

April 26, 2017

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Re: Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments (Docket No. FDA-2016-D-2335)

Dear Dr. Ostroff,

The Academy of Nutrition and Dietetics (the “Academy”) appreciates the opportunity to submit comments to the U.S. Food and Drug Administration (FDA) related to its request for information and comments, “Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments (Docket No. FDA-2016-D-2335)” (the “information collection”) and the associated “Use of the Term ‘Healthy’ in the Labeling of Human Food Products: Guidance for Industry (Docket No. FDA-2016-D-2335)” (the “industry guidance”) both of which were originally published in the Federal Register on September 28, 2016. Representing over 100,000 registered dietitian nutritionists (RDNs),¹ nutrition dietetic technicians, registered (NDTRs), and advanced-degree nutritionists, the Academy is the largest association of food and nutrition professionals in the United States and is committed to improving the nation’s health through food and nutrition. Our members work in a variety of clinical and community settings across the continuum of care, and work with industry and consumers to develop and effectively utilize product labels that encourage individuals to make healthy food choices.

A. SUMMARY OF ACADEMY’S RECOMMENDATIONS

The Academy is not able to identify or recommend adoption *at this time* of an effective legal definition for the “healthy” nutrient content claim that satisfies both (1) the Academy’s Labeling Principles; and (2) the significant statutory and regulatory requirements for nutrient content claims. Several critical issues requiring time and attention must be addressed prior to FDA’s issuance of any proposed revision: (i) the need to conduct substantial consumer research; (ii) the importance of resolving some stakeholders’ fundamentally different understandings about foundational elements of the regulatory revision; and (iii) addressing concerns about the use of a flawed scientific analysis to substantiate assertions relevant to this request for information and comment.

¹ The Academy approved the optional use of the credential “registered dietitian nutritionist (RDN)” by “registered dietitians (RDs)” to more accurately convey who they are and what they do as the nation’s food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

The Academy remains concerned about the present state of scientific analysis on questions central to this information request, specifically the inability of the Nutrition Evidence Library to support inferences about the contributions that individual food groups make to the overall effect observed for a dietary pattern. Unless and until the inferences underlying many of the proposed regulatory schemes suggested by various commenters are supported by rigorous scientific substantiation, FDA should postpone formal rulemaking revising the “healthy” definition pending an assessment of the science in question. During a delay, parties should have the opportunity to augment their filings with any new or additional research strongly substantiating their positions. In the event a longer postponement is warranted, the FDA could once again convene stakeholders for regular discussions, perhaps initially focusing on finding areas of general agreement, including coming to agreement on the foundational questions discussed below.

We reiterate the Academy’s ongoing commitment to working with government, industry, consumer, and scientific organizations in the hope of creating a balanced regulatory structure. The revised “healthy” definition must be grounded in strong science and have buy-in from all relevant groups recognizing its validity and usefulness. Universal support among stakeholders will help ensure the public can have confidence in the “healthy” label as objective, accurate, and non-biased, engendering their trust as they gain the skills to make informed decisions to build a healthier diet.

We offer specific recommendations below to improve various discrete aspects of proposed revision plans, and we are grateful for the opportunity to collaborate in this worthwhile endeavor.

B. ACADEMY'S LABELING PRINCIPLES

The Academy adopted in 2014 the following principles for labeling initiatives that guide our comments and policy stances. Those principles specifically relevant to the Academy's comments on the FDA's information collection and industry guidance are bolded below and referenced as appropriate throughout these comments.

- 1. Label claims should be clear and understandable to consumers; consumers' nutrition literacy is key to promoting understanding.**
- 2. The label must be truthful and not misleading.**
- 3. Content on the label should help consumers make informed decisions to build a healthy diet.**
- 4. Labels should help to provide understanding about the nutrient density and overall healthfulness of overall food rather than a focus on particular nutrients.**
5. Label content should have consistent type and format so products can be read and consumers can make product comparisons.
- 6. Labeling should enhance consistency among the various government nutrition recommendations.**

7. All claims should include labeling of accurate quantitative information about the dietary substance, including percent of Daily Value in a single serving of the products, when known, or the daily dietary intake necessary to achieve the claimed effect.
- 8. Consumer research is imperative before making changes to the label.**
9. The label is only a source of information, and thus sustained support for educational programs and individual counseling by registered dietitian nutritionists is essential.

C. FOUNDATIONAL QUESTIONS

After attending the FDA's March 9, 2017 Public Meeting on this topic and speaking with attendees, the Academy noted continuing disagreement about two issues in which some consensus likely must be achieved before adopting a universally acceptable definition of "healthy;" (1) whether healthy diet patterns were the primary focus of the 2015-2020 DGA, and (2) how to structure a regulatory regime when parties philosophically do not agree whether the goal is to shift consumers to a "healthy" product that may be rather different from the originally selected product or instead a food product meeting "healthier" objective standards within the same product category as the originally selected product.

