February 13, 2023

Comments on a Proposed Rule Issued by the Food and Drug Administration: "Food Labeling: Nutrient Content Claims; Definition of Term `Healthy'"

Docket No. FDA-2016-D-23335, RIN 0910-AI13

We submit these comments in response to the September 29, 2022 Federal Register Notice issuing a Proposed Rule governing food labeling, nutrient content claims, and how the government should define, measure, and label the degree to which a given food is "healthy."

Our comments are submitted on behalf of the Heartland Health Research Alliance (HHRA) and the Swette Center for Sustainable Food Systems at Arizona State University. HHRA is a non-profit organization that conducts research on the impacts of farming systems and technology on food quality, safety, and public health, with focus on women during pregnancy, the health of infants, and children's development (hh-ra.org). The Swette Center conducts transdisciplinary research and education on food system transformation for social progress, economic productivity, and environmental resiliency (sustainability-innovation.asu.edu/food/).

The signatories include Dr. Kathleen Merrigan, Executive Director of the Swette Center and Chair of the HHRA Public Policy Committee. She is a former Deputy Secretary of the USDA. Dr. Hannah Flower is a UK Nuffield Farming Scholar and medical doctor who is now also managing a family livestock farm in the UK. Dr. Donald R. Davis is a retired nutrition scientist who has conducted extensive research on how food nutritional quality impacts health outcomes, and on the impacts of farming systems on food nutritional quality. Dr. David Montgomery is a professor of geomorphology at the University of Washington in Seattle. Anne Biklé is a science writer who, with Montgomery, authored What Your Food Ate: How to Heal Our Land and Reclaim Our Health (2022) as well as several related books. Dr. Robin Mesnage is an HHRA science advisor. He conducts cutting-edge, genomics research on how food quality and dietary patterns impact health outcomes at the Buchinger Wilhelmi Clinic in Uberlinger, Germany. Dr. Charles Benbrook is the Executive Director of HHRA. He has conducted research and published on the impacts of farming systems on nutrient density, nutritional quality, and the public health outcomes associated with shifting livestock back onto forage-based rations and expanding production of organic fruits and vegetables.

Our comments begin with our recommendations in section I regarding how the FDA should label food products relative to their contribution to meeting nutritional needs linked to important, population-wide health outcomes.

In section II we propose adoption of a data-driven method to quantify the contribution of specific single-ingredient foods and multi-ingredient food products to a person's daily nutritional needs taking into account the caloric content of each serving of food. We introduce such a method, known as the NuCal System.

Section III responds to some of the questions posed by the FDA in the Proposed Rule and addresses unique and emerging challenges that will stress test the new FDA definition and labeling system. Section IV discusses practical matters that will arise in the implementation of whatever health-focused labeling system the FDA decides to adopt. Section V focuses on the FDA's assessment of the economic costs and benefits of its proposed definition of healthy foods and its accompanying labeling system.

Table of Contents

I. Introduction and Summary of Recommendations

Data compiled by the Institute of Health Metrics and Evaluation at the University of Washington show that in 2010 dietary choices accounted for the largest share of deaths, and nearly 50% more deaths than smoking (the #2 cause of death). [1] Food and diet quality are important factors driving 6 of the top 10 causes mortality across the US population. Some two-thirds of the US adult population are overweight or obese and struggle to slow the progression of one or more food quality and diet-related chronic disease. Childhood obesity alone has roughly doubled from 1988 to 2018 and nearly one in 5 children today are obese.[2]

Adverse trends in public health strongly linked to poor food quality and unhealthy diets cost America hundreds of billions of dollars every year. Unhealthy foods and poor diets impact essentially all families and show no signs of abating. Food and diet quality have profound impacts during pregnancy and impact children's development in a variety of ways and are among the public health challenges addressed by the Heartland Health Research Alliance.

In light of these sobering facts, we urge the FDA to design and implement a definition of healthy foods substantially different than the one in the Proposed Rule. The new definition should form the foundation for an accompanying labeling system that will over time result in substantial and sustained changes in food quality and food choices across a large segment of the US population.

We cannot overestimate the importance of FDA action on defining and labeling of healthy food. If consumers shift their food dollars to healthier foods, the food industry will surely begin to alter recipes and intensify its search for nutrient-dense food ingredients. The power of the marketplace could begin to alter the trajectory of agricultural and food science innovation. Investing in higher quality, nutrient-dense foods and food ingredients will, in turn, lead to changes in farming systems that will open new pathways to benefit consumers, farmers and food companies, animals, and the planet.

The Challenge

We conclude that the new definition of healthy food and the food labeling system proposed by the FDA will likely do little good in moving consumers toward healthier dietary patterns. Indeed, the FDA apparently agrees with our assessment, given FDA's sobering estimate that its proposed new definition of healthy food and labeling system will alter ***no more than 0.4% of consumer food purchase decisions***.

[1] https://www.healthdata.org/news-release/new-study-finds-poor-diet-kills-more-people-globally-tobacco-and-high-blood-pressure; https://www.healthdata.org/news-release/dietary-risks-are-leading-cause-disease-burden-us-and-contributed-more-health-loss-2010

[2] https://www.cdc.gov/obesity/data/childhood.html

In our judgement, the FDA needs to find a path forward that will allow the food industry to communicate clear, simple, and science-based nutritional quality information that has real potential to move consumer purchase priorities.

We urge the FDA to design a much more impactful system and outline one novel, hypothetical option referred to herein as the NuCal system.[3] There is great need to convey information to consumers that is clear and delivered in ways likely to support healthier food choices and dietary-patterns day in and day out.

The metric and system ultimately advanced by FDA will, we hope, guide consumer choice among those people seeking to improve their health status or trajectory via selection of more nourishing foods. The system can do so by driving home the significant nutritional differences between many highly processed foods and whole grains, fresh fruits and vegetables, nuts and many animal products.

We enthusiastically endorse FDA's core goal in this Proposed Rule:

> "FDA seeks to improve dietary patterns in the United States to help reduce the burden of nutrition-related chronic diseases and advance health equity as nutrition-related diseases are experienced disproportionally by certain racial and ethnic minority groups and those with lower socioeconomic status."

We also agree a new definition of "healthy" foods is urgently needed, coupled with a front-of-package "healthy" food labeling system. Herein we recommend core features that the FDA should include in such a system. In the FR Notice under "Our Approach", the FDA states that:

> "The *Dietary Guidelines, 2020-2025* recommends following a healthy diet pattern at every stage with a focus on meeting food group needs with nutrient-dense foods and beverages, and staying within calorie limit."

We applaud the focus on dietary patterns in federal food and nutrition programs and guidance documents. But we also conclude that the methods the FDA is proposing to integrate healthy dietary patterns into the new definition of "healthy" foods and an accompanying labeling systems are misguided.

Consumers don't pick out a dietary pattern as they move along an aisle in a supermarket. They seek out family favorites, and sometimes review food product labels on competing brands to see if an alternate brand or food form is available that delivers meaningful nutritional advantages.

[3] The hypothetical NuCal nutrition labeling system described in these comments bears no relationship to the nucal internet application design company, NuCal dietary supplements, Nucal Foods Inc., the NuCal nutrition calculator developed by the Hong Kong government, or any organization or company using the letters "nucal" in their messaging or title.

The FDA and federal government should continue relying on dietary guidelines emphasizing healthy eating patterns but do so in ways and with tools distinct from those used by the FDA to assist consumers looking for healthier food options.

Cutting to the core of our recommendations, government programs and educational materials should continue urging healthy dietary patterns by incrementally shifting the mix of different foods and beverages within the diets consumers choose on any given day. Concurrently, the FDA's new effort to promote "healthier" food choices should focus on providing consumers guidance on the healthiest choices for each of the foods and beverages within their daily diets.

Throughout these comments, we discuss "nutrient density" and by this we refer to the total amount of essential nutrients in a standard serving of food or beverages relative to the calories in the serving of food or beverage. We urge FDA to place heavy weight on the nutrient density of a serving of food relative to its caloric content. We use the word "nutrient" in the context of FDA's new health-centric labeling system to refer to those nutrients judged to be essential in promoting human health. The selection of those nutrients to include and those to exclude, or place lesser weight upon, is one of the critical challenges that lie ahead, regardless of the system chosen by the FDA.

We urge FDA to devise a system, like the NuCal system described in Section II, that ***captures and reflects the critical relationship of a specific food's overall essential nutrient content in relation to the caloric space the food takes up in a person's daily diet***.

We argue that FDA's FOPNL system should focus on health-promoting nutrients: vitamins, minerals, fatty acid profiles, antioxidant activity, and other health-relevant components in food that are not addressed in back-of-package Nutrition Facts panels.

Long-term success in promoting healthier dietary patterns and the manufacture of healthier foods will depend on how thoughtfully the FDA and other government agencies integrate and harmonize their many, ongoing efforts to promote both healthier eating patterns and healthier food and beverage choices. In addition, a new "healthy" food choice system must be supported by a significant and sustained consumer education program designed to explain what the rating system measures and reflects, and how consumers can use the system's ratings to guide health-positive food choices.

In addition, the new system must also be harmonized and reinforced via other government efforts and initiatives striving to promote healthier foods and beverages and eating patterns. These other efforts include the Dietary Guidelines, criteria governing approval of qualified health claims on food packaging, articulation of standards of identity, and in the rules applying to food advertising and promotional material.

In finalizing this rule, the health-oriented messaging must be simple, clear, and provide consumers with actionable information. By "actionable information" we mean data-driven reasons to choose brand x instead of brand y of a favorite food, as well as guidance

encompassing the nutritional benefits arising from choosing a different form of the same or similar foods. For example, choosing between frozen whole cranberries versus cranberry sauce, or unsweetened dried cranberries versus sweetened dried cranberries; pita chips versus potato chips; or salad dressings high in saturated fats and omega-6 fatty acids versus dressings high in omega-3s and monounsaturated fats.

The FDA must resist the temptation to comprehensively address ***all*** food nutritional quality issues within a single definition of "healthy". Examples of important nutritional quality information best addressed in other ways include protein levels and form, portion of nutrients from whole foods and food ingredients versus supplementation, total fat and fatty acid profiles, cholesterol levels, natural versus added versus total sugars, salt content, nutrient needs specific to life stage or health status, vegan versus vegetarian versus keto diets, and the impact of religious and cultural preferences on overall diet quality.

Our Recommendations

1. ***Single nutrients, for example Vitamin C, have been shown to confer specific health benefits. However, the variety and quantity of multiple nutrients within a serving of food is far more important for overall health and well-being. Single-nutrient based criteria in a system designed to support labeling of "healthy" foods are generally incompatible with the need for a wholistic measure of food nutritional quality.***

The Proposed Rule states: "…the criteria for `healthy' in the current [FDA] regulation are solely based on individual nutrients" (CFR p. 59170). Instead, we urge FDA to state in the Final Rule that "The new definition of `healthy' foods and beverages rests upon the aggregate sum of essential, health-promoting nutrients in a serving of food relative to the caloric space taken up by a serving of food or beverage."

To take advantage of scientific advances and promote clear messaging, the FDA must move away from single-nutrient criteria and instead base the identification and labeling of "healthy" foods on the totality of beneficial nutrients in a serving of food $product_x$ relative to the caloric space the serving takes up within the diet.

Single nutrients and components of food that can trigger adverse health outcomes when ingested in excess or at inadequate levels can best be handled in the "Nutrition Facts" panel on the back of food packages and/or through limits recommended or required via regulation. Such nutrients and food-compositional attributes include calories per serving, total and saturated fat, salt, added sugar, gluten content, and cholesterol.

There are some two-dozen essential nutrients humans must ingest via daily food choices and dietary patterns. No single food can meet daily needs for more than a few essential nutrients. But foods that contribute to a meaningful degree to daily intakes of multiple essential nutrients should score more favorably than a food containing only one or a few essential nutrients.

We applaud FDA for highlighting another key feature of the proposed FDA definition and labeling system that warrants further reflection – the many cases that failure to comply with one of FDA's current, single-nutrient benchmarks will keep an unambiguously "healthy" food from being labeled as "healthy." Avocados and salmon are good examples noted in the FDA's Proposed Rule. Surely the multiple, essential nutrients provided by fresh avocado and salmon outweigh their relatively high levels of saturated fats, which under current FDA policy, would prohibit their identification as a "healthy" foods.

For reasons outlined above, food groups should not be used as a feature in a "healthy" food labeling scheme. The food nutritional quality ratings of various foods within a food group can and should be compared to the ratings of foods in other food groups.

A high and rising percentage of the American diet is composed of dishes and food products with multiple ingredients from several food groups. It is hard enough to define and measure the "health" of a given, multi-ingredient food product based on what is in the product. Trying to do this also across and among the multiple food groups represented by the ingredients in a serving of food adds significant complexity, analytical challenges, and murkiness. It also would add little to clarity of messaging and ease of computations required to implement the system.

Pizza is a good example. Virtually all slices of pizza contain grain, dairy, and vegetable ingredients, and most also contain meat products, spices, and/or fruit. The source of each of the individual ingredients will impact nutrient composition, nutrient density, and caloric content.

How cows are fed, and their breed and production levels have major impacts on the fatty acid composition of cheese and hence nutritional quality. Some vegetables vary modestly across genetics and production systems, while nutrient density within specific grain and vegetable ingredients will vary by +/- 20% or more based on where and how a crop was produced and handled post-harvest.[4]

Each of these and many other factors will impact nutrient density, and hence contribute to determining how "healthy" one slice of pizza is compared to slices of other pizzas, even when the two slices of pizza contain similar quantities of the same ingredients. What matters is the overall impact of all these factors on nutrient density and caloric content, and ***such differences can only be taken into account by quantifying the levels of all essential nutrients in a slice of pizza.***

[4] Barański, M., Średnicka-Tober, D., Volakakis, N., Seal, C., Sanderson, R., Stewart, G., . . . Leifert, C. (2014). Higher antioxidant and lower cadmium concentrations and lower incidence of pesticide residues in organically grown crops: A systematic literature review and meta-analyses. British Journal of Nutrition, 112(5), 794-811. doi:10.1017/S0007114514001366; Reganold JP, Andrews PK, Reeve JR, Carpenter-Boggs L, Schadt CW, et al. (2010) Correction: Fruit and Soil Quality of Organic and Conventional Strawberry Agroecosystems. PLOS ONE 5(10): 10.1371/annotation/1eefd0a4-77af-4f48-98c3-2c5696ca9e7a. https://doi.org/10.1371/annotation/1eefd0a4-77af-4f48-98c3-2c5696ca9e7a

Trying to cobble together a defensible measure of the degree to which one slice of pizza compared to others is healthy via estimates of the typical levels of nutrients in the different ingredients in a slice of pizza undermines the value of efforts by farmers to grow and raise more nutrient-dense foods. It also would undercut promising and growing efforts across the food industry to seek out and incorporate healthier raw foods and ingredients in their recipes and brand-name products.

There are many valid ways to compare the nutritional quality of one food relative to others: (1) nutrients delivered by unit of weight (per ounce or 100 grams), (2) nutrients per unit of calories (i.e. 100 calories), and (3) per typical serving of food. We urge the FDA to base its new "healthy" food labeling system on the nutrients in a single serving of foods. The serving sizes used in defining "healthy" food products should be the same as the serving sizes used in the back-of-package "Nutrition Facts" panels.

