heme iron, trimethylamine N-oxide (TMAO), branched amino acids, and endocrine disruptor chemicals—could be responsible.<sup>77</sup>

### **d) Fats**

**The Dietary Guidelines for Americans should continue to advise Americans to replace foods rich in saturated fat with ones higher in monounsaturated or polyunsaturated fats.**

In 2010, the DGA recommended limiting saturated fat intake to less than 10 percent of total calories based on evidence from controlled trials and prospective cohort studies showing that saturated fat intake raises serum total and LDL-cholesterol levels, which increase the risk of cardiovascular disease. Strong evidence from controlled trials shows that replacing saturated fat with polyunsaturated and monounsaturated fats results in favorable effects on lipid profiles and a lower risk of cardiovascular events.<sup>78</sup> The DGA should continue to advise Americans to replace foods

---

<sup>76</sup> Pan, A., Sun, Q., Bernstein, A. M., Manson, J. E., Willett, W. C., & Hu, F. B. (2013). Changes in red meat consumption and subsequent risk of type 2 diabetes mellitus: three cohorts of US men and women. *JAMA internal medicine*, 173(14), 1328-1335; Pan, A., Sun, Q., Bernstein, A. M., Schulze, M. B., Manson, J. E., Willett, W. C., & Hu, F. B. (2011). Red meat consumption and risk of type 2 diabetes: 3 cohorts of US adults and an updated meta-analysis. *The American journal of clinical nutrition*, 94(4), 1088-1096; Feskens, E. J., Sluik, D., & van Woudenberg, G. J. (2013). Meat consumption, diabetes, and its complications. *Current diabetes reports*, 13(2), 298-306; InterAct Consortium. (2013). Association between dietary meat consumption and incident type 2 diabetes: the EPIC-InterAct study. *Diabetologia*, 56(1), 47-59; Micha, R., Michas, G., & Mozaffarian, D. (2012). Unprocessed red and processed meats and risk of coronary artery disease and type 2 diabetes—an updated review of the evidence. *Current atherosclerosis reports*, 14(6), 515-524; Aune, D., Ursin, G., & Veierød, M. B. (2009). Meat consumption and the risk of type 2 diabetes: a systematic review and meta-analysis of cohort studies. *Diabetologia*, 52(11), 2277-2287.

<sup>77</sup> Kim, Y., Keogh, J., & Clifton, P. (2015). A review of potential metabolic etiologies of the observed association between red meat consumption and development of type 2 diabetes mellitus. *Metabolism*.

<sup>78</sup> Mensink, R. P., Zock, P. L., Kester, A. D., & Katan, M. B. (2003). Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. *The American Journal of Clinical Nutrition*, 77 (5), 1146-1155; Hooper, L., Summerbell, C. D., Thompson, R., Sills, D., Roberts, F.

rich in saturated fat with ones higher in monounsaturated or polyunsaturated fats.

We note that some meta-analyses have reached flawed conclusions concerning the impact of lowering saturated fat on coronary heart disease and mortality. For example, Chowdhury, et al. concluded that “current evidence does not clearly support cardiovascular guidelines that encourage high consumption of polyunsaturated fatty acids and low consumption of total saturated fats.” However, that conclusion ignored, among other things, the results of its own meta-analysis (buried in a supplement) showing a 19 percent reduction in the risk of heart disease when the authors appropriately excluded a trial that replaced saturated fat with a margarine high in trans fats.<sup>79</sup> Moreover, a pooled analysis of 11 cohort studies on roughly 345,000 people reported that the risk of coronary events falls by 13 percent and the risk of coronary deaths drops by 26 percent for every 5 percent of calories from saturated fat that is replaced by polyunsaturated fat.<sup>80</sup>

For decades, researchers have acknowledged the difficulties of convincing sufficiently large numbers of subjects to sufficiently change their diets for sufficiently long periods of time to lower not just the *risk* of cardiovascular disease but cardiovascular or all-cause *mortality*. Recognizing those difficulties, the National Heart, Lung, and Blood Institute, AHA, ACC, and other health authorities have concluded that evidence from clinical trials demonstrating a reduction in LDL cholesterol and other cardiovascular risk factors are sufficient to support recommendations to lower saturated fat intake.<sup>81</sup> That conclusion is backed by a strong, consistent, and growing body of evidence from randomized controlled trials on diets that lower LDL cholesterol, along with trials on drugs that lower LDL by different mechanisms (statins and ezetimibe) and lower the risk of cardiovascular disease, cardiovascular mortality, and all-cause mortality.<sup>82</sup>

---

G., Moore, H. J., & Davey Smith, G. (2012). Reduced or modified dietary fat for preventing cardiovascular disease. *The Cochrane Library*; Mozaffarian, D., Micha, R., & Wallace, S. (2010). Effects on coronary heart disease of increasing polyunsaturated fat in place of saturated fat: a systematic review and meta-analysis of randomized controlled trials. *PLoS Medicine*, 7 (3), e1000252.

<sup>79</sup> Chowdhury, R., Warnakula, S., Kunutsor, S., Crowe, F., Ward, H. A., Johnson, L., et al. (2014). Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis. *Annals of Internal Medicine*, 160 (6), 398-406; Liebman, B. F., Katan, M. B., & Jacobson, M. F. (2014). Association of dietary, circulating, and supplement fatty acids with coronary risk. *Annals of Internal Medicine*, 161 (6), 454; Willett, W. C., Stampfer, M. J., & Sacks, F. M. (2014). Association of dietary, circulating, and supplement fatty acids with coronary risk. *Annals of Internal Medicine*, 161(6), 453.

<sup>80</sup> Jakobsen et al., 2009.

<sup>81</sup> Levy, R. I. (1985). Cholesterol and cardiovascular disease: no longer whether, but rather when, in whom, and how? *Circulation*; Eckel et al., 2014; Antonopoulos, S. (2002). Third report of the National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III) final report. *Circulation*, 106(3143), 3421.

<sup>82</sup> Kohno, T. (2014). Report of the American Heart Association (AHA) Scientific Sessions 2014, Chicago. *Circulation Journal: Official Journal of the Japanese Circulation Society*; Stone, N. J., Merz, C. N. B., ScM, F. A. C. C., Blum, F. C. B., McBride, F. P., Eckel, F. R. H., et al. (2013).

In 2011–2012, Americans aged 2 and older averaged 11 percent of calories from saturated fat, slightly more than the current DGA recommendation of under 10 percent.<sup>83</sup> Furthermore, 71 percent of the total population consumed more than 10 percent of calories from saturated fat. The American Heart Association and the American College of Cardiology recommended that people who would benefit from LDL-cholesterol lowering (*i.e.*, those at high risk for cardiovascular disease and stroke) should reduce saturated fat intake to even lower levels (*i.e.*, 5 to 6 percent of calories),<sup>84</sup> as used in the OmniHeart, Dietary Approaches to Stop Hypertension (DASH), and the Dietary Effects on Lipoproteins and Thrombogenic Activity (DELTA) trials.<sup>85</sup> That conclusion was based on the highest quality evidence.

Although we support the DGAC’s recommendation to consume less than 10 percent of calories from saturated fat, we note that the American Heart Association recommends that healthy Americans over age 2 should ideally consume no more than 7 percent of calories from saturated fat.<sup>86</sup> This lower saturated fat intake would more closely match the DASH, OmniHeart, and DELTA trials and would be more consistent with a diet rich in vegetables, fruits, low-fat dairy products, whole grains, poultry, fish, legumes, nuts, and vegetable oils, and limited in sweets, sugar-sweetened beverages, and red meat, as noted by the AHA/ACC 2013 guidelines.

The DGA should recommend that people replace foods high in saturated fat, such as red meat, full-fat dairy products, many desserts, and foods made with palm or coconut oils, with foods rich in polyunsaturated and/or monounsaturated fats, such as nuts, seeds, seafood, non-tropical oils, soyfoods, and margarines or shortenings with the least saturated fat. Americans should consume those unsaturated fats as part of a diet rich in fruits, vegetables, whole grains, legumes, and low-fat dairy products.

---

2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

<sup>83</sup> U.S. Department of Agriculture, Agricultural Research Service. (2014). Energy Intakes: Percentages of Energy from Protein, Carbohydrate, Fat, and Alcohol, by Gender and Age. *What We Eat in America*, NHANES 2011-2012. Available at [http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/1112/Table\\_5\\_EIN\\_GEN\\_11.pdf](http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/1112/Table_5_EIN_GEN_11.pdf). Accessed March 4, 2015.

<sup>84</sup> Eckel et al., 2014.

<sup>85</sup> Appel et al., 2005; Obarzanek, E., Sacks, F. M., Vollmer, W. M., Bray, G. A., Miller, E. R., Lin, P. H., et al. (2001). Effects on blood lipids of a blood pressure–lowering diet: the Dietary Approaches to Stop Hypertension (DASH) Trial. *The American Journal of Clinical Nutrition*, 74 (1), 80-89; Ginsberg, H. N., Kris-Etherton, P., Dennis, B., Elmer, P. J., Ershow, A., Lefevre, M., et al. (1998). Effects of reducing dietary saturated fatty acids on plasma lipids and lipoproteins in healthy subjects. The Delta Study, Protocol 1. *Arteriosclerosis, Thrombosis, and Vascular Biology*, 18 (3), 441-449.

<sup>86</sup> American Heart Association. (2015). Know Your Fats. Available at [http://www.heart.org/HEARTORG/Conditions/Cholesterol/PreventionTreatmentofHighCholesterol/Know-Your-Fats\\_UCM\\_305628\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/Cholesterol/PreventionTreatmentofHighCholesterol/Know-Your-Fats_UCM_305628_Article.jsp). Accessed March 20, 2015.

## e) Dietary Cholesterol

**The final Dietary Guidelines should advise Americans to limit their consumption of cholesterol-rich foods (primarily whole eggs and egg yolks) to lower their risk of heart disease and type 2 diabetes.**

The 2015 DGAC's conclusion that dietary cholesterol should no longer be considered a "nutrient of concern" has received considerable attention in the media and has been widely misinterpreted as permission to eat more eggs. Underscoring this impression, an egg industry marketing campaign is also trumpeting the inclusion of eggs in a healthy diet.<sup>87</sup> However, we are concerned that the DGAC's conclusion about dietary cholesterol is inconsistent with the AHA/ACC guidelines, evidence from clinical trials and cohort studies, and the overall dietary pattern recommended by the DGAC.

The DGAC states that it "will not bring forward [the recommendation in previous editions of the DGA to limit cholesterol to 300 mg/day] because available evidence shows no appreciable relationship between consumption of dietary cholesterol and serum cholesterol, consistent with the conclusions of the AHA/ACC report." However, the AHA/ACC did *not* conclude that there is no appreciable relationship between dietary and serum cholesterol. It concluded that "there is insufficient evidence to determine whether lowering dietary cholesterol reduces LDL-C."<sup>88</sup> The DGAC report did not present evidence to support its conclusion that there is "no appreciable relationship" between dietary cholesterol and serum cholesterol. In fact, that conclusion directly contradicts the AHA/ACC conclusion, which specifically states that "there are insufficient data to make a statement."

The AHA/ACC's conclusion is based on what it saw as insufficient research. In contrast, the DGAC's conclusion misinterprets the alleged *absence* of evidence as the *presence* of evidence that high doses of cholesterol cause no harm. We question the scientific rigor and logic of that conclusion.

Contrary to the DGAC's conclusion, dietary cholesterol is very much a "nutrient of concern," because it increases LDL cholesterol, a well-established risk factor for coronary heart disease. Furthermore, the consumption of whole eggs is associated with the risk of type 2 diabetes and the risk of coronary heart disease (CHD) in people with diabetes. The Guidelines should clarify that the healthy dietary pattern it recommends does not include one or more eggs per day. That message has been lost in the media

---

<sup>87</sup> Tinker, B. (February 19, 2015). Cholesterol in food not a concern, new report says. *CNN*. Available at <http://www.cnn.com/2015/02/19/health/dietary-guidelines/>. Accessed March 20, 2015; Whoriskey, P. (February 10, 2015). The U.S. government is poised to withdraw longstanding warnings about cholesterol. *The Washington Post*. Available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/02/10/feds-poised-to-withdraw-longstanding-warnings-about-dietary-cholesterol/>. Accessed March 20, 2015; O'Connor, A. (February 19, 2015). Nutrition panel calls for less sugar and eases cholesterol and fat restrictions. *The New York Times*. Available at [http://well.blogs.nytimes.com/2015/02/19/nutrition-panel-calls-for-less-sugar-and-eases-cholesterol-and-fat-restrictions/?\\_r=0](http://well.blogs.nytimes.com/2015/02/19/nutrition-panel-calls-for-less-sugar-and-eases-cholesterol-and-fat-restrictions/?_r=0). Accessed March 20, 2015.

