

A Planetary Health Approach to the Labeling of Plant-Based Meat

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ABSTRACT

In 2019, alternative proteins became mainstream. “Bleeding” plant-based burgers are now available at fast-food restaurants and grocery stores across the country, and the field of cellular agriculture—production of meat, dairy, and eggs from cells instead of livestock—is advancing rapidly. The replacement of conventional animal products with plant-based and cell-based alternatives signifies, for their producers and advocates, a turning point toward a more sustainable, just, and healthy food system. Yet, for the livestock industry, some consumer protection and environmental groups, and “natural” food advocates, these “Frankenfoods” or “fake foods” represent a flawed techno-fix. This paper explores these politicized narratives which have brought regulatory and legal issues of naming and labeling to the forefront of FDA’s and USDA’s agenda, have received congressional attention, and are also being addressed by state legislatures proposing and passing laws to define foods, such as “meat.” The health benefits and risks of both conventional and alternative meat products are focal issues in the conflicting narratives reported in the media and communicated through advertising campaigns. Focusing on FDA-regulated plant-based meat products that are currently or soon-to-be on the market, this paper evaluates the appropriate role of government in clarifying, and not further obfuscating, the issues. It does so by analyzing the Dietary Guidelines for Americans and FDA’s existing labeling guidance and regulations regarding “healthy” implied nutrient content claims. The paper argues for a broader approach to defining “healthy” that considers both human and planetary health and allows consumers to compare the healthfulness of alternative products with their conventional counterparts.

I. INTRODUCTION

In September 2019, RethinkX, an independent think tank, announced, “We are on the cusp of the deepest, fastest, most consequential disruption in food and agricultural production since the first domestication of plants and animals ten thousand years ago.”¹ Driving this dramatic shift are technological developments in the protein sector.

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¹ RETHINKX, RETHINKING FOOD AND AGRICULTURE 2020-2030 6 (2019), <https://www.rethinkx.com/food-and-agriculture#food-and-agriculture-download> [https://perma.cc/AH3T-XXJX].

The start of this decade marks the mainstreaming of alternative proteins. With so many existing and start-up companies creating their own versions of faux meat, it amounts to “a veggie burger arms race.”² The “bleeding” plant-based Impossible Burger is now available at fast-food restaurants across the country, plant-based meat company Beyond Meat had a record initial public offering (IPO) offering in May 2019,³ and plant-based milks are being purchased by nearly half of all U.S. households.⁴ Meanwhile, the field of cellular agriculture—production of meat, dairy, and eggs from cells instead of livestock—is advancing rapidly.⁵ The replacement of conventional animal products with plant-based and cell-based alternatives signifies, for their producers and advocates, a turning point toward a more sustainable, just, and healthy food system. Yet, for the livestock industry, some consumer protection and environmental groups, and “natural” food advocates, these “Frankenfoods” or “fake foods” represent a flawed techno-fix. These politicized narratives have brought regulatory and legal issues of naming and labeling to the forefront of Food and Drug Administration (FDA)’s and U.S. Department of Agriculture(USDA)’s agenda, have received congressional attention, and are also being addressed by state legislatures proposing and passing laws to define foods, such as “meat.”⁶ The fight for control over publicly accepted and utilized terminology also extends to the broader narrative about conventional and alternative foods’ credence attributes, including sustainability, animal welfare, and healthfulness.⁷

The public health benefits and risks of both the conventional and alternative products are a key component of the conflicting narratives reported in the media and utilized in advertising campaigns. From plant-based and emerging cell-based food producers, the public receives information about the harmful environmental impacts of animal products and their negative health impacts due to high levels of saturated fat or the use of hormones or antibiotics.⁸ From a variety of other food system stakeholders, consumers are warned of the dangers and unintended consequences of

² Jack Ewing, *Nestlé Says It Can Be Virtuous and Profitable. Is That Even Possible?*, N.Y. TIMES (Nov. 15, 2019), <https://www.nytimes.com/2019/11/15/business/nestle-environment-sustainability.html> [<https://perma.cc/5CBH-5XJF>].

³ Mike Murphy, *Beyond Meat Soars 163% in Biggest Popping U.S. IPO Since 2000*, MARKETWATCH (May 5, 2019), <https://www.marketwatch.com/story/beyond-meat-soars-163-in-biggest-popping-us-ipo-since-2000-2019-05-02> [<https://perma.cc/W9GW-4RVD>].

⁴ Forty-one point three percent of all U.S. households purchase plant-based milk. THE GOOD FOOD INST., PLANT-BASED MARKET OVERVIEW (2020), <https://www.gfi.org/marketresearch> [<https://perma.cc/T44T-6M2Q>].

⁵ See, e.g., MARTIN ROWE, BRIGHTER GREEN, BEYOND THE IMPOSSIBLE, THE FUTURES OF PLANT-BASED AND CELLULAR MEAT AND DAIRY 6 (2019), <https://brightergreen.org/news/beyond-the-impossible-the-futures-of-plant-based-and-cellular-meat-and-dairy-published/> [<https://perma.cc/VXH8-ZVQE>]; RETHINKX, *supra* note 1, at 6.

⁶ See *infra* Parts II-III.

⁷ This paper is the first in a series of articles that explores the narratives around food technologies that are meant to replace conventional meat, dairy, and eggs. Subsequent articles evaluate the communication of credence attributes by plant-based meat producers and the evolving meaning of “meat.” Nicole E. Negowetti, *Plant-Based Meat and the Narratives of Food Technology: Communicating Credence Claims* (forthcoming); Nicole E. Negowetti, *Censorship, Civil Disobedience, and the Discourse of Disruption: Toppling the “Meat” Monopoly* (forthcoming).

⁸ See, e.g., Impossible Foods, <https://impossiblefoods.com/health/> [<https://perma.cc/AX6S-8ES9>], <https://impossiblefoods.com/mission/> [<https://perma.cc/7MC9-KLW7>].

biotechnology in food production, use of herbicides such as glyphosate to grow genetically engineered soy, and nutritional inferiority of animal product “substitutes.”⁹

As the narrative debates and claims of product superiority move from the forum of social media and onto the products themselves, how will labeling guidance and regulations need to adapt and be modernized? How will these food producers be able to communicate the credence attributes of their products most effectively and truthfully? This paper delves into these questions by exploring the competing narratives and evaluates the appropriate role of government in clarifying, and not further obfuscating, the issues. Focusing on FDA-regulated plant-based meat products that are currently or soon-to-be on the market, this paper will analyze FDA’s existing labeling guidance and regulations regarding “healthy” implied nutrient content claims to recommend an approach that fulfills the agency’s consumer protection mission. The paper also evaluates the shared role of FDA and USDA in developing the Dietary Guidelines for Americans (DGA), which set forth recommendations for “healthy” diets. It argues for an approach to defining “healthy” in the DGA and in FDA regulations that considers both human and planetary health, which refers to “the health of human civilization and the state of the natural systems on which it depends,”¹⁰ and allows consumers to compare the healthfulness of alternative products with their conventional counterparts. Because nutrition, safety, and environmental sustainability are all important contributors to overall health, FDA should take a broader approach in establishing a revised regulatory definition of “healthy.”

This paper begins by providing an overview of new alternative meat products to set the stage for understanding competing narratives about the healthfulness of these products in relation to their conventional counterparts. Part III evaluates the plant-based meat industry’s communication of its products’ attributes through the framework of FDA’s ongoing efforts to modernize the definition of “healthy.” This Part delves into the debate regarding processing used to produce plant-based meat and its effect on the healthfulness of the products. Part IV analyzes the role of “sustainability” in the definition of “healthy” and recommends broadening the definition of “healthy” to encompass both human and planetary health.

II. OVERVIEW OF ALTERNATIVE PROTEINS

Products intended to replace conventional meat, dairy, and eggs are being developed and coming to market at a rapid pace, precipitated by the urgency of climate change, widespread animal suffering, and public health epidemics.¹¹ As the recent groundbreaking EAT-Lancet Report emphasized, the situation is dire¹²: “Global food production threatens climate stability and ecosystem resilience and constitutes the single largest driver of environmental degradation and transgression of planetary boundaries. . . . A radical transformation of the global food system is urgently

⁹ See, e.g., Dana Perls, *From Lab to Fork: Critical Questions on Laboratory-Created Animal Product Alternatives*, FRIENDS OF THE EARTH 9 (2018).

¹⁰ EAT, HEALTHY DIETS FROM SUSTAINABLE FOOD SYSTEMS, SUMMARY REPORT OF THE 2019 EAT-LANCET COMMISSION 7, https://eatforum.org/content/uploads/2019/07/EAT-Lancet_Commission_Summary_Report.pdf [<https://perma.cc/2RBG-YLUT>] [hereinafter EAT-LANCET COMMISSION SUMMARY REPORT].

¹¹ See *id.* at 10.

¹² *Id.* at 5.

needed.”¹³ It is now widely recognized that avoiding conventionally produced meat and dairy is the most significant way to reduce one’s environmental impact on greenhouse gas emissions, land use, biodiversity loss, water pollution, pesticide use, and antibiotic use.¹⁴ As summarized by Zheng, “[a] large body of evidence has also shown that high consumption of red meat, especially processed red meat, is associated with an increased risk of type 2 diabetes.”¹⁵ In addition, “consumption of processed red meat, [such as] bacon, hot dogs, and sausages[,] has been associated with additional health outcomes, including chronic obstructive pulmonary disease, heart failure, and hypertension.”¹⁶ Alt-proteins that shift consumption away from animal meat could play a significant role in achieving both climate and public health goals.

There is significant opportunity for disruption of the conventional meat industry. While meat consumption in the United States is declining, it remains more than three times the global average.¹⁷ Americans eat an average of 220 pounds of poultry and livestock products per year, over 100 of those pounds in red meat,¹⁸ which translates to approximately ten ounces per day. “At 222 pounds per person, overall meat consumption comes out to the equivalent of more than 800 quarter-pound burgers per person when measured by weight, or about 2.4 burgers per day.”¹⁹ These quantities of

¹³ *Id.*

¹⁴ See generally Joseph Poore & Thomas Nemecek, *Reducing Food’s Environmental Impacts Through Producers and Consumers*, 360 *SCI.* 987 (2018).

¹⁵ Yan Zheng, Ambika Satija, An Pan, Mercedes Sotos-Prieto, Eric Rimm, Walter Willett & Frank Hu, *Association of Changes in Red Meat Consumption with Total and Cause-Specific Mortality Among U.S. Women and Men: Two Prospective Cohort Studies*, *BMJ* (2019) (citing An Pan, Qi Sun, Adam Bernstein, Matthias Schulze, JoAnn Manson, Walter Willett & Frank Hu, *Red Meat Consumption And Risk Of Type 2 Diabetes: 3 Cohorts of US Adults and an Updated Meta-Analysis*, 94 *AM. J. CLINICAL NUTRITION* 1088 (2011) for type 2 diabetes; Renata Micha, Sarah Wallace & Dariush Mozaffarian, *Red and Processed Meat Consumption and Risk of Incident Coronary Heart Disease, Stroke, and Diabetes Mellitus: A Systematic Review and Meta-Analysis*, 121 *CIRCULATION* 2271 (2010) for cardiovascular disease; Daniel Demeyer, Birgit Mertens, Stefaan Smet & Michele Ulens, *Mechanisms Linking Colorectal Cancer to the Consumption of (Processed) Red Meat: A Review*, 56 *CRITICAL REV. FOOD SCI. NUTRITION* 2747 (2016) for colorectal cancer; Susanna Larsson & Nicola Orsini, *Red Meat and Processed Meat Consumption and All-Cause Mortality: A Meta-Analysis*, 179 *AM. J. EPIDEMIOLOGY* 282 (2014); Andrea Bellavia, Frej Stilling & Alicja Wolk, *High Red Meat Intake and All-Cause Cardiovascular and Cancer Mortality: Is The Risk Modified By Fruit And Vegetable Intake?*, 104 *AM. J. CLINICAL NUTRITION* 1137 (2016) for mortality).

¹⁶ Zheng et al., *supra* note 15 (citing Joanna Kaluza, *Consumption of Unprocessed and Processed Red Meat and the Risk of Chronic Obstructive Pulmonary Disease: A Prospective Cohort Study of Men*, 184 *AM. J. EPIDEMIOLOGY* 829 (2016) for obstructive pulmonary disease; Joanna Kaluza, Agneta Akesson & Alicja Wolk, *Processed and Unprocessed Red Meat Consumption and Risk of Heart Failure: Prospective Study of Men*, 7 *CIRCULATION: HEART FAILURE* 552 (2014) for heart failure; Martin Lajous, Anne Bijon, Guy Fagherazzi, Emilie Rossignol, Marie-Christine Boutron-Ruault & Françoise Clavel-Chapelon, *Processed and Unprocessed Red Meat Consumption and Hypertension in Women*, 100 *AM. J. CLINICAL NUTRITION* 948 (2014) for hypertension).

¹⁷ Carrie Daniel, Amanda Cross, Corinna Koebnick & Rashmi Sinha, *Trends in Meat Consumption in the USA*, 14 *PUB. HEALTH NUTRITION* 575, 581 (2011).

¹⁸ NATIONAL CHICKEN COUNCIL, PER CAPITA CONSUMPTION OF POULTRY AND LIVESTOCK, 1960 TO FORECAST 2021, IN POUNDS, NATIONAL CHICKEN COUNCIL (2020), <https://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/> [<https://perma.cc/VC3C-JFKC>].

¹⁹ Chase Purdy, *The Average American Will Eat the Equivalent of 800 Hamburgers in 2018*, *QUARTZ* (Jan. 4, 2018), <https://qz.com/1171669/the-average-american-will-eat-the-equivalent-of-800-hamburgers-in-2018/> [<https://perma.cc/85JU-FVVE>]; see U.S. DEP’T AGRIC., ECON. RES. SERV., *FOOD AVAILABILITY AND CONSUMPTION* (2019), <https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/food-availability-and-consumption/> [<https://perma.cc/C7GX-NGBU>] (“While Americans are

meat are derived from living, sentient animals. Just in the United States, an estimated 25,000,000 chickens, 736,000 turkeys, and 800,000 cows raised for beef are slaughtered for food each day.²⁰ Replacing those burgers with plant-based alternatives could have significant benefits for animal, human, and planetary health.

The Good Food Institute's plant-based mind categorizes plant-based meats into four groups: first, products that are functionally equivalent to meat, such as textured vegetable protein (TVP); second, natural foods with textures similar to animal-based meat, such as mushrooms and Asian jackfruit; third, products such as seitan, tofu, or tempeh that have a similar texture to meat, but do not taste like meat; and finally, products such as chicken nuggets and burgers that replicate "the taste, appearance, and function" of meat.²¹ This paper focuses on the types of products in the last category. Over the past two decades, biochemists have been able to understand how amino acids, proteins, carbohydrates, lipids, and salt work together to create meat's unique flavor and texture.²² Using this science, food companies such as Beyond Meat and Impossible Foods are developing plant-based meat products that mimic the taste, texture, and appearance of animal products.²³

Plant-based meat producers are aiming to replicate the success of the plant-based (soy, almond, oat, cashew, and many others) milk sector, which is currently worth \$2 billion.²⁴ In comparison, the plant-based meat category, which includes burgers, nuggets, strips, cutlets, and sausage links, is worth \$939 million.²⁵

Development of these products responds to and continues to drive interest among Millennials and Generation Z, a significant percentage of whom consider themselves "flexitarians."²⁶ Eighty percent of Millennials eat meat alternatives, according to 2017

consuming more vegetables and fruit than in 1970, the average U.S. diet still falls short of the recommendations in the 2015-2020 Dietary Guidelines for Americans for these major food groups. Americans, on average, consumed more than the recommended amounts from the meat, eggs, and nuts group and the grains group in 2017.")