- To what extent should a product be labeled "healthy" based solely upon its own inherent nutritional profile? And to what extent should a product demonstrate not only that it is inherently healthy, but that it also contributes to the healthiness of a meal pattern by, for example, providing additional nutritional elements for the purpose of remedying potential statistical shortfalls in a generic consumer's meal pattern? For example, should a product labeled "healthy" be required to have 100% whole grains to remedy statistics showing that consumers may not be consuming sufficient quantities of whole grains among the various non- "healthy" in their meal pattern). *We encourage the FDA to share any preliminary insights with stakeholders about different factors in definitions making a singular product healthy versus those factors that determine a product's contribution to a healthy product for its contribution to a healthy meal pattern?*
- Is the nutrient content claim intended to help steer consumers away from less healthy products in the same product line toward the healthy selection (e.g., a healthy snack in the snack food such as popcorn in the snack food aisle)? Or is the nutrient content claim intended to help shift consumers away from less healthy categories of food toward, for example, whole fresh fruits and vegetables? The DGA recommendation to "Shift to healthier food and beverage choices[, and] [c]hoose nutrient-dense foods and beverages across and within all food groups in place of less healthy choices" is similarly ambiguous. *To facilitate a common understanding, The Academy encourages the FDA to share any relevant research or consumer data on the effectiveness of the alternate shifting approaches and to clarify if possible the specific DGA recommendation and the revised nutrient content claim.*

The FDA alluded to similar issues in the questions posed in its initial request for information and comments.

D. HEALTH CLAIMS, NUTRITION EDUCATION, AND IMPROVED PURCHASING

1. Seizing the Potential of Health Claims

The Academy's position paper on functional foods highlighted a critical challenge for efforts to improve purchasing and eating habits: "Eating for health and wellness can be an elusive goal for many consumers, especially given the complex marketplace and the influx of mixed messages from varied information outlets."² There is enormous potential to cut through the cacophony of confusing, conflicting, and often-false information made about food and nutrition by establishing a scientifically sound health claim that consumers actually understand, trust, and use after having been educated on its meaning and strategies for using it. A well-designed health claim leverages the awesome power and reach of the federal government and organizes stakeholders with often-conflicting concerns and opinions to support achieving its worthy purpose. The DGA 2015-2020 edition, "in its role as the cornerstone of Federal nutrition policy and nutrition education activities," identified significant problems and concerns with Americans' food and nutrition intake. The Academy believes the 2015-2020 DGA made healthy diet patterns its primary focus and was wise to move beyond a singular focus on particular nutrients. In conjunction with forthcoming revisions to the Nutrition Facts Label, the focus on choosing and maintaining healthy diet patterns provides the predicate for updating the definition of the "healthy" nutrient content claim to reflect the best available scientific evidence.

The potential public health benefit to defining the term "healthy" is a positive, visual, point of purchase education tool for consumers who are trying to make good choices among similar products, *i.e.*, foods from the same groups (but note the Foundational Question in the section above). However, each aspect of the label, including front of package claims such as "healthy," are merely one piece of what must be a larger, comprehensive effort to educate consumers about what constitutes healthful food and eating patterns.

2. Legal and Scientific Requirements for Health Claims

Pursuant to provisions in the Nutrition Labeling and Education Act of 1990 (NLEA) and the 1997 Food and Drug Administration Modernization Act, the FDA may allow a product to bear a health claim either (1) after extensive review of the scientific evidence submitted to the FDA; (2) based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research; or (3) upon FDA exercising its enforcement discretion on an interim basis "where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation . . . [i]f FDA finds that the evidence supporting the proposed claim is credible and the claim can be qualified to prevent it from misleading consumers."³

² Crowe KM, Francis C. Position of the academy of nutrition and dietetics: functional foods. *J Acad Nutr Diet.* 2013;113(8):1096-103.

³ Label Claims for Conventional Foods and Dietary Supplements. FDA website. Accessed April 20, 2017. Available at <https://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm111447.htm>.

The Academy continues to support the Food and Drug Administration-approved health claims on food labels “*when based on rigorous scientific substantiation*.”⁴ More specifically, “[t]ools designed to help individuals choose and consume nutrient-dense foods should be grounded in science, validated against objective measures of diet quality, and most importantly, be able to effectively translate recommendations into actionable strategies.”⁵ We are optimistic that if a proposed definition of “healthy” meets the necessary scientific standards and its meaning is properly and sufficiently understood by the public, the “healthy” label could be an effective tool for enhancing consumers’ ability to make improved eating choices.

3. Reconsidering the “Healthy” Claim

The Academy recognizes the necessity to proceed cautiously when revising the “healthy” definition, because of the potential to significantly disrupt or eliminate entire food product lines by precluding some current food manufacturers’ products from continuing to use the “healthy” nutrient content claim on the label or in the product’s name. Some disruptions may be intended, and others may be the expected result of specific changes to regulatory language. In addition, the Academy is concerned about unanticipated disruptions that may result from inartfully drafted language or overly restrictive regulatory requirements that materially impact the commercial viability of products eligible for the nutrient content claim. Without a business case for a “healthy” food product, the “healthy” claim is likely to be relegated to a virtually meaningless label for fresh fruits and vegetables, which consumers already know are healthy and which are still woefully underconsumed. The Academy is hopeful that stakeholders can find a mutually acceptable—even if imperfect—new definition for a “healthy” that will help consumers shift to more nutrient-dense food and beverage choices and limit their intake of added sugars, sodium, and other nutrients to discourage. **There is no benefit to the consumer and no positive impact on health from a nutrient content claim unless the label is widely disseminated, understood, and used.**

a) Retaining or Replacing the Term “Healthy”

The Academy recognizes there is not a single proposal with universal support at this stage of the process, and in response to the FDA’s information collection and the specific questions posed therein, our members provided evidence-based input manifesting multiple substantive viewpoints. For example, several of our Academy dietetic practice groups⁶ endorsed strengthening the regulatory definition for “healthy” in-line with the DGA recommendations.