<sup>88</sup> Eckel et al., 2014.



frenzy over the DGAC's decision to de-list cholesterol as a nutrient of concern. The Guidelines should counter the mistaken impression, created by the DGAC's report, that consuming whole eggs in *any* quantity has been thoroughly investigated and deemed to be part of a healthy dietary pattern. In fact, the DGAC gave the public the green light to consume high levels of eggs based in part on cohort studies that never assessed those levels.

### ***Dietary Cholesterol Increases the Risk of Heart Disease***

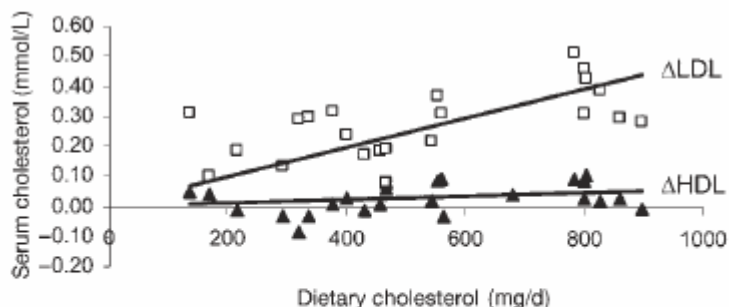
First, clinical studies show that dietary cholesterol at levels that are commonly consumed by Americans raises serum LDL-cholesterol, a well-established risk factor for heart disease.

Weggemans, *et al.*, identified 17 studies—including 11 metabolic ward studies—involving 556 individuals conducted between 1974 and 1999. The diets were designed to maintain stable body weight. The authors' meta-analysis found that for each additional 100 mg/day of dietary cholesterol, serum LDL cholesterol increased by roughly 2 mg/dL. Among the studies they included, 10 involved individuals who consumed an increase of 167 to 560 mg/day of cholesterol. (See figure below.) Those increases indicate that consuming one to three egg yolks per day would increase LDL by 4 to 12 mg/dL (0.10 to 0.31 mmol/l). The authors concluded that “the advice to limit the consumption of eggs and other foods rich in dietary cholesterol may still be important in the prevention of coronary heart disease.”<sup>89</sup>

It should be noted that most participants in the studies included in the Weggemans, *et al.*, meta-analysis were normal-weight young adults. Few of those studies have investigated the impact of dietary cholesterol on people who are middle-aged or older, who are overweight or obese, or who have diabetes, pre-diabetes, hypertension, or prehypertension, even though those groups comprise major segments of the U.S. population.

---

<sup>89</sup> Weggemans, R. M., Zock, P. L., & Katan, M. B. (2001). Dietary cholesterol from eggs increases the ratio of total cholesterol to high-density lipoprotein cholesterol in humans: a meta-analysis. *The American journal of clinical nutrition*, 73(5), 885-891.



**FIGURE 1.** Changes in serum LDL-cholesterol (□) and HDL-cholesterol (▲) concentrations with cholesterol intake in 17 studies providing 24 dietary comparisons.

In a 1997 meta-analysis of metabolic-ward studies, Clarke, *et al.*, concluded that 200 mg/day (equivalent to about one egg/day) of dietary cholesterol increases LDL cholesterol by roughly 4 mg/dL, a calculation that is consistent with Weggemans, *et al.*,<sup>90</sup> (yet there was little overlap: only two studies on a total of 21 people were included in both meta-analyses<sup>91</sup>).

The AHA/ACC report appeared to minimize the importance of the findings of Clarke by noting that earlier meta-analyses were based on 6 studies on 128 participants and that “these studies predate our search.” There is absolutely no valid scientific justification for the AHA/ACC’s or DGAC’s ignoring studies that were done before 1997. Given the strict control of diets in metabolic-ward studies—and the relative paucity of recent metabolic ward studies—the results from those studies should be given extra credence.<sup>92</sup>

In contrast to those meta-analyses, Griffin and Lichtenstein reviewed studies on the effect of dietary cholesterol on lipids conducted only between 2003 and 2013.<sup>93</sup> They included only four studies that they categorized as assessing “dietary cholesterol

<sup>90</sup> Clarke, R., Frost, C., Collins, R., Appleby, P., & Peto, R. (1997). Dietary lipids and blood cholesterol: quantitative meta-analysis of metabolic ward studies. *BMJ*, *314*(7074), 112.

<sup>91</sup> Ginsberg, H. N., Karmally, W., Siddiqui, M., Holleran, S., Tall, A. R., Blaner, W. S., & Ramakrishnan, R. (1995). Increases in dietary cholesterol are associated with modest increases in both LDL and HDL cholesterol in healthy young women. *Arteriosclerosis, thrombosis, and vascular biology*, *15*(2), 169-178; Chenoweth, W., Ullmann, M., Simpson, R., & Leveille, G. (1981). Influence of dietary cholesterol and fat on serum lipids in men. *The Journal of nutrition*, *111*(12), 2069-2080.

<sup>92</sup> The critical importance of dietary cholesterol in the induction of atherosclerosis was established in landmark animal studies by Anitschkow in 1933. Stamler, J., & Shekelle, R. (1988). Dietary cholesterol and human coronary heart disease. The epidemiologic evidence. *Archives of pathology & laboratory medicine*, *112*(10), 1032-1040.

<sup>93</sup> Griffin, J. D., & Lichtenstein, A. H. (2013). Dietary cholesterol and plasma lipoprotein profiles: randomized controlled trials. *Current nutrition reports*, *2*(4), 274-282.

supplementation while controlling for background diet” without weight loss, which applies to the vast majority of Americans. However, unlike the metabolic ward studies included in Clarke and 11 of the 17 studies included in Weggemans, Griffin and Lichtenstein considered the background diet in those studies “controlled” if subjects were only told to follow a diet (*e.g.*, an NCEP Step 1 diet or a “lacto-vegetarian” diet).

Those diets are far less controlled than diets in studies where researchers provide all meals throughout the study. Furthermore, the studies had other limitations. One study tested egg consumption along with an endurance training program.<sup>94</sup> Another had a crossover design but no washout period.<sup>95</sup> Two were funded by the egg industry, which could influence the results.<sup>96</sup> The studies in that review should carry far less weight than the earlier, controlled, metabolic-ward studies, regardless of their date of publication.

Some researchers (often with ties to the egg industry) have claimed that 70 percent of the population are hypo-responders to dietary cholesterol.<sup>97</sup> However, some studies classify subjects as hypo- or hyper-responders based on a single experiment.<sup>98</sup> In fact, when Dutch researchers retested people who were classified as hypo- or hyper-responders after a single 2-week experiment, they found that much of the initial variation in response was due to chance intra-individual fluctuation.<sup>99</sup>

The findings of controlled trials on the effects of lipids on total and LDL-cholesterol are utilized in an online calculator constructed by Martijn Katan, a leader in

---

<sup>94</sup> Vislocky, L. M., Pikosky, M. A., Rubin, K. H., Vega-López, S., Gaine, P. C., Martin, W. F., et al. (2009). Habitual consumption of eggs does not alter the beneficial effects of endurance training on plasma lipids and lipoprotein metabolism in untrained men and women. *The Journal of nutritional biochemistry*, 20(1), 26-34.

<sup>95</sup> Chakrabarty, G., Bijlani, R. L., Mahapatra, S. C., Mehta, N., Lakshmy, R., Vashisht, S., & Manchanda, S. C. (2002). The effect of ingestion of egg on serum lipid profile in healthy young free-living subjects. *Indian journal of physiology and pharmacology*, 46(4), 492-498.

<sup>96</sup> Herron, K. L., McGrane, M. M., Waters, D., Lofgren, I. E., Clark, R. M., Ordovas, J. M., & Fernandez, M. L. (2006). The ABCG5 polymorphism contributes to individual responses to dietary cholesterol and carotenoids in eggs. *The Journal of nutrition*, 136(5), 1161-1165; Flacco, M. E., Manzoli, L., Boccia, S., Capasso, L., Aleksovska, K., Rosso, A., et al. (2015). Head-to-head randomized trials are mostly industry sponsored and almost always favor the industry sponsor. *Journal of clinical epidemiology*.

<sup>97</sup> Fernandez, M. L. (2006). Dietary cholesterol provided by eggs and plasma lipoproteins in healthy populations. *Current Opinion in Clinical Nutrition & Metabolic Care*, 9(1), 8-12; Carroll, A.E. (2015). Behind New Dietary Guidelines, Better Science. *The New York Times*. Available at <http://www.nytimes.com/2015/02/24/upshot/behind-new-dietary-guidelines-better-science.html>. Accessed May 1, 2015.

<sup>98</sup> Herron, K. L., Vega-Lopez, S., Conde, K., Ramjiganesh, T., Shachter, N. S., & Fernandez, M. L. (2003). Men classified as hypo- or hyperresponders to dietary cholesterol feeding exhibit differences in lipoprotein metabolism. *The Journal of nutrition*, 133(4), 1036-1042.

<sup>99</sup> Katan, M.B., Beynen, A.C., de Vries, J.H., & Nobels, A. (1986). Existence of consistent hypo- and hyper-responders to dietary cholesterol in man. *American journal of epidemiology*, 123(2), 221-234.

the field of lipid research.<sup>100</sup> The calculator shows that, based on clinical trials, one DV's worth of cholesterol (300 mg) has about half the effect on LDL-cholesterol as one DV's worth of saturated fat (20 grams). That estimate, and the well-controlled feeding studies that the calculator relies on, indicate that dietary cholesterol still is a significant contributor to coronary heart disease—and a “nutrient of concern.” Furthermore, recent evidence suggests that egg yolks may also promote cardiovascular disease because their phosphatidylcholine leads to the production of TMAO (trimethylamine-*N*-oxide), which enhances atherosclerosis.<sup>101</sup>

In addition to the clinical studies, a number of cohort studies in the general population examined the relationship between the consumption of dietary cholesterol or eggs and cardiovascular disease, and two meta-analyses have been conducted on cohort studies on egg consumption and the risk of heart disease, stroke, and diabetes.<sup>102</sup> Neither meta-analysis found an association with eggs and stroke or heart disease.

However, those cohort studies have serious limitations. First, the range of egg consumption between the lowest- and highest-exposure groups was small, with people in the highest intake group typically consuming only one or more eggs per day. For example, in one U.S. study, only 6 percent of 37,851 men and 9 percent of 80,082 women consumed *at least* 1 egg per day, and only 1.6 percent of women reported consuming 2 eggs or more per day.<sup>103</sup> That narrow range limits the sensitivity of the studies. Furthermore, although the DGAC's cholesterol conclusion was widely interpreted as a go-ahead to eat unlimited quantities of eggs, it was based in part on cohort studies that *never examined the impact of eating more than 1 egg per day*. The DGAC has therefore—perhaps inadvertently—implicitly sanctioned an egg-rich diet without acknowledging a lack of evidence on the consequences of eating such a diet.

Yet a 20-year cohort study of roughly 21,000 U.S. male physicians reported a 22 percent increased risk of all-cause mortality among men who did not have diabetes and who consumed at least 7 eggs per week.<sup>104</sup> The same authors reported a 28 percent

---

<sup>100</sup> Katan, M.B. (2012). Katan Calculator: Predicted effect of diet on blood lipids and lipoproteins. Available at <http://www.katancalculator.nl/>. Accessed May 1, 2015.

<sup>101</sup> Tang, W. W., Wang, Z., Levison, B. S., Koeth, R. A., Britt, E. B., Fu, X., et al. (2013). Intestinal microbial metabolism of phosphatidylcholine and cardiovascular risk. *New England Journal of Medicine*, 368(17), 1575-1584.

<sup>102</sup> Shin, J. Y., Xun, P., Nakamura, Y., & He, K. (2013). Egg consumption in relation to risk of cardiovascular disease and diabetes: a systematic review and meta-analysis. *The American journal of clinical nutrition*, ajcn-051318; Rong, Y., Chen, L., Zhu, T., Song, Y., Yu, M., Shan, Z., et al. (2013). Egg consumption and risk of coronary heart disease and stroke: dose-response meta-analysis of prospective cohort studies. *BMJ*, 346, e8539.