²⁰ Matthew Zampa, *How Many Animals Are Killed for Food Every Day?*, SENTIENT MEDIA (Sept. 16, 2018), <https://sentientmedia.org/how-many-animals-are-killed-for-food-every-day/> [<https://perma.cc/WQU2-WTEL>] (last updated Mar. 1, 2020).

²¹ ROWE, *supra* note 5, at 6. See CHRISTINE LAGALLY, ERIN CLAYTON & LIZ SPECHT, THE GOOD FOOD INST., PLANT-BASED MEAT MIND MAPS: AN EXPLORATION OF OPTIONS, IDEAS, AND INDUSTRY 3–5 (2017), <https://www.gfi.org/files/PBMap.pdf> [<https://perma.cc/U837-PPXS>].

²² ROWE, *supra* note 5, at 6.

²³ See Julia Horowitz, *Meatless Farm Breaks into Booming US Market with Whole Foods Deal*, CNN BUS. (June 24, 2019), <https://www.cnn.com/2019/06/24/business/meatless-farm-whole-foods/index.html> [<https://perma.cc/6J9T-LPBV>]. Meatless Farm is another business seeking to replicate the texture and appearance of meat.

²⁴ GOOD FOOD INSTITUTE, PLANT-BASED MARKET OVERVIEW 8 (2020), <https://www.gfi.org/market-research> [<https://perma.cc/7R3E-QGX5>].

²⁵ *Id.* at 4.

²⁶ Sarah Gallagher, *Anuga Report: Flexitarians Driving Plant-Based Innovations*, SPECIALTY FOOD NEWS (Oct. 9, 2017), <https://www.specialtyfood.com/news/article/plant-based-innovations-appeal-flexitari-an-market/> [<https://perma.cc/S89L-WK4U>]. There are also blended products which are meat products blended with plant-based protein. For example, Tyson Foods launched the Raised & Rooted brand which includes plant-based nuggets and blended burgers featuring a blend of pea protein and other plant ingredients. RAISED & ROOTED, <https://www.raisedandrooted.com/> [<https://perma.cc/CN25-QPCV>] (last visited July 12, 2020); see also The BETTER MEAT CO., <https://www.bettermeat.co/why-blend> [<https://perma.cc/W9RZ-XKAS>] (last visited July 12, 2020).

report from Mintel, a market research company.²⁷ Lux Research estimates that by 2054, non-animal-based sources of processed protein will account for a third of total protein consumption.²⁸ As of the end of 2018, over \$17 billion had been invested in the plant-based industry, with \$673 million pledged in 2018 alone, the same year that had a forty percent increase over the previous year in the number of investment deals.²⁹

Beyond Meat and Impossible Foods are the leading companies that have created ground beef analogs available in grocery stores and restaurants and are developing other animal product replacements. “In May, Beyond Meat had the best IPO³⁰ of 2019, surging more than 163 percent on the day of its market debut, in addition to partnering with fast food restaurants Carl’s Jr., Dunkin, Del Taco and TGI Friday’s.”³¹ Not to be outdone, “Impossible Foods products are now in about 10,000 restaurants — including White Castle, Red Robin and Burger King,” and recently became available in grocery stores across the country.³² Impossible Foods continues to innovate its production and views itself not as a burger company, but rather, as a tech platform company that intends “to produce a full range of meats and dairy products for every region in the world to completely replace the need for animals in the food system, full stop. This is not a fad, but a necessity.”³³

Cellular agriculture is also utilizing technology to create products such as cell-based meat (also referred to as “cultivated” meat)³⁴ to replace conventional meat, seafood, dairy, and eggs. In 2013, biochemist Mark Post of Maastricht University in the

²⁷ Patty Johnson, *What Consumers Really Think About Meat Alternatives*, MINTEL BLOG (Oct. 1, 2018), <https://www.mintel.com/blog/consumer-market-news/what-consumers-really-think-about-meat-alternatives> [<https://perma.cc/W5GE-VFTS>].

²⁸ Camilla Stice, *Whoopie: Plant Sources Are Changing the Protein Landscape*, LUX RESEARCH (Dec. 22, 2014), <https://members.luxresearchinc.com/research/report/16091> [<https://perma.cc/A3CD-RV2R>].

²⁹ BRIANNA CAMERON & SHANNON O’NEILL, GOOD FOOD INSTITUTE, STATE OF THE INDUSTRY REPORT: PLANT-BASED MEAT, EGGS, AND DAIRY 10, 17 (2019), <https://www.gfi.org/non-cms-pages/splash-sites/soi-reports/files/SOI-Report-Plant-Based.pdf> [<https://perma.cc/ZNM7-A8ZQ>].

³⁰ IPO refers to refers to the process of offering shares of a private corporation to the public in a new stock issuance. Adam Hayes, *Initial Public Offering (IPO)*, INVESTOPEDIA (July 29, 2019), <https://www.investopedia.com/terms/i/ipo.asp> [<https://perma.cc/7NYP-ZKHQ>] (last updated April 28, 2020).

³¹ Jade Scipioni, *Whole Foods CEO on Plant-Based Meat Boom: Good For the Environment But Not For Your Health*, CNBC (Aug. 21, 2019), <https://www.cnbc.com/2019/08/21/whole-foods-ceo-john-mackey-plant-based-meat-not-good-for-your-health.html> [<https://perma.cc/RPY2-QQ3L>] (footnote to IPO definition supplied); see also Amelia Lucas, *Beyond Meat Surges 163% in the Best IPO So Far in 2019*, CNBC (May 2, 2019), <https://www.cnbc.com/2019/05/02/beyond-meat-ipo.html> [<https://perma.cc/SJ3H-F4SC>].

³² Scipioni, *supra* note 31; see also David Yaffe-Bellany, *The Fish Is Boneless. (Fishless, Too.)*, N.Y. TIMES (July 10, 2019), <https://www.nytimes.com/2019/07/10/business/fake-fish-impossible-foods.html> [<https://perma.cc/7W4V-2AE8>].

³³ Alina Tugend, *Is the New Meat Any Better Than the Old Meat?*, N.Y. TIMES (Sept. 24, 2019), <https://www.nytimes.com/2019/09/21/climate/plant-based-meat.html> [<https://perma.cc/73UR-2AXN>] (quoting an e-mail from Patrick Brown, founder of Impossible Foods). Similarly, Meati is a company aiming to be “the first in market to produce whole cuts of plant-based meat in the form of steak and chicken breasts.” Joe Frassler, *A Startup Just Announced the World’s First Fake-Meat “Steaks” Made from Fungi. Are We Ready?*, NEW FOOD ECONOMY (Oct. 29, 2019), <https://newfoodeconomy.org/move-over-plant-based-meat-fungi-steaks-are-here/> [<https://perma.cc/KXX6-P3E4>].

³⁴ Bruce Friedrich, *Cultivated Meat: Why GFI Is Embracing New Language*, THE GOOD FOOD INSTITUTE (Sept. 13, 2019), <https://www.gfi.org/cultivatedmeat> [<https://perma.cc/7YSA-6PKZ>].

Netherlands introduced a proof-of-concept cell-based beef patty,³⁵ and since then, more than thirty-five companies have been developing cell-based food products for humans and pets.³⁶ Although cell-based will not be available in mainstream markets in the immediate future, other products made via acellular agriculture will be available soon. In July 2019, Perfect Day released limited quantities of its “frozen dairy dessert” made via acellular agriculture.³⁷ Acellular agriculture involves using cells or microbes, such as yeast or bacteria, to reproduce fats and proteins, a form of manufacturing that is around forty years old.³⁸ Insulin, which used to require the slaughter of pigs, is now mainly developed with yeast; rennet, which used to be gathered from calves’ stomachs, now involves using genetically engineered bacteria, fungi, or yeasts.³⁹ San Francisco-based Clara Foods plans to launch its egg white product created using this fermentation process by 2020.⁴⁰ Other novel products utilize “precision fermentation” to create protein from microorganisms without the use of genetic engineering.⁴¹ In June 2019, AT Kearney, a global management consulting firm, predicted that by 2040, plant-based and cell-based meat products would occupy respectively twenty-five and thirty-five percent of the global meat market.⁴² More aspirational investors and analysts predict that plant-based and cell-based companies could create a future food system that is (animal) meatless.⁴³

³⁵ See Isha Datar & Daan Luining, *Mark Post’s Cultured Beef*, NEW HARVEST (Nov. 3, 2015), https://www.new-harvest.org/mark_post_cultured_beef [https://perma.cc/8HQZ-WB2Z]; Neil Stephens, Alexandra Sexton & Clemens Driessen, *Making Sense of Making Meat: Key Moments in the First 20 Years of Tissue Engineering Muscle to Make Food*, 3 FRONTIERS IN SUSTAINABLE FOOD SYSTEMS 1, 4 (2019) for an overview of the origins of Mark Post’s burger.

³⁶ *Lab Grown Meat Companies*, CELL BASED TECH., <https://cellbasedtech.com/lab-grown-meat-companies> [https://perma.cc/FC7F-MVNT]. For example, Memphis Meats, Blue Nalu, Finless Foods, JUST, and Adolph Farm are companies creating these products.

³⁷ Elaine Watson, *Perfect Day Gives Fans First Taste of Animal-Free Dairy with Limited Edition Ice Cream Release*, FOOD NAVIGATOR-USA (July 11, 2019), <https://www.foodnavigator-usa.com/Article/2019/07/11/Perfect-Day-gives-fans-first-taste-of-animal-free-dairy-with-limited-edition-ice-cream-release#> [https://perma.cc/DRG5-FW3E]; see *How We Do It*, PERFECT DAY (2019), <https://www.perfectdayfoods.com/how-it-works/> [https://perma.cc/9MJ5-7S4C].

³⁸ *What is Cellular Agriculture?*, NEW HARVEST (Aug. 16, 2016), https://www.new-harvest.org/what_is_cellular_agriculture [https://perma.cc/NY97-2KVD].

³⁹ *Id.*

⁴⁰ Elaine Watson, *Clara Foods Completes Series B, Joins Forces with Ingredient to Commercialize Egg Proteins . . . Minus the Chicken*, FOOD NAVIGATOR-USA (April 25, 2019), <https://www.foodnavigator-usa.com/Article/2019/04/25/Clara-Foods-completes-Series-B-joins-forces-with-Ingredient-to-commercialize-chicken-less-egg-proteins> [https://perma.cc/X4BP-H6KJ].

⁴¹ RETHINKX, *supra* note 1, at 6.

⁴² DAVE DONNAN, CARSTEN GERHARDT, FABIO ZIEMEN, GERRIT SUHLMANN & MIRKO WARSCHUN, *HOW WILL CULTURED MEAT AND MEAT ALTERNATIVES DISRUPT THE AGRICULTURAL AND FOOD INDUSTRY?*, AT KEARNEY 3, 17 (2019), <http://media.enfasis.com/adjuntos/146/documentos/000/132/0000132740.pdf> [https://perma.cc/A46G-QA9S].

⁴³ Jade Scipioni, *Tyson Foods CEO: The Future of Food Might Be Meatless*, FOX BUS. (Mar. 7, 2017), <https://www.foxbusiness.com/features/tyson-foods-ceo-the-future-of-food-might-be-meatless> [https://perma.cc/7LF3-YMBB]; Richard Branson, *Clean Meat Is the Future of Meat*, VIRGIN (Feb. 13, 2018), <https://www.virgin.com/richard-branson/clean-meat-future-meat> [https://perma.cc/U7FA-SCN3].

III. COMMUNICATING HEALTHFULNESS

Plant-based meat producers simultaneously seek to communicate similarities between their products and conventional animal-derived meat,⁴⁴ while distinguishing themselves from conventional meat products through labeling and marketing claims. Shifting from diets based heavily on animal products to those that are primarily plant-based foods offers significant environmental, public health, and animal welfare benefits.⁴⁵ Doing so could reduce greenhouse gas (GHG) emissions, reduce health risks from contaminated meat, reduce antibiotic overuse, and improve human health outcomes from plant-based diets.⁴⁶ Food companies communicate about their products through a variety of labeling claims that can focus on positive attributes that are present in, or added to, the food, or on negative attributes that are absent, or removed, from it.⁴⁷ These attributes can be nutrients such as protein or fat, ingredients such as sugar or additives, or any other characteristic of the food that is perceived as either positive (e.g., “natural”) or negative (e.g., “processed”) from a health standpoint.⁴⁸ The following sections discuss the debate regarding the definition of “healthy” and evaluate how FDA should allow food producers to utilize the claim on their products to convey health for humans and the planet.

A. The “Healthy” Debate Overview

Among the narratives and mixed messages being circulated regarding plant-based meat alternatives, the question of “healthfulness” appears to be the most contentious. For example, a recent *New York Times* article addressed the question head-on: Is plant-based meat healthy?⁴⁹ The answer was ambivalent, as perhaps it should be:

It depends on what you’re eating. It is not typically as healthy as eating unprocessed vegetables and beans, and if it’s produced for fast-food outlets, it can be downright unhealthy. The plant-based Beyond Famous Star burger with cheese at Carl’s Jr.’s is 710 calories, 40 grams of fat and 30 grams of protein.⁵⁰ The Famous Star burger with cheese is 670

⁴⁴ A forthcoming article, Nicole E. Negowetti, *Censorship, Civil Disobedience, and the Discourse of Disruption: Toppling the “Milk” and “Meat” Monopolies* (forthcoming) explores the legal, regulatory, and cultural debates regarding use of the term “meat.” See also Steph Tai, *Legalizing the Meaning of Meat*, 51 LOY. U. CHI. L.J. 743 (2020).

⁴⁵ ROWE, *supra* note 5, at 38–39.

⁴⁶ *Id.*

⁴⁷ Quentin Andre, Pierre Chandon & Kelly Haws, *Healthy Through Presence or Absence, Nature or Science? A Framework for Understanding Front-of-Package Food Claims*, 38 J. PUB. POL’Y & MARKETING 172 (2019).

⁴⁸ *Id.* at 172, 175, 186 (finding that associations between healthiness and tastiness may depend on what people understand “healthy” to mean. If people think that “healthy” means that something has been removed from the food, even if it is something nutritionally bad, then it may explain why healthy food is predictive of worse taste.)

⁴⁹ Tugend, *supra* note 33.

⁵⁰ The current nutritional information for the Beyond Famous Star with Cheese burger indicates that the burger is 770 calories, 44 grams of fat, and 33 grams of protein. CARL’S JR., NUTRITION INFORMATION, <https://www.carlsjr.com/menu/> [<https://perma.cc/PZC2-96PG>] (follow “Nutritional Info” hyperlink to download a PDF of nutritional information for all products) (last accessed July 14, 2020).

calories, 37 grams of fat and 28 grams of protein.⁵¹ For those watching their salt intake, the Beyond Famous Star is worse, with 1,550 milligrams of salt compared with 1,210⁵² for its meat brethren.⁵³

Because plant-based meat products are all processed to mimic meat—with potentially added salt, sugar, and other ingredients—they are, by definition, a departure from the whole foods, plant-based diets recommended by certain doctors and nutritionists. Indeed, although processed plant-based meat products may contain more fiber, more protein, and less fat than their animal-based counterparts,⁵⁴ health profiles of some plant-based meats and dairy may be less nutritious than the analogs they mimic—a function not merely of their taste profile or nutrition content but their availability and positioning as convenient and delicious, if not decadent, “fast” food.⁵⁵

The debate regarding which foods should be “healthy” extends to other product categories beyond plant-based meat and has become an item on FDA’s agenda for food labeling modernization⁵⁶ because the claim continues to be one of the top drivers in food purchasing decisions.⁵⁷ As the above description illustrated, the issue of healthfulness of novel plant-based meats is particularly complicated because of a plant-based health “halo” that may lead consumers to overestimate the healthfulness of an item based on the “plant-based” claim. An overwhelming number of consumers, seventy-six percent according to Mintel’s 2018 report *Plant-Based Proteins in the U.S.*, identify plant-based proteins as “healthy” options.⁵⁸ The following section explains FDA’s oversight of and efforts to modernize “healthy” claims, identifies key issues in doing so, and discusses how the issues and controversies are amplified in the context of plant-based meats.