⁴ Crowe KM, Francis C. Position of the academy of nutrition and dietetics: functional foods. *J Acad Nutr Diet*. 2013;113(8):1096-103. (Emphasis added.)

⁵ Hingle MD, Kandiah J, Maggi A. Practice Paper of the Academy of Nutrition and Dietetics: Selecting Nutrient-Dense Foods for Good Health. *J Acad Nutr Diet*. 2016;116(9):1473-9.

⁶ Dietetic Practice Groups are professional-interest groups, made up of Academy of Nutrition and Dietetics members, who wish to connect with other members within their areas of interest and/or practice. Specialized practice groups enable members to improve their job performance, gain insight into specialized areas of food and nutrition and network with colleagues. A list of dietetic practice groups is available at <http://www.eatrightpro.org/resources/membership/academy-groups/dietetic-practice-groups>.

Other dietetic practice groups expressed concern that the complex interrelationship between food and health is too-quickly dismissed and oversimplified when a food obtains a government imprimatur as “healthy” or “unhealthy” solely because it contains a specified presence and absence of a very small number of nutrients of concern. Some of these members suggested there was value in labeling products with a nutrient content claim similar to that used for the term “healthy,” but that the term itself should change to more clearly describe the claim’s actual meaning. In addition, members noted changing the labeled term when the nutrient content definition is revised allows a clean break from the previous definition, should the FDA determine that would be useful in communicating the new elements of a definition.

The FDA’s initial information collection specifically sought public comment on these questions, including whether “healthy” was the “best term to characterize foods that should be encouraged to build healthy dietary practices or patterns . . . [and what] other words or terms might be more appropriate (e.g., “nutritious”).” Several practice groups noted at the outset that the public’s broad familiarity with the term “healthy” is both helpful and unhelpful to its use as a nutrient content claim. The term is seemingly well-understood, yet it has an amorphous ‘we know it when we see it’ essence to it. Not only does “healthy” lack a specific, common definition, but the definitions are not universal or objective; what is healthy for one person is not necessarily healthy for another person with unique, individualized health concerns.

Given the concerns noted above, many of our members recommended using the term “nutrient dense” as an alternative, which provides a more specific description of the characteristics of a whole food or food product that should be encouraged as part of a healthy meal pattern.⁷ (See Section G on “nutrient-dense” foods below.) Other dietetic practice groups suggested the term “nutrient rich” for similar reasons made in support of “nutrient dense.” Should the FDA consider using another term instead of “healthy,” we note that “limited consumer research suggests the term nutrient dense does not resonate with consumers—rather, nutrient-rich or rich in nutrients is preferable.”⁸

However, if the term “healthy” continues to be legally defined for use on food labels as a nutrient content claim, the Academy strongly believes it should have a consistent meaning across food categories. The guiding principle should be whether the labeled food helps move American diets closer to goals of the DGA. We appreciate that using the same criteria for all food categories is difficult because foods in different categories have different nutrient profiles—this is, after all, the reason these foods were categorized differently. Despite the difficulty of selecting specific nutrients for describing “healthy” foods (e.g., because the nutrients that are low in the diet depend upon demographic consideration, such as some populations requiring more calcium than others; different vitamin requirements for different population groups), it would be even more confusing and

⁷ Drewnowski A. Concept of a nutritious food: toward a nutrient density score. *Am J Clin Nutr.* 2005;82(4):721-32.

⁸ Hingle MD, Kandiah J, Maggi A. Practice Paper of the Academy of Nutrition and Dietetics: Selecting Nutrient-Dense Foods for Good Health. *J Acad Nutr Diet.* 2016;116(9):1473-9 (internal citations omitted).

complicated for the same descriptor to mean different things for different food categories. The likely result would be a significant health literacy challenge.

E. DIETARY GUIDELINES FOR AMERICANS RECOMMENDATION

Pursuant to the 1990 National Nutrition Monitoring and Related Research Act (P.L. 101-445, NNMRRRA), the Secretaries of the Departments of Health and Human Services and Agriculture are tasked with developing and issuing “nutritional and dietary information and guidelines” ‘based on the preponderance of the scientific and medical knowledge’ every five years. As the industry guidance notes, “The Dietary Guidelines is the foundation of federal nutrition guidance and is fundamental in shaping federal policies and programs related to food, nutrition, and health. The Dietary Guidelines provides information and perspectives on healthy eating patterns and consumption of foods from various food groups, as well as the intake of specific macronutrients such as fats, sugars, and micronutrients such as vitamins and minerals. The Academy strongly encourages the FDA to defer to the DGA’s recommendations for nutrition guidance generally and specifically, which also serves to enhance consistency among the various government nutrition recommendations.