<sup>103</sup> Hu, F. B., Stampfer, M. J., Rimm, E. B., Manson, J. E., Ascherio, A., Colditz, G. A., et al. (1999). A prospective study of egg consumption and risk of cardiovascular disease in men and women. *JAMA*, 281(15), 1387-1394. The median intake in the highest quintile was 0.79 eggs per day for men and 0.67 eggs per day for women.

<sup>104</sup> Djoussé, L., & Gaziano, J. M. (2008). Egg consumption in relation to cardiovascular disease and mortality: the Physicians' Health Study. *The American journal of clinical nutrition*, 87(4), 964-969.

higher risk of heart failure among physicians who ate one egg per day and a 64 percent higher risk among those who ate at least two eggs per day.<sup>105</sup> Similarly, when researchers tracked more than 14,000 African-American and white adults in the Atherosclerosis Risk in Communities Study for 13 years, they found a 23 percent increased risk of heart failure for each serving of eggs consumed per day.<sup>106</sup> In addition, a number of cohort studies have reported an increased risk of type 2 diabetes or of CVD in people with type 2 diabetes.

### ***Dietary Cholesterol Increases the Risk of Heart Disease or Mortality in People with Type 2 Diabetes***

Cohort studies consistently report that egg consumption is associated with a higher risk of heart disease or mortality in people with type 2 diabetes. For example, in a study of 1,941 adults aged 70 to 79, those who had type 2 diabetes and consumed eggs (possibly more than one per occasion) at least three times per week had five times the risk of incident CVD compared to those who consumed eggs less than once a week.<sup>107</sup> Similarly, in a study that tracked 37,851 men for 8 years and 80,082 women for 14 years, men with diabetes who consumed one or more eggs per day had twice the risk of coronary heart disease—and women with diabetes had a 49 percent higher risk—than those who consumed less than one egg per week.<sup>108</sup>

When researchers tracked approximately 21,000 male physicians for 20 years in the study mentioned in the prior section, the risk of all-cause mortality among those with diabetes was twice as high if they consumed at least five to six eggs per week versus if they ate less than 1 egg per week.<sup>109</sup> And among 5,672 women with type 2 diabetes, every 200 mg of cholesterol per 1,000 calories was associated with a 37 percent higher risk of cardiovascular disease.<sup>110</sup>

In two meta-analyses of those and/or other studies, Shin, *et al.*, reported that among people with diabetes, those who consumed the most eggs (at least one per day) had a 69 percent higher risk of CVD than those who consumed the least (less than 1 egg per week or never), while Rong, *et al.*, reported that people with diabetes who consumed the most eggs had a 54 percent higher risk of coronary heart disease than those who

---

<sup>105</sup> Djoussé, L., & Gaziano, J. M. (2008). Egg consumption and risk of heart failure in the Physicians' Health Study. *Circulation*, 117(4), 512-516.

<sup>106</sup> Nettleton, J. A., Steffen, L. M., Loehr, L. R., Rosamond, W. D., & Folsom, A. R. (2008). Incident heart failure is associated with lower whole-grain intake and greater high-fat dairy and egg intake in the Atherosclerosis Risk in Communities (ARIC) study. *Journal of the American Dietetic Association*, 108(11), 1881-1887.

<sup>107</sup> Houston, D. K., Ding, J., Lee, J. S., Garcia, M., Kanaya, A. M., Tylavsky, F. A., et al. (2011). Dietary fat and cholesterol and risk of cardiovascular disease in older adults: the Health ABC Study. *Nutrition, Metabolism and Cardiovascular Diseases*, 21(6), 430-437.

<sup>108</sup> Hu et al., 1999.

<sup>109</sup> Djoussé & Gaziano, 2008 (*AJCN*).

<sup>110</sup> Tanasescu, M., Cho, E., Manson, J. E., & Hu, F. B. (2004). Dietary fat and cholesterol and the risk of cardiovascular disease among women with type 2 diabetes. *The American journal of clinical nutrition*, 79(6), 999-1005.

consumed the least.<sup>111</sup>

The DGAC’s failure to describe the impact of dietary cholesterol on people with diabetes is irresponsible. People with diabetes comprise a large and growing segment of the population and face a greater risk of heart disease than others. Since 2001, health authorities including the National Heart, Lung, and Blood Institute have considered people with diabetes to have the same elevated risk of a cardiovascular event as those who have existing coronary heart disease. The risk of cardiovascular disease is 70 percent higher among people aged 20 or older with diagnosed diabetes than among others, according to the CDC.<sup>112</sup> Accordingly, cholesterol goals for people with diabetes (e.g., LDL less than 100 mg/dL) are far stricter than those for people without the disease.

Furthermore, diabetes is remarkably prevalent in the United States. An estimated 14 percent of men and 11 percent of women aged 20 or older have diabetes.<sup>113</sup> However, an estimated 28 percent of these people are undiagnosed, according to the National Diabetes Statistics Report.<sup>114</sup> Even if the Dietary Guidelines were to warn people with diabetes to limit their intake of whole eggs, the 8.1 million Americans with undiagnosed disease would have no way of knowing that frequent eating of eggs might raise their risk of CVD. That’s a reason to encourage the general population to limit their egg (yolk) intake.

Furthermore, an estimated 37 percent of adults aged 20 years or older—and 51 percent of those aged 65 or older—have pre-diabetes.<sup>115</sup> To our knowledge, studies have not examined the association between egg consumption and risk of CVD in people with pre-diabetes. However, the sheer size of this at-risk group and the “diabetes tsunami” that experts predict in the coming years are cause for concern and another reason why the Dietary Guidelines should encourage the entire population to reduce consumption of cholesterol.

### ***Higher Levels of Egg Consumption Increase the Risk of Developing Type 2 Diabetes***

Egg consumption is consistently associated with a higher risk of type 2 diabetes. When researchers tracked roughly 20,000 men in the Physicians’ Health Study for 20 years, those who consumed at least 7 eggs per week had a 58 percent higher risk of type 2 diabetes than those who consumed no eggs. Similarly, among approximately 36,000 women who were followed for 12 years in the Women’s Health Study, those who

---

<sup>111</sup> Shin et al., 2013; Rong et al., 2013.

<sup>112</sup> Centers for Disease Control and Prevention. (2014). *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services.

<sup>113</sup> Rates increase with age, to 26 percent among adults aged 60 years and older, and are higher in African Americans (18 percent) and Hispanics (19 percent) than in non-Hispanic whites (10 percent). These percentages include people whose diabetes is undiagnosed. Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Table D1.27, p. 92.

<sup>114</sup> CDC, *National Diabetes Statistics Report, 2014*

<sup>115</sup> *Id.*

consumed at least 7 eggs per week had a 77 percent higher risk of type 2 diabetes.<sup>116</sup> In a meta-analysis of those and other studies that tracked more than 69,000 people for nearly 15 years, Shin, *et al.*, found that the people in the highest category of egg consumption (at least 1 egg per day) had a 42 percent higher risk of type 2 diabetes than those in the lowest category of consumption (less than 1 egg per week).<sup>117</sup>

Those findings are especially troubling given the current prevalence of type 2 diabetes, which imposes an enormous economic and human toll. Diabetes increases the risk not just of heart disease and stroke but also of blindness, kidney disease, and amputations.<sup>118</sup> Experts estimate that in 2012, the disease cost the nation \$176 billion in direct medical expenses and \$69 billion in indirect costs (including disability, work loss, and premature death).<sup>119</sup> Despite these high costs, the DGAC ignored the evidence that dietary cholesterol may raise the risk of type 2 diabetes.

***The DGAC's Dismissal of Concerns about Dietary Cholesterol Undermines the Advice on Healthy Dietary Patterns. The Final Guidelines Must Clearly State the Limited Role of Eggs in a Healthy Dietary Pattern.***

The DGAC's conclusion that dietary cholesterol is not a nutrient of concern threatens to undermine the DGAC's advice on dietary patterns. The key dietary pattern recommended by the DGAC is "rich in vegetables, fruit, whole grains, seafood, legumes, and nuts; moderate in low- and non-fat dairy products and alcohol (among adults); lower in red and processed meat; and low in sugar-sweetened foods and beverages and refined grains." Although the pattern doesn't include an unlimited quantity of whole eggs, many people may now wrongly believe that it does because of publicity following the release of the DGAC's report.<sup>120</sup>

---

<sup>116</sup> Djoussé, L., Gaziano, J. M., Buring, J. E., & Lee, I. M. (2009). Egg consumption and risk of type 2 diabetes in men and women. *Diabetes Care*, 32(2), 295-300. Although the same authors found no increased risk of diabetes in the Cardiovascular Health Study, that cohort of older people was far smaller (3,898 men and women) with only 313 new cases of diabetes. Djoussé, L., Kamineni, A., Nelson, T. L., Carnethon, M., Mozaffarian, D., Siscovick, D., & Mukamal, K. J. (2010). Egg consumption and risk of type 2 diabetes in older adults. *The American journal of clinical nutrition*, 92(2), 422-427.

<sup>117</sup> Egg consumption has not been linked to a higher risk of type 2 diabetes in Finnish and Japanese studies, possibly because the consumption of eggs in those populations is associated with unmeasured factors that lower the risk of diabetes. Virtanen, J. K., Mursu, J., Tuomainen, T. P., Virtanen, H. E., & Voutilainen, S. (2015). Egg consumption and risk of incident type 2 diabetes in men: the Kuopio Ischaemic Heart Disease Risk Factor Study. *The American journal of clinical nutrition*, 101(5), 1088-1096; Kurotani, K., Nanri, A., Goto, A., Mizoue, T., Noda, M., Oba, S., et al. (2014). Cholesterol and egg intakes and the risk of type 2 diabetes: The Japan Public Health Center-based Prospective Study. *British Journal of Nutrition*, 112(10), 1636-1643.

<sup>118</sup> CDC, *National Diabetes Statistics Report*, 2014

<sup>119</sup> *Id.*

<sup>120</sup> Abutaleb, Y. (February 19, 2015). "Love to eat eggs? U.S. panel now says they're not a health risk." *Reuters*. Available at <http://www.reuters.com/article/2015/02/19/us-usa-health-diet-idUSKBN0LN21O20150219>. Accessed May 7, 2015; Healy, M. (February 19, 2015).

"Cholesterol is back on the menu in new federal dietary guideline." *LA Times*. Available at

The DGAC's report provides "three USDA Food Patterns (Healthy U.S.-style, Healthy Vegetarian, and Healthy Mediterranean-style) at the 2000 calorie level."<sup>121</sup> Those patterns include only 3 eggs (3 oz.) per week.<sup>122</sup> The patterns presumably limit eggs to conform to the DASH and OmniHeart clinical trials that provide strong evidence for the AHA/ACC's and DGAC's dietary pattern guidelines. The 2,100-calorie DASH and OmniHeart diets contained less than 150 mg of cholesterol per day.<sup>123</sup>

Similarly, the USDA Healthy Mediterranean-Style Pattern contains only 232 mg of cholesterol for a 2,000-calorie diet and the Healthy Vegetarian Pattern contains only 120 mg of cholesterol in a 2,000-calorie diet.<sup>124</sup> USDA's Food Patterns presumably limit eggs to leave room for the fruits, vegetables, and other foods in the DGAC's healthy dietary pattern. Eggs are also limited in the Healthy Eating Index and in most variations of a Mediterranean diet, which, like DASH/OmniHeart diets, have been associated with a lower risk of disease. Therefore, it is critical that the DGA clarify that a healthy dietary pattern would contain only about three whole eggs per week.

In summary, the DGAC's conclusion that dietary cholesterol is not a "nutrient of concern" is not based on the best scientific evidence available—that is, controlled clinical studies, especially metabolic-ward studies, demonstrating that dietary cholesterol raises LDL cholesterol, a known risk factor for heart disease. Furthermore, the DGAC relied on the AHA/ACC, rather than conduct its own review of studies on dietary cholesterol, yet the DGAC's conclusion (*i.e.*, there is "no appreciable relationship" between dietary and serum cholesterol) significantly overstates that made by the AHA/ACC (*i.e.*, there is "insufficient evidence" to determine whether lowering dietary cholesterol lowers LDL).

Moreover, the DGAC's conclusions about dietary cholesterol are misleading the public about a healthy intake of whole eggs. The DGAC ignored consistent evidence from cohort studies reporting that people who consume one or more eggs per day have an increased risk of type 2 diabetes and an increased risk of cardiovascular disease if they already have diabetes. By ignoring this evidence, the DGAC has led the public to believe that a healthy dietary pattern could contain an unlimited quantity of eggs, even though the DGAC's own healthy dietary patterns allow only 3 whole eggs per week. It is crucial that the final DGA clearly and definitively correct these serious misconceptions.