B. Existing “Healthy” Regulations and Calls for Modernization

The Nutrition Labeling and Education Act of 1990 (NLEA)⁵⁹ amended the Federal Food, Drug, and Cosmetic Act (FDCA) to, in part, give FDA the authority to regulate

⁵¹ It appears that the values for the Famous Star with Cheese have not changed. *Id.*

⁵² The current nutritional information indicates 1600 mg sodium for the Beyond Famous Star with Cheese and 1270 mg of sodium for the Famous Star with cheese. *Id.*

⁵³ Tugend, *supra* note 33 (internal footnotes to Carl’s Jr. nutritional information supplied).

⁵⁴ Emily Atkin, *The Promise and Problem of Fake Meat*, NEW REPUBLIC (June 7, 2019), <https://newrepublic.com/article/153998/promise-problem-fake-meat-beyond-burger-impossible-foods> [<https://perma.cc/ZPJ9-RGSP>].

⁵⁵ Bee Wilson, *The Trouble with Fake Meat*, GUARDIAN (Jan. 27, 2019), <https://www.theguardian.com/food/2019/jan/27/the-trouble-with-fake-meat-beetroot-burgers-food-substitutes> [<https://perma.cc/RJT3-JJC8>].

⁵⁶ U.S. FOOD & DRUG ADMIN., USE OF THE TERM HEALTHY ON FOOD LABELING (2018), <https://www.fda.gov/food/food-labeling-nutrition/use-term-healthy-food-labeling> [<https://perma.cc/4TT5-9YCZ>].

⁵⁷ INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION, 2016 FOOD & HEALTH SURVEY: CONSUMER ATTITUDES TOWARD FOOD SAFETY, NUTRITION & HEALTH, EXECUTIVE SUMMARY 6 (2016), https://foodinsight.org/wp-content/uploads/2016/05/2016_executivesummary_final_web.pdf [<https://perma.cc/PL27-NMS5>].

⁵⁸ Mintel Press Team, *Taste Is the Top Reason US Consumers Eat Plant-Based Proteins*, MINTEL PRESS OFFICE (Feb. 15, 2018), <https://www.mintel.com/press-centre/food-and-drink/taste-is-the-top-reason-us-consumers-eat-plant-based-proteins> [<https://perma.cc/X2AS-SS6J>].

⁵⁹ Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (Nov. 8, 1990).

the use of certain claims in the labeling of food: health claims,⁶⁰ nutrient content claims, and structure/function claims.⁶¹ Specifically, NLEA added section 403(r) to the FDCA. Section 403(r)(1)(A) of the FDCA provides that a food⁶² is misbranded if it bears claims, either express or implied, that characterize the level of a nutrient which is of a type required to be declared in labeling⁶³ (a “nutrient content claim”), unless such claim is made in accordance with section 403(r)(2) of the FDCA, which provides that such a claim may be made only if it has been defined by FDA by regulation.⁶⁴ As FDA has explained previously, one purpose of NLEA was to regulate the use of nutrient content claims that appear on food labels and labeling “in order to help consumers make appropriate dietary choices.”⁶⁵ In addition, as FDA noted in its rulemaking implementing NLEA, “section 403(r) of the [FDCA] itself, repeatedly uses the phrase ‘. . . will assist consumers in maintaining healthy dietary practices to describe the information for which provision is being made.’”⁶⁶

Although the term “healthy” is ubiquitous and “famously nebulous,”⁶⁷ 21 C.F.R. § 101.65(d) provides such regulatory definition for use of the term “healthy” or related terms (such as “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a food.⁶⁸ The “healthy” nutrient content claim can be used if the food meets certain nutrient conditions; and, when used with an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”), suggests that a food, because of its nutrient content, may be useful in creating a diet that is

⁶⁰ A food manufacturer may make an expressed or implied statement about relationship of a food substance to a disease or health-related condition for general U.S. population or subpopulation (e.g., women, elderly). General requirements are set forth in 21 C.F.R. § 101.14 (2019). FDA may allow a product to bear a health claim either (1) after extensive review of the scientific evidence submitted to FDA; (2) based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government with responsibility for public health protection or nutrition research; or (3) upon FDA exercising its enforcement discretion on an interim basis “where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. . . . [i]f FDA finds that the evidence supporting the proposed claim is credible and the claim can be qualified to prevent it from misleading consumers.” U.S. FOOD & DRUG ADMIN., LABEL CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (2018), <https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements> [<https://perma.cc/J7G6-6F2S>].

⁶¹ U.S. FOOD & DRUG ADMIN., *supra* note 60 (“Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, ‘calcium builds strong bones.’ In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, ‘fiber maintains bowel regularity,’ or ‘antioxidants maintain cell integrity.’”).

⁶² FDCA defines the term “food” to mean articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article. FDCA § 201(f), 21 U.S.C. § 321(f) (2020).

⁶³ FDCA defines “labeling” as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article. FDCA § 201(m), 21 U.S.C. § 321(m).

⁶⁴ FDCA §§ 402(r)(1)-(2), 21 U.S.C. §§ 343(r)(1)-(2).

⁶⁵ Final Rule Governing Food Labeling, Fed. Reg. 2302, 2375 (Jan. 6, 1993) (citing 136 Cong. Rec. 33,428 (1990)).

⁶⁶ *Id.* (citing FDCA §§ 403(r)(2)(A)(ii)(II), (r)(2)(A)(iii)(I)).

⁶⁷ Sam Bloch, *FDA Commissioner Scott Gottlieb Wants to Define “Healthy” and “Natural,”* NEW FOOD ECONOMY (Mar. 29, 2018), <https://newfoodeconomy.org/fda-scott-gottlieb-natural-clean-labels-national-food-policy-conference/> [<https://perma.cc/TZT9-YVTK>].

⁶⁸ 21 C.F.R. § 101.65(d)(2) (2019).

consistent with dietary recommendations.⁶⁹ The nutrient conditions for bearing a “healthy” nutrient content claim include specific criteria for nutrients to limit in the diet, such as total fat, saturated fat, cholesterol, sodium, as well as requirements for nutrients to encourage in the diet, including vitamin A, vitamin C, calcium, iron, protein, and fiber.⁷⁰ The criteria are linked to elements in the Nutrition Facts label and serving size regulations.⁷¹ The nutrient criteria to use the claim can vary for different food categories, such as fruits and vegetables, or seafood and game meat.⁷²

FDA has policed use of the claim and prior to 2016 issued Warning Letters for misbranding to food companies whose products were labeled and advertised as “healthy,” but failed to meet the requirements of 21 C.F.R. § 101.65(d).⁷³ For example, in a Warning Letter to Cytosport Inc., maker of Muscle Milk products, FDA alleged that products which were labeled “Healthy, Sustained Energy” in connection with the statements “Protein Nutrition Shake” and “25 g Protein” were misbranded.⁷⁴ In addition, FDA noted that the webpage⁷⁵ included the claim “healthy sustained energy.”⁷⁶ FDA found that the product’s fat and saturated fat content exceeds the three gram of fat per reference amounts customarily consumed (RACC) of food maximum in the “low fat” definition (21 C.F.R. § 101.62(b)(2)) and the one gram of saturated fat per RACC of food maximum in the “low saturated fat” definition (21 C.F.R.

⁶⁹ *Id.* §§ 101.65(d)(1), (d)(2)(i).

⁷⁰ *Id.*

⁷¹ *See* 21 C.F.R. §§ 101.9, 101.12.

⁷² *See* 21 C.F.R. § 101.65(d)(2).

⁷³ *See, e.g.*, U.S. FOOD & DRUG ADMIN., WARNING LETTER TO PREMIER ORGANICS INC. (Aug. 12, 2014), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/premier-organics-inc-431656-08122014> [<https://perma.cc/H29S-Q4RE>] (alleging that Artisana Coconut Butter Whole Coconut Flesh 16 oz. product is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product bears the claims “The Art of Healthy Foods” and “healthy . . . food . . .” in connection with the statement “preserves the life-essential fatty acids, enzymes, vitamins and minerals.”). However, as noted by FDA, “this product does not meet the requirements for use of the nutrient content claim ‘healthy’ that are set forth in 21 CFR 101.65(d)(2)” because it is not “low saturated fat” as defined in 21 C.F.R. § 101.62(c)(2). *Id.* FDA was satisfied that labeling changes had been made and issued a Closeout Letter. *See* U.S. FOOD & DRUG ADMIN., CLOSEOUT LETTER TO PREMIER ORGANICS INC. (Nov. 7, 2014), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/premier-organics-inc-close-out-letter-11714> [<https://perma.cc/89EB-RHA5>].

⁷⁴ U.S. FOOD & DRUG ADMIN., WARNING LETTER TO CYTOSPORT INC. (June 29, 2011), http://fda-warning-letters.blogspot.com/2011/06/department-of-health-and-human-services_29.html [<https://perma.cc/F4AP-KH8H>].

⁷⁵ The webpage referred to in the Warning Letter, <http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink>, no longer exists and redirects to muscle-milk.com, which does not currently display “healthy” claims (as of July 15, 2020). MUSCLE MILK, <https://www.muscle-milk.com/> (last visited July 15, 2020). However, the problematic language is archived in the Wayback Machine, and appears as late as September 2, 2011. WAYBACK MACHINE, *Cytosport.com on September 2, 2011*, <https://web.archive.org/web/20110902140724/http://www.cytosport.com:80/products/muscle-milk/muscle-milk-ready-to-drink> [<https://perma.cc/2APB-XSC7>] (last visited July 15, 2020). As of October 19, 2011, the “healthy” claims no longer appeared on the older website. WAYBACK MACHINE, *Cytosport.com on October 29, 2011*, <https://web.archive.org/web/20111019232219/http://www.cytosport.com/products/muscle-milk/muscle-milk-ready-to-drink> [<https://perma.cc/T3AN-Q7AJ>] (last visited July 15, 2020).

⁷⁶ U.S. FOOD & DRUG ADMIN., *supra* note 74.

§ 101.62(c)(2)), and therefore did not meet the requirements for the use of the nutrient content claim “healthy” on food labeling.⁷⁷

The debate regarding “healthy” claims began to receive increased public attention when, in March 2015, FDA issued a Warning Letter to KIND, LLC, makers of fruit and nut bars, notifying the company that its products were misbranded.⁷⁸ FDA reviewed the company’s website, which was included on product labels of several varieties of Kind Fruit & Nut bars products, and found that the products had an implied nutrient content claim because they bore statements suggesting that the product may be useful in maintaining healthy dietary practices, and those statements were made in connection with claims or statements about nutrients.⁷⁹ Specifically, the products were labeled “Healthy and tasty, convenient and wholesome.”⁸⁰ The website also stated, “There’s healthy. There’s tasty. Then there’s healthy and tasty” and “all of our snacks are pretty much the nirvana of healthful tastiness.”⁸¹ In addition, the webpage stated “KIND Peanut Butter Dark Chocolate + Protein is a healthy and satisfying blend of peanuts and antioxidant-rich dark chocolate.”⁸² Because the products exceed one gram of saturated fat per 40 gram RACC and exceed the maximum of fifteen percent of calories from saturated fat in the “low saturated fat” definition, they do not meet the requirements for use of the nutrient content claim “healthy” on a food label [21 C.F.R. 101.65(d)(2)] and were considered misbranded within the meaning of section 403(r)(1)(A) of the Act.⁸³ Ultimately, FDA informed KIND that it would not object to the use of the term “healthy” as part of its marketing philosophy and not the nutrient content claim,⁸⁴ and in April 2016, FDA issued a Closeout Letter indicating that KIND had “satisfactorily addressed the violations contained in the Warning Letter.”⁸⁵

Although its dispute with FDA was resolved, the Warning Letters spurred nearly a dozen class action lawsuits that were filed around the country and consolidated in a multidistrict litigation pending in the Southern District of New York.⁸⁶ The plaintiffs brought suit under state consumer protection laws and argued

⁷⁷ *Id.*

⁷⁸ FOOD & DRUG ADMIN., WARNING LETTER TO KIND, LLC (Mar. 17, 2015), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kind-llc-03172015> [<https://perma.cc/6GKT-UQHG>].

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ According to FDA press officer Lauren Kotwicki, “In our discussions with KIND, we understood the company’s position as wanting to use ‘healthy and tasty’ as part of its corporate philosophy, as opposed to using ‘healthy’ in the context of a nutrient content claim. FDA evaluates the label as a whole and has indicated that in this instance it does not object.” Robin Hilmantel, *FDA Decides to Let KIND Call Its Bars ‘Healthy’ Again*, TIME (May 10, 2016), <https://time.com/4324042/kind-bars-healthy-fda/> [<https://perma.cc/A2T8-DXRK>].

⁸⁵ U.S. FOOD & DRUG ADMIN., CLOSEOUT LETTER TO KIND LLC (April 20, 2016), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kind-llc-closeout-letter-42016> [<https://perma.cc/U26H-94SK>].

⁸⁶ *In re KIND LLC “Healthy and All Natural” Litig.*, 209 F. Supp. 3d 689 (S.D.N.Y. 2016); see August Horvath, Caroline Hudson & Yvonne McKenzie, *Food Litigation Trends: New and Undefined Label*

that KIND's use of the term "healthy" did not meet FDA's regulatory definition of the term, and was therefore misleading.⁸⁷ After FDA reversed its position regarding use of the term "healthy" on KIND product labels, the plaintiffs withdrew their claims related to "healthy."⁸⁸ However, litigation against the company also involved other challenges to their label, which are continuing in the courts.⁸⁹

While KIND was in discussions with the agency regarding use of "healthy" on its product labels and marketing, KIND filed a Citizen Petition in December 2015 challenging the set of criteria used to define eligibility for the "healthy" food claim on the basis that existing nutrient limits and requirements disqualified some foods that are currently recommended as key components of a healthful diet, and that outdated information regarding total fat content and cholesterol remained in effect as grounds for classification.⁹⁰ In the Petition, KIND argued that the "healthy" regulation was inconsistent with the 2015 Dietary Guidelines,⁹¹ which emphasized the importance of eating certain foods, not just nutrients, including vegetables, fruits, whole grains, legumes, and nuts and seeds.⁹²

Claims in 2017, FDLI UPDATE MAGAZINE (Nov./Dec. 2017), <https://www.fdpi.org/2017/12/food-litigation-trends-new-undefined-label-claims-2017/> [<https://perma.cc/R77Y-UV3W>].

⁸⁷ Horvath et al., *supra* note 86.

⁸⁸ *Id.*; see also *In re* KIND LLC "Healthy and All Natural" Litig., 209 F. Supp. 3d 689 (S.D.N.Y. 2016).