Basing the new healthy food labeling system on nutrients in a serving of food will provide the FDA and food industry with options to harmonize and leverage the information on front-of-package "healthy" food labels with the per serving "Nutrition Facts" information on the back of packaging. Over time, the content of both sets of information can be revised to maximize the clarity and impact of the combined information they convey.

2. ***The definition of "healthy" and how it is measured should be based on a metric reflecting the degree to which one food or food product contributes to universally accepted, essential nutrient needs compared to other foods and brands.***

Food choices, and food-product nutritional quality, impact health outcomes in exceedingly complex ways. Dozens of factors specific to each person play a role in how food choices and dietary patterns alter that individual's health at each stage of life.

In order to achieve the FDA's stated goals in labeling "healthy" food, the essential nutrients included within the system should have widely accepted, near-universal positive impacts on public health trends. The labeling system should not incorporate, or should place little weight on macronutrients that nearly all Americans consume in sufficient quantities on most days. These would include, at a minimum, protein, fat, and carbohydrates.

We urge the FDA to include language such as the following in the Final Rule:

> "The conceptual and analytical foundation of `healthy' food labeling must highlight and encapsulate the primary, population-wide ways that poor food nutritional quality can trigger morbidity and mortality: overweight and obesity, diabetes, cardiovascular disease and stroke, neurological problems, liver disease, bone health, reproductive problems, and cancer. This is why, for example, protein is not included in the definition and measurement of `healthy' food, not because protein is unimportant, but because a shortage of protein is not a significant concern in most contemporary US diets."

3. ***The definition of "healthy" and a new FOPNL system should focus on essential nutrients, particularly those that function as primary prevention for chronic disease, rather than striving to alert consumers to those components in food products that can become unhealthy when consumed in excess (e.g., salt and some fats).***

If front-of-package nutrition labels (FOPNL) are intended to represent the relative healthfulness of a given food, then they should focus wholistically on the ***essential nutrients people must obtain from food on a daily basis***, including the approximate two dozen nutrients for which the FDA and other government agencies have established a Recommended Daily Intake (RDA), Dietary Reference Intake (DRI), Adequate Intake (AI), Estimated Average Requirement (EAR), or their functional equivalent.

In addition, a future FOPNL system should include widely recognized attributes of health-promoting food products that are critical only in certain food groups and not yet covered by a government-set RDA or DRI or EAR. These include, in particular, total antioxidant activity in the case of plant-based products, and in animal products, the omega-6 to omega-3 ratio and saturated fat content adjusted to exclude fatty acids that are known to be heart healthy or heart-health neutral.

But "healthy" involves not just the "essential" nutrients we need to stay alive, but also antioxidants and anti-inflammatory compounds not yet considered "essential" in healthy diets. If the FDA's goal in advancing this Proposed Rule is to promote healthy eating, the FDA must expand the health-promoting nutrients in food to include phytochemicals and other health promoting dietary constituents that are not yet regarded as "essential".

Both salt and fat content in food are primary features in back-of-package "Nutrition Facts" panels. Consumers are generally aware of the adverse health consequences from excessive intakes of salt and total and saturated fat. Sugar content and source, cholesterol, and dietary fiber are also featured among the "Nutrition Facts" presented for every food product, lessening the need for these constituents in food to play a significant, or any, role in front-of-package healthy food labeling and messaging.

4. ***The healthfulness of one serving of food compared to other foods should ideally be based on a single, continuous metric. Values for this metric can then be arrayed along a nutritional quality continuum for simplicity of messaging and to help consumers recognize the magnitude of differences arising from their food choices.***

As argued above, the metric driving FDA's "healthy" labeling system should be a ratio encompassing both nutrient and caloric density. It should be calculated for, and applied to single servings of foods and beverages, thereby fostering comparisons across foods, beverages, and food groups. Such a metric will produce a single, equitable measure of nutritional quality that is equally applicable and easy to measure in the case of single ingredient and multi-ingredient foods.

The higher the nutritional-quality metric ratio, the more nutrients supplied relative to caloric space taken up in a person's daily diet, and thus the higher the ***calorie-adjusted nutritional quality score*** for a serving of a given food or beverage.

Such a metric can then be used to array foods along a continuum ranging from those foods that deliver few if any nutrients relative to their caloric content, in contrast to foods delivering more meaningful amounts of nutrients known to be associated with positive health outcomes.

Some labeling systems incorporate red, yellow, green colors in denoting zones along the nutritional quality continuum. Other methods or symbols could also prove effective in driving home differences in food nutritional quality, but we are unaware of one that is as simple and readily understood.

5. ***The new healthy food labeling system should have three basic informational and communication goals and must be designed to serve these goals rigorously and clearly.***

First, the system should support delineation of three zones along a food nutritional quality continuum (see the red-yellow-green continuum below). The zones should identify those foods that significantly promote health (i.e. nutrient-rich foods) in contrast to foods that contribute little to health (i.e., nutrient-poor foods that contain mostly empty calories). The former types of food would be in the green zone and the latter in the red zone. Yellow zone foods are those that land between the green and red zones.

Second, the system and associated communication and public education efforts should encourage and guide consumers in switching from: (a) less healthy food options to other foods providing a more significant contribution to daily nutrient intakes, and (b) within a food product category, foods that rate higher along the continuum, and ideally fall near or within the green zone.

Third, the system should support and deliver information to consumers that takes little effort to understand and which can directly inform and guide healthier food choices.

To achieve the goals set forth by the FDA in this proposed rule, the new system must not shy away from using words and phrases that are clear and impactful, e.g. the most nutrient dense foods relative to caloric content should be called "nutrient rich" or something equally simple and accurately descriptive, and food largely devoid of essential nutrients should be labeled "empty calories" or "nutrient-poor" with respect to meeting nutrient needs linked to positive health outcomes. The general public is familiar with the term "junk food," and while FDA may not choose to use this language, the terminology adopted by the FDA and food industry should communicate an equally clear message.

6. ***The basic metric used to array foods along the nutritional quality continuum should be based on the degree to which the nutrients in a given serving of food meet a person's nutritional needs relative to the caloric space taken up in that person's daily allotment of calories.***

A food-specific "calorie-adjusted nutritional quality" score or value combines two vital characteristics of food into a simple yet meaningful metric. This metric can then be used in a labeling system to help consumers identify changes in their diets that will enable them to consume sufficient amounts of health 'essential' and health-promoting nutrients, while staying within their daily calorie allowance.

7. ***A nutrient profiling system developed and/or embraced by the US government should be the foundation for calculating food and beverage-specific, calorie-adjusted nutritional quality scores per serving of food or beverage. The USDA and FDA should devote sufficient resources to support the testing of foods and beverages so that all the necessary data are available to compute nutritional quality index scores for all common foods and beverages in the US diet.***

A nutrient profiling system will be needed to calculate the percentage of daily nutrient needs provided by a serving of food. Such systems add together for a serving of food a series of fractions representing the amount of $nutrient_x$ in milligrams in the food divided by the daily RDA/RDI or equivalent for that nutrient, also expressed in milligrams. These essential-nutrient specific ratios can then be added together and would then represent the essential nutrient contribution stemming from a single serving of a given food.

Nutrient profiling systems are straightforward conceptually but many devils lurk in the details. Decisions must be made regarding what nutrients to include in the calculations and which to exclude, how to set RDA-equivalent benchmark intake levels consistent with health promotion, and how to handle foods for which one or more nutrients are present in a single serving at levels in excess of the applicable RDA-equivalent.

In making these and many other technical choices, the FDA should keep in the mind the need to create a definition and labelling system that will most clearly and accurately distinguish between foods in terms of their contribution to public health, without getting bogged down in nuance and complexity.

8. ***Weights assigned to different essential nutrients can in some cases be adjusted in light of the degree to which intake levels are inadequate across much of the US population, coupled with the severity and reversibility of the adverse health consequences stemming from inadequate intakes.***

Inadequate intakes of nutrients pose different risks, as do excessive intakes of some nutrients. The degree to which the intake of a nutrient is less than the applicable RDA-equivalent can impact the severity of adverse impacts. Some impacts are transitory and reversible, others can

be life changing. To the extent possible and generally applicable across the US population, differential weights should be imposed on the nutrients incorporated in nutrient profiling systems.

The goal should be to, in general and for most people, base calorie-adjusted nutritional quality scores on nutrient content taking into account the severity of the adverse health outcomes stemming from inadequate nutrient intakes.

9. ***The science guiding the calculation of a food's calorie-adjusted nutritional quality value will evolve. As a result, RDA-equivalent intake benchmarks for specific nutrients could change, as could weights across nutrients and the methods relied on to calculate nutrient-specific input data.***

Research on how food nutritional quality impacts health outcomes is vital and dynamic. The food industry is constantly changing the mix and contents of products offered for sale in the hope of convincing consumers their product or their brand confers some health-related benefit.

FDA needs a core metric that will readily accommodate new science and insights. In addition, the metric should create an economic incentive for the food industry to reformulate food products to score better within the system. This is a valuable system attribute and goal, since it is easier and more likely that the food industry can incrementally reformulate branded food products to make them more nutritious than it is to motivate consumers to make significant changes in the mix of foods they choose to include in daily diets.

10. ***The new definition of healthy food and accompanying labeling system must integrate multiple attributes of healthy food into a single, easy to understand metric that reliably distinguishes between healthy choices and foods that contribute modesty, if at all in meeting a person's nutritional needs.***

A new definition of healthy food, by itself, will do little to change consumer food choices. The definition must be applied to specific foods and brands and the results clearly displayed on packaging. Ideally, the system will eventually be applied to all food products a consumer encounters in the marketplace. Ongoing research to refine the underlying metrics, improve the clarity of messaging about the system, and consumer education will be critical.

Reaching consensus on a new definition and labeling system, devising the best ways to apply it, and motivating consumers to use it will take a sustained commitment and ongoing investments in the public and private sectors. The effort must span a generation to achieve the degree of improvement both needed and possible in the healthfulness of the US food supply and dietary patterns.

II. The NuCal System

The NuCal system is driven by a novel food nutritional-quality metric that encompasses several of the critical attributes of healthy food products highlighted by the FDA in its Proposed Rule. Our hope is that a system like NuCal will be built upon an inclusive health-centric metric that will accurately convey to consumers the enormous differences between foods relative to the degree to which they contribute to health-promoting dietary patterns.

The core NuCal metric is a ratio:

(Percent of total essential nutrient needs met in a day from the nutrients in one serving of food) divided by (Percent of the daily caloric space taken up by the serving of food)

The cumulative percentage in the numerator across some 24 nutrients would come from a nutrient profiling system: the higher this percentage, the more nutrient needs satisfied by a single serving of the food in a day.

The denominator is simply the caloric content of a single serving of food, as expressed in the back-of-panel Nutrition Facts panel, relative to total daily caloric intake consistent with maintaining healthy bodyweight. We applaud the FDA's suggestion that a typical, healthy daily diet delivers 2,000 calories. The lower this percentage of caloric space taken up, the better, and the higher the calorie-adjusted nutritional quality score for a given food.

Calculating this ratio makes it possible to form a bridge between the information conveyed in FOPNL healthy-food information and the information and messaging in back-of-package Nutrition Facts panels. It will also provide consumers meaningful information that is designed to help inform choices based on the healthfulness of one serving of food compared to one serving of other foods.

Two of us (Davis and Benbrook) developed a table calculating calorie-adjusted nutritional quality scores for 196 foods. The foods are ranked in the table by the NuCal system metric from highest (a value of just over 17 for raw spinach and boiled turnip greens, to the lowest scoring foods and beverages (sugar-based drinks).

The 196 foods include dozens of single-ingredient fresh, whole foods, multiple versions of common and widely consumed foods like milk (whole, 2%, 1%) and bread (white and enriched, whole grain), cereals, common meals or center-of-plate options (a burger and fries, slice of pizza, fish and chips). Values for some foods are reported based on different food forms (grapes versus raisins or grape juice) and methods of cooking (fresh versus fried or boiled). Details on the ranking of the 196 foods are contained in Appendix A.

The Nutritional Quality Index (NQI) is the nutrient profiling system used in the calculations. It was developed by Benbrook and Davis as part of work carried out for The Organic Center. It is similar to several nutrient profiling systems that have been developed around the world to

advance research on food nutritional quality and/or serve as a basis for health-oriented food labeling systems.[5] The system produces what we called a food's Nutritional Quality Index (NQI) score. The NQI encompasses 27 nutrients: eleven vitamins, eight minerals, protein, fiber, antioxidant activity as measured by total ORAC, lutein + zeaxanthin, linoleic acid, linolenic acid, lycopene, and choline. RDA-equivalent values and serving sizes are taken from US government guidance documents, or recommended levels of intake advanced by other countries or organizations with expertise in food and nutritional science.

A food's NQI value is the sum of that food's contribution to daily nutrient needs in a single serving added together across the above 27 nutrients. The food's share of a given nutrient, say vitamin C, is a simple ratio – the amount of vitamin C in the food, divided by the minimum amount of vitamin C the person should ingest in a day to promote good health. We have posted a report describing the data and methods incorporated in the NQI, along with and some of its applications of it on the HHRA website at hh-ra.org/NQI.

The nutritional quality scores generated by the NQI are similar to those produced by other nutrient profiling systems that contain roughly the same set of nutrients. While the FDA will need to wrestle with and resolve many computation details in developing its version of a nutrient profiling system, the ultimate ratings that come out of it will likely track those from the NQI and other similar systems.

Establishing Zones Along the NuCal System Continuum

There is no one correct way to delineate the green-yellow-red zones along a calorie-adjusted nutritional quality continuum. But however it is done, the continuum should provide a clear and widely accepted delineation of unarguably healthy versus nutrient-deficient foods. The core message to consumers is then simple—look for options that reflect healthier choices, i.e. foods that score closer to, or deeper within the green zone along the continuum, while avoiding red-zone foods.

Through assessment of the NuCal scores for the 196 foods, we set the threshold between moderately healthy, yellow zone foods and green-zone foods at a metric value of 4, and the threshold between the yellow and red zones at 0.5.

Hence, a food at the low end of the green zone provides 8-fold or more nutrition bang for the calorie buck than a food at the top of the red zone (4 divided by 0.5).

[5] World Health Organization (2010) Nutrient Profiling. Report of a WHO/IASO Technical Meeting, London, United Kingdom 4–6 October 2010. Geneva: WHO; http://www.who.int/nutrition/publications/profiling/WHO_IASO_report2010.pdf; Poon T, Labonté MÈ, Mulligan C, Ahmed M, Dickinson KM, L'Abbé MR. Comparison of nutrient profiling models for assessing the nutritional quality of foods: a validation study. Br J Nutr. 2018 Sep;120(5):567-582. doi: 10.1017/S0007114518001575. Epub 2018 Jul 17. PMID: 30015603; PMCID: PMC6137431.

Foods in the red zone along the continuum contain one-half or less of daily nutrient needs relative to the calories they provide. Foods in the yellow zone have NuCal system scores at or above 0.5 and less than 4.0.

Table 1 provides NuCal metric scores and rankings for 23 foods within the green zone of the calorie-adjusted nutritional quality continuum. Raw spinach tops the list with a score just over 17 and is among the four foods scoring 10 or higher. These are surely among the nutrient-rich foods Americans should seek out and include in healthy dietary patterns.