---

<http://www.latimes.com/science/sciencenow/la-sci-sn-dietary-guidelines-cholesterol-20150219-story.html>. Accessed May 7, 2015; Editorial Board. (February, 2015). "Scientists get egg on their faces." *Chicago Tribune*. Available at <http://www.chicagotribune.com/news/opinion/editorials/ct-cholesterol-guidelines-edit-0223-20150220-story.html>. Accessed May 7, 2015.

<sup>121</sup> DGAC Report, Table D1.32; Table 3, Appendix E-3.7.

<sup>122</sup> The USDA Healthy Vegetarian Pattern allows 4 eggs per week for those who consume 2,800 calories per day and 1 to 2 eggs for those who consume 1,000 to 1,400 calories per day. DGAC Report, Table A1, Appendix E-3.7.

<sup>123</sup> Appel et al., 1997; Appel et al., 2005.

<sup>124</sup> The cholesterol levels in a Healthy Mediterranean-Style Pattern range from 92 mg/day for a 1,000-calorie diet to 300 mg/day for a 3,200-calorie diet. Cholesterol levels in a Healthy Vegetarian-Style Pattern range from 78 mg per day for a 1,000-calorie diet to 160 mg/day for a 3,200-calorie diet. DGAC Report, Tables B1, B2, Appendix E-3.7.



## **f) Fruits and Vegetables**

### **We concur with the DGAC report that additional measures are needed to encourage consumption of fruits and vegetables as part of a healthy diet.**

Americans currently eat a diet that is low in vegetables and fruits, and this dietary pattern contributes to increased risk of chronic disease and poor health. Among the U.S. population, 90 percent do not eat the daily-recommended amount of vegetables, and 80 percent do not eat the daily-recommended amount of fruit. Americans eat few vegetables, and consumption has even declined by about 10 percent since 2003.<sup>125</sup> Fruit intake has declined by about 16 percent since the late 1990s, and consumption of fresh fruit has remained low, but stable. With the exception of children 1–8 years of age, fruit and vegetable intake among children is low.

Fresh, frozen, and canned fruits and vegetables contribute many important nutrients of public health concern, including fiber, potassium, iron, folate, and vitamin A. The DASH and OmniHeart diets, which are rich in fruits and vegetables, lower blood pressure, LDL cholesterol, and triglycerides.<sup>126</sup> A diet rich in fruits and vegetables is associated with a decreased risk of cardiovascular disease.<sup>127</sup> High intakes of vegetables and fruits were the only dietary characteristics consistently associated with many positive health outcomes. Therefore, the DGAC recommends that the U.S. population be encouraged to eat a diet rich in fruits and vegetables.

We agree that it will take bold action to achieve healthy dietary patterns in the U.S. and that environmental and policy changes are important in achieving this goal. The DGAC notes the importance of implementing comprehensive nutrition standards to increase fruits and vegetables in school meals. School-based environmental modifications that also include nutrition education and parent involvement are especially effective in increasing children's fruit and vegetable consumption. The DGA also should recommend that the Supplemental Nutrition Assistance Program (SNAP) give further consideration to financial incentives for people to buy more fruits and vegetables, because studies have shown that discounting the cost at stores or farmers markets leads to greater purchases and, presumably, consumption.<sup>128</sup>

---

<sup>125</sup> U.S. Department of Agriculture, Economic Research Service. (2014). Food Availability (Per Capita) Data System: Loss-Adjusted Food Availability Documentation. Available at [http://www.ers.usda.gov/data-products/food-availability-\(per-capita\)-data-system/loss-adjusted-food-availability-documentation.aspx](http://www.ers.usda.gov/data-products/food-availability-(per-capita)-data-system/loss-adjusted-food-availability-documentation.aspx). Accessed March 20, 2015.

<sup>126</sup> Appel et al., 1997.

<sup>127</sup> Wang, X., Ouyang, Y., Liu, J., Zhu, M., Zhao, G., Bao, W., & Hu, F. B. (2014). Fruit and vegetable consumption and mortality from all causes, cardiovascular disease, and cancer: systematic review and dose-response meta-analysis of prospective cohort studies. *BMJ*, 349, g4490; WCRF/AICR, 2007; Thomson, 2014.

<sup>128</sup> U.S. Department of Agriculture, Food and Nutrition Service. (September, 2014). Evaluation of the Healthy Incentives Pilot (HIP) Final Report: Summary. Available at <http://www.fns.usda.gov/sites/default/files/HIP-Final-Summary.pdf>. Accessed March 20, 2015; Dimitri, C., Oberholtzer, L., Zive, M., & Sandolo, C. (2014). Enhancing food security of low-

We urge USDA and HHS to:

1. Strengthen their efforts to encourage all Americans to make half their plates fruits and vegetables at every meal;
2. Strengthen and promote policies that increase children's access to more fruits and vegetables in school meals and the school food environment;
3. Promote policies that increase access to more fruits and vegetables in all other federal nutrition programs;
4. Fund research on best practices, behavioral economics, and multi-component interventions that will add to the evidence base concerning how to most effectively increase American's fruit and vegetable consumption;
5. Support private efforts to promote the consumption of fruits and vegetables.

#### **g) Whole Grains**

**We support the Report's emphasis on whole grains as part of a healthful diet and encourage USDA and HHS to provide clear recommendations to help people translate this advice into healthier consumption patterns.**

The DGA should include a strong recommendation to consume fewer grains and to substitute refined grains with whole grains, as recommended by the DGAC. The advice should be clear that people should substitute refined grains with whole grains, and not eat more whole grains, as most Americans eat too many grain foods. The DGA should recommend that Americans limit their consumption of all grains, particularly white flour and white rice, to four or five small servings a day (for a 2,000-calorie diet) and that at least half those grains should be whole grains. The Guidelines should not advise people to consume at least 3 ounce-equivalents of whole grains per day. Instead, it should focus on percentage of whole grains advice.

To effectively encourage Americans to consume more whole grains without inadvertently encouraging people to overconsume refined grains, it is important that the DGA clearly and articulately address whole grains in the diet.

First, the DGA should clearly recommend that consumers reduce their overall grain intake. As the DGAC pointed out, Americans eat too many grain-based foods. People get the wrong message when recommendations advise them to "Eat *more* whole grains," since that message could lead people to overeat. Instead, the DGA should warn that most people consume excessive amounts of grains (from breads, cereals, pasta, rice, tortillas, pizza crust, cakes, cookies, pies, etc.), and clearly recommend that consumers

---

income consumers: An investigation of financial incentives for use at farmers markets. *Food Policy*.

reduce grain intake *overall* and replace refined grains with whole grains. Furthermore, the DGA should include illustrations to convey an appropriate size serving of pasta, rice, etc.

Second, the DGA should continue to recommend that consumers *replace* foods made with refined grains with 100 percent whole grains, including wheat berries, quinoa, rolled or steel-cut oats, brown rice, whole wheat bread, or foods labeled “100 percent whole grain.” The USDA and HHS should recommend that the percentage of total grains that are whole grains be labeled on foods to help guide consumers. Furthermore, the Guidelines should warn consumers that foods with labels such as “8 grams whole grain” or “made with whole grains” may be mostly refined grain. This straightforward advice would help people follow the Guidelines by encouraging them to avoid foods with high amounts of refined grains.

Third, the DGA should not advise people to consume at least 3 ounce-equivalents of whole grains per day. Instead, focus on the percentage of whole grains advice. The 2010 DGA states that the minimum recommended amount of whole grains for most Americans is 3-ounce equivalents per day (e.g., 1 one-ounce slice of bread; 1 ounce uncooked pasta or rice; ½ cup cooked rice, pasta, cereal; 1 tortilla; 1 pancake; 1 ounce ready-to-eat cereal). To give consumers examples of ways to meet the recommendation, the Guidelines provides three examples (Figure 4-1 of 2010 DGA). However, practically no one understands what an “ounce-equivalent” of grains means.

Consumers cannot assume that one slice of bread or one serving of breakfast cereal is an “ounce-equivalent,” because the weight of a single serving can vary widely. For example, the weight of one serving (1 cup) of Post Shredded Wheat cereal is 1.7 ounces, while one large blueberry muffin weighs almost 5 ounces. Foods labeled as containing “8 grams of whole grain per serving” can be misleading. Moreover, for example, 8 grams of whole grain in a 57-gram serving of uncooked pasta would be only 14 percent whole grain. A 55-gram serving of Post Selects Blueberry Morning cereal contains 17 grams of whole grain and 16 grams of sugars per 55 gram serving. That leaves up to 22 grams of refined grain per serving (assuming other ingredients are minor). Thus, someone would consume more refined grain than whole grain from this “whole grain-rich” cereal. And few consumers take time to check serving sizes to see how many ounce equivalents they contain. Ultimately, the Guidelines risks that Americans ignore the whole grain advice altogether—or consume excess calories from bread, cereal, rice, etc.—if they do not communicate adequately about how to implement recommendations.

Instead of the current confusion, the Guidelines should advise consumers to look for foods that are 100 percent whole grain, or at least with whole grain the first ingredient.

## D) Water Promotion

**We support the development of policies to promote water as the primary beverage of choice. We also support public education and policy changes to encourage access to clean water, including a symbol for water as part of the graphics for MyPlate.**

Water is an essential nutrient.<sup>129</sup> Without water, human life can be sustained for only a few days. Adequate hydration is crucial for the proper function and regulation of the kidneys and heart thus affecting heart rate, blood pressure, vaso-vagal response, lipid regulation, removal of body waste products, and thermoregulation; good hydration also supports mental concentration, mood, skin health, helps prevent headaches, and lubricates joints. While hydration can come from many sources, low intake of plain water is associated with poor dietary quality and physical inactivity in youth.<sup>130</sup>

Between 2005 and 2010, more than a quarter (28 percent) of children aged 4–13 years old in the United States did not have a drink of plain water on two consecutive days.<sup>131</sup> Plain water accounted for less than one-third of total daily dietary water intake from beverages and foods for children aged 4-13 years old.<sup>132</sup> While it is possible to meet all hydration needs with other sources, plain tap water is ideal because, unlike sugar-sweetened beverages, it does not contain calories and has virtually no adverse effects.<sup>133</sup>

Recent research shows that substituting drinking water for sugar drinks (sodas, juice drinks, pre-sweetened tea and coffee drinks, sports drinks, and energy drinks) can

---

<sup>129</sup> National Research Council. (2005). *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride and Sulfate*. Washington DC; The National Academies Press.

<sup>130</sup> Park, S., Blanck, H. M., Sherry, B., Brener, N., & O'Toole, T. (2012). Factors associated with low water intake among US high school students—National Youth Physical Activity and Nutrition Study, 2010. *Journal of the Academy of Nutrition and Dietetics*, 112 (9), 1421-1427.

<sup>131</sup> Drewnowski, A., Rehm, C. D., & Constant, F. (2013). Water and beverage consumption among children age 4–13y in the United States: analyses of 2005–2010 NHANES data. *Nutr J*, 12 (1), 85.