Not only should FDA seek to avoid adopting conflicting dietary advice and recommendations, it should seek to synthesize these recommendations with existing and forthcoming standards enshrined in regulations. Dietary advice should be consistent and represent the best of our scientific evidence base. If it differs across federal agencies or programs, the differences must be explained by different legal requirements or scientific standards or other transparent objective reasons. It is just as important to have consistent messages across different sectors of the food supply. If FDA updates the definition of “healthy” while grocery stores themselves are exempt and able to use the term “healthy” for any marketing reason they choose, consumers will become even more confused.

The 2015-2020 DGA’s overarching guidance and key considerations are:

1. Follow a healthy eating pattern across the lifespan. All food and beverage choices matter. Choose a healthy eating pattern at an appropriate calorie level to help achieve and maintain a healthy body weight, support nutrient adequacy, and reduce the risk of chronic disease.
2. Focus on variety, nutrient density, and amount. To meet nutrient needs within calorie limits, choose a variety of nutrient-dense foods across and within all food groups in recommended amounts.
3. Limit calories from added sugars and saturated fats and reduce sodium intake. Consume an eating pattern low in added sugars, saturated fats and sodium. Cut back on foods and beverages higher in these components to amounts that fit within healthy eating patterns.
4. Shift to healthier food and beverage choices. Choose nutrient-dense foods and beverages across and within all food groups in place of less healthy choices. Consider cultural and personal preferences to make these shifts easier to accomplish and maintain.

5. Support healthy eating patterns for all. Everyone has a role in helping to create and support healthy eating patterns in multiple settings nationwide, from home to school to work to communities.

F. RESEARCH

1. Consumer Research Needs

The Academy is grateful for the opportunity to suggest important consumer research to be undertaken to better understand both the current environment of consumer understanding and engagement and identify whether the types of tools, rules, and educational initiatives being considered are likely to accomplish their goals. Below are several specific consumer research items the Academy supports examining further:

- We are concerned that the term “healthy” has the potential to cause consumer confusion because it seems to imply is that a single food should meet all dietary needs, which is not the case for non-medical foods. Academy members expressed concern that labeling individual food products as “healthy” may actually make it less likely that consumers understand that the DGA recommends that a healthy eating pattern includes vegetables, fruits, whole grains (while limiting, not eliminating, refined grains), fat-free and low-fat dairy products and nutrient-dense protein sources, because it is unlikely that a packaged meal would include all of these groups in portion-sizes recognized as servings.
- Given the possibility that only a very restricted subset of nutrients will be relevant in determining whether a food product is “healthy,” the FDA should study whether designation of some products as “healthy” leads consumers to deem unlabeled products “unhealthy” with associated negative feelings.
- The FDA has a responsibility to determine current consumer understandings of the term “healthy,” and we encourage specifically asking respondents to provide multiple definitions to ascertain more relevant definitions. Legal definitions do not necessarily reflect consumer understanding, and terms in common usage such as “health.”
- Perhaps most importantly, FDA has the responsibility of coordinating the education of consumers on the use and changing meanings of the term, since there will not likely be a readily available definition on packages. Nutrition education—and particularly funding therefor—has long been the missing piece of federal nutrition initiatives, and the Academy will continue to work with Congress to find funding for critical nutrition education priorities.

2. Evidence Regarding the Impact of Label Claims on Consumer Nutrient Intake

Analysis of data from the *What We Eat in America* component of the National Health and Nutrition Examination Survey (NHANES) suggests that the use of a “healthy” label claim has had a tangible impact on the nutrient intake of Americans. Ollberding, Wolf, and

Contento⁹ compared responses to questions about food label reading habits to dietary intake in the 2005-2006 NHANES results and found significant relationships between label reading and nutrient intake. For the 43.8% of respondents who reviewed health claims at least some of the time, saturated and total fat intakes were significantly lower than the nationally representative average intake. While one could conceive of an upstream cause for both behaviors, such as a general interest in healthy eating, the same analysis found that this group of label-readers did not have significantly lower intakes of total energy or sugar, which would be expected in the generally health conscious consumer. This evidence of lower intakes of nutrients recommended for limitation that are prerequisites for the current “healthy” label claim but not others suggests that the specific requirements set by FDA for label claims may result in changes in dietary behavior and nutrient intake. Regardless whether positive changes in dietary behavior and nutrient intake occurs through changes in consumer behavior in response to labels or changes in the market of available food products offered by food manufacturers’ responses to label claim requirements, the FDA should make this decision with great concern for potential unintended consequences of a decision to go back to refocusing on nutrients instead of focusing on dietary patterns.

G. Nutrient Dense Foods

The Academy and its members have long touted the benefits of nutrient-dense foods as inherently healthy foods: “[r]egular consumption of nutrient-dense foods for health promotion and disease prevention continues to be a mainstay of dietary recommendations provided by registered dietitian nutritionists (RDNs) and nutrition and dietetics technicians, registered (NDTRs).”¹⁰ We strongly agree with the 2015-2020 DGA and its Key Recommendations that Americans should select a variety of nutrient-dense foods and beverages across and within food groups and should shift to nutrient-dense foods and beverages from less healthy options.