⁸⁹ Horvath et al., *supra* note 86. Consumer protection lawsuits were filed against KIND claiming their "non-GMO" and "natural" labeling is false and creating unjust enrichment. See, e.g., *In re* Kind LLC "Healthy and All Natural" Litig., 209 F. Supp. 3d at 691. As noted by Horvath, "[a]nother wave of recent litigation involving the term 'healthy' focuses on the use of added sugar in products advertised or marketed as healthy and nutritious." Horvath et al., *supra* note 86 (referring to *Hadley v. Kellogg Sales Co.*, 243 F. Supp. 3d 1074 (N.D. Cal. 2017) (dismissing the Complaint under Rule 9(b) based on the plaintiff's failure to plead how much added sugar the products contained and how much added sugar is "excessive" or unhealthy), *Krommenhock v. Post Foods, LLC*, 225 F. Supp. 938 (N.D. Cal. 2017) (denying a motion to dismiss, finding the pleading was sufficient to allege a viable claim), and *Truxel v. General Mills Sales, Inc.*, No. C 16-4957 JSW, 2019 WL 3940956 (N.D. Cal. Aug. 13, 2019) (dismissing the case without leave to amend)).

⁹⁰ Citizen Petition Letter from KIND LLC to Food & Drug Admin. (Dec. 1, 2015), <https://s3.amazonaws.com/kind-docs/citizen-petition.pdf> [<https://perma.cc/H28W-ZZJZ>]. In March 2019, KIND filed another Citizen Petition, requesting that FDA revise the requirements for all nutrient content claims by considering the overall quality of the food, rather than just the quantity of a certain nutrient when regulating nutritional claims on labeling. Citizen Petition Letter from KIND LLC to Food & Drug Admin. (Mar. 12, 2019), <https://s3.amazonaws.com/kind-docs/nutrient-content-claim-citizen-petition.pdf> [<https://perma.cc/DCK3-R2XQ>] [hereinafter 2019 KIND Citizen Petition]. KIND argued that "[a]s currently structured, FDA's nutrient content claim regulatory framework allows the use of claims based solely on the quantity of particular nutrients, without any consideration for the quality of the food bearing the claim; this does not assist consumers in making dietary choices consistent with current recommendations and science, and encourages the widespread fortification of foods that are not good dietary choices." *Id.* The Petition requests that FDA revise its nutrient content claim by requiring that foods can utilize a nutrient content claim "highlighting the presence or absence of a nutrient" only "if the food contains a meaningful amount of at least one health-promoting food, such as: vegetables, fruits (especially whole fruits), whole grains, legumes, nuts, and seeds, which are recommended in the most recent Dietary Guidelines of Americans." *Id.*

⁹¹ U.S. DEP'T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS 2015-2020 (2015), <https://health.gov/dietaryguidelines/2015/guidelines/> [<https://perma.cc/J39P-XP94>].

⁹² 2019 KIND Citizen Petition, *supra* note 90, at 1; see also Press Release, KIND, FDA Reverses Stance, Affirms Kind Can Use "Healthy" On Its Labels (May 10, 2016), <https://www.kindsnacks.com/media-center/press-releases/fda-reverses-stance.html> [<https://perma.cc/97DV-3GL5>] ("The current regulatory definition of healthy is inconsistent with federal guidelines and scientific research, as today we know it's advisable to prioritize eating whole foods, including nuts, plants, whole grains and seafood," said

In September 2016, FDA issued a Guidance Document on “healthy” claims and indicated that it would take enforcement discretion toward products with disqualifying amounts of total fat if the majority of total fat is unsaturated and toward products with at least ten percent of the Daily Value (DV) of non-qualifying nutrients vitamin D or potassium.⁹³ FDA explained its approach to healthy foods as those which can contribute to “healthy dietary practices.”⁹⁴ This vision was repeated in the preamble to the final rule for the “healthy” claim which stated, “The agency finds, therefore, that the fundamental purpose of a ‘healthy’ claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines.”⁹⁵

As one lawyer opined, “FDA’s conclusion that KIND’s use of ‘healthy and tasty’ to describe its corporate philosophy was not a nutrient content claim confirms that certain uses of ‘healthy,’ and other similar terms, are outside the scope of the FDA’s nutrient content claim regulations altogether.”⁹⁶ Those other uses include to provide dietary guidance or, as KIND did, to describe a corporate philosophy.⁹⁷ Nevertheless, labeling statements must still be truthful and non-misleading.⁹⁸ “[T]he FDA may still issue warning letters or take other enforcement action regarding ‘healthy’ claims that are not covered by the ‘healthy’ guidance and do not otherwise comply with the FDA’s regulations”⁹⁹ and these warning letters can inspire consumer protection litigation if use of the terms was misleading.

David L. Katz, MD, MPH, FACPM, FACP, Director of the Yale University Prevention Research Center, who has served as a nutrition adviser to KIND.”). Dr. Walter Willett, a professor of epidemiology and nutrition at the Harvard T.H. Chan School of Public Health, signed KIND’s Citizen Petition from 2015 because he regards the “healthy” regulation as outdated. Hilmantel, *supra* note 84. “These are from an era when all fats were regarded as bad and thus all carbohydrates were regarded as good. Thus, many foods loaded with refined starch and sugar have been allowed to be labelled as ‘healthy.’ The FDA needs to review their rules in light of current evidence, and hopefully this will be a nudge in the right direction.” *Id.*

⁹³ U.S. FOOD & DRUG ADMIN., USE OF THE TERM “HEALTHY” IN THE LABELING OF HUMAN FOOD PRODUCTS: GUIDANCE FOR INDUSTRY 5 (2016) <https://www.fda.gov/media/100520/download> [<https://perma.cc/DP5K-NZHW>].

⁹⁴ Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 58 Fed. Reg. 2944, 2946 (Jan. 6, 1993).

⁹⁵ Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 Fed. Reg. 24232, 24233 (May 10, 1994).

⁹⁶ Jessica O’Connell, Miriam Guggenheim & Jeannie Perron, *What to Know About FDA’s New ‘Healthy’ Guidance*, LAW360 (Oct. 17, 2016), <https://www.law360.com/articles/851871/what-to-know-about-fda-s-new-healthy-guidance> [<https://perma.cc/RLB8-A77R>].

⁹⁷ *Id.*

⁹⁸ *Id.* Misleading or deceptive use of “healthy” statements will likely subject a company to litigation. See Sam Bloch, *Kellogg Agrees to Stop Marketing Sugary Cereals as “Healthy”*, NEW FOOD ECONOMY (Oct. 24, 2019), <https://newfoodeconomy.org/kellogg-sugary-cereal-healthy-label/> [<https://perma.cc/17F2-9SYJ>] (stating that the Kellogg Company “entered into a settlement agreement with a class of five plaintiffs in California and New York, who alleged Kellogg used deceptive health and wellness claims to market high-sugar cereals and breakfast bars. . . . Under the settlement . . . the company can no longer advertise certain products, where added sugars represent at least 10 percent of calories, as ‘healthy.’ Nor can it promote them with phrases like ‘start with a healthy spoonful’ or ‘invest in your health.’ The company can use the word . . . only in connection with a claim about a specific nutrient. Nor will they be marketed as ‘wholesome,’ ‘nutritious,’ or ‘beneficial.’ Those terms can be used to describe only a specific nutrient or ingredient—in a phrase like ‘contains nutritious whole grain wheat.’”).

⁹⁹ O’Connell et al., *supra* note 96. FDA has continued to issue warning letters citing violations of its “healthy” nutrient content claim regulations even after acknowledging the need to reevaluate those regulations. See, e.g., U.S. FOOD & DRUG ADMIN., WARNING LETTER TO MIDDLEFIELD ORIGINAL CHEESE

In late 2016, FDA opened a comment period on regulation of the term “healthy” which extended until April 2017, and in 2017, FDA hosted a public meeting to discuss the issues related to revising the regulation.¹⁰⁰ Themes from the public meeting on “healthy” claims demonstrated the difficulty of developing a definition for the term.¹⁰¹ Key points, as summarized by FDA, included:

- Foods are healthy only within the context of a healthy dietary pattern. Overconsumption of any food regardless of the food components or nutrients can be unhealthy; however, . . . the level of an individual nutrient that is healthy for one individual is also affected by other factors.
- One’s understanding of which foods are healthy may depend on his or her health goals. For example, someone trying to lose weight may think of healthy differently than someone wanting to build muscle.
- Consumers’ perceptions of what “healthy” means can be influenced by their background, values, culture, family, education, generation, and other personal factors.
- Consumers do not necessarily think of foods as healthy or in absolute terms. They may think of a food as healthy relative to other options in that food group. For example, opting for zero calorie soda may be a better choice compared to regular soda.¹⁰²

Other key themes included the potential breadth of the term “healthy” which makes it subject to wide interpretation.¹⁰³ Participants of the FDA meeting emphasized that “devising a universal, one-size-fits-all definition of ‘healthy’ could prove challenging because health, and one’s perception of what that means, is subjective.”¹⁰⁴ One person’s conception of what constitutes a “healthy” food may vary considerably from those of others, and current nutrition science may not even inform those differing understandings.¹⁰⁵

It was also discussed that “[c]onsumers can sometimes merge ‘healthy’ with other product claims such as ‘organic,’ ‘non-GMO,’ ‘gluten free,’ and ‘hormone free.’ Some people perceive foods with these attributes as healthy, though this assertion is not based on nutritional make-up of the food.”¹⁰⁶

CO-OP (Aug. 29, 2016), <http://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm518515.htm> [<https://perma.cc/UXL7-4FS6>]; U.S. FOOD & DRUG ADMIN., WARNING LETTER TO CV. ARIRA PANGINDO (Jan. 27, 2016), <http://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm484873.htm> [<https://perma.cc/7MUW-EQH9>].

¹⁰⁰ U.S. FOOD & DRUG ADMIN., SUMMARY OF THEMES HEARD FROM STAKEHOLDERS DURING BREAKOUT SESSIONS AT THE PUBLIC MEETING ON USE OF THE TERM “HEALTHY” IN THE LABELING OF HUMAN FOOD PRODUCTS (2017), <https://www.fda.gov/media/104527/download> [<https://perma.cc/V4YV-59CP>].

¹⁰¹ *Id.*

¹⁰² *Id.* at 2.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

To revise the “healthy” definition, participants of the public meeting seemed to favor one that incorporated both “nutrient-based and food component-based criteria.”¹⁰⁷ Doing so would better align the definition with the Dietary Guidelines for Americans and would allow nutrient-dense foods, such as avocados and nuts, which do not qualify as “healthy” under the current regulatory definition, to utilize the term.¹⁰⁸ The approach would also help promote healthy diets that include more fruits and vegetables and less processed food.¹⁰⁹ For example, in written comments, the American Heart Association (AHA) supported the adoption of a hybrid approach that includes both food group-based and nutrient-based criteria.¹¹⁰ In particular, AHA recommended limiting the claim to nutrient-dense foods such as vegetables, fruits, whole grains, low-fat and non-fat dairy products, lean and extra-lean meats, poultry, fish, legumes, non-tropical (not coconut or palm kernel oil) vegetable oils, and nuts and seeds, or the Dietary Guidelines for Americans, provided that they also meet nutrient criteria.¹¹¹

The Institute for Food Technologists (IFT) also recommended a hybrid approach for use of the term “healthy,” which would combine nutrient limits and a descriptive statement about how the food helps achieve dietary recommendations.¹¹² IFT suggested that “[f]oods which exceed recommended limits for sodium, added sugars, and saturated fat should be excluded from labeling as ‘healthy.’”¹¹³ IFT proposed that “[a] descriptive statement should be used on food and beverage products bearing the term “healthy” to indicate their contribution to overall healthy dietary patterns. For example, potential labeling statements for such products might include: “Provides 1 serving of whole grains, part of a healthy eating pattern,” or “Contributes to a healthy eating pattern, provides 1 serving of whole grains.”¹¹⁴

IFT argued that “[t]he definition for a ‘healthy’ food should align with the three healthy eating patterns recommended by the 2015-2020 DGA,”¹¹⁵ and that a failure to promote consistency in consumer-facing messaging across different federal programs, including the National School Lunch Program and the Supplemental Nutrition Assistance Program, about the definition of “healthy” could contribute to consumer confusion and inaction.¹¹⁶ Other groups, such as the Union of Concerned Scientists, also recommended a whole foods approach to defining “healthy” and recommended that a category of foods be excluded—processed and red meats, on the basis of its

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ Comment Letter from Am. Heart Ass’n to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for “Use of the Term ‘Healthy’ in the Labeling of Human Food Products; Request for Information and Comments” 2, 16 (April 26, 2017).

¹¹¹ *Id.* at 3, 5.

¹¹² Comment Letter from Institute of Food Technologists to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for “Use of the Term ‘Healthy’ in the Labeling of Human Food Products; Request for Information and Comments” 2 (Apr. 26, 2017), <https://www.regulations.gov/document?D=FDA-2016-D-2335-1112> [<https://perma.cc/K8N4-SSHL>].

¹¹³ *Id.* at 1–2.

¹¹⁴ *Id.* at 2.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

classification of processed meat by the World Health Organization International Agency for Research on Cancer as carcinogenic to humans and red meat as probably carcinogenic to humans.¹¹⁷

In a 2018 statement regarding FDA's Nutrition Innovation Strategy, then-Commissioner Scott Gottlieb acknowledged that although consumers are increasingly seeking healthier options, FDA "rules didn't always allow disclosure of these features in a consistent format that let consumers easily access this information or that made it easy for food manufacturers to compete to offer these options," including information to help consumers "assemble smart diets."¹¹⁸ Echoing KIND's critiques of the regulation, Gottlieb explained that:

People don't eat nutrients. They eat foods. And foods need to be assembled into diets that give people proper nutrition. That's why having modern, science-based definitions around terms like "healthy," when used on food labels, and giving careful consideration to how foods carrying these labels can be part of good diets, can help consumers make more informed decisions about their meals.¹¹⁹

As Dr. Marion Nestle, professor of nutrition, food studies, and public health, put it, "Health claims are not about health; they are about marketing."¹²⁰ For KIND, being able to label their products healthy further appealed to their targeted audience—those seeking healthy snacks. But a healthy claim may be disadvantageous for some plant-based meat producers. For example, the failure of McDonald's healthy version of the hamburger, the McLean Deluxe "was a sharp lesson to the industry, even if in some ways it merely confirmed what generations of parents have well known: if you want to turn off otherwise eager eaters to a dish, tell them it's good for them."¹²¹ Studies suggest that food choices are not influenced by calorie information on menus, and that

¹¹⁷ Comment Letter from Union of Concerned Scientists to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for "Use of the Term 'Healthy' in the Labeling of Human Food Products; Request for Information and Comments" 2-3 (May 5, 2017), <https://www.regulations.gov/document?D=FDA-2016-D-2335-1098> [<https://perma.cc/Q258-L3XT>]. The UCS states that "It is the recommendation of UCS that 21 CFR § 101.65(d) regulations establish minimum quantities or proportions of health-promoting foods, including vegetables, fruits, whole grains, and/or dairy, that a food item must contain to bear the 'healthy' claim." *Id.* at 4.

¹¹⁸ U.S. FOOD & DRUG ADMIN., STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON FDA'S NEW STEPS TO ADVANCE HEALTH THROUGH IMPROVEMENTS IN NUTRITION UNDER THE AGENCY'S NUTRITION INNOVATION STRATEGY (June 26, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-new-steps-advance-health-through-improvements> [<https://perma.cc/RGV8-9JFR>].

¹¹⁹ *Id.*

¹²⁰ Elaine Watson, *KIND Petitions FDA to Update 'Outdated' Food Labeling Rules*, FOOD NAVIGATOR-USA (Dec. 1, 2015), <https://www.foodnavigator-usa.com/Article/2015/12/01/KIND-petitions-FDA-over-healthy-nutrient-content-claim> [<https://perma.cc/3ZW9-FXL3>].