<sup>132</sup> *Id.*

<sup>133</sup> Popkin, B. M., Armstrong, L. E., Bray, G. M., Caballero, B., Frei, B., & Willett, W. C. (2006). A new proposed guidance system for beverage consumption in the United States. *The American Journal of Clinical Nutrition*, 83 (3), 529-542.

help reduce intake of calories from added sugars among both children and adults<sup>134</sup> and reduce the risk of dental caries.<sup>135</sup>

Science-based organizations, such as the Institute of Medicine's Committee on Accelerating Progress in Obesity Prevention,<sup>136</sup> Centers for Disease Control and Prevention,<sup>137</sup> and the American Heart Association's Voices for Healthy Kids,<sup>138</sup> embrace the importance of water in chronic disease prevention and have called for improvements in community-wide drinking water access. The American Academy of Pediatrics encourages water as the best source of hydration for young people.<sup>139</sup>

We recommend that HHS and USDA promote plain tap water as the primary beverage of choice. That recommendation would build on that provided in the 2010 DGA ("To limit excess calories and maintain healthy weight, individuals are encouraged to drink water and other beverages with few or no calories...") and the strengthened recommendations for drinking water made in the 2015 DGAC report:

- "Strategies are needed to encourage the U.S. population to drink water when they are thirsty. Water provides a healthy, low-cost, zero-calorie beverage option,"<sup>140</sup> and

---

<sup>134</sup> Pan, A., Malik, V. S., Schulze, M. B., Manson, J. E., Willett, W. C., & Hu, F. B. (2012). Plain-water intake and risk of type 2 diabetes in young and middle-aged women. *The American Journal of Clinical Nutrition*, 95 (6), 1454-1460; Pan, A., Malik, V. S., Hao, T., Willett, W. C., Mozaffarian, D., & Hu, F. B. (2013). Changes in water and beverage intake and long-term weight changes: results from three prospective cohort studies. *International Journal of Obesity*, 37 (10), 1378-1385; Tate, D. F., Turner-McGrievy, G., Lyons, E., Stevens, J., Erickson, K., Polzien, K., et al. (2012). Replacing caloric beverages with water or diet beverages for weight loss in adults: main results of the Choose Healthy Options Consciously Everyday (CHOICE) randomized clinical trial. *The American Journal of Clinical Nutrition*, 95 (3), 555-563; Wang, Y. C., Ludwig, D. S., Sonneville, K., & Gortmaker, S. L. (2009). Impact of change in sweetened caloric beverage consumption on energy intake among children and adolescents. *Archives of Pediatrics & Adolescent Medicine*, 163 (4), 336-343; Zheng, M., Rangan, A., Olsen, N. J., Andersen, L. B., Wedderkopp, N., Kristensen, P., et al. (2015). Substituting sugar-sweetened beverages with water or milk is inversely associated with body fatness development from childhood to adolescence. *Nutrition*, 31 (1), 38-44.

<sup>135</sup> Guido, J. A., Martinez Mier, E. A., Soto, A., Eggertsson, H., Sanders, B. J., Jones, J. E., et al. (2011). Caries prevalence and its association with brushing habits, water availability, and the intake of sugared beverages. *International Journal of Paediatric Dentistry*, 21 (6), 432-440.

<sup>136</sup> Institute of Medicine. (2012). *Accelerating Progress in Obesity Prevention: Solving the Weight of the Nation*. Washington, DC: The National Academies Press.

<sup>137</sup> Centers for Disease Control and Prevention. (2014). *Water & Nutrition*. Available at <http://www.cdc.gov/healthywater/drinking/nutrition/>. Accessed September 5, 2014.

<sup>138</sup> American Heart Association. (2015). *Voices for Healthy Kids: Healthy Drinks*. Available at [http://www.heart.org/HEARTORG/Advocate/Voices-for-Healthy-Kids--Healthy-Drinks\\_UCM\\_460610\\_SubHomePage.jsp](http://www.heart.org/HEARTORG/Advocate/Voices-for-Healthy-Kids--Healthy-Drinks_UCM_460610_SubHomePage.jsp). Accessed September 5, 2014.

<sup>139</sup> Schneider, M. B., & Benjamin, H. J. (2011). Sports drinks and energy drinks for children and adolescents: are they appropriate? *Pediatrics*, 127 (6), 1182-1189.

<sup>140</sup> U.S. Department of Agriculture and Department of Health and Human Services. (2015). *Scientific Report of the 2015 Dietary Guidelines Advisory Committee*. Available at

- “Approaches might include: Making water a preferred beverage choice. Encourage water as a preferred beverage when thirsty.”<sup>141</sup>

In addition to including strong language on drinking water in the 2015 DGA, including such slogans such as “Water: First for Thirst,” we recommend education and promotion to encourage water as a preferred beverage. In 2014, national leaders in nutrition urged DGAC to encourage a symbol for water on MyPlate.<sup>142</sup> MyPlate is a powerful teaching tool for young people, to whom SSBs are heavily marketed.<sup>143</sup> The addition of a water symbol would enable MyPlate to promote water consumption along with its other messages. Such a MyPlate message would synergize with the Partnership for a Healthier America’s Drink Up campaign to raise public awareness about the benefits of drinking water,<sup>144</sup> as well as with key strategies of the Centers for Disease Control and Prevention designed to decrease consumption of SSBs.<sup>145</sup>

Encouraging water consumption would build demand for improved access to clean and safe tap water, needed in many homes, schools, and other sites across the country,<sup>146</sup> as recommended by the DGAC:

- “Free, clean water should be available in public settings, as well as child care facilities, schools, worksites, publically funded athletic stadiums and arenas, transportation hubs (e.g., airports) and other community places and should be promoted in all settings where beverages are offered;” and,

---

<http://www.health.gov/dietaryguidelines/2015-scientific-report/06-chapter-1/d1-3.asp>. Accessed March 8, 2015.

<sup>141</sup> *Id.*

<sup>142</sup> Ritchie L, et al. (2014). Letter to Chairwoman Millen and Members of the Dietary Guidelines Advisory Committee, September 10, 2014. Available at [www.npi.ucanr.edu/files/207504.pdf](http://www.npi.ucanr.edu/files/207504.pdf). Accessed March 8, 2015.

<sup>143</sup> Yale Rudd Center for Food Policy and Obesity. (2013). Study Synopses: Sugar-Sweetened Beverage (SSB) Marketing to Youth. Available at [http://www.yaleruddcenter.org/resources/upload/docs/what/policy/SSBtaxes/SSBStudies\\_Marketing\\_to\\_Youth.pdf](http://www.yaleruddcenter.org/resources/upload/docs/what/policy/SSBtaxes/SSBStudies_Marketing_to_Youth.pdf). Accessed September 3, 2014; RWJF. (2012). Food and Beverage Marketing to Children and Adolescents: Limited Progress by 2012, Recommendations for the Future. Available at [http://www.rwjf.org/content/dam/farm/reports/issue\\_briefs/2013/rwjf404379](http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2013/rwjf404379). Accessed September 3, 2014.

<sup>144</sup> Partnership for a Healthier America. (2015). Drink Up Campaign. Available at <http://ahealthieramerica.org/our-work/you-are-what-you-drink/>. Accessed September 3, 2014.

<sup>145</sup> Centers for Disease Control and Prevention. (2010). The CDC Guide to Strategies for Reducing the Consumption of Sugar-Sweetened Beverages. Available at [http://www.cdph.ca.gov/SiteCollectionDocuments/StratstoReduce\\_Sugar\\_Sweetened\\_Bevs.pdf](http://www.cdph.ca.gov/SiteCollectionDocuments/StratstoReduce_Sugar_Sweetened_Bevs.pdf). Accessed September 3, 2014.

<sup>146</sup> Hood, N. E., Turner, L., Colabianchi, N., Chaloupka, F. J., & Johnston, L. D. (2014). Availability of drinking water in US public school cafeterias. *Journal of the Academy of Nutrition and Dietetics*, 114 (9), 1389-1395; Patel, A. I., Hecht, K., Hampton, K. E., Grumbach, J. M., Braff-Guajardo, E., & Brindis, C. D. (2014). Tapping into water: key considerations for achieving excellence in school drinking water access. *American Journal of Public Health*, 104 (7), 1314-1319.

- “Make water accessible in public settings, child care facilities, schools, worksites and other community places where beverages are offered.”

Finally, adding water to the MyPlate graphic would support effective implementation of the provisions of the Healthy, Hunger-Free Kids Act of 2010 requiring ready access to water in childcare and in schools, also recommended by the DGAC.

## **E) Sustainability**

### **We endorse the DGAC’s recognition of sustainability—or food security—as an essential component of federal dietary guidance.**

To improve population nutrition while ensuring food security over the long-term, dietary patterns and the food production methods to support them must be sustainable. We specifically endorse the conclusion of the DGAC that “the availability and acceptability of healthy and sustainable food choices will be necessary to attain food security for the U.S. population over time.” We commend the DGAC’s careful consideration of the scientific evidence on this topic and its recognition of sustainability as an essential component of federal dietary guidance.

Contrary to what is suggested by the industry outcry over the inclusion of these topics in the expert report, the scope of the committee’s review was limited to the impact of food-related production and consumption patterns on future food security. That is an essential and appropriate topic. It makes little sense for the committee or the final Guideline to recommend healthy dietary patterns that are rich in fruits and vegetables if the future availability of these are threatened by climate change and other man-made environmental consequences of current consumption.

The sustainability moniker is, perhaps, unduly broad—a better name for the inquiry would be “food security,” as it suggests the more tailored exploration of issues related to the expert report’s investigation. Moreover, the expert report used its environmental analysis as a supplement to the core nutrition principles it articulated; not as a primary source. It concluded, rightly, that the public health goal to encourage greater consumption of fruits and vegetables has a fortunate alignment with the environmental footprint associated with food production.

The Committee’s findings reflect a rigorous and comprehensive assessment of the latest scientific evidence and were prepared in close consultation with experts spanning nutrition, agricultural, and environmental sciences. Its prioritization of these issues is consistent with a range of scientific consensus organizations, including the National Research Council, a committee of the Institute of Medicine, and the Academy of Nutrition and Dietetics.<sup>147</sup> Furthermore, the DGAC’s findings are well aligned with

---

<sup>147</sup> Institute of Medicine. (2014). *Sustainable Diets: Food for Healthy People and a Healthy Planet: Workshop Summary*. Washington, DC: The National Academies Press; National Research Council. (2010). *Toward sustainable agricultural systems in the 21st century*. Washington, DC: The National Academies Press; Nordin, S. M., Boyle, M., & Kemmer, T. M. (2013). *Position of*

dietary guidance published by the governments of Germany, Sweden, the Netherlands, Australia, and Brazil.<sup>148</sup>

More specifically, the DGAC's comprehensive review of the literature found moderate to strong evidence that, "dietary patterns that promote health also promote sustainability." The DGAC's conclusion supports the assertion that sustainable dietary choices support both long-term and short-term nutritional health and are closely linked to the choices recommended for optimal nutrition. Less resource-intensive dietary patterns support nutrition and reduce greenhouse-gas emissions, land, water, and energy use, and ecosystem harm. Our nation's ability to meet future food needs will depend on those environmental outcomes, particularly in the context of a changing climate, with more extremes in weather such as drought, resource shortages, changes in global dietary patterns, and population growth.<sup>149</sup> The DGAC's review of the effects of individual and population-level dietary patterns on food security is both timely and in the interest of public health.

The DGAC's review indicates that a broad range of dietary patterns high in plant-based foods and low in animal-based foods are more nutritious and sustainable than the U.S. population's current average dietary pattern. Consistent with current scientific literature, the DGAC notes that diets high in animal-based foods, particularly red and processed meats, are associated with an increased risk of heart disease, diabetes, and cancer, and worse environmental outcomes.

Seafood consumption is another key dietary component in which health and food security go hand in hand. However, in recognition of overfishing and rising global demand, the DGAC encourages the consumption of a variety of seafood associated with sustainable fishing and aquaculture practices. We applaud the DGAC's attention to sustainable seafood production methods. While the report is not comprehensive in its examination of which methods are best to conserve resources and protect public health, consideration of food security should be part of the Dietary Guidance concerning seafood.

In summary, we endorse the DGAC's conclusion that, "linking health, dietary guidance, and the environment will promote human health and the sustainability." The DGAC's findings reflect a substantial body of science that illustrates the synergies between healthy dietary choices and a more secure food system.

---

the Academy of Nutrition and Dietetics: Nutrition security in developing nations: Sustainable food, water, and health. *Journal of the Academy of Nutrition and Dietetics*, 113 (4), 581-595.

<sup>148</sup> Health Council of the Netherlands. (June 2011). Guidelines for a healthy diet: the ecological perspective. Publication no. 2011/08E; Nordic Council of Ministers, Nordic Council of Ministers Secretariat. (2012). Nordic Nutrition Recommendations 2012: Integrating nutrition and physical activity; German Council for Sustainable Development. (2013). The Sustainable Shopping Basket: A guide to better shopping.

<sup>149</sup> Nellemann, C. (Ed.). (2009). *The environmental food crisis: the environment's role in averting future food crises: a UNEP rapid response assessment*. UNEP/Earthprint.



*Comments Concerning Additional Issues of Significance to Consumer and Public Health*

- 1) **We support the DGAC’s recommendation for increasing fish consumption, but disagree with its blanket assessment that the health benefits outweigh the risks from methylmercury, particularly as concerns the risks of consuming albacore tuna. Far clearer messages are required to enable consumers—especially pregnant women—to maximize the benefits of consuming fish while minimizing risks.**

Our support for the DGAC’s assessment that a healthy dietary pattern includes “seafood” is tempered by the discussion of methylmercury risks in albacore tuna in Chapter 5. We strongly disagree with its simplistic “one-size fits all” conclusion that the health benefits of seafood consumption outweigh the risks due to mercury. While that is true for many individuals, it is not true for people who consume above-average amounts of high-mercury fish, and/or who are members of vulnerable subpopulations. And, even for individuals for whom the benefits of seafood consumption outweigh the risks of mercury, their net benefits increase when mercury levels are lower.