Table 1. Nutrition Contribution Values for 23 Foods in the Green Zone of the Continuum

	NQI Value		Per Serving			Nutritional Contribution Value
	Per Serv.	% Nutrient Needs Met	Serv. Size	Calories	% Daily Caloric Need	
SPINACH,raw	0.059	5.88%	1 cup	6.9	0.35%	17.05
TURNIP,greens,boiled	0.123	12.26%	1/2 cup	14	0.72%	17.02
LETTUCE,Romaine	0.061	6.12%	1 cup	8.0	0.40%	15.32
KALE,boiled	0.138	13.83%	1/2 cup	18	0.91%	15.20
ASPARAGUS,boiled	0.088	8.76%	1/2 cup	20	0.99%	8.84
BROCCOLI,boiled	0.121	12.05%	1/2 cup	27	1.37%	8.83
BRUSSEL sprouts, boiled	0.118	11.83%	1/2 cup	28	1.40%	8.42
ONION,green tops	0.034	3.43%	1/2 cup	10	0.48%	7.14
LIVER,calf,braised	0.562	56.20%	3 oz.	164	8.20%	6.85
ARTICHOKE,boiled	0.137	13.73%	1/2 cup	45	2.23%	6.17
BELL PEPPER,green	0.046	4.55%	1/2 cup	15	0.75%	6.07
ALL-BRAN,Kellogg (fortified)	0.218	21.78%	1 ounce	74	3.69%	5.90
CELERY,raw	0.021	2.15%	1/2 cup	8.2	0.41%	5.26
LETTUCE,iceberg	0.021	2.09%	1 cup	8.0	0.40%	5.24
CARROT,boiled	0.070	7.01%	1/2 cup	27	1.37%	5.13
SQUASH,winter,baked	0.096	9.56%	1/2 cup	38	1.91%	5.01
TOMATO,red	0.041	4.05%	1/2 cup	16	0.81%	5.00
CABBAGE,green,raw	0.027	2.68%	1/2 cup	11	0.56%	4.76
CAULIFLOWER,boiled	0.034	3.40%	1/2 cup	14	0.71%	4.77
CRANBERRY,raw	0.107	10.74%	1 cup	46	2.30%	4.67
STRAWBERRY	0.106	10.58%	1 cup	49	2.43%	4.35
GREEN beans,boiled	0.047	4.66%	1/2 cup	22	1.10%	4.22
RASPBERRY	0.130	13.03%	1 cup	64	3.20%	4.08

A serving of calf's liver is the food contributing the most significant mix of essential nutrients, as reflected in the remarkable 56.2% score in the parameter "% Nutrient Needs Met." But it is also by far the most calorie dense food, with one serving taking up 8.2% of a person's daily 2,000 calorie allotment. These two parameter values result in a NuCal system score of 6.85, about the midpoint of foods landing in the green zone.

Also note that a breakfast cereal, Kellogg All-Bran, makes it into the green zone on account of nutritional supplements added to the recipe.

In the full list of 196 foods, 32 foods (16%) fall within the green zone when the threshold is set at 4.0 or above. If the green-zone threshold were lowered to two, another 18 of the 196 foods

would fall within the green zone. The total of 41 green zone foods would now represent 21% of all foods arrayed along the continuum, but markedly lessen the differences between green and yellow zone foods, and green and red zone foods.

Table 2 reports calorie-adjusted nutritional quality scores for 42 foods in the yellow zone. These foods are associated with NuCal system scores between 0.5 and 4.0. Note that Kellogg Special K cereal has the highest score in the yellow zone, because it provides 15.8% of nutrient needs per 108 calories in a single serving, but does not move as far long the continuum as the green-zone alternative, Kellogg's All-Bran cereal. Table 1 reports that All-Bran cereal meets 21.8% of total nutrient needs via a 74 calorie serving.

Table 2. Nutrition Contribution Values for 42 Foods in the Yellow Zone of the Continuum

	NQI Value		Per Serving			Nutritional Contribution Value
	Per Serv.	% Nutrient Needs Met	Serv. Size	Calories	% Daily Caloric Need	
SPECIAL K,Kellogg	0.158	15.83%	1 ounce	108	5.38%	2.94
PLUM	0.043	4.29%	Medium	30	1.52%	2.83
ORANGE	0.075	7.54%	Medium	62	3.08%	2.45
CHEERIOS,General Mills	0.127	12.73%	1 ounce	104	5.21%	2.44
WATERMELON	0.054	5.44%	1 cup	46	2.28%	2.39
CUCUMBER,unpeeled	0.009	0.93%	1/2 cup	7.8	0.39%	2.38
SALMON,pink,canned	0.141	14.10%	3 oz.	118	5.90%	2.39
BLUEBERRY	0.099	9.89%	1 cup	84	4.22%	2.35
GRAPEFRUIT,pink/red	0.056	5.57%	1/2 each	52	2.58%	2.16
CORN FLAKES,Kellogg	0.092	9.16%	1 ounce	103	5.13%	1.79
APRICOT	0.066	6.58%	1 cup	74	3.72%	1.77
CHERRY	0.074	7.36%	1 cup	87	4.35%	1.69
APPLE	0.055	5.50%	Medium	67	3.33%	1.65
EGG,raw	0.056	5.57%	1 large	72	3.58%	1.56
ORANGE juice,fresh	0.081	8.13%	1 cup	112	5.60%	1.45
PINEAPPLE	0.055	5.52%	1 cup	83	4.13%	1.34
MILK, 1% fat	0.068	6.82%	1 cup	102	5.12%	1.33
ORANGE juice,Frz.conc+water	0.074	7.38%	1 cup	112	5.60%	1.32
CORN POPS,Kellogg	0.072	7.22%	1 ounce	110	5.52%	1.31
MILK, 2% fat	0.068	6.84%	1 cup	122	6.10%	1.12
BEEF,rib eye,lean,broiled	0.095	9.50%	3 oz.	175	8.75%	1.09
GRAPE juice,bottled+vit.C	0.078	7.82%	1 cup	152	7.59%	1.03
POTATO, boiled in skin, peeled	0.034	3.45%	1/2 cup	68	3.39%	1.02
SHREDDED WHEAT	0.048	4.82%	1 ounce	96	4.79%	1.01
GRAPE, red and green	0.052	5.23%	1 cup	104	5.21%	1.00
MILK,whole	0.073	7.26%	1 cup	149	7.44%	0.98
OIL,soybean	0.059	5.86%	1 Tbsp.	120	6.01%	0.98
PORK, spareribs, lean+fat, roasted	0.096	9.60%	3 oz.	203	10.15%	0.95
BANANA	0.049	4.93%	Medium	105	5.25%	0.94
OATMEAL,dry	0.049	4.87%	1 ounce	108	5.38%	0.90
Pizza Hut cheese pizza	0.096	9.62%	1 slice	250	12.48%	0.77
YOGURT,plain,whole	0.055	5.49%	1 cup	149	7.47%	0.74
CHEESE,Swiss	0.039	3.87%	1 oz.	108	5.39%	0.72
BREAD,white,enriched	0.023	2.34%	1 slice	67	3.33%	0.70
BREAD,French	0.024	2.40%	1 slice	72	3.61%	0.67
RICE,brown,long grain,raw	0.034	3.37%	1 ounce	105	5.25%	0.64
BACON,cooked	0.047	4.70%	1 oz.	154	7.70%	0.61
CHICKEN,breast+wing, breaded, fried, fast food	0.079	7.90%	3 oz.	258	12.90%	0.61
RICE cake,brown rice	0.030	2.97%	2 cakes	104	5.22%	0.57
Burrito, bean & cheese	0.198	19.82%	2 each	703	35.15%	0.56
French fries, McDonalds	0.168	16.85%	Medium	616	30.78%	0.55
RAISINS,raw	0.058	5.77%	1/2 cup	218	10.91%	0.53

In the full ratings of 196 foods, 133 (68%) fall within the yellow zone. The foods near the top of the yellow zone are 6 to almost 8-fold more nutritious per calorie than the foods near the bottom. Accordingly, consumers who incrementally seek out and consume foods in the upper

part of the yellow zone will be substantially improving the healthfulness of their overall dietary pattern.

Across the 42 foods in Table 2, a bean and cheese burrito delivers the greatest share of daily nutrient needs (19.8%), but would take up 35% of the caloric space in a person's daily allotment of 2,000 calories. This is why cheese-bean burritos land near the bottom of the yellow zone with a NuCal system metric score of 0.56.

Unpeeled cucumbers account for the lowest contribution in meeting nutrient needs among the 42 foods in Table 2 (0.93%), but take up only 0.39% of daily caloric space. This combination of modest nutrient content but also very few calories results in a NuCal score of 2.38.

Table 3 covers 15 foods landing in the red zone along the continuum. In the full list of 196 foods, 31 (15.8%) land in the red zone on account of NuCal metric scores below 0.5. Such foods take up twice as much or more of the caloric space in a person's diet relative to the percentage of nutrient needs satisfied.

Table 3. Nutrition Contribution Values for 15 Foods in the Red Zone of the Continuum

	NQI Value		Per Serving			Nutritional Contribution Value
	Per Serv.	% Nutrient Needs Met	Serv. Size	Calories	% Daily Caloric Need	
COOKIE, Oreo	0.038	3.80%	3 each	159	7.97%	0.48
Chicken pot pie	0.237	23.70%	1 pie	1007	50.34%	0.47
Big Mac with cheese	0.271	27.09%	1 each	1177	58.83%	0.46
RICE, white, long grain, enr., raw	0.024	2.37%	1 ounce	104	5.18%	0.46
MARGARINE	0.007	0.68%	1 pat	31	1.57%	0.44
PIE, apple	0.056	5.56%	1 piece	296	14.81%	0.38
DONUT, glazed	0.038	3.81%	1 medium	242	12.09%	0.32
COOKIE, animal crackers	0.020	1.96%	1 oz.	127	6.33%	0.31
CREAM,whipping,heavy	0.016	1.58%	2 Tbsp	104	5.18%	0.31
CAKE, yellow, vanilla icing	0.036	3.64%	1 piece	239	11.94%	0.31
BUTTER	0.003	0.31%	1 pat	36	1.79%	0.17
GATORADE, FRUIT-FLAVORED	0.007	0.75%	20 fl. oz.	158	7.92%	0.09
HONEY	0.001	0.11%	1 Tbsp.	64	3.19%	0.04
COKE, PEPSI	0.002	0.22%	12 fl. oz.	136	6.81%	0.03
SPRITE, 7-UP	0.002	0.19%	12 fl. oz.	148	7.38%	0.03

Note that one food in the red zone – chicken pot pie – meets 23.7% of daily nutrient needs, yet lands in the red zone because of the even bigger portion of a 2,000 calorie diet (50%). A Big Mac with cheese falls just below a chicken pot pie, meeting 27.1% of nutrient needs but taking up 58.8% of a 2,000-calorie daily allotment.

The three sugar-based beverages in Table 3 provide almost no nutritional value, yet take up 6% to almost 8% of daily caloric space. Given the number, diversity, and popularity of sugar-sweetened drinks, including some ways coffee is served and consumed, the foods and beverages in the red zone along the continuum account for a significant share of daily caloric

intake. While we have not attempted to estimate the share of total calories associated with intake of red-zone foods and beverages, we suspect the share is well over 30%. The quickest and most impactful way to improve the overall healthfulness of the American diet is to reduce the number of servings of foods that land within the red zone, while also increasing the number of daily servings of green zone foods.

Consuming a serving of orange juice with a NuCal score of 1.45 instead of a coke or 7-Up would enhance the NuCal metric score for a single beverage serving by 48-fold!

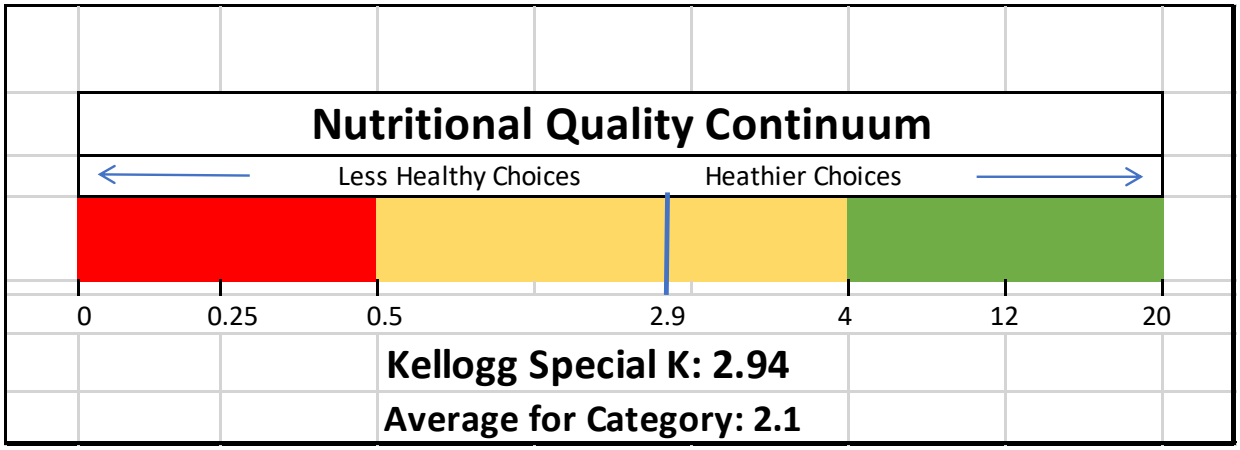
The NuCal Metric Continuum

One of the distinct advantages of a single-metric system like NuCal that integrates nutrient content and calories per serving is the simplicity of graphically conveying differences in calorie-adjusted nutritional quality across servings of different foods and beverages.

FOPNL system impact will depend heavily on the clarity of the nutrition-health information conveyed by the system, coupled with the trust and confidence consumers place in the data and science supporting the system. The FDA, working in partnership with other agencies, can and must take on both the data and analytical challenges that lie ahead in crafting a new labeling system. Only the federal government can marshal the scientific and analytical resources to develop, vet, continuously improve and keep up-to-date a system like NuCal.

The government is also the only entity that can effectively respond to all the inevitable complaints and criticisms that any meaningful FPNL system will generate.

Below we provide a rough mockup of how a NuCal system continuum rating for a specific product might look like on the front of a food package.



Once consumers become familiar with the system, nearly the full informational benefit of the system can be gleaned by simply noting where the vertical line is arrayed along the continuum.

The information in the system would be further leveraged by adding information regarding competing, similar food products. For many major, well-defined food products like chips, types of bread and cereals, and fast-food meals, the utility of the system would be enhanced by providing an average of typical scores for similar products.

The FDA would have the data required to make such an average food type or even food group calculation by virtue of its collection of similar nutrient-content data across all food products choosing to make a healthy food claim in front-of-package labeling.

III. Responses to Questions Posed by the FDA

1. Should specific nutrients be included in the criteria (such as vitamins, minerals etc.) in addition to the food group criteria?

As referenced above, we argue that the degree to which a food or food product contributes to a person's daily requirement of essential nutrients, relative to the calorie 'space' it takes up in the diet, should determine how 'healthy' a given food product is. Therefore, we recommend that several specific essential nutrients should be included in a healthy food labelling system.

A key question is which specific nutrients should be included within a healthy food label.

The US dietary reference intakes (DRIs) include recommended intakes for macronutrients, including protein, fat, sugar, salt among others, as well as micronutrients including vitamins and minerals. We have used these DRIs within our hypothetical NuCal system and urge FDA to do the same.