¹²¹ David H. Freedman, *How Junk Food Can End Obesity*, ATLANTIC (July/Aug. 2013), <https://www.theatlantic.com/magazine/archive/2013/07/how-junk-food-can-end-obesity/309396/> [<https://perma.cc/9QJ2-KVWP>]. When McDonald's began offering healthier menu items more recently, it did not make any health claims. *Id.* ("We're just saying it's new, it tastes great, come on in and enjoy it. Maybe once the product is well seated with customers, we'll change that message. If customers learn that they can eat healthier foods at McDonald's without even realizing it," he added, "they'll be more likely to try healthier foods there than at other restaurants") (quoting Greg Watson).

eaters who are not health-conscious may actually use calorie counts to avoid low-calorie food, perhaps because they assume such foods are worse-tasting and less filling, and a worse value.¹²² As a result of these findings, food companies aiming to sell healthier versions of their foods to the mainstream, rather than just to a small population already seeking for health foods, may have to do so in a covert way by emphasizing taste, not health benefits.¹²³ Perhaps this is the path to success and widespread acceptance of plant-based meat. According to Oxford University neuroscientist Charles Spence, “People expect something to taste worse if they believe it’s healthy. . . . And that expectation affects how it tastes to them, so it actually *does* taste worse.”¹²⁴

For plant-based producers who want to tout their products’ health benefits, the question is how to communicate those attributes, given FDA’s struggles to modernize the term “healthy.” This might not be a complicated question for producers of a whole-foods based plant-based burger, such as one made of beans and sweet potatoes. The challenge, however, is particularly acute for those plant-based meats that are intended to so closely resemble their conventional counterparts that their nutritional composition is closely, but perhaps not exactly, analogous. To illustrate, “while Beyond Meat and Impossible Foods burger patties are lower in total and saturated fat than a beef burger patty and contain zero cholesterol (they are similar in calories and protein), they are also both higher in sodium” than an animal-based burger.¹²⁵ Given the current status of “healthy” as a nutrient content claim, the plant-based burgers would not qualify for the claim and “[w]ithout further studies, there is no evidence to substantiate that these nutrient differences alone offer a significant health benefit.”¹²⁶

It must be recognized that because of marketing and success, attention has been focused on the two leading companies and their products, Beyond Meat and Impossible Foods, and in much of the conversations, their products stand in as representative of the alternative protein sector. However, there are start-up companies developing products that claim to be nutritionally superior to the burger replacements that currently mimic meat.¹²⁷ One example is the company Prime Roots, which is developing a fungi protein they refer to as a “superprotein” because it is a complete source of protein as well as micronutrients that are often lacking in plant-based proteins such as B-Vitamins.¹²⁸ Companies are already showing increased interest in a wider variety of plant sources, as well as legumes, fungi, grains, and seeds, for their products.¹²⁹ Roquette and ADM are investing in a study on peas for use in plant-based

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ Frank Hu, Brett Otis & Gina McCarthy, *Can Plant-Based Meat Alternatives Be Part of a Healthy and Sustainable Diet?*, 322 JAMA 1547, 1547 (Aug. 26, 2019).

¹²⁶ *Id.*

¹²⁷ I am excluding from comparison earlier generations of “veggie” burgers created with actual plant-based ingredients that were primarily marketed to vegetarians and were not intended to mimic meat.

¹²⁸ *FAQ*, PRIME ROOTS, <https://www.primeroots.com/pages/faq> [https://perma.cc/HY6C-JTDH].

¹²⁹ Jeff Gelski, *Plant Protein Options for Meat Alternatives*, FOOD BUSINESS NEWS (Mar. 30, 2018), <https://www.foodbusinessnews.net/articles/11501-plant-protein-options-for-meat-alternatives> [https://perma.cc/CT7E-BB6Q].

meat and dairy,¹³⁰ and ADM is opening a legume-processing plant in North Dakota to produce pea protein.¹³¹ Celeste Holz Schietinger, director of research at Impossible Foods, has publicly discussed the textural possibilities of the protein RuBisCo, “which is found in leaves, making it the most abundant protein source on the planet.”¹³² Students of Peggy Lemaux, a cooperative extension specialist in the department of plant and microbial biology at UC Berkeley, are researching “ancient grains” such as sorghum and millet;¹³³ duckweed (Lemna),¹³⁴ Lupin,¹³⁵ flaxseed, hemp,¹³⁶ and various nuts are also being explored for their potential to expand the varieties of non-animal-based meat products.¹³⁷ Thus, a new generation of plant-based meats may mimic meat while having the nutritional benefits of plants. These products may also fit within a nutrient-based definition of “healthy.”

C. Impact of “Processing” on Healthfulness

Although FDA’s “healthy” regulation focuses on nutrient content of foods and makes no mention of “processing,” the popular debate regarding the healthfulness of plant-based proteins meant to mimic meat (in contrast to tofu, tempeh, seitan, and other less high-tech plant-based proteins), the issue of “processing” dominates the discussion. The long list of ingredients in Beyond Burger and Impossible Burger is frequently cited as proof the products are not healthy.¹³⁸ Debates about these “processed” foods have created confusion about the various attributes of these products. On one hand, plant-based meats are benefiting from the halo of plant-based foods as nutritionally, environmentally, ethically superior. A recent consumer survey showed that while taste tops the list of reasons to eat plant-based proteins, perceived health benefits are on consumers’ minds, “as nearly half (46 percent) of Americans agree that plant-based proteins are better for you than animal-based options, and three

¹³⁰ Niamh Michail, *Roquette Looks to Plant Milk Category for Future Pea Potential*, FOOD NAVIGATOR (Jan. 4, 2019), <https://www.foodnavigator.com/Article/2019/01/04/Roquette-looks-to-plant-milk-category-for-future-pea-potential> [https://perma.cc/3C66-YWK9]; Rod Nickel & P. J. Huffstutter, *Big Ag Turns to Peas to Meet Soaring Global Protein Demand*, REUTERS (May 18, 2018), <https://www.reuters.com/article/us-crops-protein/big-ag-turns-to-peas-to-meet-soaring-global-protein-demand-idUSKCN1I1B3> [https://perma.cc/AB5B-JQWC].

¹³¹ Nickel & Huffstutter, *supra* note 130.

¹³² Rowe, *supra* note 5, at 11 (citing Fred van de Velde, Arno Alting & Laurice Pouvreau, *From Waste Product to Food Ingredient: The Extraction of Abundant Plant Protein RuBisCo*, NEW FOOD MAGAZINE (May 13, 2011), <https://www.newfoodmagazine.com/article/4461/from-waste-product-to-food-ingredient-the-extraction-of-abundant-plant-protein-rubisco/> [https://perma.cc/RV3U-M4DR]).

¹³³ Rowe, *supra* note 5, at 11.

¹³⁴ Adi Menayang, *Duckweed: A Promising New Source of Plant-Based Protein?*, FOOD NAVIGATOR (Sept. 1, 2016), <https://www.foodnavigator-usa.com/Article/2016/09/01/New-study-looks-at-duckweed-protein-nutritional-value-to-humans> [https://perma.cc/3VCX-M5FF].

¹³⁵ *There’s a New Dairy Free Ingredient in Town: Lupin*, PLANT BASED NEWS (Nov. 17, 2017), <https://www.plantbasednews.org/lifestyle/new-plant-based-milk-made-lupin> [https://perma.cc/8SBC-JRTT].

¹³⁶ Niamh Michail, *Innova Sees Plant-based Promise in Lupin, Hemp, and Flax Seed*, FOOD NAVIGATOR (July 13, 2018), <https://www.foodnavigator.com/Article/2018/07/13/Innova-sees-plant-based-promise-in-lupin-hemp-and-flax-seed> [https://perma.cc/HVJ9-PDV3].

¹³⁷ Rowe, *supra* note 5, at 11.

¹³⁸ Kelsey Piper, *Meatless Meat Is Becoming Mainstream—and It’s Sparking a Backlash*, VOX (Oct. 7, 2019), <https://www.vox.com/future-perfect/2019/10/7/20880318/meatless-meat-mainstream-backlash-impossible-burger> [https://perma.cc/RA6M-H98E].

quarters (76 percent) say plant-based foods are healthy.”¹³⁹ However, the counter-narrative is that these products are no better than other unhealthy, processed foods and less beneficial than humanely raised meat.

To prove this point, in August 2019, the Center for Consumer Freedom (CCF), a nonprofit that lobbies on behalf of the fast-food, meat, alcohol, and tobacco industries, placed advertisements in the *Wall Street Journal* and *New York Post* highlighting many of the ingredients in fake bacon and fake sausage, pointing out that many of the plant-based meat options are highly processed and suggesting this is contrary to what may be perceived of as “healthy.”¹⁴⁰ In addition to the advertisements, the group has launched a website “to provide the public with a tool to compare the ingredients found in fake meat side-by-side with real meat.”¹⁴¹ The ads and website set out to demonstrate that plant-based meats are unhealthy¹⁴² as part of an offensive attack against the plant-based meat industry.¹⁴³

The messaging regarding “unhealthfulness” of processed plant-based meats has not been limited to meat industry advocacy groups. In a *JAMA* opinion article, Harvard T.H. Chan School of Public Health Professor Frank Hu and colleagues cautioned against directly extrapolating the potential benefits found in previous research on plant-based foods and dietary patterns to plant-based meat alternatives, “given their highly processed nature.”¹⁴⁴ There was also much controversy around comments by John Mackey, CEO of Whole Foods, the natural-foods retailer which first stocked and helped launch Beyond Meat.¹⁴⁵ He referred to plant-based burgers as “super, highly processed foods.”¹⁴⁶ Additionally, when asked whether Chipotle would serve these alternative meats, CEO Brian Niccol said, “unfortunately it wouldn’t fit in our ‘food with integrity’ principles because of the processing.”¹⁴⁷

¹³⁹ Mintel Press Team, *supra* note 58.

¹⁴⁰ Ctr. for Consumer Freedom Team, *Ad: Fake Meat Grows in Factories, Not on Vines*, CTR. FOR CONSUMER FREEDOM (Aug. 13, 2019), <https://www.consumerfreedom.com/2019/08/ad-fake-meat-grows-in-factories-not-on-vines/> [<https://perma.cc/WY9M-P77K>]; *see also* the companion website, CLEAN FOOD FACTS, <https://wellness.consumerfreedom.com/> [<https://perma.cc/9C77-PLA7>] (redirected from CleanFoodFacts.com).

¹⁴¹ Ctr. for Consumer Freedom Team, *supra* note 140; *see also* CLEAN FOOD FACTS, *supra* note 140.

¹⁴² Ctr. for Consumer Freedom Team, *supra* note 140; *see also* CLEAN FOOD FACTS, *supra* note 140; Elaine Watson, *Impossible Whopper a ‘Huge Hit’ Says Burger King, Beyond Meat Raises Forecasts, as Brands Hit Back at Ads Attacking ‘Ultra-Processed’ Plant-Based Burgers*, FOOD NAVIGATOR-USA (OCT. 28, 2019), <https://www.foodnavigator-usa.com/Article/2019/10/29/Impossible-Whopper-a-huge-hit-says-Burger-King-as-brand-hits-back-at-ads-attacking-ultra-processed-plant-based-meat> [<https://perma.cc/46GX-PD3E>].

¹⁴³ Jacob Bunge & Heather Haddon, *America’s Cattle Ranchers Are Fighting Back Against Fake Meat*, WALL ST. J. (Nov. 27, 2019), https://www.wsj.com/articles/americas-cattle-ranchers-are-fighting-back-against-fake-meat-11574850603?mod=hp_lead_pos5 [<https://perma.cc/FM5L-LJ5J>]. According to Richard Berman, CCF’s executive director, the nonprofit also plans to publicize the findings of food-science labs that it hired to study the potential health risks associated with meat alternatives. “I’m on offense,” Berman says. *Id.*

¹⁴⁴ Hu et al., *supra* note 125, at 1547.

¹⁴⁵ Jon Schumacher, *How Whole Foods CEO John Mackey Is Leading a Revolution in Health and Business*, ENTREPRENEUR (Jan. 3, 2019), <https://www.entrepreneur.com/article/325128> [<https://perma.cc/4ZPT-M9LS>].

¹⁴⁶ Piper, *supra* note 138.

¹⁴⁷ *Id.*; *see also* Scipioni, *supra* note 43; Janelle Bitker, *Four Ethical Questions About Plant-Based ‘Meat’*, S.F. CHRON. (Oct. 2, 2019), <https://www.sfchronicle.com/food/article/Four-ethical->

As one commentator questioning the meaning of “processed” observed, “the term can refer to any food that has been modified—to preserve it, to enhance its flavor, to add nutrients, or to make plant proteins taste like a hamburger. . . . [T]hat word—‘processed’—can obscure more than it clarifies.”¹⁴⁸ The FDCA defines “processed food” as “any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.”¹⁴⁹ According to the Institute of Food Technologists, processing is “one or more of a range of operations, including washing, grinding, mixing, cooling, storing, heating, freezing, filtering, fermenting, extracting, extruding, centrifuging, frying, drying, concentrating, pressurizing, irradiating, microwaving, and packaging.”¹⁵⁰ Put another way, it is “the alteration of foods from the state in which they are harvested or raised to better preserve them and feed consumers.”¹⁵¹ It can also include pasteurization and fortification.¹⁵² The debate regarding the impacts of “processing” on the healthfulness of food reflects the difficulty FDA faces in defining “healthy.” “Nutrition scientists, food scientists, food manufacturers, and health professionals are having difficulty communicating among themselves and to consumers about the role of processed foods in nutrition and health” due to the use of different definitions, varying perceptions of the groups, and differences in professional and academic training.¹⁵³ For example, an eater who “desires a diet that is low in pesticides, hormones, and additives may describe it as one that does not contain “processed” foods, but a food scientist interprets this request as a desire to omit all foods that are heat-treated, frozen, or otherwise transformed during manufacture.”¹⁵⁴ A nutritionist is interested in processed foods from the perspective of the foods’ nutrient contribution to the diet.¹⁵⁵ Thus, all three may misunderstand each other and aim for different outcomes.¹⁵⁶

As explained by Ruth MacDonald, a nutrition scientist at Iowa State University, the “idea that we can classify food as being good or bad based on its degree of

questions-about-plant-based-14486312.php#photo-18357150 [https://perma.cc/65LF-36MV] (quoting Alameda, CA restaurant Scolari’s Good Eats announcement it would no longer sell Impossible Burger this summer, swapping it on the menu for a falafel burger because “While we know many of our patrons enjoy this form of meat, we have decided this due to it being highly processed, we believe in real food made from raw quality ingredients by hand without toxic GMOs, unknown ingredients and fillers.”).

¹⁴⁸ Piper, *supra* note 138.

¹⁴⁹ 21 U.S.C. § 321(gg).

¹⁵⁰ John D. Floros, Rosetta Newsome, William, Gustavo Barbosa-Canovas, Hongda Chen, C. Dunne, J. German, Richard Hall, Dennis Heldman, Mukund Karwe, Stephen Knabel, Theodore Labuza, Daryl Lund, Martina Newell-McGloughlin, James Robinson, Joseph Sebranek, Robert Shewfelt, William Tracy, Connie Weaver & Gregory Ziegler, *Feeding the World Today and Tomorrow: The Importance of Food Science and Technology, An IFT Scientific Review*, 9 COMPREHENSIVE REV. FOOD SCI. FOOD SAFETY 572, 579 (2010).