The DGAC relied heavily on a model developed by a Food and Agricultural Organization and World Health Organization expert consultation in 2010 in reaching its conclusions.<sup>150</sup> However, that model only considers a small fraction of the adverse neurodevelopmental effects associated with mercury, and has not been validated. Furthermore, many epidemiological studies published since the consultation contradict its findings.

The implication that pregnant women could safely consume 12 ounces a week of canned albacore tuna with net benefits for infant development and that the FDA/EPA advice should therefore consider loosening its current recommendation of 6 ounces per week of that tuna variety, is out of step with the scientific evidence and public health goals. Available varieties of canned albacore tuna contain 0.35 ppm mercury, on average.<sup>151</sup> In contrast, other top-consumed seafood choices contain 25 to 40 times less mercury on average, including canned salmon (0.008 ppm), shrimp (0.009 ppm), and tilapia (0.013 ppm).<sup>152</sup> FDA lists 49 commercial species with lower average mercury levels than canned albacore tuna. Twelve ounces of canned albacore tuna contains on

---

<sup>150</sup> Food and Agriculture Organization of the United Nations & World Health Organization. (2011). Consultation on the Risks and Benefits of Fish Consumption. Rome, 25–29 January 2010. FAO Fisheries and Aquaculture Report. No. 978. Rome, FAO. 50.

<sup>151</sup> FDA. (2014). Mercury Levels in Commercial Fish and Shellfish (1990-2010). Available at <http://www.fda.gov/food/foodborneillnesscontaminants/metals/ucm115644.htm>.

<sup>152</sup> *Id.*

average 119 µg of mercury. That dose exceeds the levels found to cause harm in recent epidemiological studies.<sup>153</sup>

Prenatal and infant periods are critical points of neurological development. Advising the public, especially pregnant and breastfeeding mothers, to consume fish high in fatty acids and low in mercury would greatly benefit the public health, particularly cognitive development. Advice to pregnant women regarding fish consumption needs to balance two important objectives: women need to eat more fish to obtain neurodevelopmental benefits from omega-3 polyunsaturated fatty acids, but they should choose low-mercury fish, to minimize methylmercury exposure, which poses substantial, well-documented hazards to neurodevelopment.

A generalized statement that benefits outweigh the risks of contaminants is unhelpful and for some consumers, dangerously inaccurate. As recognized by the Institute of Medicine, advice to consumers should be “tailored to individual circumstances to better inform consumers.”<sup>154</sup> While it is true that for the majority of consumers, the benefits of seafood consumption outweigh the risks, there is a substantial minority for whom the risks may outweigh the benefits, depending on the amount consumed and the species selected. The needs of these individuals, who include women who are or may become pregnant, breastfeeding women, children, and high-seafood consumers, including subsistence fishers, should not be overlooked by broad-brush population-based assessments. For pregnant and nursing women, and small children, clear guidance is needed on how to choose varieties of seafood that are low in mercury and high in omega-3 fatty acids. Furthermore, even for consumers for whom the benefits outweigh the risks, the benefits will outweigh the risks even more if they choose species lower in methylmercury.

The Guidelines should clearly identify “excellent choices,” “good choices,” “choices good in moderation,” and “do not eat” for women who are pregnant, may become pregnant, or who are breastfeeding. Advice should, in addition, define similar choices for children of different ages so that parents could effectively manage their children’s exposure. Finally, advice is also needed for people who eat large quantities of high-mercury species. Doing that would help Americans optimize fish consumption so as to maximize benefits and minimize risks.

---

<sup>153</sup> See, e.g., comment #4032, submitted by Dr. Edward Groth; comment #233 submitted on behalf of 13 scientific experts to the Dietary Guidelines Advisory Committee; comment #207 from Stoney Brook University to the Dietary Guidelines Advisory Committee; and comment #4032 submitted on the Scientific Report of the 2015 DGAC.

<sup>154</sup> Nesheim, M. C., & Yaktine, A. L. (Eds.). (2007). *Seafood Choices: Balancing Benefits and Risks*. National Academies Press. Available at <http://www.nap.edu/catalog/11762/seafood-choices-balancing-benefits-and-risks>.

**2) The Dietary Guidelines should not state that aspartame is safe, as such a conclusion is not supported by the evidence, and other scientific authorities are undertaking more thorough reviews of the safety of aspartame. We are concerned that aspartame is a carcinogen and also that aspartame may affect reproduction.**

We urge that that the Dietary Guidelines not state that aspartame is safe. Stating that aspartame is safe, as suggested by the report, would be premature, irresponsible, and probably incorrect, for five reasons:

- 1) In April 2014, aspartame was designated “high priority” for review by the authoritative International Agency for Research on Cancer (IARC).<sup>155</sup> We expect that IARC’s review will be the most definitive review of the cancer evidence on aspartame, carefully considering studies on both animals and humans. In contrast, the DGAC only considered human studies included in the European Food Safety Authority’s review; the DGAC did not consider animal studies. Yet this is an inexcusable omission: three independent, well-conducted animal studies that were more sensitive than any previous study found that aspartame caused cancer. IARC’s conclusions may well contradict the DGAC’s less-informed finding that aspartame appears to be safe.
- 2) The U.S. National Toxicology Program (NTP) and the independent and respected Ramazzini Institute (RI), both involved in identifying agents that cause cancer, have an ongoing partnership.<sup>156</sup> NTP and RI collaborated to develop an immunohistochemistry method to better characterize lesions identified as leukemias/lymphomas in some RI studies (including studies on aspartame),<sup>157</sup> because different pathologists have reported different numbers of leukemias/lymphomas in some RI studies.<sup>158</sup> Those lesions are difficult to

---

<sup>155</sup> World Health Organization International Agency for Research on Cancer. (2014). Report of the Advisory Group to Recommend Priorities for *IARC Monographs* during 2015-2019. Lyon, France. Available at: <http://monographs.iarc.fr/ENG/Publications/internrep/14-002.pdf>.

<sup>156</sup> U.S. Department of Health and Human Services National Toxicology Program. (2014). Partnerships. Available at: <http://ntp.niehs.nih.gov/about/org/partnerships/index.html>.

<sup>157</sup> Soffritti, M., Padovani, M., Tibaldi, E., Falcioni, L., Manservigi, F., & Belpoggi, F. (2014). The carcinogenic effects of aspartame: The urgent need for regulatory re-evaluation. *American journal of industrial medicine*, 57(4), 383-397; Personal communication, David Malarkey, Group Leader/NTP Pathologist, NTP Pathology Group, April 8, 2015.

<sup>158</sup> U.S. Department of Health and Human Services National Toxicology Program & U.S. Environmental Protection Agency. (2011). Summary Report of the National Toxicology Program and Environmental Protection Agency-Sponsored Review of Pathology Materials from Selected Ramazzini Institute Rodent Cancer Bioassays. Available at [ntp.niehs.nih.gov/ntp/about\\_ntp/partnerships/international/summarypwg\\_report\\_ri\\_bioassays.pdf](http://ntp.niehs.nih.gov/ntp/about_ntp/partnerships/international/summarypwg_report_ri_bioassays.pdf); Pathology Working Group (PWG) Reports for Ramazzini Institute Studies: Pathology QA (Quality Assurance) Review and PWG Coordinator’s Report for Ramazzini Institute Acrylonitrile Studies; for Ethyl-tertiary-butyl Ether; for Vinyl Chloride; for Methyl-tertiary-butyl Ether

diagnose using light microscopy<sup>159</sup> and were the most frequent cancer type found in the two rat studies of aspartame conducted by the RI.<sup>160</sup> (Other cancer types were also found in both rat studies and the study in mice<sup>161</sup> of aspartame.) An international pathology working group is planned for 2016, which will use results from this method.<sup>162</sup> That review should resolve, or, at a minimum, greatly reduce uncertainty over the extent to which aspartame causes leukemias/lymphomas in rats. It is plausible that that international review, using results from the NTP-funded method, will produce conclusions that contradict the finding of the DGAC that aspartame appears to be safe.

- 3) The DGAC did not include any members who were toxicologists or otherwise expert in reviewing animal carcinogenicity studies and thus was unable to independently assess the three cancer bioassays<sup>163</sup> that found an association between aspartame and various cancers in rats and mice. The Committee did invite an FDA Division Director from the Office of Food Additive Safety, who, while not a toxicologist (his academic degrees are in engineering and technology management), would presumably have access to toxicologists on staff. However, FDA is on record as stating that it “could not conduct a complete and definitive review” of the first bioassay on aspartame since it was provided “only limited data and information” and that it “has not received any data” on the other two studies.<sup>164</sup> Therefore, the DGAC was unable to assess a major portion of the evidence on aspartame’s possible long-term effects in rodents. Meanwhile, the pathology data from the three RI studies are being electronically transferred to the

---

Studies; and Methyl Alcohol Studies. Available at <http://www.nih.gov/icd/od/foia/index.htm>. Accessed April 29, 2015.

<sup>159</sup> Gift, J. S., Caldwell, J. C., Jinot, J., Evans, M. V., Cote, I., & Vandenberg, J. J. (2013). Scientific considerations for evaluating cancer bioassays conducted by the Ramazzini Institute. *Environmental health perspectives*, 121(11-12), 1253.

<sup>160</sup> Soffritti, M., Belpoggi, F., Esposti, D. D., Lambertini, L., Tibaldi, E., & Rigano, A. (2006). First experimental demonstration of the multipotential carcinogenic effects of aspartame administered in the feed to Sprague-Dawley rats. *Environmental Health Perspectives*, 379-385; Soffritti, M., Belpoggi, F., Tibaldi, E., Degli Esposti, D., & Lauriola, M. (2007). Life-span exposure to low doses of aspartame beginning during prenatal life increases cancer effects in rats. *Environmental Health Perspectives*, 115(9), 1293.

<sup>161</sup> Soffritti, M., Belpoggi, F., Manservigi, M., Tibaldi, E., Lauriola, M., Falcioni, L., & Bua, L. (2010). Aspartame administered in feed, beginning prenatally through life span, induces cancers of the liver and lung in male Swiss mice. *American journal of industrial medicine*, 53(12), 1197-1206.

<sup>162</sup> Personal communication, Fiorella Belpoggi, Director, Cesare Maltoni Cancer Research Center, Ramazzini Institute.

<sup>163</sup> *Id.*

<sup>164</sup> Citizen Petition Denial Letter Responses from FDA/CFSAN to Paul Stoller, MD, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0156-0003>; and Betty Martini, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2002-P-0247-0023>. Accessed October 24, 2014.

Toxicology Data Management System Enterprise (TDMSE) of the NTP<sup>165</sup> and is available on the RI website.<sup>166</sup>

- 4) The DGAC relied on an assessment by the European Food Safety Authority (EFSA) that was severely flawed. It was produced by panelists with conflicts of interest<sup>167</sup> who cut and pasted sections from an industry review on aspartame into a draft of the report.<sup>168</sup> EFSA glossed over key positive animal study findings, overlooked weakness of negative studies, and ignored information and analysis conducted by U.S. government scientists relevant to interpretation of the RI data.<sup>169</sup>
- 5) Most important, there is compelling evidence that aspartame causes cancer in animals. As previously noted, cancers at multiple sites were observed in two species in three high-quality rodent bioassays. Those studies were published in peer-reviewed journals, including two papers in *Environmental Health Perspectives*, which is published by the U.S. National Institute of Environmental Health Sciences (NIEHS). The finding in a recent prospective human cohort study<sup>170</sup> of a statistically significant increased risk in the incidence of similar (lymphohematopoietic<sup>171</sup>) tumor types as seen in two animal studies lends further support to the conclusion that aspartame is likely carcinogenic in humans,

---

<sup>165</sup> Personal communication, John Bucher, Associate Director, NTP and Director, NTP Division, April 7, 2015.

<sup>166</sup> Ramazzini Institute. (2015). Carcinogens. Available at <http://www.ramazzini.org/centro-di-ricerca/cancerogeni/>.