One food component we think is not adequately represented in Dietary Reference Intakes is the total antioxidant activity (TAA) Antioxidants are health-promoting bioactive phytochemicals in food that delay or inhibit oxidative stress and inflammation in the body.

Nutrients with antioxidant properties include vitamins, minerals, carotenoids, flavonoids and polyphenols. Polyphenols are naturally occurring plant-chemicals that are abundant in fruits, vegetables, and other plant foods.

Evidence has suggested a link between dietary polyphenols and the prevention of cardiovascular diseases, cancers, osteoporosis, neurodegenerative diseases and diabetes mellitus[6]. Importantly, polyphenols are the ***most*** abundant source of antioxidants in the diet[7]; one study showed that 1g of apple had a total antioxidant activity (TAA) of 83, of which only

[6] Scalbert A, Manach C, Morand C, Rémésy C, Jiménez L. Dietary polyphenols and the prevention of diseases. Crit Rev Food Sci Nutr (in press).

[7] Augustin Scalbert, Ian T Johnson, Mike Saltmarsh, Polyphenols: antioxidants and beyond, *The American Journal of Clinical Nutrition*, Volume 81, Issue 1, January 2005, Pages 215S–217S, https://doi.org/10.1093/ajcn/81.1.215S.

0.32 came from the vitamin C content, with the remainder from the polyphenol content of apples[8]. Yet there is no recommended daily intake level for polyphenols. We argue that incorporating TAA as a specific component within the healthy food labelling system would better reflect a foods overall nutritional quality, compared with relying only on the vitamin and mineral content.

Granted, adding TAA as an essential nutrient in calorie-adjusted nutritional quality scores would constitute a degree of double counting, since a portion of the TAA from a serving of food is from individual vitamins also incorporated in the nutrient profiling system. But given the heart-promoting importance of ample antioxidant intakes and the significant gap between current and recommended TAA intakes, such double counting is equivalent to adding weight to this vital component of the diet and, we argue, clearly justified.

Another key nutritional parameter lacking DRI benchmark intake levels is omega fatty acid. Fats are divided into three classes: saturated fatty acids (SFA), mono-unsaturated fatty acids (MUFA) and poly-unsaturated fatty acids (PUFA). Within the class of PUFA, there are fatty acid complexes known as omega-6 and omega-3. These complexes include gamma-linolenic acid (GLA) and arachidonic acid (AA), which are omega-6, and eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) which are omega-3[9].

The human body can manufacture most fatty acid complexes; exceptions are linolenic acid (LA), an omega-6 fatty acid, and alpha-linolenic acid (ALA), an omega-3 fatty acid. These two fatty acids, LA and ALA, are regarded as “essential” and must be provided through the diet. They are also “conditional” essential fatty acids, because while the body can synthesize them, it often does so in sufficient quantities. This is one of several reasons why dietary intake levels of fatty acids matter.

Equally important is the overall level of omega-6 and omega-3 fatty acids, since both are essential up to a given level of intake, but can promote various chronic diseases when ingested at excessive levels. A third parameter is also key – the relationship of omega-6 to omega-3 fatty acids. Too much omega-6 relative to omega-3 converts an otherwise healthy mix of fatty acids into an incrementally less healthy mix.

To date, dietary guidelines have promoted the increased consumption of PUFA, irrespective of their omega-6 or omega-3 content. Several benefits of increased omega-3 intake have been

[8] Eberhardt, M., Lee, C. & Liu, R. Antioxidant activity of fresh apples. Nature 405, 903–904 (2000). https://doi.org/10.1038/35016151.

[9] Enig MG. Know your fats: The complete primer for understanding the nutrition of fats, oils and cholesterol. Silver Spring, MD: Bethesda Press; 2010.

proposed including: lower risk of CVD[10], improved brain development, modulation of the immune system, reduced risk of dementia and a delay in general decline of cognitive function[11].

Omega-6 fatty acids are also essential for health, however the balance of dietary omega 6:3 can have significant consequences. The biosynthetic pathway of both omegas-3 and 6 share an enzyme; omega-6-desaturase. This enzyme converts ALA into EPA and DHA (generally a good thing), but also converts LA into AA (generally not good). If there are high levels of plasma LA caused by high dietary intake of omega-6 PUFA, the pathway converting ALA into DHA and EPA is inhibited[6].

In addition, the conversion of LA to AA, the omega-6 pathway, is regarded as more efficient than the conversion of ALA to EPA and DHA via the omega-3 pathway[12]. Consequentially, dietary intake of ALA can have a variable effect on conversion to EPA and DHA, and hence alter the levels of EPA and DHA needed via food. One study showed that supplementation with linseed oil (ALA) produced a moderate rise in platelet EPA, whereas supplementation with fish oil (EPA & DHA) produced a much greater rise in platelet EPA and DHA[13].

The ratio of omega-6:3 in the modern western diet is estimated at 15-20:1[14], a level widely regarded as not healthy for a variety of reasons. Such highly skewed intake levels are in stark contrast to the dietary ratio consumed by our Paleolithic ancestors, which is estimated to be near 1:1[15]. The shift in omega-6 to omega-3 intakes from near 1:1 to 15:1 or more has been brought about by markedly increased intakes of dietary omega-6 via grains, corn and soybean-based cooking oils, and grain-fed livestock, coupled with reduced intakes of dietary omega-3, via fish and grass-fed meat and dairy.

Modern industrial farming where ruminant animals are fed mostly grain as opposed to mostly forage-based diets has contributed significantly to the shift in PUFA intakes in Western diets. Animal fat now contains 4 to 8 or more units of omega-6 for each unit of omega-3[9]. Consequences of a high plasma omega-6:3 ratio are thought to include: increased risk of thrombosis, LDL oxidation (implicated in coronary artery disease [CAD]), higher levels of

[10] Hu Y, Hu FB, Manson JE. Marine omega-3 supplementation and cardiovascular disease: an updated meta-analysis of 13 randomized controlled trials involving 127 477 participants. J Am Heart Assoc. 2019;8(19):e013543.
[11] Ruxton CHS, Reed SC, Simpson MJA, et al. (2007) The health benefits of omega-3 polyunsaturated fatty acids: a review of the evidence. J Hum Nutr Diet 20, 275–285.
[12] Galli C, Calder PC. Effects of fat and fatty acid intake on inflammatory and immune responses: a critical review. Ann Nutr Metab. 2009;55(1-3):123-39. doi: 10.1159/000228999. Epub 2009 Sep 15. PMID: 19752539.
[13] Sanders T.A, Roshanai F. (1983) The influence of different types of omega 3 polyunsaturated fatty acids on blood lipids and platelet function in healthy volunteers. Clin. Sci. 64, 91-99.
[14] Simopoulos AP, De Meester F (eds): A Balanced Omega-6/ Omega-3 Fatty Acid Ratio, Cholesterol and Coronary Heart Disease. World Rev Nutr Diet. Basel, Karger, 2009, vol 100, pp 1–21. doi: 10.1159/00023570
[15] Hibbeln, J. R. , Nieminen, L. R. G. , Blasbalg, T. L. , Riggs, J. A. , & Lands, W. E. M. (2006). Healthy intakes of ω-3 and ω-6 fatty acids: Estimations considering worldwide diversity. American Journal of Clinical Nutrition, 83, 1483S–1493S.

inflammation and an increased risk of cognitive impairment[16] [17]. Excess omega-6 PUFA from refined vegetable oils has been associated with increased risk of cancer and CAD[18].

For these reasons, a healthy food label needs to aid consumers in choosing foods with a ratio of omega-6:3 fatty acids below 4:1 and as close to 1:1 as possible.

It is not sufficient to rely on average fatty acid levels in different animal products as a proxy for the nutrients that a given food contains***. How our food is produced can have a significant impact on its nutritional profile.*** One study found that organic milk, compared to conventionally produced milk, contained 60% greater amounts of ALA, 33% greater EPA, 25% less LA and 17% less AA[19].

A further study showed that 100% grass-fed, whole-fat organic milk contained 52% higher omega-3 PUFA than organic whole milk from cows fed supplemental grain-based feeds, and remarkably, 147% higher omega-3 levels than conventional milk from grain-fed cows. In addition, the whole-fat milk from 100% grass-fed cows contained 36% and 52% lower levels of omega-6 fatty acids compared to organic and conventional milk respectively[11]. The omega-6:3 ratio is clearly and significantly altered by the production method and primary source of feed: 5.8:1 for conventional milk, 2.3:1 for organic milk and 0.95:1 for grass-fed milk.

A healthy food label that assumes all milk is nutritionally equivalent would fail to provide consumers with information that could enable them to consume a far healthier ratio of omega-6:3 fatty acids.

2. ***Is FDA right in concluding that food groups should be among the criteria used to define healthy food.***

No, we do not feel that food groups can play a constructive role in the definition of "healthy" foods. There is far too much variability in the nutritional quality of foods ***within food groups,*** as well as in ***brands of an individual food within a group***. Implying that all foods within a food group are equivalent as part of a system designed to help consumers recognize healthier food options is, we believe, a seriously flawed approach that will undermine much of the utility of a properly designed system.

[16] Benbrook CM, Davis DR, Heins BJ, Latif MA, Leifert C, Peterman L, Butler G, Faergeman O, Abel-Caines S, Baranski M. Enhancing the fatty acid profile of milk through forage-based rations, with nutrition modeling of diet outcomes. Food Sci Nutr. 2018 Feb 28;6(3):681-700. doi: 10.1002/fsn3.610. PMID: 29876120; PMCID: PMC5980250.

[17] Ili C, Calder PC. Effects of fat and fatty acid intake on inflammatory and immune responses: a critical review. Ann Nutr Metab. 2009;55(1-3):123-39. doi: 10.1159/000228999. Epub 2009 Sep 15. PMID: 19752539.

[18] Felton CV, Crook D, Davies MJ, Oliver MF. Dietary polyunsaturated fatty acids and composition of human aortic plaques. Lancet 1994;344:1195–6.

[19] Benbrook CM, Butler G, Latif MA, Leifert C, Davis DR. Organic production enhances milk nutritional quality by shifting fatty acid composition: a United States-wide, 18-month study. PLoS One. 2013 Dec 9;8(12):e82429. doi: 10.1371/journal.pone.0082429. PMID: 24349282; PMCID: PMC3857247.

We appreciate the effort made by FDA scientists to identify and propose a way to incorporate food groups in the definition of "healthy" food and in an associated FOPNL system. On the positive side, including food groups in the definition of "healthy" food and its associated labeling scheme would serve as a bridge to other dietary and nutrition guidance from the FDA and USDA, spanning MyPlate, the Dietary Guidelines for Americans, and advice regarding healthy eating patterns. However, the problems and compromises – and complexity – that would accompany such an effort will be significant and far exceed the modest benefits from efforts to do so.

3. ***Comment on the use of a limit for saturated fat based on the ratio of total fat, including any data supporting this approach.***

The FDA proposes to maintain saturated fat as a nutrient to limit. They seek comment on the use of a limit for saturated fat based on the ratio of saturated fat to total fat.

In the US, food manufacturers are required to publish the total fat and saturated fat content of a food or food product in the back-of-package Nutritional Facts panel. This provides the consumer with clear information which they can utilize in the context of their personal dietary choices and needs.

The question that the FDA poses here is whether a limit of the saturated fat content, either as a ratio of total fat or as a singular quantity, should be considered as part of the criteria for the "healthy" food label. We argue that the information about saturated fat content is adequately addressed in the Nutrition Facts panel. We further argue that saturated fat does not inherently mean a food is not healthy, and that not all saturated fatty acids contribute to metabolic syndrome and cardiovascular disease (CVD).

We believe that saturated fat content, either as a singular quantity or as a ratio of total fat, should not be included within the new healthy food labelling system, at least not initially. In our judgement, doing so would significantly complicate application of the definition and labeling system for many foods, and furthermore assumes[20] that the content of Nutrition Facts panel is not doing an adequate job in helping consumers take account of the saturated fats in a given food product.

The diet-heart hypothesis is well known. It originates from the 1960s when cholesterol and saturated fat were identified as possible culprits for heart disease. Current conventional wisdom holds that:

- Consumption of naturally occurring saturated fats causes heart disease,

[20] We question this assumption and believe that the way Nutrition Facts Panels convey information on total and saturated fat is clear and widely relied upon by consumers interested in altering their intake of certain fats. In the future, we believe the FDA and other government agencies do need to revisit the content of Nutrition Facts Panels to more accurately deal with the fact that not all saturated fats are equal relative to posing CVD and other health risks, and indeed some are heart-healthy.

- Consumption of cholesterol-containing foods contributes to heart disease,
- Consumption of polyunsaturated oils can help cure and prevent heart disease, and
- Elevated levels of serum cholesterol is linked to increased risk of CVD, and derives from a diet high in saturated fats and cholesterol.

Although these beliefs are widely accepted, the medical literature is divided as to whether dietary SFA is harmful, neutral or even beneficial for health. Several recent meta-analyses have concluded that there is no significant association between dietary fat and coronary heart disease and all-cause mortality[21] [22] [18].

The subject of dietary SFA is complex and the same rules may not apply to all individuals or all stages of life. For some a diet low in SFA may be perfectly appropriate. However for others, the intake of fat, including SFA, may be healthy as part of an overall nutritious diet. Several trials have drawn inconclusive results as to whether a high fat or high carbohydrate diet promotes weight gain or loss. People in both diet groups can either lose, gain or remain weight neutral, reflecting the heterogeneity of human responses to variable fat intakes and diets.

The original fat hypothesis, and the advice to reduce dietary fat, led to an onslaught of low-fat foods swamping the market. Consumers moved away from saturated-fat laden butter to margarine containing trans fats in the tragically misplaced hope of improving heart health. Evidence subsequently emerged of the significant harms caused by trans fatty acids, and thankfully, industrial partially hydrogenated oils (PHO)s, the main source of trans fats in the US diet, are now banned.

Current dietary guidelines have shifted away from a reduction in total fat and placed greater emphasis upon the types and quality of fats consumed. This trend has led to recommendations to increase consumption of polyunsaturated fats (PUFA) and especially omega-3 PUFAs, while also reducing total SFA. In line with this guidance over recent decades, there has been a large increase in the consumption of oils from vegetable sources, most of which are high in PUFA. Historically these oils would have been difficult to produce and required industrial processing to make them widely available and sufficiently stable.

Simultaneously, we have reduced our dietary fats from animal sources that are generally high in SFA, while maintaining an overall, relatively stable total fat intake[4]. Although several studies do indicate that diets inordinately rich in SFAs are deleterious to health, and diets supplemented with PUFAs are beneficial, particularly for cardiovascular health, there remains the question as to what the most health-promoting mixture of different classes of dietary fats is. In any event,

[21] De Souza RJ, Mente A, Maroleanu A, etal . Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. BMJ 2015;351:h3978. 10.1136/bmj.h3978 26268692

[22] Siri-Tarino PW, Sun Q, Hu FB, Krauss RM. Meta-analysis of prospective cohort studies evaluating the association of saturated fat with cardiovascular disease. Am J Clin Nutr 2010;91:535-46. 10.3945/ajcn.2009.27725 20071648

substantial data suggests that significant reductions in dietary SFA and cholesterol intakes may not be appropriate for everyone.

In crafting healthy food labels, the food matrix or composition containing saturated fat is crucial to consider, and hereafter is referred to as the "food context". This concept encompasses both macronutrient and the micronutrient content, as well as polyphenols present alongside saturated fatty acids. The food context has been shown to significantly impact lipid digestion, nutrient absorption and postprandial lipidaemia, all important for overall health[23].