¹⁵¹ Connie M. Weaver, Johanna Dwyer, Victor Fulgoni, Janet King, Gilbert Leveille, Ruth MacDonald, Jose Odovas & David Schnakenberg, *Processed Foods: Contributions to Nutrition*, 99 AM. J. CLINICAL NUTRITION 1525, 1525 (2014).

¹⁵² See, e.g., *id.* at 1529, 1532; Piper, *supra* note 138.

¹⁵³ Weaver et al., *supra* note 151, at 1525, 1534–35.

¹⁵⁴ *Id.* at 1535.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

processing . . . makes no sense from a nutritional perspective” or “from a food science perspective either.”¹⁵⁷ In accord with this view, the American Frozen Food Institute supports a definition of “healthy” that is “based on nutrient content and the food’s role in a healthy diet” and does not include “extraneous factors like processing, the presence of ingredients derived from plants that were genetically engineered, or sustainability.”¹⁵⁸ This position obviously stems from concern that processing, defined to include the use of biotechnology, would preclude eligibility for a “healthy” claim. FDA’s longstanding position, announced in its 1992 policy statement and reaffirmed in 2015 final guidance to industry on voluntary claims regarding whether a food is derived from a genetically engineered plant, is that foods developed from biotechnology do not differ from their traditional counterparts “in any meaningful or uniform way”¹⁵⁹ and that biotechnology does “not change the essential nature of the plant.”¹⁶⁰ The question of how processing, defined more broadly, does affect food in a “meaningful way” is being explored by health researchers.

Recognizing that almost all foods are processed to some extent, if only by preservation, and it is therefore unhelpful to criticize foods as being “processed,” food classifications have been devised that distinguish types of processing and their health impacts.¹⁶¹ Asserting that “[t]he significance of industrial processing—and in particular methods and ingredients developed or created by modern food science and technology—on the nature of food and on the state of human health, is so far understated,”¹⁶² Brazilian public health researchers developed a classification system called NOVA,¹⁶³ and coined the term “ultra-processed”¹⁶⁴ for foods that are “formulations of food substances often modified by chemical processes and then assembled into ready-to-consume hyper-palatable food and drink products using flavours, colours, emulsifiers and . . . other cosmetic additives.”¹⁶⁵

¹⁵⁷ Matt Simon, *Let’s All Just Chill About Processed Foods*, WIRED (Sept. 9, 2019), <https://www.wired.com/story/processed-foods/> [<https://perma.cc/7AMM-J8HB>].

¹⁵⁸ Comment Letter from Am. Frozen Food Indus. to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for “Use of the Term ‘Healthy’ in the Labeling of Human Food Products; Request for Information and Comments” 1 (Apr. 26, 2017).

¹⁵⁹ Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992).

¹⁶⁰ Comment Letter from Am. Frozen Food Indus. to Food & Drug Admin., *supra* note 158, at 4.

¹⁶¹ Carlos A. Monteiro, Geoffrey Cannon, Renata B. Levy, Jean-Claude Moubarac, Maria Lc Louzada, Fernanda Rauber, Neha Khandpur, Gustavo Cediel, Daniela Neri, Euridice Martinez-Steele, Larissa G. Baraldi & Patricia C. Jaime, *Ultra-Processed Foods: What They Are and How to Identify Them*, 22 PUB. HEALTH NUTRITION 936, 937 (2019).

¹⁶² Carlos A. Monteiro, Geoffrey Cannon, Renata Levy, Jean-Claude Moubarac, Patricia Jaime, Ana Martins, Daniela Canella, Maria Louzada, & Diana Parra, *NOVA. The Star Shines Bright*, 7 WORLD NUTRITION 28, 29 (2016).

¹⁶³ *Id.* at 28, 34. Currently the NOVA classification involves four food categories, defined thus: group 1, unprocessed or minimally processed foods; group 2, processed culinary ingredients; group 3, processed foods; group 4, ultra-processed foods. *Id.* at 31–33, 35.

¹⁶⁴ Monteiro et al., *supra* note 162, at 938 (“Ultra-processed foods include carbonated soft drinks; sweet or savoury packaged snacks; chocolate, candies (confectionery); ice cream; mass-produced packaged breads and buns; margarines and other spreads; cookies (biscuits), pastries, cakes and cake mixes; breakfast ‘cereals’; pre-prepared pies and pasta and pizza dishes; poultry and fish ‘nuggets’ and ‘sticks’, sausages, burgers, hot dogs and other reconstituted meat products; powdered and packaged ‘instant’ soups, noodles and desserts . . .”).

¹⁶⁵ *Id.* at 937.

In the ten years since Brazilian researchers coined the term “ultra-processed foods,” there has been a growing body of evidence associating consumption of such foods with poor diet quality, increased cardiovascular risk factors, and adverse health outcomes such as obesity and metabolic syndrome.¹⁶⁶ Thus, a public health strategy has evolved to encourage the avoidance of “ultra-processed” foods.¹⁶⁷ Advocates of this strategy assert that ultra-processed foods are intrinsically unhealthy due to their ingredients, manufacturing processes, and tendency to replace fresher, unprocessed or minimally-processed foods.¹⁶⁸ Going further, they assert that food processing is an important factor when evaluating food, nutrition, and public health.¹⁶⁹

Recent findings “add to growing evidence of an association between ultra-processed food and adverse health outcomes that has important implications for dietary advice and food policies,” such as labeling and marketing to determine the “healthiness” of individual food products.¹⁷⁰ A recent short-term controlled feeding study found that consuming diets high in ultra-processed food causes excess caloric intake and weight gain.¹⁷¹ Researchers at the National Institutes of Health completed “the first randomized, controlled trial to show that eating a diet made up of ultra-processed foods actually drives people to overeat and gain weight compared with a diet made up of whole or minimally processed foods.”¹⁷² Researchers “recruited 20 healthy, stable-weight adults—10 men and 10 women—to live in an NIH facility for

¹⁶⁶ See Michael J Gibney, *Ultra-Processed Foods: Definitions and Policy Issues*, CURRENT DEV. IN NUTRITION, at 5 (Feb. 2019).

¹⁶⁷ *Id.* (arguing that more debate on such advice is needed). This advice is reflected in the official Brazilian dietary recommendations. BRAZ. MINISTRY OF HEALTH, DIETARY GUIDELINES FOR THE BRAZILIAN POPULATION 39 (2014) <https://www.foodpolitics.com/wp-content/uploads/Brazilian-Dietary-Guidelines-2014.pdf> [<https://perma.cc/22JE-W63H>].

¹⁶⁸ Monteiro et al., *supra* note 162, at 938; see Carlos Monteiro, Geoffrey Cannon, Jean-Claude Moubarac, Renata Levy, Maria Louzada & Patrícia Jaime, *The UN Decade of Nutrition, the NOVA Food Classification and the Trouble with Ultra-Processing*, 21 PUB. HEALTH NUTRITION 5, 5–6, 12 (2018); Bernard Srour, Leopold Fezeu, Emmanuelle Kesse-Guyot, Benjamin Alles, Caroline Mejean, Roland Andrianasolo, Eloi Chazelas, Melanie Deschasaux, Serge Hercberg, Pilar Galan, Carlos Monteiro, Chantal Julia & Mathilde Touvier, *Ultra-Processed Food Intake and Risk of Cardiovascular Disease: Prospective Cohort Study (NutriNet-Santé)*, BMJ (2019); Mark A Lawrence & Phillip I Baker, *Ultra-Processed Food and Adverse Health Outcomes*, BMJ (2019).

¹⁶⁹ Carlos Monteiro, *Nutrition and Health. The Issue Is Not Food, nor Nutrients, so Much as Processing*, 12 PUB. HEALTH NUTRITION 729 (2009).

¹⁷⁰ Lawrence & Baker, *supra* note 168, at 1.

¹⁷¹ Kevin D. Hall, Alexis Ayuketah, Robert Brychta, Hongyi Cai, Thomas Cassimatis, Kong Y. Chen, Stephanie T. Chung, Elise Costa, Amber Courville, Valerie Darcey, Laura A. Fletcher, Ciaran G. Forde, Ahmed M. Gharib, Juen Guo, Rebecca Howard, Paule V. Joseph, Suzanne McGehee, Ronald Ouwerkerk, Klaudia Raisingier, Irene Rozga, Michael Stagliano, Mary Walter, Peter J. Walter, Shanna Yang & Megan Zhou, *Ultra-Processed Diets Cause Excess Calorie Intake and Weight Gain: An Inpatient Randomized Controlled Trial of Ad Libitum Food Intake*, 30 CELL METABOLISM 67 (2019), [https://www.cell.com/cell-metabolism/fulltext/S1550-4131\(19\)30248-7](https://www.cell.com/cell-metabolism/fulltext/S1550-4131(19)30248-7) [<https://perma.cc/VQ86-4RL9>]; see Maria Godoy, *It's Not Just Salt, Sugar, Fat: Study Finds Ultra-Processed Foods Drive Weight Gain*, NPR (May 16, 2019), <https://www.npr.org/sections/thesalt/2019/05/16/723693839/its-not-just-salt-sugar-fat-study-finds-ultra-processed-foods-drive-weight-gain> [<https://perma.cc/Y9ZA-YJMQ>] (“Dariusz Mozaffarian, dean of Tufts University’s Friedman School of Nutrition Science and Policy, agrees that the findings are striking. . . . ‘These are landmark findings that the processing of the foods makes a huge difference in how much a person eats,’ says Mozaffarian. That’s important, because the majority of foods now sold in the U.S.—and increasingly, around the globe—are ultra-processed.”).

¹⁷² Godoy, *supra* note 171; accord Hall et al., *supra* note 171.

a four-week period. All their meals were provided for them.”¹⁷³ The group consuming the ultra-processed foods gained weight,

even though each meal offered on the two different diets contained the same total amount of calories, fats, protein, sugar, salt, carbohydrates and fiber. Study participants were allowed to eat as much or as little as they wanted but ended up eating more of the ultra-processed meals, even though they did not rate those meals as being tastier than the unprocessed meals.¹⁷⁴

In addition, two large recent European cohorts found positive associations between consumption of ultra-processed foods and cardiovascular disease and all-cause mortality.¹⁷⁵

Critics of the ultra-processed food concept argue that the definition of “ultra-processed” has varied over time as food processing technologies have evolved, “that in modern societies it is unrealistic to advise people to avoid ultra-processed foods, and that reformulating the nutrient composition of processed foods is a more effective way to reduce exposure to ‘risk’ nutrients such as saturated fat.”¹⁷⁶ One author recommends targeting processed foods for reformulation as a strategy to improve national diets.¹⁷⁷ The WHO and United Nations Food and Agriculture Organization (FAO) support this strategy, as do several countries.¹⁷⁸ For example, the United Kingdom now seeks to reduce energy intake by twenty percent through reformulation and portion-size approaches.¹⁷⁹ “Given that the NOVA classification of ultra-processed foods accounts for about half the daily energy intake of populations in developed economies, it is reasonable to question how the replacement of that energy, in full or in part, might be achieved” and to question “the realistic feasibility of this strategy” given the rise in consumerism, urbanization, time scarcity, fresh food accessibility and affordability, and decline in home cooking.¹⁸⁰

In response, proponents of “ultra-processed” restrictions argue that advocating for reformulation of ultra-processed foods, rather than avoiding them altogether, “underplays the complexity of potential harm: these foods deliver risk nutrients into the body, displace nutritious foods from the diet, and as the products of industrial processing they can have peculiar physical structures or chemical compositions that

¹⁷³ Godoy, *supra* note 171; *accord* Hall et al., *supra* note 171, at 68.

¹⁷⁴ Godoy, *supra* note 171; *accord* Hall et al. *supra* note 171, at 68–71.

¹⁷⁵ Srour et al., *supra* note 168; Rico-Campà, Miguel Martinez-Gonzalez, Ismael Alvarez, Raquel de Deus Mendonca, Carmen de la Fuente-Arillaga, Clara Gomez-Donoso & Maira Bes-Rastrollo, *Association Between Consumption of Ultra-Processed Foods and All-Cause Mortality: SUN Prospective Cohort Study*, *BMJ* (2019).

¹⁷⁶ Lawrence & Baker, *supra* note 168, at 1.

¹⁷⁷ Gibney, *supra* note 167, at 6.

¹⁷⁸ *Id.*

¹⁷⁹ *Plans to Cut Excess Calorie Consumption Unveiled*, PUB. HEALTH ENG., (Mar. 6, 2018), <https://www.gov.uk/government/news/plans-to-cut-excess-calorie-consumption-unveiled> [<https://perma.cc/A74V-J4SS>].

¹⁸⁰ Gibney, *supra* note 167, at 5–6.

are also risk factors for adverse health outcomes.”¹⁸¹ In addition to processing that creates “calorically dense and highly palatable products” that are laden with sugar, salt, and fat, “food processing can also lead to the loss of some nutrients and phytochemicals naturally present in plant foods.”¹⁸² While randomized clinical trials have demonstrated that replacing red meat with nuts, legumes, and other plant-based protein foods reduces levels of total and low-density lipoprotein cholesterol¹⁸³ and long-term epidemiologic studies have also shown that this shift from red meat to plant foods is associated with lower risks of chronic diseases and total mortality,¹⁸⁴ these benefits may not also be attributable to plant-based meat alternatives.

Even though legumes are sourced for protein in the branded meatless options, their health benefits are somewhat blunted by the high degree of processing involved. For instance, moderate amounts of whole soy foods, like edamame (soybeans), have been linked to reduced rates of cancer. This protection is often attributed to isoflavones, a subgroup of plant compounds called flavonoids thought to provide health benefits.¹⁸⁵

Although the Impossible Burger is made of soy, one burger “contains less than 8 percent of the isoflavones found in one serving of whole soy foods (one serving is roughly a quarter of a block of tofu or 1 cup of soymilk)”¹⁸⁶ because plant-based meat alternatives incorporate purified plant protein rather than whole foods, with Beyond Burgers using pea protein isolate and Impossible Burgers using soy protein isolate and concentrate.¹⁸⁷

In light of emerging public health studies, plant-based meat companies should endeavor to continue to improve the nutritional profiles of their products and aim to source and utilize healthier ingredients;¹⁸⁸ however, processing is the hallmark of

¹⁸¹ Lawrence & Baker, *supra* note 168, at 1–2; Carlos Monteiro & Geoffrey Cannon, *Product Reformulation Will Not Improve Public Health*, 3 WORLD NUTRITION 406 (2012).

¹⁸² Hu et al., *supra* note 125, at 1547.

¹⁸³ Marta Guasch-Ferré, Ambika Satija, Stacy Blondin, Marie Janiszewski, Ester Emlen, Lauren O’Connor, Wayne Campbell, Frank Hu, Walter Willett & Meir Stampfer, *Meta-Analysis of Randomized Controlled Trials of Red Meat Consumption in Comparison with Various Comparison Diets on Cardiovascular Risk Factors*, 139 CIRCULATION 1828 (2019).

¹⁸⁴ Zheng et al., *supra* note 15.

¹⁸⁵ Emily Gelsomin, *Impossible and Beyond: How Healthy Are These Meatless Burgers?* HARV. HEALTH BLOG (Aug. 15, 2019, 10:30 AM), <https://www.health.harvard.edu/blog/impossible-and-beyond-how-healthy-are-these-meatless-burgers-2019081517448> [<https://perma.cc/TWN7-2JK4>].