To equip Academy members with the background, research, and tools needed to effectively incorporate the DGA recommendations that had just been released into nutrition education plans for clients and consumers, the Academy published a practice paper entitled “Selecting Nutrient-Dense Foods for Good Health.”¹¹ The paper succinctly encapsulates the five overarching guidelines: “The DGA stress that to stay within energy requirements while meeting nutrition needs, choices in each food group must be nutrient-dense, and when possible, without additional calories from added sugars, refined grains, solid fats, or a combination of those. Shifting from typical foods to more nutrient-dense choices is an important principle in maintaining caloric balance.”¹²

⁹ Ollberding NJ, Wolf RL, Contento I. Food label use and its relation to dietary intake among US adults. *J Am Diet Assoc* [Internet]. 2010 Aug [cited 2016 Dec 12];110(8):1233–7. Available from: <http://linkinghub.elsevier.com/retrieve/pii/S0002822310005274>

¹⁰ Hingle MD, Kandiah J, Maggi A. Practice Paper of the Academy of Nutrition and Dietetics: Selecting Nutrient-Dense Foods for Good Health. *J Acad Nutr Diet*. 2016;116(9):1473–9.

¹¹ *Id.*

¹² *Id.*

It will not be an easy task to encourage individuals to shift their purchases and improve their meal patterns to include more nutrient-dense foods and fewer selections that contain high amounts of nutrients to discourage. In fact, “research suggests American diets are energy-rich and nutrient-poor. The DGA’s definition of ‘nutrient-dense foods’ are those that ‘provide vitamins, minerals, and other substances that contribute to adequate nutrient intakes or may have positive health effects, with little or no solid fats and added sugars, refined starches, and sodium.’” The Academy believes that ideally, these foods and beverages are in forms that retain naturally occurring components, such as dietary fiber.¹³ According to the DGA Executive Summary, “All vegetables, fruits, whole grains, seafood, eggs, beans and peas, unsalted nuts and seeds, fat-free and low-fat dairy products, and lean meats and poultry—when prepared with little or no added solid fats, sugars, refined starches, and sodium—are nutrient dense foods.”¹⁴

The above list includes products readily recognized as nutrient-dense, but other products with a more complicated profile are not so easily classified, according to a research review in the practice paper:

Nicklas and colleagues identified several challenges related to recommending nutrient-dense foods in a 2014 commentary. They questioned whether nutritious foods that are also very energy-dense (e.g., olive oil, avocados, meats, and nuts and seeds) should be recommended with the same enthusiasm as less-energy-dense foods. As Nicklas and colleagues point out, fruits and vegetables vary widely in their nutrient-density scores (e.g, dried fruit vs fresh fruit vs fruit juice); thus, generalizations about the nutrient density of entire food groups is not nuanced enough, and ignores health benefits gained from incorporating highly-energy-dense foods that are also high in nutrient density into the overall diet. The DGA address the varying nutrient density within each category, and a primary focus the guidelines present for nutrition educators and consumers is shifts within each food group from typical to nutrient-dense choices, an important principle for maintaining calorie balance.¹⁵

H. Focusing on Food Patterns Rather Than Nutrients and Food Groups

The Academy adopted the principle that “labels should help to provide understanding about the healthfulness of overall food rather than a focus on particular nutrients” because

¹³ Hingle MD, Kandiah J, Maggi A. Practice Paper of the Academy of Nutrition and Dietetics: Selecting Nutrient-Dense Foods for Good Health. *J Acad Nutr Diet*. 2016;116(9):1473-9 (internal citations omitted).

¹⁴ Hingle MD, Kandiah J, Maggi A. Practice Paper of the Academy of Nutrition and Dietetics: Selecting Nutrient-Dense Foods for Good Health. *J Acad Nutr Diet*. 2016;116(9):1473-9 (internal citations omitted).

¹⁵ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.

it provides context and more accurately reflects how people eat and how they think about eating. As a result, the Academy was thrilled with the 2015-2020 DGA's unambiguous statement that the focus of policy has shifted away from discussing individual foods as healthful and unhealthful and instead towards dietary patterns.

An eating pattern is more than the sum of its parts; it represents the totality of what individuals habitually eat and drink, and these dietary components act synergistically in relation to health. As a result, the eating pattern may be more predictive of overall health status and disease risk than individual foods or nutrients. Thus, eating patterns, and their food and nutrient components, are at the core of the 2015-2020 Dietary Guidelines for Americans. The goal of the Dietary Guidelines is for individuals throughout all stages of the lifespan to have eating patterns that promote overall health and help prevent chronic disease.¹⁶

The Academy agrees wholeheartedly with the DGA's rationale for focusing on meal patterns: "Previous editions of the Dietary Guidelines focused primarily on individual dietary components such as food groups and nutrients. However, people do not eat food groups and nutrients in isolation but rather in combination, and the totality of the diet forms an overall eating pattern. The components of the eating pattern can have interactive and potentially cumulative effects on health. These patterns can be tailored to an individual's personal preferences, enabling Americans to choose the diet that is right for them."¹⁷ The healthfulness of a food in a dietary pattern relates to the portion-size of the food, its nutrient density, and its composition in terms of nutrients of concern, not simply the presence of absolute amounts of a single nutrient.