Reducing SFA intake derived from whole foods means reducing consumption of red meat, eggs, high fat dairy and coconut oil. Indeed, all naturally occurring sources of fat will include some SFA, mono-unsaturated fatty acids (MUFA) and PUFA; beef fat contains on average 50% SFA, with the remainder made up of mostly MUFA and a small amount of PUFA. Olive oil is 75% MUFA, 14% SFA and 10% PUFA[4].

Beef, although relatively high in SFA, is a nutrient-dense whole food containing healthy protein, bioavailable iron, minerals and vitamins. Cheese, high in a mixture of medium and long-chain SFA, also contains protein, calcium, magnesium and the probiotic lactic acid bacteria. Eggs contain 13 essential vitamins and minerals along with protein, omega-3, lutein, zeaxanthin and choline. All of these whole foods can contribute to healthy dietary patterns.

When dietary SFA is studied within the context of food source, its association with increased CVD is less certain. For example, ***some studies suggest that consumption of full-fat dairy has a neutral effect on cardiovascular disease risk***[24], whereas other studies suggest it confers a beneficial effect on all-cause mortality, ischemic heart disease, stroke, diabetes, metabolic syndrome, weight gain and colorectal cancer[25] [26] [27] [28] [29]. Milk is not just SFA but a complex food with a host of different nutrients, nor is all milk just "milk". Considering the context of the SFA in a serving of food is important for understanding which foods can form part of a healthy diet and should be promoted through a healthy food label.

---

[23] Michalski MC, Genot C, Gayet C, etal. Steering Committee of RMT LISTRAL. Multiscale structures of lipids in foods as parameters affecting fatty acid bioavailability and lipid metabolism. Prog Lipid Res 2013;52:354-73. 10.1016/j.plipres.2013.04.004. 23624223

[24] German JB, Gibson RA, Krauss RM, Nestel P, Lamarche B, et al. (2009) A reappraisal of the impact of dairy foods and milk. Eur J Nutr 48: 191–203.

[25] Elwood PC, Pickering JE, Givens DI, Gallacher JE (2010) The consumption of milk and dairy foods and the incidence of vascular disease and diabetes: an overview. Lipids 45: 925–939.

[26] Rosell M, Hakansson NN, Wolk A (2006) Association between dairy food consumption and weight change over 9 y in 19,352 perimenopausal women. Am J Clin Nutr 84: 1481–1488

[27] Stancliffe RA, Thorpe T, Zemel MB (2011) Dairy attenuates oxidative and inflammatory stress in metabolic syndrome. Am J Clin Nutr 94: 422–30.

[28] Bonthuis M, Hughes MCB, Ibiebele TI, Green AC, van der Pols JC (2010) Dairy consumption and patterns of mortality of Australian adults. Eur J Clin Nutr 64: 569–577

[29] Larsson SC, Bergkvist L, Wolk A (2005) High-fat dairy food and conjugated linoleic acid intakes in relation to colorectal cancer incidence in the Swedish Mammography Cohort. Am J Clin Nutr 82: 894–900

This is another reason why a multi-nutrient profiling system should be relied on in quantifying degrees of healthfulness across specific food products, ***based on what is actually in the product, which takes into account where and how the ingredients in the product were grown or raised.***

It may also be prudent to consider heterogeneity amongst the individual fatty acids; not all SFA are equal in terms of benefits and harms. For example, caproic, caprylic and capric acids are thought to have a much lower impact on serum cholesterol and LDL than lauric, myristic and palmitic acids[30]. Caprylic acid and capric acid have antiviral activity[31], and in mice has been reported to have antitumor activity[32]. The complexity and diversity of function of each individual fatty acid remains poorly understood and further research is needed to understand the role and health implications within representative diets. Limiting dietary SFA as a single nutrient is too simplistic and ignores the context within which SFA is found and the fact that not all SFA are homogeneous with regards to their effect on disease risk.

For manufactured multi-ingredient food products, it is important to consider what the manufacturers will add to recipes when SFA levels are reduced. Will the new ingredients contain healthy levels and mixes of PUFA, MUFA, carbohydrate, and protein? Observational and interventional data has suggested that replacement of SFA with PUFA/MUFA may reduce risk of CVD. But if the SFA is replaced with refined carbohydrates, this can lead to an increase in mortality[33].

Although PUFAs are often regarded as wholly beneficial, there may be variance within the category. Evidence suggests that replacement with rapeseed/canola oil significantly reduces risk of CAD[34], whereas such evidence does not exist for other PUFAs such as corn, sunflower and palm oil.

Evidence from the Sydney Diet Heart Study and the Minnesota Coronary Trial suggest there may be health risks associated with very high intakes of plant oils, such as corn and sunflower, containing only or largely omega-6 fatty acids[35] [36]. It is only in recent decades that we have

[30] Nicolosi RJ. Dietary fat saturation effects on low-density-lipoprotein concentrations and metabolism in various animal models. Am J Clin Nutr 1997;65(suppl):1617S–27S.
[31] Thormar H, Isaacs EE, Kim KS, Brown HR. Inactivation of visna virus and other enveloped viruses by free fatty acids and monoglycerides. Ann N Y Acad Sci 1994;724:465–71.
[32] Burton AF. Oncolytic effects of fatty acids in mice and rats. Am J Clin Nutr 1991;53(suppl):1082S–6S
[33] Forouhi NG, Krauss RM, Taubes G, Willett W. Dietary fat and cardiometabolic health: Evidence, controversies, and consensus for guidance. BMJ. 2018
[34] de Lorgeril M, Renaud S, Mamelle N, et al. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. Lancet1994;343:1454-9. doi:10.1016/S0140-6736(94)92580-1 pmid:7911176
[35] Ramsden CE, Zamora D, Leelarthaepin B et al. Use of dietary linoleic acid for secondary prevention of coronary heart disease and death: evaluation of recovered data from the Sydney Diet Heart Study and updated meta-analysis. BMJ2013;346:e8707. doi:10.1136/bmj.e8707 pmid:23386268
[36] Ramsden CE, Zamora D, Majchrzak-Hong S, et al. Re-evaluation of the traditional diet-heart hypothesis: analysis of recovered data from Minnesota Coronary Experiment (1968-73). BMJ2016;353:i1246. doi:10.1136/bmj.i1246 pmid:27071971

increased our consumption of plant-derived PUFA, and the long-term effects of this are as yet unknown. Some studies have suggested very high intakes of PUFAs could carry risks of adverse health effects, one study advising that PUFA should not total >10% daily energy intake[37]. But again, not all PUFAs are created equal.

Non-fat based fat substitutes include carbohydrate-based products such as Oatrim, cellulose, maltodextrin, protein-based products such as simplesse, and lipid analogues such as Olean and Caprenin. The health effects of these replacements have not been rigorously studied. Olean for example is a molecule for which the body lacks the enzymes needed for metabolism, and hence cannot provide any calories. Of concern, Olean absorbs fat soluble vitamins, holding on to them as it passes through the digestive tract. As a result, it may cause deficiencies in the fat soluble vitamins A,D,E and K[4].

Accordingly, a proposed limit on SFA content within the FDA's healthy food labelling system should also ideally consider the health consequences of any subsequent shift in the ingredient composition of processed foods.

Our comments reflect the state of knowledge and the absence of definitive and universal evidence linking reductions in dietary SFA intake to reduced risk of CVD. We do, however, seek to highlight the complexity of the issues surrounding fat quality and content. We believe that at the present time, sufficient and clear information on total and saturated fat content is provided to the consumer by the Nutrition Facts panel.

We are confident that a healthy food product labelling system that guides consumers towards whole, natural and largely unprocessed foods containing a diversity of nutrients will promote positive public-health outcomes well in excess of a system focused on single-nutrient avoidance and substitution. A healthy food labelling system that reduces SFA without considering the specific fatty acids or the food context could result in reduced intake of nutrient dense foods that reliably promote health.

4. ***Comment on the FDA proposal not to limit amount of trans fats, as they do not think it is necessary if the saturated fat limit will adequately disqualify foods containing trans fats from meeting the healthy definition.***

The FDA acknowledges the Dietary Guidelines 2020-2025 state that trans-fat consumption be as low as possible. They refer to the previous FDA statement that PHOs are not GRAS and therefore have mostly been eliminated from the food supply. However, FDA acknowledges that there are still sources of trans fats in the diet, including from refined vegetable oils and naturally occurring sources from ruminant animals.

PHOs are banned, a step which has eliminated most trans fats. There are small quantities of naturally occurring trans fats from ruminants, but they have a different biochemical structure

[37] Felton CV, Crook D, Davies MJ, Oliver MF. Dietary polyunsaturated fatty acids and composition of human aortic plaques. Lancet 1994;344:1195–6.

and are not thought to be harmful. For these reasons, we recommend that the FDA not include trans-fat in the definition of health food. If the FDA determines new steps are warranted to further reduce or limit trans-fat in specific foods, the agency has the tools to do so directly.

5. ***Comment on the FDA proposal not to limit amount of cholesterol, as they do not think it is necessary if the saturated fat limit will adequately disqualify foods containing trans fats from meeting the healthy definition.***

We agree that the FDA should not address cholesterol in the definition of healthy food.

In the Dietary Guidelines 2020-2025, consumers are advised to limit dietary cholesterol consumption to the full extent possible without compromising the nutritional adequacy of the diet. The FDA proposes no limit for the amount of cholesterol within the healthy food label, as they argue that dietary cholesterol is found only in animal-source food that typically contains saturated fats, and therefore, cholesterol will be sufficiently limited by the proposed limits for saturated fat.

The FDA raises two anomalies -- eggs and shellfish. These foods are relatively high in cholesterol, but lower in saturated fats and therefore could meet the proposed healthy food label criteria. They report this would be an acceptable outcome as these foods are considered 'nutrient dense' and are encouraged by the dietary guidelines.

Like our discussion around SFA intake, we argue that evidence for the benefit of reducing dietary cholesterol is not sufficient to apply a maximum intake level across a great diversity of foods, including many that are clearly healthy.

Aggressive efforts to reduce dietary cholesterol intakes will not provide universal benefit for all. Dietary cholesterol has been shown to increase serum LDL, and thus is thought to increase the risk of cardiovascular disease. However, a reduction in serum LDL through dietary intervention is not always associated with a reduction cardiovascular disease risk. When saturated fat is replaced by carbohydrates, LDL is lowered, but cardioprotective HDL is also lowered, whilst triglycerides are increased[38]. Estrogen/progestin therapy and cholesteryl ester transport protein inhibitors have shown substantial ability to reduce LDL, but no equivalent CVD benefit has been shown[39] [40].

Alternatively, while the cardiovascular disease benefits of Mediterranean-style diets have been demonstrated in multiple trials and lines of evidence, such diets have not been associated with

[38] Mensink RP, Zock PL, Kester AD, Katan MB. 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. Am J Clin Nutr2003;77:1146-55. doi:10.1093/ajcn/77.5.1146 pmid:12716665

[39] Manson JE, Hsia J, Johnson KC, Rossouw JE, Assaf AR, Lasser NL, Trevisan M, Black HR, Heckbert SR, Detrano R et al. Estrogen plus progestin and the risk of coronary heart disease. N Engl J Med. 2003;349(6):523–34.

[40] Armitage J, Holmes MV, Preiss D. Cholesteryl ester transfer protein inhibition for preventing cardiovascular events: JACC review topic of the week. J Am Coll Cardiol. 2019;73(4):477–87.

any significant reductions in LDL[41] [42]. Of note, while dietary SFAs have been shown to increase concentrations of large cholesterol-enriched LDL particles[43], it is in fact the smaller cholesterol-deplete LDL particles that appear to play a causal role in coronary artery diease[25]. So, as in the case of SFAs, all forms and sources of cholesterol are also not equal relative to expected health impacts.

The two examples that the FDA gives -- eggs and fish -- are examples of how food context is critical in helping to decide whether a food should be included among "healthy food" options. Despite their relatively high levels of cholesterol, egg and fish consumption is encouraged because of all the beneficial nutrients that these foods offer.

IV. How the FDA can Transition to a New Definition of "Healthy" Foods and an Associated Labeling System

1. Front-of-package labeling must be simple to be effective.

A common problem with most existing Front-of-Package Nutrition Labels (FOPNL) is that they strive to convey too much information and in doing so, the impact of each component or unit of information in the label is muffled or diluted.

A second major problem is that most FOPNLs encompass one or more of the macronutrients and food-nutritional-quality parameters already covered in the back-of-package Nutrition Facts panels, effectively duplicating the information. A new FOPNL scheme in the US should augment the information conveyed in the Nutrition Facts panel, not reiterate it or compete with it.

Two of the most consequential decisions the FDA will have to make in crafting a new, health-outcome-focused FOPNL scheme are: (1) What is included in a single, clear metric, and (2) To what does the metric apply (a serving of food, 100 calories of each food, 100 grams of food)?

Re #1, the ideal metric will provide consumers with clear, unambiguous information about the healthfulness of one food product compared to others. It is particularly important that the

[41] de Lorgeril M, Renaud S, Mamelle N, Salen P, Martin JL, Monjaud I, Guidollet J, Touboul P, Delaye J. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. Lancet. 1994;343(8911):1454–9.

[42] Fito M, Guxens M, Corella D, Saez G, Estruch R, de la Torre R, Frances F, Cabezas C, Lopez-Sabater MDC, Marrugat J et al. . Effect of a traditional Mediterranean diet on lipoprotein oxidation: a randomized controlled trial. Arch Intern Med. 2007;167(11):1195–203.

[43] Bergeron N, Chiu S, Williams PT, S MK, Krauss RM. Effects of red meat, white meat, and nonmeat protein sources on atherogenic lipoprotein measures in the context of low compared with high saturated fat intake: a randomized controlled trial. Am J Clin Nutr. 2019;110(1):24–33.

system clearly identify those foods that unambiguously deliver substantial nutrients in contrast to other foods that deliver few if any.

We argue that the FOPNL scheme should focus on vitamins, minerals, fatty acid profiles, antioxidant activity, and other health-relevant components in food that are not addressed in back-of-package Nutrition Facts panels.

The combinations of nutrients included in an assessment of specific foods within a food group will vary across food groups, as will the weights placed on specific nutrients or nutrient-based attributes (e.g. measures of the healthfulness of fatty acid profiles, a key nutrition metric in the case of animal products).

Such nutrients and components of food should include, at a minimum, those for which the US government has established an RDA/RDI or its functional equivalent.

The only way to create a single, integrated quantitative estimate of the healthfulness of food across two dozen or more essential nutrients is via a nutrient profiling system (NPS). There is no perfect nutrient profiling system. Arguments can and will be made for and against including specific nutrients within such a system. There are many technical details that have to be worked through:

- On what basis will the RDA/RDI or equivalent benchmarks for healthy, daily intakes be set for specific nutrients? How to deal with varying nutritional needs across population cohorts?
- What to do when a serving of food contributes more than the RDA/RDI level for a given nutrient?
- Whether to alter the weight placed on specific nutrients to reflect general adequacy in typical diets?
- The actual test or tests to be used in quantifying the levels of individual nutrients (e.g. total antioxidant activity, fatty acid profiles).