<sup>167</sup> Milstone, E. (2013). EFSA on Aspartame January 2013: A lost, but not the last, opportunity. Submitted 2/22/13 to Ms. Claudia Heppner, Head of EFSA “Food Ingredients and Packaging” Unit and Mr. George Kass, Senior Scientific Officer, EFSA “Food Ingredients and Packaging” Unit. Available at [http://sro.sussex.ac.uk/43821/1/EM\\_Letter\\_to\\_EFSA\\_on\\_Aspartame\\_22Feb2013.pdf](http://sro.sussex.ac.uk/43821/1/EM_Letter_to_EFSA_on_Aspartame_22Feb2013.pdf). The panel’s composition changed slightly (two additional members were added) by the time the final report was published.

<sup>168</sup> Cicolella, A. (2013). Re-evaluation of Aspartame. Available at <http://www.efsa.europa.eu/en/events/documents/130409-p08.pdf>. Accessed April 29, 2014. Submitted to EFSA as part of the public consultation on the draft EFSA scientific opinion on the re-evaluation of aspartame as a food additive.

<sup>169</sup> *Id.*; Milstone, 2013; *See also* Comments submitted by Center for Science in the Public Interest, Kathleen Burns PhD, Director, Sciencecorps, James Huff PhD, Guest Researcher, National Institute of Environmental Health Sciences (for affiliation purposes only), Ronald Melnick PhD, Ron Melnick Consulting LLC on Draft scientific opinion on the re-evaluation of aspartame as a food additive, EFSA Panel on Food Additives and Nutrient Sources added to Food Consultation. Available at <http://www.cspinet.org/new/pdf/aspartame-efsa-final-comments-21913.pdf>.

<sup>170</sup> Schernhammer, E. S., Bertrand, K. A., Birmann, B. M., Sampson, L., Willett, W. C., & Feskanich, D. (2012). Consumption of artificial sweetener—and sugar-containing soda and risk of lymphoma and leukemia in men and women. *The American journal of clinical nutrition*, 96(6), 1419-1428.

<sup>171</sup> Leukemias and lymphomas (seen in the rodent studies) and non-Hodgkins lymphoma and multiple myeloma, and possibly leukemia, in the human study.

although a subsequent study did not find an increase.<sup>172</sup> The fact that results were only observed in men and not women is not a scientifically sound basis for dismissing the results of the Schernhammer<sup>16</sup> study. As the study authors noted, compared to women, men have higher activity of an enzyme that converts methanol (a breakdown product of aspartame) to formaldehyde, a known human carcinogen. Formaldehyde, as well as chemicals that metabolize to formaldehyde, cause lymphohematopoietic and other cancers in animal studies conducted by the RI as well as other laboratories.<sup>173</sup> The evidence that formaldehyde caused these cancers in humans came well after the development of the base of evidence in animal studies.

Thus, the DGAC's conclusion that aspartame is or appears to be safe is premature at best and very likely wrong. We urge that the final Guidelines not include any statement about the safety of aspartame, other than noting that the studies that have been conducted raise safety questions and need to be analyzed in greater detail. The safety of aspartame should instead be reviewed for the 2020 Dietary Guidelines after the IARC evaluation and the international pathology review are completed.

In addition the Committee's particular advice to consumers regarding consumption of aspartame is problematic and would be very difficult for consumers to implement. We do commend the Committee for recommending water as the preferred beverage and for its recognition of water as a healthy, low-cost, zero-calorie beverage option. We urge that recommendation be included prominently in the Guidelines. We agree that low-calorie sweeteners should not be recommended as a primary replacement/substitute for added sugars in foods and beverages.

However, the report indicates that if individuals choose to drink beverages that are sweetened with aspartame, they should stay below the aspartame Acceptable Daily Intake (ADI). But a recommendation that exposure not exceed the ADI is not appropriate for suspected carcinogens, because carcinogens should be assumed to cause cancer at rates proportional to the amounts consumed, unless there are specific reasons why that might not be the case. In fact, as noted by Scherhammer, *et al.*, aspartame caused cancers in animal studies at levels much lower than the ADI. If anything, the Guidelines should recommend that the amount of artificial sweeteners be listed on labels.

The report also states that “[t]o be cautious, adults and children should be aware of the amount of aspartame they are consuming, given the need for more long-term human studies.” That statement is unhelpful. First, consumers cannot “be aware” of the amount they are consuming since the amount of aspartame contained in products is not

---

<sup>172</sup> McCullough, M. L., Teras, L. R., Shah, R., Diver, W. R., Gaudet, M. M., & Gapstur, S. M. (2014). Artificially and Sugar-Sweetened Carbonated Beverage Consumption Is Not Associated with Risk of Lymphoid Neoplasms in Older Men and Women. *The Journal of nutrition*, jn-114.

<sup>173</sup> Gift et al., 2013.

even listed on labels (as it is in Canada). Second, most consumers are not aware that aspartame can be present in foods that are not labeled “sugar-free” or “diet,” such as cereal (*e.g.*, General Mills Original Fiber One) and yogurt (*e.g.*, Dannon Light and Fit Strawberry Non Fat Yogurt, Yoplait Light Yogurt Very Vanilla Fat Free). Finally, even if, through considerable research, individuals could determine how much aspartame they were consuming, it is unclear how that knowledge would be useful to them.

The report states that “aspartame in amounts *commonly consumed* is safe and poses minimal health risk for *healthy* individuals without phenylketonuria” (emphasis added). The amount “commonly consumed” is not defined or described. Furthermore, aspartame appears to be a potent carcinogen, judging from the RI animal studies; significant increases in cancers relative to controls were noted in animals treated with much smaller doses than are generally used in animal studies. Amounts “commonly consumed” may thus increase the risk of cancer to an unacceptable degree. Also, many people who consume aspartame and other no- or low-calorie sweeteners suffer from metabolic disorders and are not healthy; yet there is no advice directed toward them.

Aspartame is also associated with a risk of pre-term delivery, as the DGAC report notes. In light of that, and since *in utero* exposure to suspected human carcinogens is of particular concern, pregnant women should be advised to avoid aspartame.

**3) For clarity of message and to protect public health, we strongly urge that the 2015 Guidelines maintain the definition of “moderate drinking” as a maximum of one drink a day for women and two drinks a day for men as was recommended in the 2010 Dietary Guidelines.**

The DGAC’s scientific report repeats the mistake made by the advisory panel in 2010, but was appropriately corrected in the final 2010 Guidelines. It effectively increases the maximum of one drink a day to three for women and from a maximum of two drinks a day to four for men by using the word “average.”<sup>174</sup> An “average” of two drinks a day for a man over the course of a week would allow four drinks on three days of that week, as an example of how this advice could be interpreted.

The higher recommended limits are based on the finding that few people who drink at those limits or less meet clinical standards for alcohol use disorder. Five drinks at a time for men or four drinks for women are often defined as a “binge” or as “heavy episodic drinking.” Drinking at those levels will bring the average adult close to the .08 legal limit for drinking and driving.

---

<sup>174</sup> U.S. Department of Agriculture and Department of Health and Human Services. (2015). Scientific Report of the 2015 Dietary Guidelines Advisory Committee. Available at: <http://health.gov/dietaryguidelines/2015-scientific-report/>. Appendix E5, lines 249-252.

Alcohol consumption at these “average” levels fails to reflect the evidence regarding alcohol’s role in health and would lead to greater alcohol-related injury and death on our roadways and elsewhere. The report repeatedly characterizes alcohol consumption as “a component of a healthy dietary pattern,” but the report itself recommends against starting to drink as a health measure.<sup>175</sup>

The report also contradicts itself, stating “there is an inverse association between dietary patterns that are...moderate in alcohol...and risk of colon/rectal cancer”<sup>176</sup> while Table D2.2 presents evidence that alcohol is a convincing or probable cause of six kinds of cancer, including colorectal cancer. Alcohol’s role in depression is ignored.<sup>177</sup> Yet the literature on alcohol’s role in depression is well documented.<sup>178</sup>

Finally, significant problems related to alcohol use can occur from drinking at these proposed maximums. According to the National Highway Traffic Safety Administration, in 2012 more than 1,700 Americans died in automobile crashes where the driver’s blood alcohol concentration (BAC) was between .01 and .07,<sup>179</sup> the level to which BAC could rise after consumption of three drinks for women or four drinks for men on a single occasion.

In practice, impairment begins at levels substantially lower than .08 (as reflected in the fact that most European countries set the maximum BAC for drivers at .05 or lower),<sup>180</sup> which underscores the need to retain the maximums of one drink per day for women and two drinks per day for men that were in the 2010 Dietary Guidelines.

- 4) The Committee’s advice to pregnant women on caffeine is incorrect. Even moderate intake of caffeine during pregnancy appears to be associated with serious risks, including low birth weight. Moreover, the committee failed to consider the evidence linking coffee consumption by pregnant women to childhood leukemia. The advice should be to avoid caffeine in coffee or other non-*de-minimis* forms during pregnancy.**

Regarding caffeine consumption during pregnancy, the Committee concluded that “[b]ased on existing evidence, pregnant women, or women planning to become pregnant, should be cautious and adhere to current recommendations of the ACOG [American College of Obstetrics and Gynecology] regarding caffeine consumption, and consume no

---

<sup>175</sup> *Id.*, Part A, p. 4, lines 133-134.

<sup>176</sup> *Id.*, Part D, chapter 2, p. 30.

<sup>177</sup> *Id.*, Part D, chapter 2, p. 38.

<sup>178</sup> Boden, J. M., & Fergusson, D. M. (2011). Alcohol and depression. *Addiction*, 106(5), 906-914.

<sup>179</sup> National Highway Traffic Safety Administration. (2012). Traffic Safety Facts. p. 42. Available at <http://www-nrd.nhtsa.dot.gov/Pubs/812032.pdf>. Accessed April 16, 2015.

<sup>180</sup> European Transport Safety Council. (2014). Blood Alcohol Content (BAC) Drink Driving Limits Across Europe. Available at <http://etsc.eu/blood-alcohol-content-bac-drink-driving-limits-across-europe/>. Accessed April 16, 2015.



more than 200 mg per day.” Yet substantial evidence published after ACOG’s advice indicates that following that recommendation could increase the risk of both adverse pregnancy outcomes and childhood leukemia. We urge the Guidelines to instead use language similar to the clearer, stronger language that FDA did in its advice from 1981 on “Caffeine and Pregnancy,” which recommended that “Pregnant women should avoid caffeine-containing foods and drugs if possible, or consume them only sparingly.”<sup>181</sup>

First, the data indicate an incremental risk of adverse pregnancy outcomes associated with “moderate” levels of caffeine. Caffeine has diverse acute and chronic pharmacological effects and readily crosses the placenta; also, the fetus has a relative inability to metabolize the drug. Those phenomena provide strong and biologically plausible mechanisms by which maternal consumption of caffeine could affect pregnancy outcomes.

A series of four successive reviews published from 1985 to 1997 investigating the evidence that caffeine contributes to fetal growth restriction and low birth weight concluded most recently, in 1997, that the evidence was “strong.”<sup>182</sup> Since then, findings from new studies converge to indicate the now scientifically robust finding that maternal caffeine contributes to low birth weight. A recent large prospective study, Sengpiel et al. (2013), examined caffeine consumption in nearly 60,000 pregnant women.<sup>183</sup> A robust dose-response relation was found for the outcomes of low birth weight and small for gestational age. Those findings were confirmed in the latest comprehensive meta-analysis of maternal caffeine consumption and pregnancy outcomes by Chen et al. (2014).<sup>184</sup> The finding of a dose-response relation *without a discernible threshold* is strongly indicative of a causal contribution of caffeine to low birth weight.

The Committee appears to have taken no notice of the Chen meta-analysis, relying instead upon a 2014 meta-analysis by Greenwood, *et al.* The Goodwin study also concluded that there is evidence across multiple studies for an incremental dose-response curve for caffeine and multiple serious birth outcomes:

An increment of 100 g [*sic*: mg] caffeine was associated with a 14% (95% CI 10–19%) increase in risk of spontaneous abortion, 19% (5–35%) stillbirth, 2% (-2 to

---

<sup>181</sup> FDA. (1981). Caffeine and Pregnancy. HHS Publication No. (FDA) 81-1081.

<sup>182</sup> James, J. E., & Paull, I. (1985). Caffeine and human reproduction. *Reviews on environmental health*, 5(2), 151-167; James, J. E. (1991). *Caffeine and health* (pp. 42-7). London: Academic Press; James, J. E. (1997). *Understanding caffeine: A biobehavioral analysis*. Sage Publications, Inc.