This direction from the current Dietary Guidelines is consistent with the Academy's position that the total diet or overall pattern of food eaten is the most important focus of healthy eating, which stipulates that all foods can fit into a healthy overall pattern when accounting for portion size and diet variety.¹⁸ With this overall pattern approach to healthy eating, there is little doubt that any individual food item can contribute to healthy eating pattern when the quantity and frequency of its contribution remains moderate. Finally, the Academy notes that notwithstanding significant consumer misconceptions^{19 20}

¹⁶ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans, 8th Edition [Internet]. 2015. Available from: <http://health.gov/dietaryguidelines/2015/>

¹⁷ *Id.*

¹⁸ Freeland-Graves JH, Nitzke S, Academy of Nutrition and Dietetics. Position of the academy of nutrition and dietetics: total diet approach to healthy eating. *J Acad Nutr Diet* [Internet]. 2013 Feb [cited 2016 Dec 12];113(2):307–17. Available from: <http://linkinghub.elsevier.com/retrieve/pii/S2212267212019934>

¹⁹ Ares G, Vidal L, Allegue G, Giménez A, Bandeira E, Moratorio X, et al. Consumers' conceptualization of ultra-processed foods. *Appetite*. 2016 105, 611-7.

²⁰ SFGATE. Processed Food Definition. Accessed April 18, 2017. Available at <http://healthyeating.sfgate.com/processed-food-definition-2074.html>

²¹ about the nutritional profile of processed foods generally—some of which are repeated without evidence in some comments submitted to FDA in this docket— processed foods help consumers construct diets with recommended dietary patterns that are safe, nutritious, convenient and affordable.^{22-23 24 25 26 27 28 29}

I. LIMITATIONS IN ASSESSING INDIVIDUAL FOOD GROUPS' CONTRIBUTIONS TO DISEASE RISK

The DGA's focus on dietary patterns led to improved, synthesized messaging of nutrition recommendations and fostered an intuitive public understanding of the nutrition guidance because dietary patterns represent the way in which Americans actually eat—by consuming foods, not nutrients. In addition, there was a scientific basis for the change in focus discussed in the Dietary Guidelines Advisory Committee's scientific report's (the "Scientific Report") conclusion: "Because foods are consumed in combinations, it is difficult, if not impossible, to determine their separate effects on health"³⁰. The Academy's formal comments on the Scientific Report specifically highlighted the lack of evidence available to define the health impacts of individual foods:

The Academy supports the use of dietary pattern analysis as a framework for generating public health recommendations and the use of NEL systematic review on the topic, which employed state-of-the-art evidence synthesis techniques. It is important, however,

²¹ Mötteli S, Keller C, Siegrist M, Barbey J, Bucher T. Consumers' practical understanding of healthy food choices: a fake food experiment. *British Journal of Nutrition* 2016, 116, 3, 559-66.

²² Khalatbari-Soltani S, Marques-Vidal P. Not as bad as you think: a comparison of the nutrient content of best price and brand name food products in Switzerland. *Preventive Medicine Reports* 2016, 3, 222-8.

²³ Eicher-Miller HA, Fulgoni VL 3rd, Keast DR. Energy and Nutrient Intakes from Processed Foods Differ by Sex, Income Status, and Race/Ethnicity of US Adults. *Journal of the Academy of Nutrition and Dietetics* 2015, 115, 6, 907-18.

²⁴ Mötteli S, Keller C, Siegrist M, Barbey J, Bucher T. Consumers' practical understanding of healthy food choices: a fake food experiment. *British Journal of Nutrition* 2016, 116, 3, 559-66.

²⁵ Not all processed foods are unhealthy. Harvard Health Publications. Available at <http://www.health.harvard.edu/staying-healthy/not-all-processed-foods-are-unhealthy>

²⁶ Dwyer JT, Fulgoni VL 3rd, Clemens RA, Schmidt DB, Freedman MR. Is "processed" a four-letter word? The role of processed foods in achieving dietary guidelines and nutrient recommendations. *Advanced Nutrition* 2012, 3, 4, 536-48.

²⁷ Eicher-Miller HA, Fulgoni VL, Keast DR. Processed Food Contributions to Energy and Nutrient Intake Differ among US Children by Race/Ethnicity. *Nutrients* 2015, 7, 12, 10076-88.

²⁸ Eicher-Miller HA, Fulgoni VL 3rd, Keast DR. Contributions of processed foods to dietary intake in the US from 2003-2008: a report of the Food and Nutrition Science Solutions Joint Task Force of the Academy of Nutrition and Dietetics, American Society for Nutrition, Institute of Food Technologists, and International Food Information Council. *Journal of Nutrition* 2012, 142, 2065S-2072S.

²⁹ International Food Information Council (2015) *The 2015 Food & Health Survey: Consumer Attitudes toward Food Safety, Nutrition & Health*. <http://www.foodinsight.org/2015-food-health-survey-consumer-research> (accessed August 2016)

³⁰ Dietary Guidelines Advisory Committee. Scientific Report of the 2015 Dietary Guidelines Advisory Committee. 2015.

to recognize and articulate the limitations of this approach and accordingly, to present the findings in a manner consistent with their most accurate interpretation.