The FDA will need to make judgements over what to include and how, based on tradeoffs between accuracy, cost, compliance burden, and clarity of messaging. Over time the sophistication of the system, and its ability to accommodate more nuanced differences will evolve***. But from the beginning, such a system can and should clearly delineate nutritionally-superior food choices from foods that contribute modestly, if at all to meeting a person's need for essential, health-promoting nutrients and constituents in food.***

Throughout the process, the FDA will need to remind stakeholders that the quest for a comprehensive FOPNL system that meets all needs and reflects all nuances is a long-run aspiration, and that the absence of comprehensive perfection should not prevent adoption of a useful system designed to accommodate continuous improvement, scientific advances, and better methods over time.

One logical path forward adopted in many laws and science-heavy agency initiatives would be to develop and apply the system, initially, to fresh and largely whole foods in their most frequently consumed forms (e.g. apples, applesauce, grapes, raisins, hamburger, French fries, eggs, milk). Once consumers understand how to read the FOPNLs, the FDA and food industry could then progressively add new types of multi-ingredient, heavily processed foods into the system (e.g. breads, cereals, cookies, energy bars, various types of pizza, ready-to-eat meals).

The new FOPNL system should be designed to foster easy comparisons by consumers of the healthfulness of ***one serving of food compared to one serving of other foods***. These comparisons will be useful both among competing brands of the same or similar food products, and across food groups.

Grounding a new FOPNL system on the nutrients in one serving of food will help harmonize and reinforce the information on macronutrients covered in back-of-package Nutrition Facts panels, which are also expressed "per serving." Doing so will avoid an added layer of messaging challenges and considerable confusion among consumers who strive to use both front and back-panel information to make decisions about the best choices across competing products.

So, to keep the message simple and align it and leverage its impact with back-of-panel Nutrition Facts, ***the new labeling scheme should be based on a single metric spanning all or most of the critical, health-promoting nutrients in a single serving of food.***

Single-nutrient based criteria in a system designed to support labeling of "healthy" food, taking into account all of the nutrients in the food, are incompatible with the need for a wholistic measure of food nutritional quality. Single nutrients or food attributes obviously can impact health outcomes, but ***the mix and level of multiple nutrients in a serving of food is by far more important.***

Coordination Across Federal Policies and Agencies and Specific Implementation Challenges

The FDA and government should recognize that designing and implementing a meaningful FOPNL system will take many years. An effective, funded, and sustained consumer education program will be essential so that consumers come to understand – and believe in – the information and insights provided by a new FOPNL system.

It is inconceivable that such an important, novel system can be hatched fully formed and equally effective across all food groups. Continuous assessment and modifications will be needed as long as the system is in place.

Upon launch of the new system, government agencies should provide research grants to assure completion of rigorous, data-driven assessments of the impact of the system across population groups, socio-economic parameters, and within all major food groups and across food groups.

The goals should include identifying aspects of the system that consumers find most and least useful, terms or concepts that are sometimes misunderstood, and better ways to reflect the unique nutritional attributes of foods within certain food groups (e.g. a mix of food ingredients that enhance or undermine nutrient bioavailability). Insight gained should routinely flow into system upgrades and refinements.

Harmonization Across Government Initiatives

The Food and Drug Administration (FDA) and Federal Trade Commission (FTC) share responsibility for the veracity and science supporting advertising and promotional claims associated with dietary supplements and food products. A Memorandum of Understanding called the "FDA-FTC Liaison Agreement" spells out the division across agencies of responsibilities and roles, and seeks to harmonize their actions to the full extent possible. In addition, "Both agencies apply the same basic principles in assessing the quality and adequacy of the science substantiating those claims." (Guidance document, p. 4)

As more and more food-as-medicine products and marketing campaigns strive to capture the attention of consumers, the importance of such FDA-FTC collaboration and harmonization will grow. The proliferation of new advertising and promotional platforms also is bound to add new challenges for government agencies responsible for policing the veracity and science behind various healthy food claims and marketing pitches.

The FTC issued new regulatory guidance on December 20, 2022 regarding advertising that makes health-related claims and statements (see "Health Products Compliance Guide"[44]). According to the FTC, this policy update is the first in 25 years. The relevance of this updated FTC guidance to the FDA's effort to create and implement an effective, healthy food FOPNL is clear in this passage from the FTC announcement regarding the new guidance document:

> "The revised business guide represents a substantial update to the staff's 1998 guide, `Dietary Supplements: An Advertising Guide For Industry'. Since that guide was issued, the FTC has brought more than 200 cases challenging false or misleading advertising claims for dietary supplements, foods, over-the-counter drugs, and other health-related products. The revised guide draws on those cases with 23 new examples."

As more food-as-medicine products are brought to market and then promoted via advertising and point-of-purchase information, the importance of the FTC's role in overseeing promotion-related health claims will increase. Two "common-sense" principles are set forth by the FTC:

[44] https://www.ftc.gov/news-events/news/press-releases/2022/12/ftc-announces-new-business-guidance-marketers-sellers-health-products

> "1. Advertising must be truthful and not misleading; and
>
> 2. Before disseminating an ad, advertiser must have adequate substantiation for all objective product claims conveyed, expressly or by implication, to consumers acting reasonably."

The FTC explains that the type of product and nature of any claims made will determine the scope of the information required to substantiate that a claim is not deceptive or misleading.

The FDA has promulgated detailed criteria and a process to vet and approve petitions from food companies wanting to make health claims, or qualified health claims on food product packaging[45]. In general, the FDA takes into account two criteria in judging whether "significant scientific agreement" supports a health claim.

First, that a given nutrient or compositional attribute in food products is reliably associated with a distinct, meaningful health benefit, and second, that the food product contains more of a positive attribute or less of a negative one than competing products.

In general, a food product bearing a qualified health claim like "A good source of fiber" or "Promotes heart health" must contain 25% or more of a health-promoting nutrient, compared to the average level across competing products, or 25% or less of something known to be associated with an adverse health outcome.

Once a FOPNL system is in place, the FDA and food industry will need to give careful thought to avoid situations where a single-nutrient qualified health claim that appears on the front of packaging raises confusion or undercuts the impact of new FOPNL. For example, a caloric-dense, low-nutrient food that scores poorly in NuCal, or any future FDA FOPNL system, might be allowed to feature on the front of packaging a qualified health claim indicative of a health benefit (e.g. "a good source of fiber").

The FDA could easily avoid such conflicts by imposing a new requirement that must be met for the FDA to evaluate a petition from a food company seeking to make a nutrient-specific qualified health claim, e.g. the food product must land in the upper one-half of the continuum of foods ranked by their scores developed for the new FOPNL system.

Addressing Unique Nutritional Needs Among Population Subgroups

Nutritional needs vary across the US population and change as people age. The health status of a person at a particular time can alter nutritional needs. The availability and cost of food impacts the choices available to consumers, and sometimes substantially.

[45] https://www.fda.gov/food/food-labeling-nutrition/qualified-health-claims

So an important, complex challenge will arise -- How can a FOPNL system meet all the needs of pregnant women, infants, and children, or people suffering from a GI tract problem, or individuals with a degenerative chronic disease driven by inflammation?

In short, it cannot. If an effort is made to do so, the complexity of the system will mushroom and its impact will be muddled.

The FDA's new FOPNL system must strive to provide guidance to consumers that will, in general, benefit all consumers. To succeed, the system must not strive to encompass all nutrition-related consequences of food choices across all people of all ages, as well as across all underlying health conditions that impact nutrient needs. Such an effort would soon bog down and likely would never make it into the marketplace.

Over time as the new system is vetted, tested, and refined, the government should work to provide additional information to guide food choices among people hoping to promote health or alleviate symptoms from a chronic disease, or deal with some other health problem via changes in food choices and dietary patterns. Such information could be provided in a variety of ways that will differ across food groups and types of packaging (e.g. QR codes, point of purchase information, in advertising, and on websites).

Government agencies could agree on a short, initial list of circumstances and subpopulations with significant, consistent differences in nutrient intake requirements to optimally promote health. For example:

- Pregnant women,
- Infants and children through age four,
- People combating type 2 diabetes and/or metabolic syndrome,
- Individuals with a GI tract problem, and
- People with a degenerative neurological disease or condition.

In each of the above cases, adjustments can easily be made in the weights assigned to each of the nutrients contained in the nutrient profiling system deployed by the FDA. Some nutrients could be added and others excluded to more sharply focus on those nutrients thought to be most significantly associated with promotion of a given, positive food-health outcome.

The government could then compute population-subgroup focused nutritional quality scores for a wide range of whole, processed, and multi-ingredient foods, irrespective of brands. Such additional rankings would not be placed on labels, but instead made accessible via information on labels. Such an approach would not assist consumers when choosing among brands of a given food product, but it would help consumers recognize foods that should be avoided or sought out in light of adjusted nutritional-quality scores.

Incentivize Health-Positive Changes in the Nutrient Composition of Branded Food Products

Many studies to date have failed to confirm a significant or lasting positive impact of existing FOPNL systems in changing consumer behavior and/or in encouraging food companies to alter recipes to improve rankings along the food-nutritional quality continuum[46].

There are several reasons why, but the most important typically are:

- The complexity of the systems,
- An effort to convey too much information and guidance across both macro- and micro nutrients,
- Conflicting information across parameters that force consumers to weigh positive attributes against negative ones,
- Inadequate time and investments in consumer education focused on what the symbols mean and what drives the ratings of specific food products, and
- Lack of clarity in what different symbols mean.

Some, and perhaps even most, food companies won't consider changes in recipes and ingredients until it becomes clear that consumers are responding to the information conveyed via a new, FDA-designed and endorsed FOPNL. Once market share begins dropping, even modestly, because consumers are shifting to competing brands that rate higher in a FOPNL system, responses are likely to be swift and substantive.

But many things have to come first before judgements are made regarding whether a FOPNL system like NuCal, or any other system, has stimulated constructive changes in recipes and ingredient lists. It will take several years after a new FOPNL system is put in place for consumers to fully understand the system and come to rely on its ratings in day-to-day food choices. But as the sophistication of the system grows and as consumers gain familiarity with it and come to trust it, the potential to incentivize positive changes in food-product recipes will rise and leverage change in two, self-reinforcing ways (better choices by consumers, healthier choices in the marketplace brought forward by companies determined to not lose market share).

Consumers Need Better Nutrition Information on All Food Groups

The FDA's Proposed Rule states that its new definition of healthy, and its forthcoming FOPNL system will not be applied in the case of animal sources of protein regulated by the USDA's Food Safety and Inspection System. We urge the FDA to work out a process with USDA to

[46] Braesco and Drewnowski, 2023: https://www.mdpi.com/2072-6643/15/1/205/htm

assure that the new definition of "healthy" in the context of food applies equally well to ***all major food groups, including meat, poultry, and egg products.***

Animal products play a vital role the American diet. The nutritional quality of animal products has slipped steadily over the last one-half century. Animal products play a major role in determining the mix and balance across fatty acids ingested during any given day.

Grass-fed beef, pork, eggs, and dairy products often have substantially higher levels of one or more of the specific saturated fats known to be hearth healthy or heart-health neutral, coupled with lower levels of some saturated fats most strongly linked to adverse CVD outcomes.

Multiple benefits will accrue to society, consumers, animals, and the environment by a gradual shift on livestock farms away from heavy reliance on corn, soybeans and other grain-based concentrate feeds, and toward more grass and forage-based feeds.

Moreover, ***this shift in how animals are fed will be essential to reduce the net contribution of agriculture to national greenhouse gas emission targets***. For these reasons, the new FDA definition of healthy foods and its FOPNL system should incorporate fatty acid profiles among the more heavily weighted nutritional attributes within a new definition of healthy foods and its associated labeling system.

If the FDA concludes that new legislation will be required to accomplish this key goal, the forthcoming farm bill is an appropriate vehicle through which to seek Congressional direction and a mandate to promote labeling that will increase demand for healthier foods that are also climate friendly.

As discussed previously, substantial evidence points to the now markedly elevated ratio of omega-6 to omega-3 fatty acids in many foods as among the most critical, health-outcome-relevant nutritional attributes of food. The typical American diet now delivers around 15 units of omega-6s for each unit of omega-3 fatty acids. Health-promoting benchmarks have been set between 4:1 and 1:1 for this critical ratio.

We urge the FDA to calculate, report, and base future decisions regarding the healthfulness of foods on the omega-6 to omega-3 ratio in foods as typically prepared and eaten. This new metric is essential in order to use the power of consumer demand to shift this ratio downward toward a level more assuredly compatible with heart health and climate-smart farming.

Rating Healthfulness of Combination Foods

The FDA proposes a complex approach in determining whether multi-ingredient, combination foods and prepared meals (i.e. macaroni and cheese, a fish taco) warrant labeling as healthy.

The already considerable drawbacks of trying to base the definition of healthy food on some number of servings from certain food groups are exacerbated in combination foods. There is no chance for the FDA's definition of healthy food, and accompanying labeling system, to deliver a clear and meaningful message if the FDA were to proceed with its proposed methods for dealing with combination foods.

One of the unambiguous advantages of the NuCal system, or any similar system, is that it would require no special rules, no new exceptions, nor would it impose any new interpretation and communication challenges when comparing single ingredient foods to those with multiple ingredients. The nutrient levels in combination foods (e.g. a Big Mac, slice of pepperoni pizza) would be tested as sold and/or typically consumed, and reported as a single number and rating, just like all other foods.

Doing so would add about a dozen new nutrients to those food companies are already required to measure to support the values in Nutrition Facts panels.

This approach will help the FDA alert consumers to a common occurrence in the US food supply – ***a combination food that renders healthy food ingredients less healthy via added salt, fats, and other ingredients***.

Dealing with Novel Foods and Issues

Over time novel food products will reach the market that pose unique challenges within the context of any FOPNL system. Contemporary examples include:

- Plant-based and cellular-based meat, fish, poultry, and dairy products;
- The nutritional quality of crops grown in soils versus in hydroponic systems and between wild caught and farm-raised fish, or genetically engineered farm-raised fish; and
- The nutritional advantages or disadvantages of crops grown from genetically engineered seeds or produced within certified organic systems.

A NuCal-like system could accurately inform consumers about the nature and magnitude of such differences, assuming the system incorporates fatty acid profiles and other key nutrients present in various types of food.

Political controversy over how competing food products can lawfully be labeled, and the claims that can be made about a specific health attribute associated with a food product, will also surely proliferate. The FDA and government, the Congress, policymakers, the food industry and courts need a solid, quantitative basis to work through future controversies, just as consumers need the same information to make smarter food choices.

V. Implementation Issues and Economic and Public Health Impacts and Outcomes

We applaud the FDA for acknowledging that it will take at least three years to implement the Final Rule, once it is published. In all likelihood, it will actually take much longer. This is why the FDA should consider staggered implementation time-frames ranging from 1-2 years in the case of vital, but relatively simple changes in current policy, to 5- to 10-years for more complex and novel aspects of the new system.

Educating consumers about the new metrics, labeling system, and the symbols used to convey differences across food products will take several years and indeed will be an ongoing challenge and obligation.

Securing the Data Needed to Quantify the Nutrient Content and Composition of Food Products

Questions may arise over the feasibility and cost of obtaining the data needed to compute calorie-adjusted nutritional quality scores across food product. Currently, food manufacturers are required to test their products for all the nutrients covered in Nutrition Facts panels and such testing is routinely done by inhouse and contract laboratories[47].