¹⁸⁶ *Id.*

¹⁸⁷ Beyond Meat, <https://www.beyondmeat.com/products/the-beyond-burger/>, [<https://perma.cc/25AG-M8UE>]; Impossible Foods, [https://faq.impossiblefoods.com/hc/en-us/articles/360018937494-What-are-the-ingredients#:~:text=Water%2C%20Soy%20Protein%20Concentrate%2C%20Coconut,and%20Minerals%20\(Zinc%20Glucanate%2C%20Thiamine](https://faq.impossiblefoods.com/hc/en-us/articles/360018937494-What-are-the-ingredients#:~:text=Water%2C%20Soy%20Protein%20Concentrate%2C%20Coconut,and%20Minerals%20(Zinc%20Glucanate%2C%20Thiamine) [<https://perma.cc/A6Q2-UM7Y>].

¹⁸⁸ This in fact, is a goal of many plant-based meat producers, and efforts have been made to reduce sodium. The Impossible Burger 2.0, launched in 2019, reduced the amount of salt and saturated fat in its burger. David Lipman, *How We Know You’ll “Like Very Much” the New Impossible Burger*, IMPOSSIBLE FOODS (Jan. 7, 2019), <https://medium.com/impossible-foods/how-we-know-youll-like-very-much-the-new-impossible-burger-3d841683cec1> [<https://perma.cc/4SEW-NRK3>] (“We aimed to improve the nutritional profile and did exactly that, delivering a new product with fewer calories, lower total fat, lower saturated fat and lower sodium. We swapped the wheat protein for soy protein—higher quality protein

plant-based meats and techniques will continue to become more sophisticated to more closely mimic conventional animal products. Equating all “processing” with unhealthfulness can discount its benefits and, in the case of plant-based meats, misses the point of the products, which is to turn plants into meat. For example, the Food Process Engineering Laboratory at Wageningen University in the Netherlands is collaborating with the company Vegetarian Butcher to transform plants into muscle-like structures and textures using a Couette cell device which “consists of two concentric cylinders, one of which rotates around the other while the ingredients are sandwiched in between.”¹⁸⁹ “By exerting force on the proteins in the mixture, the ingredients lengthen into fibres and wind around one another . . . [to create] a gelatinous red slab of plant meat that contains long, thick, elastic muscle-like fibres which look and flake apart like pulled pork or beef.”¹⁹⁰ When the plant-based slabs of meat are grilled, it sizzles, browns, and smells like an animal-based steak.¹⁹¹ The innovative processing is what confers benefits to the products and its consumers. For example, Perfect Day uses “natural type of microflora known to produce large amounts of pure protein for food” and through biotechnology, flora is altered so it can ferment sugar and create real dairy protein, in a much less resource-intensive way than conventional dairy farming.¹⁹²

Processing can bring health benefits as well.¹⁹³ Impossible Burger fortifies its burgers with vitamin B₁₂ and zinc, both of which are typically found in animal-based foods and of which vegans may be deficient.¹⁹⁴

According to Dr. Barry Popkin, a nutrition professor at the University of North Carolina, making ultra-processed foods convenient, plentiful, and healthy is a steep challenge for the food industry¹⁹⁵: “‘Let’s see if they can produce ultra-processed food that’s healthy and that won’t be so seductive and won’t make us eat so much extra,’ he says. ‘But they haven’t yet.’”¹⁹⁶

As Dr. Hu explained, how plant-based meat is consumed must be part of the healthfulness assessment. For example, when plant-based burgers are often consumed at fast-food restaurants, they are served on a large refined grain bun with salty condiments, cheese, fries, and a sugar-sweetened beverage.¹⁹⁷ In this scenario, it’s

by PDCAAS (Protein Digestibility-Corrected Amino Acid Score) standards—and reduced the amount of coconut oil while adding sunflower oil.”).

¹⁸⁹ *Plant-Based Meat Could Create a Radically Different Food Chain*, ECONOMIST (Oct. 12, 2019), <https://www.economist.com/international/2019/10/12/plant-based-meat-could-create-a-radically-different-food-chain> [<https://perma.cc/UD8A-HAV6>].

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Got a Question?*, PERFECT DAY (2020), <https://www.perfectdayfoods.com/faq/#gmos> [<https://perma.cc/79CL-CVQR>].

¹⁹³ See Roger Clemens & Peter Pressman, *Let’s Clear Up the Confusion About Processed Food and Health*, 73 FOOD TECH. 2 (2019) (“There is no ambiguity about the fact that widespread food processing has made our food supply safer, more robust, and of greater nutritional value. . . . Let us be mindful and evidence based about the benefits and the risks of processing and take care not to throw the baby out with the bathwater.”).

¹⁹⁴ Gelsomin, *supra* note 185.

¹⁹⁵ Godoy, *supra* note 171.

¹⁹⁶ *Id.*

¹⁹⁷ Hu et al., *supra* note 125, at 1548.

unlikely that simply substituting a plant-based patty for a beef patty improves overall nutrition and diet quality.¹⁹⁸ More research should be conducted to address questions about the health effects of plant-based meat and their role in a low-carbon sustainable diet; rigorously designed, independently funded studies are needed. Although it may not be feasible to conduct large long-term trials on disease outcomes, at the population level it will be important to examine whether an increase in the consumption of plant-based meat alternatives actually leads to a significant reduction in red meat intake—the ultimate goal of these meat alternatives.

The conclusion of Dr. Hu and his colleagues was that plant-based meat alternatives “may have some role in improving human and planetary health, but there is no evidence to suggest that they can substitute for healthy diets focused on minimally processed plant foods.”¹⁹⁹ They further suggested that federal nutrition policies and the dietary guidelines should continue to recommend plant-based diets that include foods such as nuts, seeds, legumes, pulses, and minimally processed meat alternatives such as tofu, seitan, and tempeh.²⁰⁰

There is little to argue within those recommendations. A world without a need for plant-based meat alternatives would probably be a healthier one; however, the comparison between plant-based meat alternatives and tofu or tempeh misunderstands how and why these meat analog products are being consumed—as a substitute for animal-based meat. While some groups have asked FDA not to consider processing or other production methods in redefining healthy, others have asked that processed foods be categorically excluded from the definition.²⁰¹ As with all nutritional information (as made evident in the discussion of revising the “healthy” regulation), clear guidance and information for consumers is needed.

Ensuring the healthfulness of processed foods is a responsibility that stakeholders across the food system should take.²⁰² Innovations in food processing technology can reduce calorie intake, enhance gut health, enhance health benefits of foods, reduce allergenicity, improve food safety, and reduce waste.²⁰³ Research from government and public health researchers should assess the health risks and benefits of processing and such assessments should be communicated from public health researchers, the government, and companies themselves as the products evolve. In line with the Dietary Guidelines approach to healthy food patterns, communication should answer the question of how these products fit in with an overall healthy diet. In regards to plant-based meat, with guidance from FDA and public health professionals, consumers should understand whether it is health-promoting to eat certain plant-based burgers daily, to occasionally substitute them for a conventional burger, or add it to a generally whole food plant-based diet that mainly includes unprocessed foods. These are the types of questions to which answers could help consumers make decisions about diets, but the impact of this information communicated on labels to good health is also

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ Comment Letter from N.Y.C. Dep’t of Health and Mental Hygiene to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335-0731 for “Use of the Term ‘Healthy’ in the Labeling of Human Food Products; Request for Information and Comments” (Apr. 25, 2017).

²⁰² Weaver et al., *supra* note 151, at 1538.

²⁰³ *Id.* at 1538 table 5.

another area of research. In short, the vigorous debate regarding the benefits versus risks of “processing” is a distraction from the core issues regarding whether and how plant-based meat alternatives can contribute to a planetary health diet. Rejecting plant-based meats solely because they are “processed” or “ultra-processed,” and thus dismissing them as “unhealthy,” ignores the reality of average Americans’ consumption habits and misses an opportunity to meet people where they are.

D. Rethinking the “Healthy” Definition: A Comparative Approach to Health

Despite the challenges of defining the term “healthy,” as revealed in FDA’s public meeting, reforming the healthy definition to help consumers better understand and assess the nutritional value of a food and its contribution to one’s overall diet would be a positive step towards “promoting public health through efforts to empower consumers to make better and more informed decisions about their diets and health, foster the development of healthier food options, and expand the opportunities to use nutrition to reduce morbidity and mortality due to chronic disease.”²⁰⁴ Given the increasing calls from international health organizations to avoid red and processed meat and reduce the consumption of animal products in general,²⁰⁵ consumers could benefit from FDA guidance that helps them navigate the healthfulness of plant-based meat alternatives.

Information that may be most beneficial to consumers is the relative healthfulness of these alt-meats in comparison to the product it’s meant to replace, such as a beef hamburger. Plant-based meat producers would likely adopt a comparative claim on their burgers, such as “healthier than animal-based processed meat” to tout the nutritional benefits of plant-based burgers currently on the market compared to conventional ground beef. There are scientific challenges to comparing the overall healthfulness of a product based only on nutrient content, but plant-based burgers offer a slightly healthier combination of fats, low to no trans fats, lower risk of foodborne illness, and possibly lower cancer risk.²⁰⁶ Given the metrics of nutrition, safety, and diet-related disease—all of which are important contributors to overall health—it behooves FDA to take a broader approach in establishing a revised regulatory definition of “healthy.”

The issue of comparing analogous products meant to replace their conventional counterparts raises the question of how broad a definition of “health” must be to achieve the aims of FDA, the food producers, and a resilient food system. Meat consumption in the United States and in most industrialized countries must significantly decrease to meet climate goals,²⁰⁷ and it should be beyond dispute that a

²⁰⁴ U.S. FOOD & DRUG ADMIN., FDA NUTRITION INNOVATION STRATEGY (2018), <https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy> [<https://perma.cc/DT67-BSSD>].

²⁰⁵ INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, CLIMATE CHANGE & LAND, SUMMARY FOR POLICYMAKERS 24, https://www.ipcc.ch/site/assets/uploads/sites/4/2020/02/SPM_Updated-Jan20.pdf [<https://perma.cc/W4F7-2X2W>].

²⁰⁶ Chana Davis, *Viewpoint: Impossible and Beyond Burgers Are Delicious, But Are They Good for You?*, GENETIC LITERACY PROJECT (Nov. 21, 2019), https://geneticliteracyproject.org/2019/11/21/viewpoint-impossible-and-beyond-burgers-are-delicious-they-can-also-be-good-for-you/?mc_cid=c0dd67a18b&mc_eid=4ad9fe1bfd [<https://perma.cc/EY6Q-4Y8V>].

²⁰⁷ Tamara Lucas & Richard Horton, *The 21st-Century Great Food Transformation*, 393 LANCET 386, 386 (2019); Helen Harwatt, William Ripple, Abhishek Chaudhary, Matthew Betts & Matthew Hayek, *Scientists Call for Renewed Paris Pledges to Transform Agriculture*, 4 LANCET J. PLANETARY HEALTH e9

shift towards whole food, plant-based diets would contribute to both human and planetary health.²⁰⁸ A study of U.S. women and men found that “an increase in red meat consumption over eight years was directly associated with risk of death during the subsequent eight years, and was independent of initial red meat intake and concurrent changes in lifestyle factors.”²⁰⁹ When red meat consumption was decreased and consumption of nuts, fish, poultry without skin, dairy, eggs, whole grains, or vegetables increased over eight years, in the subsequent eight years, this dietary pattern was associated with a lower risk of death.²¹⁰ These findings suggest that substituting animal-based protein sources with plant-based foods can increase longevity.²¹¹

The challenge of reducing meat consumption goal is complex, given the reality that consumer behavior is motivated primarily by taste, price, and convenience.²¹² Thus, through novel ingredients and processing techniques, plants are made into meat that satisfies a typical American palate. The implications of this strategy in regards to humans’ connection to animals, other people, and our environment is a topic of great interest to this author and will be explored in forthcoming publications,²¹³ but the focus here is on communication of this strategy and transparency about the attributes of these products. As Impossible Foods CFO David Lee explained in an interview with McKinsey:

The Impossible burger was never designed to compete with the health benefits of, say, a piece of broccoli. It was designed to compete in the \$1.7 trillion global meat and dairy market in which meat eaters want to eat meat not just every week but at every meal. They want it as a part of their everyday life. So if people could have an Impossible burger as part of their everyday life, they’re forgoing the cholesterol that they’d get from a cow,

(2019) (“If the livestock sector were to continue with business as usual, this sector alone would account for 49 percent of the emissions budget for 15°C by 2030, requiring other sectors to reduce emissions beyond a realistic or planned level.”).

²⁰⁸ See Walter Willett, Johan Rockström, Brent Loken, Marco Springmann, Tim Lang, Sonja Vermeulen, Tara Garnett, David Tilman, Fabrice DeClerck, Amanda Wood, Malin Jonell, Michael Clark, Line J. Gordon, Jessica Fanzo, Corinna Hawkes, Rami Zurayk, Juan A. Rivera, Wim De Vries, Lindiwe Majele Sibanda, Ashkan Afshin, Abhishek Chaudhary, Mario Herrero, Rina Agustina, Francesco Branca, Anna Lartey, Shenggen Fan, Beatrice Crona, Elizabeth Fox, Victoria Bignet, Max Troell, Therese Lindahl, Sudhvir Singh, Sarah E. Cornell, K. Srinath Reddy, Sunita Narain, Sania Nishtar & Christopher J. L. Murray, *Food in the Anthropocene: The EAT–Lancet Commission on Healthy Diets from Sustainable Food Systems*, 393 LANCET 447 (2019) [hereinafter EAT–Lancet Report].

²⁰⁹ “This association with mortality was observed with increased consumption of processed and unprocessed meat, but was stronger for processed meat.” Zheng et al., *supra* note 15.

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² See Anju Aggarwal, Colin Rehm, Pablo Monsivais & Adam Drewnowski, *Importance of Taste, Nutrition, Cost and Convenience in Relation to Diet Quality: Evidence of Nutrition Resilience Among US Adults Using National Health and Nutrition Examination Survey (NHANES) 2007–2010*, 90 PREV. MED. 84 (2016).

²¹³ See Nicole E. Negowetti, *Censorship, Civil Disobedience, and the Discourse of Disruption: Toppling the “Milk” and “Meat” Monopolies* (forthcoming).

because the Impossible burger has no cholesterol. And it has 10 to 20 percent fewer calories.²¹⁴

To allow plant-based meat companies to convey the health-promoting benefits of their products while also ensuring transparency and preventing misleading or false claims, FDA could require a brief explanation of how a product is “healthy” on the product label and made available in greater detail on the company’s website accessed through a QR code on the label. Including a descriptive statement about how the food is aligned with dietary recommendations would allow consumers to evaluate choices and determine whether the food fits within an overall healthy dietary pattern for them.²¹⁵ FDA should also conduct research on how consumers understand such qualified “healthy” statements to develop a rule that most accurately and clearly conveys this information to consumers.

The question of whether the “healthy” claim can be used to make comparisons between foods has been raised in discussions about modernizing the regulatory definition. For example, the Academy of Nutrition and Dietetics explained that attendees of FDA’s March 9, 2017 Public Meeting on defining “healthy” disagreed about whether FDA’s goal in devising a regulatory definition is to shift consumers to a “healthy” product in a different food category or to a food within the same product category that is somehow objectively “healthier.”²¹⁶ In other words, the debate centered on how the “healthy” claim is intended to help consumers compare products and choose the “better,” more nutritious, option. Should the “healthy” claim help steer consumers away from less healthy foods and toward the healthy choice within the same product category (e.g., a healthy snack such as popcorn, instead of potato chips, in the snack food aisle)?²¹⁷ Or is the “healthy” claim intended to shift consumers away from less healthy categories of food (e.g., highly-sweetened snack foods) toward, for example, fruits and vegetables?²¹⁸ To facilitate a common understanding of the goals for establishing a definition, the Academy “encouraged FDA to share any relevant research or consumer data on the effectiveness of the alternate shifting approaches.”²¹⁹ Such information would be particularly useful in the context of plant-based meat alternatives.