<sup>183</sup> Sengpiel, V., Elind, E., Bacelis, J., Nilsson, S., Grove, J., Myhre, R., et al. (2013). Maternal caffeine intake during pregnancy is associated with birth weight but not with gestational length: results from a large prospective observational cohort study. *BMC medicine*, 11(1), 42.

<sup>184</sup> Chen, L. W., Wu, Y., Neelakantan, N., Chong, M. F., Pan, A., & van Dam, R. M. (2014). Maternal caffeine intake during pregnancy is associated with risk of low birth weight: a systematic review and dose–response meta-analysis. *BMC medicine*, 12(1), 174.

6%) preterm delivery, 7% (1–12 %) low birth weight, and 10% (95% CI 6–14%) SGA [small for gestational age].<sup>185</sup>

As that indicates, for miscarriage, and only slightly less so with low birth weight and SGA, a consistent positive association across virtually all of the studies included in the meta-analysis was found. As the authors note, adjustment for smoking and other differences among studies were not consistently associated with the observed differences in the results; the heterogeneity in results “mostly reflected variation in the size of the association, rather than whether there was an association.”<sup>186</sup> The Greenwood authors also acknowledge the plausible biological mechanisms, evidence from animal studies, mounting evidence from observational human studies, and dose-response slopes.

Furthermore, Greenwood *et al.* note that there is no identifiable threshold below which the associations are not apparent. Although the authors state that the size of the associations are modest and might be explained by bias in study design or publication, the results of the meta-analysis for miscarriage in particular are striking in that the lowest estimated effect at the 95 percent confidence interval is a 10 percent increase in risk of miscarriage per 100 mg/caffeine. Thus, associations exist within the range for normal, even low, consumption of coffee, which contains on the order of 100 mg/cup (although associations are stronger above 300 mg/day). In plain terms, the data show that for each cup of coffee consumed, there is a significantly increased risk of miscarriage, low birth weight, and SGA.

Women should be informed of the increase in risks associated with 100 mg of caffeine, rather than being referred to a general policy that is widely understood, on pregnancy-advice sites, as indicating that there are *no* risks to pregnancy at levels of maternal consumption of 200 mg/day or lower.<sup>187</sup> While in absolute terms the risk of adverse pregnancy outcomes may remain small, the magnitude of incremental risk being increased by a purely voluntary activity (*i.e.*, 14 percent for miscarriage per 100 mg of caffeine, or 28 percent per two cups of coffee) is not. Consumption of coffee may confer some benefit to some pregnant women; however, some women may only be drinking coffee while pregnant out of longstanding habit or an addiction to caffeine—and those women might choose differently if advised of the risks.

---

<sup>185</sup> Greenwood, D. C., Thatcher, N. J., Ye, J., Garrard, L., Keogh, G., King, L. G., & Cade, J. E. (2014). Caffeine intake during pregnancy and adverse birth outcomes: a systematic review and dose–response meta-analysis. *European journal of epidemiology*, 29(10), 725-734.

<sup>186</sup> *Id.*

<sup>187</sup> American College of Obstetricians and Gynecologists. (2013). Committee Opinion: Moderate Caffeine Consumption During Pregnancy. Number 462, August 2010, Reaffirmed 2013. Available at <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Moderate-Caffeine-Consumption-During-Pregnancy>. Accessed Nov. 1, 2014.

Critically, the risk curve lacks a “threshold” as suggested by the current advice and is instead linear for miscarriage, low birth weight, and SGA. While the impact of a miscarriage or stillbirth is obviously devastating, it is also the case that low birth weight and SGA inflicts serious health consequences, some of them life-long, for children, as noted in the Greenwood meta-analysis.<sup>188</sup> SGA is associated with “increased risk of perinatal mortality and morbidity, including perinatal asphyxia,” as well as “increased incidence of obesity, hypertension, hypercholesterolemia, cardiovascular disease, and type 2 diabetes.”<sup>189</sup> Furthermore, it makes sense to include a safety factor in recommending a dose of caffeine well below the lowest observed effect level.

The only sound evidence-based recommendation that can be made at this time is for caffeine abstinence or *de minimis* consumption during pregnancy. In that context, caffeine abstinence refers specifically to avoidance of coffee, tea, cola and other caffeine-containing sodas, caffeine-containing “energy” drinks or other caffeine-containing supplements and drugs. The negligible caffeine content of chocolate and chocolate confectionaries, chocolate cake, hot chocolate, and decaffeinated coffee and tea is such that those products generally need not form part of the maternal caffeine-avoidance regimen.<sup>190</sup> Given the increase in risks, the final Guidelines should indicate that: “*Pregnant women should avoid caffeine-containing foods and beverages.*”

On another aspect of caffeine, the Committee failed to consider two meta-analyses on maternal coffee consumption and childhood leukemia—one in 2014 that found a dose-related increased risk of childhood acute leukemia (both acute lymphoblastic leukemia and acute myeloid leukemia)<sup>191</sup> associated with maternal coffee consumption and another in 2011 that found an increased risk of childhood acute leukemia associated with maternal coffee consumption, especially among non-smoking mothers.<sup>192</sup> CSPI and two distinguished experts<sup>193</sup> called that issue to the attention of the Committee, but were ignored.

As those comments indicated, the evidence linking maternal coffee consumption during pregnancy and childhood acute leukemia is strong, and the increased lifetime

---

<sup>188</sup> Greenwood, 2014, p. 732.

<sup>189</sup> *Id.*

<sup>190</sup> James, 1991; James, 1997.

<sup>191</sup> Cheng, J., Su, H., Zhu, R., Wang, X., Peng, M., Song, J., & Fan, D. (2014). Maternal coffee consumption during pregnancy and risk of childhood acute leukemia: a metaanalysis. *American journal of obstetrics and gynecology*, 210(2), 151-e1.

<sup>192</sup> Milne, E., Royle, J. A., Bennett, L. C., De Klerk, N. H., Bailey, H. D., Bower, C., et al. (2011). Maternal consumption of coffee and tea during pregnancy and risk of childhood ALL: results from an Australian case-control study. *Cancer Causes & Control*, 22(2), 207-218.

<sup>193</sup> Comments from CSPI (comment ID #836), comments from Dr. Peter Infante, former Director, Office of Standards Review, Health Standards Program, U.S. Occupational Safety and Health Administration (comment ID #865 and #815), and Dr. Steven Bayard, former Director, Office of Risk Assessment, Directorate of Science, Technology and Medicine, US Occupational Safety and Health Administration (comment ID #823).

childhood acute leukemia risk due to maternal coffee drinking of 1–2 cups per day during pregnancy was calculated as 19 per 100,000—an unacceptable risk. Those meta-analyses provide further justification for advising women to avoid coffee/caffeine during pregnancy.

- 5) The Committee failed to consider the safety of artificial food dyes. Yet artificial food dyes have been demonstrated to negatively impact behavior in susceptible children and in Europe are generally used only with warning labels. The final Guidelines should call for individuals and institutions to phase food dyes out of the diets of children and to emphasize the health value from a rainbow of real fruits and vegetables instead.**

A possible link between food ingredients and adverse behaviors such as hyperactivity was first raised in the 1970s, and while it attracted the attention of scientists as well as the public, the Food and Drug Administration (FDA) largely dismissed it. (The FDA even sponsored one of the early studies that found that some children were affected by dyes.) Over the past 40 years, numerous studies have demonstrated that food dyes and other ingredients can prompt adverse behavioral responses in children.

FDA has acknowledged the growing body of evidence that dyes can affect behavior. After evaluating the numerous studies implicating artificial dyes in behavioral disorders, the agency concluded in 2011 that:

Exposure to food and food components, including artificial food colors and preservatives, may be associated with adverse behaviors, not necessarily related to hyperactivity, in certain susceptible children with Attention Deficit Hyperactivity Disorder (ADHD) and other problem behaviors, and possibly in susceptible children from the general population.<sup>194</sup>

FDA official Mitchell Cheeseman cited that finding in an article responding to criticism of the agency's inaction on food dyes.<sup>195</sup> The agency, however, still has not pursued regulatory action to protect the public by banning dyes or requiring a notice on labels warning that the dyes may cause adverse behavioral reactions.

That contrasts with the British Food Standards Agency, which has encouraged the food industry to stop using certain food dyes; lists food establishments with products free from these food dyes; and advises consumers to eliminate certain food dyes from the diet

---

<sup>194</sup> U.S. Food and Drug Administration Food Advisory Committee. (2011). Overview and Evaluation of Proposed Association Between Artificial Food Colors and Attention Deficit Hyperactivity Disorders (ADHD) and Problem Behaviors in Children. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM273033.pdf>.

<sup>195</sup> Cheeseman, M. A. (2012). Artificial food color additives and child behavior. *Environmental health perspectives*, 120(1), a15.

of children showing signs of hyperactivity or ADHD.<sup>196</sup> The European Parliament requires that foods throughout the European Union (EU) that contain certain food dyes bear a warning notice, “may have an adverse effect on activity and attention in children.”<sup>197</sup> As a result of those actions, few foods marketed in the EU contain some of the dyes most commonly used in the United States (including Red 40, Yellow 5, and Yellow 6, which together comprise more than 90 percent of the dyes used in this country).

Meanwhile, the evidence of harm to children continues to mount. Three separate meta-analyses, including one sponsored by an arm of the food industry, have concluded that dyes can trigger hyperactivity or ADHD symptoms in sensitive children.<sup>198</sup> A recent review concludes that “food colo[r] elimination is a potentially valuable treatment approach for ADHD.”<sup>199</sup> It is important to recognize that ADHD can be debilitating to children and their families, because it makes it challenging for children to study, focus on hobbies, and maintain friendships. While the number of children with ADHD who are adversely affected by food dyes is not known, dyes nevertheless contribute an entirely preventable amount to the enormous costs to society of ADHD in children, estimated to be between \$36 billion and \$54.2 billion (in 2005 dollars, assuming a prevalence of 5 percent).<sup>200</sup> Indeed, removing dyes from the food supply may be one of the only public health measures that could be deployed to reduce behavioral problems in children.

---

<sup>196</sup> UK Food Standards Agency. (2014). Products Free From the Colours Associated with Hyperactivity. Available at <http://www.food.gov.uk/policy-advice/additivesbranch/foodcolours/colourfree/#.UIL9gRD0hD4>; UK Food Standards Agency. Food Additives and Children’s Behavior. Available at <http://www.food.gov.uk/policy-advice/additivesbranch/foodcolours/colourfree/#.UIL9gRD0hD4>.

<sup>197</sup> European Union. (2008). Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF>.

<sup>198</sup> Sonuga-Barke, E. J., Brandeis, D., Cortese, S., Daley, D., Ferrin, M., Holtmann, M., et al. (2013). Nonpharmacological interventions for ADHD: systematic review and meta-analyses of randomized controlled trials of dietary and psychological treatments. *American Journal of Psychiatry*, 170(3), 275-289; Nigg, J. T., Lewis, K., Edinger, T., & Falk, M. (2012). Meta-analysis of attention-deficit/hyperactivity disorder or attention-deficit/hyperactivity disorder symptoms, restriction diet, and synthetic food color additives. *Journal of the American Academy of Child & Adolescent Psychiatry*, 51(1), 86-97; Schab, D. W., & Trinh, N. H. T. (2004). Do artificial food colors promote hyperactivity in children with hyperactive syndromes? A meta-analysis of double-blind placebo-controlled trials. *Journal of Developmental & Behavioral Pediatrics*, 25(6), 423-434.

<sup>199</sup> Stevenson, J., Buitelaar, J., Cortese, S., Ferrin, M., Konofal, E., Lecendreux, M., et al. (2014). Research Review: The role of diet in the treatment of attention-deficit/hyperactivity disorder—an appraisal of the evidence on efficacy and recommendations on the design of future studies. *Journal of Child Psychology and Psychiatry*, 55(5), 416-427.

<sup>200</sup> Pelham, W. E., Foster, E. M., & Robb, J. A. (2007). The economic impact of attention-deficit/hyperactivity disorder in children and adolescents. *Ambulatory Pediatrics*, 7(1), 121-131.

Moreover, artificial dyes are sometimes used in school foods and often used in snack foods as cheap substitutes for real fruits and vegetables, misleading children about the healthfulness of their diet and the foods they are being served. Children should be eating a rainbow of real nutrients. The Guidelines' emphasis on increasing the fruits and vegetables consumed by children would be well served by policies that require labeling or prohibitions to protect children from artificial dyes.