Routine testing already done by food analytical labs for manufacturers report levels of ~20 nutrients, including close to one-half of the nutrients that the FDA will likely require in a future nutrient profiling system developed to implement a FOPNL system. Adding the additional tests needed to implement a FOPNL will not markedly alter the total costs of food packaging and labeling, and will represent a tiny fraction of national advertising and promotion budgets for any national brand-name food product.

A possible, rough timeline for key decisions and steps in implementing the proposed labeling system follows, along with discussion of how the needed data can be secured.

Issuance of Final Rule setting forth the details of the new labeling system must come first, and hopefully will be issued by the end of 2023.

The final rule will list the nutrients and compositional characteristics of food products that must be provided to the FDA in order for the agency to compute each food products calorie-adjusted nutritional quality score. The nutrients will include those already covered in Nutrition Facts panels, plus around a dozen more including:

[47] E.g. see the food testing service offered by Anresco https://anresco.com/services/food-testing/nutritional-labeling/)

- Nutrients for which the government has set a RDA or equivalent benchmark daily intake level,
- Total antioxidant activity,
- PUFA profiles allowing calculation of omega-6/omega-3 fatty acid ratios, and
- Levels of specific saturated fatty acids (allowing heart-healthy or heart-neutral fatty acids to be removed from the calculation of saturated fat levels subject to limitations in specific foods).

It is important to emphasize that in the case of multi-ingredient foods, the NuCal score would be based on ***everything in the food*** as purchased by a consumer, including any added supplemental nutrients, and furthermore, the measured levels of nutrient would reflect the cumulative impact of how food was grown and animals raised.

In the case of a piece of $brand_x$ pepperoni pizza, the pizza slice would be placed in a blender, chopped up into a slurry, and a sample of the slurry would be tested for nutrient concentrations. ***The reported levels would take into account all the factors pushing up or down the level of any specific nutrient***. The computation of a NuCal score for the piece of pizza poses few practical and analytical challenges beyond those already addressed in compiling the information needed for Nutrition Facts panels.

The FDA's Final Rule would also set forth the requirements governing how many samples of a food product need to be tested, on what schedule, along with sample-selection and handling criteria. These technical requirements would mirror those now applicable to the testing required to support information in Nutrition Fact panels.

The Notice would also describe the analytical methods that must be used, requirements for lab certification, and other QA/QC provisions.

While the Final Rule is moving through the decision process, the FDA should alert commercial labs of the forthcoming, new testing requirements so that the labs can augment their standard, Nutrition Facts testing programs to encompass the additional nutrients and compositional characteristics that will be soon be required.

The Final Rule would also specify the process and schedule that companies must follow in submitting new batches of test results covering their brand name products. The testing and reporting processes applicable to different food groups and food forms would be fully described. In most instances, the FDA would likely require more thorough testing prior to approving a significant enhancement of health-promoting claims and content in FOPNLs.

The FDA would make available via its website an analytical portal through which food manufacturers can upload their nutrient content data and calculate the calorie-adjusted nutritional quality score associated with a given brand name product.

Then in the case of the NuCal system, food manufacturers would have the data needed to place the required vertical bar along the nutritional quality continuum corresponding to the score associated with a given product (see above for the mockup of one possible continuum design).

Note that the mockup contains information on the average nutritional quality score for similar products. Including this information right below or alongside the score for the product bearing the label will provide consumers key information regarding whether their choice of product is more, less, or roughly equivalent to competing products in terms of nutritional quality. The FDA can compute such averages from the data submitted to it by other food manufacturers.

Over time consumers would learn how to quickly evaluate the information in the box displaying the nutritional quality continuum. A quick visual check of where the vertical black bar is placed along the system continuum will provide actionable information, especially if coupled with a sustained education program describing how to use the ratings in the NuCal system.

The messaging could include advice to consumers to assure that ***day to day, at least one serving of food lands within the highly nutritious green zone and that few or no servings of food are chosen that fall within the red zone.***

Estimate of Costs and Benefits

The FDA's estimates in the Proposed Rule of the costs and benefits of the new definition of healthy and the system laid out for a new FOPNL are, we believe, highly speculative and very disappointing.

Obviously, the impact of the proposed definition and labeling system on consumer choices will be driven by whether it alters consumer behavior in ways that more closely align food choices with nutrient needs and healthier dietary patterns.

The FDA appears to not place much confidence in the new system it is proposing. In estimating benefits accruing from the system, the FDA projects that only 0% to 0.4% of the people that try to follow the current dietary guidelines would make "meaningful, long-lasting food purchase decisions." It is hard to imagine why a system able to change purchase decisions among less than 1% of the US population is worth pursuing.

Hence, we conclude it is imperative that the FDA consider alternative healthy food definitions and labeling systems that show much greater promise in increasing the percentage of consumers that will, over time, use the system to make incrementally more healthy food and dietary pattern choices.

We believe NuCal is one such system alternative, and no doubt there will be many others that will be described in comments submitted in response to this rulemaking. The FDA's task is drawing upon the most promising ideas and tactics in creating its new system.

A Key Reality Check

Government agencies are reticent to speak clearly about the nutritional quality of branded food products. Private sector opposition to labeling systems that draw attention to the enormous differences in nutritional quality across food and beverage products is no doubt part of the reasons why the FDA is proposing a system focused mostly on dietary patterns and food groups. By doing so, the FDA hopes to minimize the political blowback and pressure brought on by commodity groups and food companies selling products high in calories and/or largely or wholly devoid of nutrients.

If the outcome of this rulemaking is going to make a real and sustained difference in changing consumer food choices, ***the system must place a higher priority on clarity of messaging than on avoidance of ruffled feathers***. In short, the system must make it easy for consumers to distinguish between generally healthy and unambiguously unhealthy foods.

The definition of healthy foods and the associated labeling scheme we recommend is designed to do just that. By taking into account both the content of essential nutrients ***and*** calories in a serving of food, the system will highlight foods that deliver lots of nutritional value relative to the space different foods take up in a consumer's daily allotment of calories.

Another advantage of a NuCal-like system is that consumer messaging can and should focus on the two extremes along the nutritional quality-caloric intake continuum, i.e. green zone foods versus red zone foods. In such comparisons, the differences in nutritional quality are large, obvious, and easily defended.

If a NuCal-like food labeling system were put in place, the core messages to consumers will deliver benefits if sustained over time by:

- Minimizing the servings of red zone foods consumed per day and increasing the servings of high scoring green zone foods, and
- Helping consumers locate brands of favorite foods that score better along the continuum.

Such a system will surely expose the FDA to political pressures, since the system would likely work as intended and shift market shares toward foods that deliver more nutrients per calorie.

That is, after all, the end goal and primary reason for the FDA and food industry to invest the resources it will require to develop, vet, and incrementally improve a health-outcome-driven system designed to guide consumers who want to make wiser food choices.

Appendix A. List of 196 Foods Ranked According to the NuCal System Metric

Nutritional Contribution Continuum Values for 196 Foods Based on NQI Values and Typical Serving Sizes Sizes									
Yellow = variations on the same food	Nutritional Quality Index			% Nutrient Needs Met	Per Serving		% Daily Caloric Need	Nutritional Contribution Metric	USDA Number
Rose = fortified nutrients inflate NQI	Per 100 g	Per 100 Cal.	Per Serv.		Serv. Size	Calories			
MUSTARD greens,boiled	0.129	0.859	0.090	9.02%	1/2 cup	11	0.53%	17.17	11799
SPINACH,raw	0.196	0.852	0.059	5.88%	1 cup	6.9	0.35%	17.05	11457
TURNIP,greens,boiled	0.170	0.851	0.123	12.26%	1/2 cup	14	0.72%	17.02	11569
LETTUCE,Romaine	0.130	0.766	0.061	6.12%	1 cup	8.0	0.40%	15.32	11251
KALE,boiled	0.213	0.760	0.138	13.83%	1/2 cup	18	0.91%	15.20	11234
COLLARDS,boiled	0.188	0.722	0.178	17.84%	1/2 cup	25	1.24%	14.45	11162
ENDIVE,raw	0.078	0.461	0.039	3.92%	1 cup	8.5	0.43%	9.22	11213
ASPARAGUS,boiled	0.097	0.442	0.088	8.76%	1/2 cup	20	0.99%	8.84	11012
BROCCOLI,boiled	0.155	0.441	0.121	12.05%	1/2 cup	27	1.37%	8.83	11091
SQUASH,zucchini,boiled	0.066	0.441	0.060	5.95%	1/2 cup	14	0.68%	8.82	11478
BRUSSEL sprouts,boiled	0.152	0.421	0.118	11.83%	1/2 cup	28	1.40%	8.42	11099
ONION,green tops	0.096	0.357	0.034	3.43%	1/2 cup	10	0.48%	7.14	11292
LIVER,calf,braised	0.659	0.343	0.562	56.20%	3 oz.	164	8.20%	6.85	17203
PUMPKIN,boiled	0.065	0.325	0.080	8.00%	1/2 cup	25	1.23%	6.50	11423
ARTICHOKE,boiled	0.163	0.308	0.137	13.73%	1/2 cup	45	2.23%	6.17	11008
OKRA,boiled	0.067	0.306	0.054	5.38%	1/2 cup	18	0.88%	6.12	11279
BELL PEPPER,green	0.061	0.303	0.046	4.55%	1/2 cup	15	0.75%	6.07	11333
ALL-BRAN,Kellogg	0.767	0.295	0.218	21.78%	1 ounce	74	3.69%	5.90	08001
CABBAGE,boiled	0.066	0.286	0.049	4.93%	1/2 cup	17	0.86%	5.71	11110
CELERY,boiled	0.048	0.265	0.036	3.58%	1/2 cup	14	0.68%	5.31	11144
CELERY,raw	0.042	0.263	0.021	2.15%	1/2 cup	8.2	0.41%	5.26	11143
LETTUCE,iceberg	0.037	0.262	0.021	2.09%	1 cup	8.0	0.40%	5.24	11252
CARROT,boiled	0.090	0.257	0.070	7.01%	1/2 cup	27	1.37%	5.13	11125
SQUASH,winter,baked	0.093	0.251	0.096	9.56%	1/2 cup	38	1.91%	5.01	11644
TOMATO,red	0.045	0.250	0.041	4.05%	1/2 cup	16	0.81%	5.00	11529
CABBAGE,green,raw	0.060	0.238	0.027	2.68%	1/2 cup	11	0.56%	4.76	11109
CAULIFLOWER,boiled	0.054	0.236	0.034	3.40%	1/2 cup	14	0.71%	4.77	11136
CRANBERRY,raw	0.107	0.233	0.107	10.74%	1 cup	46	2.30%	4.67	09078
RADISH,red	0.037	0.229	0.021	2.12%	1/2 cup	9.3	0.46%	4.56	11429
STRAWBERRY	0.070	0.218	0.106	10.58%	1 cup	49	2.43%	4.35	09316
GREEN beans,boiled	0.074	0.211	0.047	4.66%	1/2 cup	22	1.10%	4.22	11053
RASPBERRY	0.106	0.204	0.130	13.03%	1 cup	64	3.20%	4.08	09302