We note that for all topics in this section, the evidence synthesis provided by the NEL cannot support any inferences about the contributions that individual food groups make to the overall effect observed for a dietary pattern. In the reviews, the majority of the available evidence was provided by studies using scoring systems to assess adherence to predefined diet patterns, and the NEL identified diet patterns that associated outcomes of interest. **The NEL discussed the similarities and differences of the dietary patterns with regard to food groups, but no analytical approach was used to compare the contributions of these food group components to either overall scores or to the predictive performance of individual food groups.**³¹ Without these analyses, it cannot be said whether any individual food group was correctly identified as positively or negatively contributing to the pattern score and disease risk. As a result, the possibility remains that individual food groups have a diminished or even opposite effect of what is expected, an effect that could be masked by other components of the diet pattern assessment techniques that are strongly performing.

The NEL reviews also considered direct evidence for specific food groups, but, across all reviews, the evidence base for these analyses was smaller and the results were inconsistent. For example, in the cardiovascular disease review, dairy “was reported both negatively and positively in different studies. One study reported an unfavorable association between total dairy and CHD risk; however, two studies reported a favorable association between total dairy and HTN.” It is also noteworthy that not a single study included in the review for cardiovascular disease is reported to have identified saturated fat as having an unfavorable association with cardiovascular disease, which is discussed in detail . . . below.³²

The Academy remains very concerned about the ambiguity and confusion arising from the research noted above, specifically the extent to which organizations still may be relying upon unsupported inferences or conclusions thereof—including in response to this very

³¹ Nutrition Evidence Library. "A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes." United States Department of Agriculture. 2014. Accessed April 28, 2015. Nutrition Evidence Library. "2015 DGAC Dietary Patterns NEL Systematic Reviews" United States Department of Agriculture. 2015. Accessed April 28, 2015.

³² Academy of Nutrition and Dietetics Comments to HHS and USDA re Dietary Guidelines Advisory Committee. May 8, 2015. Accessed April 18, 2017. Accessed <http://www.eatrightpro.org/resource/news-center/on-the-pulse-of-public-policy/regulatory-comments/dgac-scientific-report>.

request for information. We strongly encourage the FDA to review the present status of the research to ascertain whether the gaps in the NEL's scientific process have been remedied. Discounting extrapolated arguments relying upon these inferences is critical to ensure that the "healthy" claim is based on rigorous scientific substantiation and is validated against objective measures of diet quality.

J. CONSIDERATIONS FOR SPECIFIC FOODS AND PROCESSES IN A DEFINITION

1. Added Sugars

The Academy strongly supports updating any "healthy" definition to limit added sugars, consistent with the recent revisions to the Nutrition Facts Panel. Added sugars, especially in combination with solid fats and excess energy intake, have been linked to health concerns, including overweight and obesity, type 2 diabetes, prediabetes, and cardiovascular disease.³³ Between 2003 and 2006, added sugars (sugar, high- fructose corn syrup, etc.) provided about 14% of total calories for the average American, and 25% or more of calories for more than 36 million Americans,³⁴ intake that is neither healthy nor sustainable.

2. Whole Grains

The Academy has long demonstrated its commitment to improving the nutritional quality of grains marketed and sold to children and to adults. Grains are important sources of many nutrients, including dietary fiber, B vitamins (thiamin, riboflavin, niacin, and folate), and minerals (iron, magnesium, and selenium). Dietary fiber from whole grains may help reduce blood cholesterol levels and is associated with lower risk of heart disease, obesity, and type 2 diabetes.³⁵ Whole grains are notably under consumed among preschool children and their parents.³⁶

According to the 2015-2020 DGA, "the 2015-2020 Dietary Guidelines provides guidance for choosing a healthy diet and focuses on preventing the diet-related chronic diseases that continue to affect our population."³⁷ They specifically included a "Key Recommendation for healthy eating patterns" specifically recommending of grains consumed that "at least half [...]of which are whole grains." We strongly support efforts in schools, homes, day care

³³ US Departments of Agriculture and Health and Human Services. Dietary Guidelines for Americans, 2010. 7th ed. Washington, DC: US Government Printing Office; 2010.

³⁴ Marriott BP, Olsho L, Hadded L, *et al.* "Intake of added sugars and selected nutrients in the United States, National Health and Nutrition Examination Survey (NHANES) 2003–2006," *Crit Rev Food Sci Nutr* 2010, vol. 50, pp. 228-58.

³⁵ O'Neil, C. E., Nicklas, T. A., Zanovec, M., Cho, S. S., & Kleinman, R. (2011). Consumption of whole grains is associated with improved diet quality and nutrient intake in children and adolescents: the National Health and Nutrition Examination Survey 1999–2004. *Public health nutrition*, 14(02), 347-355.

³⁶ Ball, S. C., Benjamin, S. E., & Ward, D. S. (2008). Dietary intakes in North Carolina child-care centers: Are children meeting current recommendations? *Journal of the American Dietetic Association*, 108(4), 718-721.