Beginning of the Yellow Zone Along the Nutrition Contribution Continuum									
MUSHROOM,boiled	0.055	0.197	0.043	4.29%	1/2 cup	22	1.09%	3.93	11261
SPECIAL K,Kellogg	0.557	0.147	0.158	15.83%	1 ounce	108	5.38%	2.94	08067
PLUM	0.065	0.141	0.043	4.29%	Medium	30	1.52%	2.83	09279
WHEATIES,General Mills	0.488	0.141	0.139	13.85%	1 ounce	99	4.93%	2.81	08089
CUCUMBER,peeled	0.016	0.134	0.011	1.08%	1/2 cup	8.0	0.40%	2.68	11206
KIWI,peeled	0.080	0.131	0.143	14.34%	1 cup	110	5.49%	2.61	09148
PAPAYA, red fleshed	0.053	0.123	0.077	7.68%	1 cup	62	3.12%	2.46	09226
ORANGE	0.058	0.122	0.075	7.54%	Medium	62	3.08%	2.45	09200
CHEERIOS,General Mills	0.448	0.122	0.127	12.73%	1 ounce	104	5.21%	2.44	08013
TROUT,rainbow,farmed,baked/broiled	0.202	0.120	0.172	17.20%	3 oz.	143	7.15%	2.41	15241
WATERMELON	0.036	0.119	0.054	5.44%	1 cup	46	2.28%	2.39	09326
CUCUMBER,unpeeled	0.018	0.119	0.009	0.93%	1/2 cup	7.8	0.39%	2.38	11205
LEMON juice	0.026	0.119	0.008	0.81%	1/8 cup	6.8	0.34%	2.38	09152
SALMON,pink,canned	0.166	0.119	0.141	14.10%	3 oz.	118	5.90%	2.39	15084
BLUEBERRY	0.067	0.117	0.099	9.89%	1 cup	84	4.22%	2.35	09050
TUNA,light,canned in water,drained	0.127	0.109	0.108	10.80%	3 oz.	99	4.95%	2.18	15121
GRAPEFRUIT,pink/red	0.045	0.108	0.056	5.57%	1/2 each	52	2.58%	2.16	09112
CANTALOUPE	0.036	0.105	0.056	5.56%	1 cup	53	2.65%	2.10	09181
PEACH	0.039	0.099	0.058	5.80%	Medium	59	2.93%	1.98	09236
SALMON,Atlantic,farmed,baked/broiled	0.196	0.095	0.167	16.70%	3 oz.	176	8.80%	1.90	15237
SWEET potato,peeled,boiled	0.068	0.089	0.078	7.75%	1/2 cup	87	4.33%	1.79	11510
CORN FLAKES,Kellogg	0.323	0.089	0.092	9.16%	1 ounce	103	5.13%	1.79	08020
LIME juice	0.022	0.088	0.007	0.68%	1/8 cup	7.7	0.39%	1.77	09160
APRICOT	0.042	0.088	0.066	6.58%	1 cup	74	3.72%	1.77	09021
SHRIMP,boiled/steamed	0.104	0.088	0.089	8.90%	3 oz.	101	5.05%	1.76	15151
RYE flour,dark (whole)	0.285	0.088	0.081	8.10%	1 ounce	92	4.62%	1.76	20063
CHEERIOS,Frosted,General Mills	0.329	0.087	0.094	9.35%	1 ounce	107	5.37%	1.74	08267
HERRING-Sardine,Atlantic,baked/broiled	0.177	0.087	0.151	15.10%	3 oz.	173	8.65%	1.75	15040
RICE KRISPIES,Kellogg	0.333	0.086	0.095	9.47%	1 ounce	110	5.50%	1.72	08065
TANGERINE	0.045	0.085	0.040	3.96%	Medium	47	2.33%	1.70	09218
CHERRY	0.053	0.085	0.074	7.36%	1 cup	87	4.35%	1.69	09070
MILK,soy,fortified	0.036	0.084	0.088	8.78%	1 cup	104	5.22%	1.68	16139
MILK,nonfat	0.028	0.083	0.069	6.91%	1 cup	83	4.17%	1.66	01085
APPLE	0.043	0.083	0.055	5.50%	Medium	67	3.33%	1.65	09003
TUNA,light,canned in oil,drained	0.163	0.082	0.139	13.90%	3 oz.	169	8.45%	1.64	15119
EGGPLANT,boiled	0.028	0.081	0.014	1.42%	1/2 cup	18	0.88%	1.62	11210
NECTARINE	0.035	0.080	0.050	4.98%	1 medium	62	3.12%	1.60	09191
GARLIC,raw	0.118	0.079	0.004	0.35%	1 clove	4.5	0.22%	1.58	11215
EGG,raw	0.111	0.078	0.056	5.57%	1 large	72	3.58%	1.56	01123
MANGO	0.047	0.078	0.077	7.68%	1 cup	99	4.95%	1.55	09176
CORN,yellow,boiled	0.074	0.077	0.056	5.57%	1/2 cup	72	3.60%	1.55	11168
FROOT LOOPS,Kellogg	0.288	0.077	0.082	8.18%	1 ounce	106	5.30%	1.55	08030
ORANGE juice,fresh	0.033	0.073	0.081	8.13%	1 cup	112	5.60%	1.45	09206
Applesauce,cnd+vit.C	0.030	0.072	0.074	7.42%	1 cup	103	5.17%	1.44	09401
TILAPIA,baked/broiled	0.091	0.071	0.078	7.80%	3 oz.	109	5.45%	1.43	15262
PEAR	0.041	0.071	0.073	7.32%	Medium	103	5.16%	1.42	09252
EGG YOLK,raw	0.227	0.070	0.039	3.86%	1 yolk	55	2.74%	1.41	01125
AVOCADO	0.111	0.069	0.083	8.34%	1/2 cup	120	6.00%	1.39	09037
ONION,boiled	0.030	0.067	0.031	3.12%	1/2 cup	46	2.31%	1.35	11283
PINEAPPLE	0.033	0.067	0.055	5.52%	1 cup	83	4.13%	1.34	09266
MILK, 1% fat	0.028	0.067	0.068	6.82%	1 cup	102	5.12%	1.33	01082
ORANGE juice,Frz.conc+water	0.030	0.066	0.074	7.38%	1 cup	112	5.60%	1.32	09215
CORN POPS,Kellogg	0.254	0.065	0.072	7.22%	1 ounce	110	5.52%	1.31	08068
CHICKEN,breast,Broil (no bone, skin)	0.108	0.065	0.092	9.20%	3 oz.	141	7.05%	1.30	05064
HAM,regular(9%fat),roasted	0.111	0.063	0.095	9.50%	3 oz.	152	7.60%	1.25	10136
BARLEY,whole,raw	0.221	0.062	0.063	6.27%	1 ounce	101	5.03%	1.25	20004
EGG WHITE,raw	0.032	0.062	0.011	1.07%	1 white	17	0.86%	1.25	01124
PRUNE,dried	0.149	0.062	0.259	25.94%	1 cup	418	20.88%	1.24	09291
HONEYDEW	0.022	0.061	0.037	3.71%	1 cup	61	3.06%	1.21	09184
Applesauce,canned	0.025	0.060	0.062	6.19%	1 cup	103	5.17%	1.20	09019
FROSTED Mini-Wheats	0.213	0.060	0.060	6.05%	1 ounce	101	5.06%	1.20	08459
TRITICALE,flour,whole	0.196	0.058	0.056	5.58%	1 ounce	96	4.80%	1.16	20070
BUCKWHEAT,flour,whole	0.191	0.057	0.054	5.43%	1 ounce	95	4.76%	1.14	20011
YOGURT,plain,nonfat	0.032	0.057	0.078	7.81%	1 cup	137	6.86%	1.14	01118
KAMUT,raw	0.190	0.056	0.054	5.40%	1 ounce	96	4.79%	1.13	20138
CRANBERRY juice,unsweetened	0.026	0.056	0.066	6.55%	1 cup	116	5.82%	1.13	43382
FLOUR,whole wheat	0.191	0.056	0.054	5.42%	1 ounce	97	4.83%	1.12	20080
MILK, 2% fat	0.028	0.056	0.068	6.84%	1 cup	122	6.10%	1.12	01079
CATFISH,farmed,baked/broiled	0.080	0.056	0.068	6.80%	3 oz.	123	6.15%	1.11	15235
BREAD,whole wheat	0.138	0.056	0.037	3.72%	1 slice	67	3.33%	1.12	18075
BEEF,rib eye,lean,broiled	0.111	0.054	0.095	9.50%	3 oz.	175	8.75%	1.09	13098
CHEESE,cottage, 1% fat	0.038	0.053	0.043	4.35%	1/2 cup	81	4.07%	1.07	01016
BREAD,7-grain (whole)	0.141	0.053	0.037	3.66%	1 slice	69	3.45%	1.06	18035
QUINOA,grain	0.194	0.053	0.055	5.50%	1 ounce	105	5.23%	1.05	20035
Chicken noodle soup	0.031	0.052	0.077	7.71%	1 cup	149	7.44%	1.04	06419
GRAPE juice,bottled+vit.C	0.031	0.051	0.078	7.82%	1 cup	152	7.59%	1.03	09130
GRAPE juice,Concord+vit. C	0.031	0.051	0.078	7.82%	1 cup	152	7.59%	1.03	N0235
POTATO,boiled in skin,peeled	0.044	0.051	0.034	3.45%	1/2 cup	68	3.39%	1.02	11831
BARLEY,pearled,flour	0.179	0.051	0.051	5.07%	1 ounce	100	5.00%	1.02	20005
SHREDDED WHEAT	0.170	0.050	0.048	4.82%	1 ounce	96	4.79%	1.01	08147
GRAPE, red and green	0.035	0.050	0.052	5.23%	1 cup	104	5.21%	1.00	09132
MILK,buttermilk,cultured	0.020	0.049	0.048	4.82%	1 cup	98	4.90%	0.98	01088
Fruit coctail in juice	0.028	0.049	0.069	6.95%	1 cup	141	7.07%	0.98	09097
AMARANTH,grain	0.181	0.049	0.051	5.14%	1 ounce	105	5.27%	0.98	20001
MILK,whole	0.030	0.049	0.073	7.26%	1 cup	149	7.44%	0.98	01077
OIL,soybean	0.431	0.049	0.059	5.86%	1 Tbsp.	120	6.01%	0.98	04044
PORK,loin,lean+fat,roasted	0.119	0.048	0.101	10.10%	3 oz.	211	10.55%	0.96	10023
WILD RICE,raw	0.171	0.048	0.048	4.84%	1 ounce	101	5.07%	0.96	20088
Lasagne, meat + sauce	0.068	0.047	0.077	7.68%	4 oz.	163	8.14%	0.94	22916
BEEF,ground,cooked,15% fat	0.109	0.047	0.092	9.20%	3 oz.	198	9.90%	0.93	23569

PORK,spareribs,lean+fat,roasted	0.113	0.047	0.096	9.60%	3 oz.	203	10.15%	0.95	10188
BANANA	0.042	0.047	0.049	4.93%	Medium	105	5.25%	0.94	09040
CORN meal,whole	0.170	0.047	0.048	4.82%	1 ounce	103	5.14%	0.94	20020
OATMEAL,dry	0.171	0.045	0.049	4.87%	1 ounce	108	5.38%	0.90	08120
CHOCOLATE CHIPS, semisweet	0.214	0.045	0.061	6.09%	1 oz.	136	6.82%	0.89	19080
BREAD,rye	0.111	0.043	0.022	2.22%	1 slice	52	2.58%	0.86	18060
CHICKEN,whole,roasted	0.103	0.043	0.087	8.70%	3 oz.	204	10.20%	0.85	05009
MILLET,dry	0.161	0.042	0.046	4.56%	1 ounce	107	5.37%	0.85	20031
BREAD,wheat,enriched	0.110	0.041	0.027	2.75%	1 slice	67	3.33%	0.83	18064
WHEY,fluid,sweet	0.011	0.041	0.027	2.71%	1 cup	66	3.32%	0.82	01114
CORN meal,degermed,enr.	0.151	0.041	0.043	4.28%	1 ounce	105	5.25%	0.81	20022
GRAPE juice,bottled	0.024	0.040	0.061	6.06%	1 cup	152	7.59%	0.80	09135
CHEESE,mozzarella,part skim	0.101	0.040	0.029	2.86%	1 oz.	72	3.60%	0.79	01028
CHEESE,cottage, 4.5% fat	0.038	0.039	0.044	4.35%	1/2 cup	111	5.54%	0.79	01012
Pizza Hut cheese pizza	0.100	0.039	0.096	9.62%	1 slice	250	12.48%	0.77	Not recor
APPLE juice,canned,+vit.C	0.017	0.038	0.043	4.30%	1 cup	114	5.70%	0.75	09400
Applesauce,cnd+sugar	0.026	0.038	0.063	6.27%	1 cup	167	8.36%	0.75	09020
BREAD,oatmeal	0.099	0.037	0.027	2.69%	1 slice	73	3.63%	0.74	18039
YOGURT,plain,whole	0.022	0.037	0.055	5.49%	1 cup	149	7.47%	0.74	01116
CHEESE,Swiss	0.137	0.036	0.039	3.87%	1 oz.	108	5.39%	0.72	01040
BREAD,white,enriched	0.094	0.035	0.023	2.34%	1 slice	67	3.33%	0.70	18069
MILK,evaporated,canned	0.046	0.034	0.058	5.82%	1/2 cup	169	8.44%	0.69	01153
Pizza Hut super supreme pizza	0.106	0.034	0.134	13.42%	1 slice	392	19.62%	0.68	21276
SORGHUM,grain	0.114	0.034	0.032	3.25%	1 ounce	96	4.81%	0.67	20067
RYE flour,light	0.119	0.033	0.034	3.39%	1 ounce	101	5.07%	0.67	20065
BREAD,French	0.096	0.033	0.024	2.40%	1 slice	72	3.61%	0.67	18029
RICE,brown,long grain,raw	0.119	0.032	0.034	3.37%	1 ounce	105	5.25%	0.64	20036
HIGH-C, canned drink	0.015	0.031	0.038	3.79%	1 cup	122	6.08%	0.62	14323
BACON,cooked	0.167	0.031	0.047	4.70%	1 oz.	154	7.70%	0.61	10124
CHICKEN,breast+wing,breaded,fried,fast foo	0.093	0.031	0.079	7.90%	3 oz.	258	12.90%	0.61	21036
CHICKEN,leg+thigh,fried,fast food	0.090	0.031	0.077	7.70%	3 oz.	248	12.40%	0.62	21035
Fried chicken, fast food	0.152	0.031	0.248	24.83%	Breast,wing	805	40.26%	0.62	Not recor
Fruit coctail in heavy syrup	0.028	0.030	0.072	7.22%	1 cup	238	11.90%	0.61	09100
CHEESE,cheddar	0.120	0.030	0.034	3.41%	1 oz.	114	5.71%	0.60	01009
CHEESE,American	0.110	0.029	0.031	3.12%	1 oz.	106	5.32%	0.59	01042
APPLE juice,Frz,+vit.C,diluted	0.014	0.029	0.034	3.39%	1 cup	117	5.83%	0.58	09411
FLOUR,all purpose,enriched	0.105	0.029	0.030	2.98%	1 ounce	103	5.17%	0.58	20081
RICE cake,brown rice	0.110	0.028	0.030	2.97%	2 cakes	104	5.22%	0.57	19816
Burrito, bean & cheese	0.107	0.028	0.198	19.82%	2 each	703	35.15%	0.56	Not recor
French fries, McDonalds	0.148	0.027	0.168	16.85%	Medium	616	30.78%	0.55	Not recor
Ham & cheese sandwich	0.094	0.027	0.138	13.75%	1 each	514	25.70%	0.54	Not recor
RAISINS,raw	0.079	0.026	0.058	5.77%	1/2 cup	218	10.91%	0.53	09298
FLOUR,cake,enriched	0.091	0.025	0.026	2.60%	1 ounce	103	5.14%	0.50	20084
Beginning of the Red Zone Along the Nutrition Contribution Continuum									
CORNBREAD from mix	0.075	0.024	0.021	2.13%	1 ounce	89	4.46%	0.48	18023
COOKIE, Oreo	0.112	0.024	0.038	3.80%	3 each	159	7.97%	0.48	18166
Chicken pot pie	0.109	0.024	0.237	23.70%	1 pie	1007	50.34%	0.47	Not recor
Big Mac with cheese	0.130	0.023	0.271	27.09%	1 each	1177	58.83%	0.46	Not recor
CREAM,half and half	0.030	0.023	0.009	0.89%	2 Tbsp	39	1.95%	0.46	01049
RICE,white,long grain,enr.,raw	0.083	0.023	0.024	2.37%	1 ounce	104	5.18%	0.46	20044
MARGARINE	0.137	0.022	0.007	0.68%	1 pat	31	1.57%	0.44	04629
Shrimp, breaded, fast food	0.094	0.021	0.154	15.40%	6-8 shrimp	745	37.23%	0.41	Not recor
Croissant + egg, cheese, ham	0.094	0.020	0.143	14.33%	1 each	720	36.02%	0.40	21013
ICE CREAM, vanilla	0.039	0.019	0.026	2.60%	1/2 cup	137	6.83%	0.38	19095
PIE, apple	0.044	0.019	0.056	5.56%	1 piece	296	14.81%	0.38	18301
APPLE juice,canned	0.008	0.018	0.020	2.01%	1 cup	114	5.70%	0.35	09016
CREAM,sour,cultured	0.032	0.016	0.008	0.76%	2 Tbsp	46	2.32%	0.33	01056
APPLE juice,Frz,diluted	0.008	0.016	0.019	1.91%	1 cup	117	5.83%	0.33	09018
DONUT, glazed	0.063	0.016	0.038	3.81%	1 medium	242	12.09%	0.32	18436
COOKIE, animal crackers	0.069	0.015	0.020	1.96%	1 oz.	127	6.33%	0.31	18150
CREAM,whipping,heavy	0.053	0.015	0.016	1.58%	2 Tbsp	104	5.18%	0.31	01053
CAKE, yellow, vanilla icing	0.057	0.015	0.036	3.64%	1 piece	239	11.94%	0.31	18141
SUCANAT	0.056	0.015	0.007	0.71%	1 Tbsp.	48	2.39%	0.30	N0076
CHEESE,cream	0.050	0.015	0.014	1.44%	2 Tbsp	99	4.96%	0.29	01017
Hushpuppy, fast food	0.037	0.014	0.029	2.89%	5 each	200	10.02%	0.29	21129
OIL, olive	0.110	0.012	0.015	1.49%	1 Tbsp.	119	5.97%	0.25	04053
Onion rings, breaded, fast food	0.031	0.011	0.025	2.54%	8-9 rings	229	11.45%	0.22	Not recor
SYRUP, maple	0.027	0.010	0.005	0.53%	1 Tbsp.	52	2.60%	0.20	19353
CARAMELS	0.038	0.010	0.011	1.08%	1 oz.	108	5.42%	0.20	19074
BUTTER	0.061	0.009	0.003	0.31%	1 pat	36	1.79%	0.17	01001
GATORADE, FRUIT-FLAVORED	0.001	0.005	0.007	0.75%	20 fl. oz.	158	7.92%	0.09	14460
HONEY	0.005	0.002	0.001	0.11%	1 Tbsp.	64	3.19%	0.04	19296
COKE, PEPSI	0.001	0.002	0.002	0.22%	12 fl. oz.	136	6.81%	0.03	14400
SPRITE, 7-UP	0.001	0.001	0.002	0.19%	12 fl. oz.	148	7.38%	0.03	14145
SUGAR	0.001	0.000	0.000	0.01%	1 Tbsp.	49	2.44%	0.00	19335