³⁷ Message From the Secretaries. U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans, 8th Edition [Internet]. 2015. Available from: <http://health.gov/dietaryguidelines/2015/>.

centers, and restaurants to make it easier for Americans to meet the recommendation that just over 50% of grains should be whole grains. Given that the 2015-2020 DGA is the gold standard and recently made its recommendation based upon healthy eating patterns, the FDA should simply adopt it, decline to make arbitrary changes that lack a basis in evidence, and enhance consistency among government nutrition guidance.

3. Proteins

The 2015-2020 DGA's Key Recommendation for protein in a healthy eating pattern is to consume "a variety of protein foods, including seafood, lean meats and poultry, eggs, legumes (beans and peas), and nuts, seeds, and soy products." Contrary to some reports, and as the Congressional Research Service confirmed, "the 2015-2020 DGA does not include a Key Recommendation to reduce consumption of red and processed meat (as advised by the 2015 DGAC report)."³⁸ Red meat is consistently present in healthy eating patterns when consumed in moderate amounts to ensure under consumed proteins, such as fish, nuts, and legumes, are included in the pattern without exceeding protein limits.

4. Oils

The Academy supports exempting most vegetable oils (except palm, palm kernel, and coconut) from the saturated fat limit because they are high in unsaturated fats and consistent with a healthy eating pattern.

5. Fruits, Vegetables, and Certain Other Foods

In general, most foods present in high amounts in a healthy eating pattern, as defined by the *DGAC Report*, are eligible for a "healthy" claim because they contain 10 percent of the DV for at least one of one or more beneficial nutrients (e.g., calcium, vitamin D, iron, potassium, fiber, or protein). However, because certain fruits and vegetables do not meet this minimum, the FDA should continue to exempt these foods—whole, raw fruits or vegetables, and single-ingredient or mixtures of frozen or canned fruits and vegetables—from any complex regulatory rubric the FDA were to adopt. The Academy supports this exemption to help consumers identify foods that form the foundation of a healthy eating pattern, to increase fruit and vegetable intake, and to avoid confusing consumers.

Likewise, FDA should exempt single-ingredient or mixtures of whole grains, nuts, and seeds (such as whole-grain brown rice, walnuts,³⁹ and Brazil nuts) that do not meet the beneficial nutrient criteria. FDA should also exempt plain or sparkling water—without added caloric, low-calorie, or calorie-free sweeteners or other caloric ingredients—from the beneficial nutrient minimums to encourage consumers to choose water instead of sugar drinks.

However, we note that one of the fundamental problems with the proposal to create a regulatory definition of a concept such as "healthy" is that the definitions seem wise until they do not anymore, whether because of the mounting numbers of exceptions and

³⁸ Dabrowska A. Dietary Guidelines for Americans: Frequently Asked Questions. Congressional Research Service. Accessed April 18, 2017. Available at <https://fas.org/sgp/crs/misc/R44360.pdf>.

³⁹ FDA already exempts walnuts, for example, from a similar nutrient requirement for a qualified health claim about nuts and heart disease. See <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064923.htm>.

exemptions and variances or because of advances in scientific understanding. It is critical that any definition is recognized by all stakeholders as grounded in science, such that there are clear legal and scientific reasons for exemptions beyond arbitrary policy and political reasons.

6. Fortification

Some Academy members questioned whether nutrient density calculations would include only naturally-occurring nutrients, or whether nutrients added through fortification and enrichment would also be factors. The Academy agrees that there can be benefits from fortification, but notes FDA's admonition that fortification can also "result in over- or under-fortification in consumer diets and create imbalances in the food supply."⁴⁰ In short, and as a general rule, the Academy believes we should encourage whole, nutrient dense foods with naturally occurring nutrients of public health concern. Accordingly, should the FDA use nutrients of concern as a determinative factors in defining "healthy," we would support requiring that only naturally occurring nutrients of public health concern may be included in calculations for the purpose of determining whether that product is eligible to carry the "healthy" nutrient content claim. We encourage the FDA to provide specific detail of and evidence for its rationale for whichever decision it makes on the fortification issue.

K. Definitions Should Reflect Current Science

The Academy believes is important for the FDA to commit to updating the definitions as needed, including but not limited to events such as a determination of significant scientific agreement or the issuance of an authoritative statement from a scientific body of the US government or the National Academy of Sciences that could trigger a reevaluation of a nutrient content claim. Accordingly, the Academy is pleased that the industry guidance confirms that as the body of scientific evidence changes, "the recommendations based on that science in the Dietary Guidelines will help FDA shape additional updates to regulations on nutrition related claims and information that are permitted on the food label."

Conclusion

The Academy appreciates the opportunity to comment on the request for information and guidance and draft industry guidance related to the "healthy" nutrient content claim. Please contact either Jeanne Blankenship at 312-899-1730 or by email at jblankenship@eatright.org or Pepin Tuma at 202-775-8277 x6001 or by email at ptuma@eatright.org with any questions or requests for additional information.

Sincerely,

⁴⁰ FDA Issues Guidance on Fortification of Foods. FDA website. Accessed April 20, 2017. Available at <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm471542.htm>.

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