For meat replacements that are intended to closely mimic meat, the benefits are largely measured in comparison to their conventional counterparts. The acceptability of the products rests on consumers’ willingness to make tradeoffs—for example, to eat a processed food or genetically engineered food, or to pay more for a version of

²¹⁴ Joshua Katz, *An Incredible Year for Impossible Foods*, MCKINSEY & CO. (Aug. 2019), <https://www.mckinsey.com/industries/agriculture/our-insights/an-incredible-year-for-impossible-foods> [<https://perma.cc/2SDL-LRN9>].

²¹⁵ Comment Letter from Instit. of Food Technologists to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for “Use of the Term ‘Healthy’ in the Labeling of Human Food Products; Request for Information and Comments” 5 (Apr. 26, 2017).

²¹⁶ Comment Letter from Acad. of Nutrition and Dietetics to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for “Use of the Term ‘Healthy’ in the Labeling of Human Food Products; Request for Information and Comments” 3 (April 26, 2017).

²¹⁷ *Id.*

²¹⁸ *Id.* The Academy also noted that the Dietary Guidelines for Americans recommendation to “[s]hift to healthier food and beverage choices[s], and [c]hoose nutrient-dense foods and beverages across and within all food groups in place of less healthy choices is similarly ambiguous.”

²¹⁹ *Id.*

meat that does not involve animal slaughter, that is produced with less water or land, or that is healthier for a variety of reasons—perhaps not so dramatically in terms of health measured nutrient by nutrient, but “health” considered broadly—from a perspective that considers how the product is made. Meat created from animals confined in factory farms and administered hormones and antibiotics should not be considered healthy to humans or non-human animals. Allowing a “healthier than conventional meat because . . .” claim can signal to consumers the benefit of plant-based meats over their animal-derived counterparts.

E. Communicating Healthfulness Without a “Healthy” Claim

One way of communicating healthfulness without using the term “healthy” could be through dietary guidance statements on food labels which must be truthful and non-misleading. Unlike “health claims” which require (1) a substance (whether a food, food component, or dietary ingredient) and (2) a disease or health-related condition or nutrient content claims such as “healthy” or “low-fat,” statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in maintaining good health are considered to be dietary guidance rather than health claims. In its 2015 Citizen Petition, KIND proposed that FDA undertake rulemaking to define a “dietary guidance statement” as “a statement in food labeling about the usefulness of a food, or a category of foods, in maintaining healthy dietary practices.”²²⁰ KIND’s proposed definition of “dietary guidance statement” would:

include a statement that focuses on general dietary patterns, practices, and recommendations that promote health (e.g., “Nuts are part of a healthy diet”), and a statement that highlights the presence or amount of a food or category of foods in relation to a general health benefit or healthful diet (e.g., “Contains healthy whole grains”) or recommends the substitution of a food or food category that is consistent with current dietary recommendations for a food or food category that is less beneficial to health (e.g., “Eat foods made from healthy whole grains instead of refined grains”).²²¹

KIND called on FDA to allow food companies to use claims that communicate how specific foods can be part of a diet that meets current dietary recommendations. KIND requested FDA to establish requirements for such dietary guidance statements to ensure that they are not misleading to consumers.²²²

Similar to KIND’s proposal, in its comments to FDA regarding defining “healthy,” the American Meat Institute (AMI) proposed that “products that do not meet the nutrient content but promote health,” such as those based on food groups that Americans should consume, could also meet some type of “healthy” standard.²²³ This approach, ironically, could perhaps be used to explain the benefits of plant-based meat

²²⁰ Citizen Petition Letter from KIND LLC to Food & Drug Admin. 3 (Dec. 1, 2015), <https://s3.amazonaws.com/kind-docs/citizen-petition.pdf> [<https://perma.cc/GD5N-XDHJ>].

²²¹ *Id.*

²²² *Id.*

²²³ Comment Letter from Meat Inst. to Food & Drug Admin. Re: Docket No. FDA-2016-D-2335 for “Use of the Term Healthy in the Labeling of Human Food Products; Request for Information and Comments” (Apr. 26, 2017).

alternatives in comparison to conventional meat. If plant-based meats do not satisfy the nutrient requirements for a regulatory “healthy” definition, perhaps plant-based meat producers might make dietary statements such as “eat plant-based diets for good health” or “eat foods made from plants, rather than animals.” Such claims would undoubtedly signal to consumers that eating the “plant-based” burger is “healthy.” While these claims could be beneficial from a marketing perspective, they could also be challenged either by FDA or plaintiffs’ attorneys as being misleading if not substantiated. To avoid potential confusion by consumers, FDA should issue guidance clarifying how such claims regarding plant-based foods can be communicated on food labels, and indicate to consumers that a particular food carrying such a label is healthy only as part of an overall healthy diet.²²⁴

IV. BROADENING THE SCOPE OF THE “HEALTHY” CLAIM

In addition to comparisons made to conventional meat, in questioning whether plant-based burgers are “healthy,” one blogger from the Harvard T.H. Chan School of Public Health concluded that: “The answer may depend on whether your priorities lie with your personal health or the health of the planet.”²²⁵ This indicates that the issue of sustainability is key in the assessment of these products’ benefits. The question of whether plant-based meat alternatives should be considered part of a healthy, low-carbon diet (one that aims to reduce greenhouse gases due to the methods of production, packaging, processing, transport, preparation, and waste of food) that can help reduce reliance on industrial meat production, was explored in the JAMA opinion piece by Harvard T.H. Chan School of Public Health Professor Frank B. Hu and colleagues. According to the authors, “the answer to that question remains far from clear given the lack of rigorously designed, independently funded studies.”²²⁶ While describing the detrimental impacts of conventional livestock production and the health effects of eating meat-centric diets, the paper did acknowledge that environmental factors can and should be strong motivators of food choice.²²⁷ The relationship between public and environmental health is an issue that FDA should consider in redefining “healthy” to facilitate informed food choice.

The American Heart Association (AHA) highlighted the complexity of determining eligibility criteria for the term “healthy” in food labeling and lack of consensus, and thus recommended that FDA consider “the philosophical questions” that are relevant to doing so, as the agency already did in its original rule on “healthy” in 1994.²²⁸ Specifically, AHA suggested that the agency consider the current goal and purpose of labeling foods “healthy” and develop a set of guiding principles to help govern its careful and thoughtful consideration of these issues.²²⁹ A broader conception of “health” that includes environmental health could be part of such an overarching goal setting. AHA urged FDA to thoroughly re-consider issues such as consumer

²²⁴ See Comment Letter from N.Y.C. Dep’t of Health & Mental Hygiene, *supra* note 201.

²²⁵ Gelsomin, *supra* note 185. The author’s bottom line was that “meatless burgers are good for the planet, but not always good for our health.”

²²⁶ Hu et al., *supra* note 125, at 1547.

²²⁷ *Id.*

²²⁸ Comment Letter from Am. Heart Ass’n to Food & Drug Admin., *supra* note 110, at 2.

²²⁹ *Id.*

perception of “healthy” foods in light of current societal context.²³⁰ FDA based its original “healthy” rule on the understanding that consumers equated healthfulness with the nutrient content of food.²³¹ However, more recent consumer research has indicated that many consumers now consider a broader set of attributes—such as those dealing with a food’s production and sourcing—to define whether it is healthy. For example, a review of qualitative studies examining consumer perceptions of “healthy” foods and diets found a diverse, complex set of definitions.²³² The authors reported that consumers define healthy eating not only in terms of nutrients and components, but also in how foods are produced, processed, and prepared (e.g., natural, homemade, and organic).²³³ Because of this change in consumer perception, new educational approaches, such as the inclusion of descriptive claim statements on food labels, may be warranted and useful.²³⁴ Collaboration between FDA and USDA will be necessary to advance such consumer education efforts. This change in consumer perception, coupled with mounting evidence regarding links between human and environmental health, warrant a broad approach to healthfulness as a food labeling claim.

An example of a comprehensive approach to “healthy” can be found in the Prevention Institute’s criteria for “healthy” foods established in 2009 and supported by a network of health care and nutrition professionals.²³⁵ The criteria “is not limited to the nutrients that a food contains,” but rather, takes a food systems approach and considers food to be healthy if it was “produced, processed, and transported in a way that prevents the exploitation of farmers, workers, and natural resources, and the cruel treatment of animals.”²³⁶ In contrast, the American Meat Institute (AMI) has taken the position that production methods and practices, such as animal husbandry, which do not affect nutritional quality, should not be included in the criteria.²³⁷

The AHA acknowledged consumers’ views of health and wellness are becoming more inclusive, reflecting a rising wariness of “chemical,” “artificial,” and “processed” ingredients. In regards to the consideration of other factors beyond nutrient content, such as the degree of processing and the absence of artificial colors or preservatives, production method and treatment of the environment, and accessibility and affordability, AHA has taken the position that the definition of

²³⁰ *Id.*

²³¹ *Id.*

²³² Carole Bisogni, Margaret Jastran, Marc Seligson & Alyssa Thompson, *How People Interpret Healthy Eating: Contributions of Qualitative Research*, 44 J. NUTRITION EDUC. BEHAV. 282 (2012).

²³³ *Id.*

²³⁴ Comment Letter from Am. Heart Ass’n to Food & Drug Admin., *supra* note 110, at 2.

²³⁵ *Setting the Record Straight: Nutrition and Health Professionals Define Healthful Food*, PREVENTION INST. (Mar. 2009), <https://www.preventioninstitute.org/publications/setting-the-record-straight-nutrition-and-health-professionals-define-healthful-food#download> [<https://perma.cc/QG3K-6X23>]. The Institute’s Healthful Food Principles indicates that healthful food is wholesome in that it (1) “includes whole and minimally processed fruits, vegetables, whole grains, legumes, nuts, seeds, eggs, dairy, meats, fish, and poultry;” (2) “contains naturally occurring nutrients (e.g., vitamins, minerals, phytonutrients);” (3) “is produced without added hormones or antibiotics;” and (4) “is processed without artificial colors or flavors or unnecessary preservatives.” *Id.* In addition, it is produced in a way that “[u]pholds the safety and quality of life of all who work to feed us,” “[t]reats all animals humanely,” “[p]rotects the finite resources of soil, water, air, and biological diversity,” “[s]upports local and regional farm and food economies,” and “[r]eplaces fossil fuels with renewable energy sources.”

²³⁶ *Id.*

²³⁷ Comment Letter from Meat Inst. to Food & Drug Admin., *supra* note 223.

“healthy” should be linked to health outcomes.²³⁸ The organization expressed concerns about the lack of legal or scientific definition or standard for many of these factors, and insufficient scientifically sound evidence linking them to health outcomes.²³⁹ In contrast, there are strong links between health outcomes and a person’s food intake and its nutrient content.²⁴⁰ Similarly, American Frozen Food Institute (AFFI) acknowledged that “while sustainability is important to our planet’s health, there is no regulatory definition of a ‘sustainable’ food or product. . . . [I]t would be nearly impossible to measure each food’s contribution to sustainability as part of the criteria for a healthy claim.”²⁴¹ Moreover, argued the AFFI, “a product’s ‘sustainability’ profile is simply not relevant to whether the food helps consumers achieve a healthy diet.”²⁴² Thus, the AFFI took the position that sustainability and other considerations regarding how a food is produced, such as whether a food is “‘natural,’ ‘locally produced,’ contains added colors, etc., should not be part of the criteria for healthy, which is and should be fundamentally a nutrient content claim that focuses on nutrients and the role of the food in the diet.”²⁴³

Despite the challenges of incorporating sustainability into a definition of healthy, increasing evidence demonstrates the imperative of considering the linkage between human and planetary health. Thus, in revising the definition of “healthy,” FDA should consider broader public health goals and current consumer understanding of the term, and thus reconsider whether “healthy” should remain categorized as an implied nutrient content claim.

A. Sustainability and Planetary Health Claims

One way of more broadly understanding “healthy” is to consider both human and planetary health—oft falling under the catch-all term “sustainability.” “Sustainable diets” have been defined by the FAO as:

diets with low environmental impacts which contribute to food and nutrition security and to healthy life for present and future generations. Sustainable diets are protective and respectful of biodiversity and ecosystems, culturally acceptable, accessible, economically fair and affordable; nutritionally adequate, safe and healthy; while optimizing natural and human resources.²⁴⁴

²³⁸ Comment Letter from Am. Heart Ass’n to Food & Drug Admin., *supra* note 110, at 4.

²³⁹ *Id.*

²⁴⁰ *Id.* The AHA provided as an example, the 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk, initiated by the National Heart, Lung, and Blood Institute and published by the AHA and the American College of Cardiology (ACC). These guidelines are “based on a systematic evidence analysis of predominantly randomized controlled trials that focused on diet and physical activity modifications to reduce cardiovascular risk.” *Id.* They are also “closely aligned with the 2015–2020 Dietary Guidelines for Americans (DGA) and are designed to help achieve the AHA’s 2020 Strategic Impact Goals for cardiovascular health promotion and disease reduction.” *Id.*

²⁴¹ Comment Letter from Am. Frozen Food Indus. to Food & Drug Admin., *supra* note 158, at 4.

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ FOOD AND AGRIC. ORG., SUSTAINABLE DIETS AND BIODIVERSITY - DIRECTIONS AND SOLUTIONS FOR POLICY, RESEARCH AND ACTION 7 (2010), <http://www.fao.org/3/i3004e/i3004e.pdf> [<https://perma.cc/KK6Z-Q2F9>].

The term “planetary health” refers to the “health of human civilization and the state of the natural systems on which it depends.”²⁴⁵ This concept was put forth in 2015 by the Rockefeller Foundation-Lancet Commission on Planetary Health to transform the field of public health, which has traditionally focused on the health of human populations without considering natural systems²⁴⁶:

The EAT-Lancet Commission builds upon the concept of planetary health and puts forth the new term “planetary health diet” to highlight the critical role that diets play in linking human health and environmental sustainability and the need to integrate these often-separate agendas into a common global agenda for food system transformation to achieve the Sustainable Development Goals (SDGs) and Paris Agreement.²⁴⁷

FDA’s definition of “healthy” has been criticized for its inconsistency with the Dietary Guidelines for Americans’ (DGA) dietary patterns, rather than a nutrient-based approach, but the DGA also avoids incorporating planetary health into its recommendations. The DGA, first released in 1980, provide science-based advice for the formation of federal food and nutrition and nutrition education programs that help Americans achieve and maintain a healthy weight, promote health, and prevent chronic disease.²⁴⁸ Federal dietary guidance publications are required by law to be consistent with the Dietary Guidelines.²⁴⁹ U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) jointly publish the Dietary Guidelines every five years.²⁵⁰ As part of this process, the Dietary Guidelines Advisory Committee (DGAC)—a group of nationally recognized experts in the field of nutrition, medicine, and public health—reviews the existing guidelines and additional topics for which new scientific evidence is available, culminating in an Advisory Report.²⁵¹ The purpose of the report is to inform the Federal government of the latest research on diet, nutrition, and health topics and to provides the Federal government with a foundation for developing the Dietary Guidelines for Americans, but HHS and USDA ultimately decide whether and how to utilize the report’s information when drafting national nutrition policies.²⁵²

²⁴⁵ EAT-LANCET COMMISSION SUMMARY REPORT, *supra* note 10, at 7.

²⁴⁶ Sarah Whitmee, Andy Haines, Chris Beyrer, Frederick Boltz, Anthony G. Capon, Bráulio Ferreira de Souza Dias, Alex Eze, Howard Frumkin, Peng Gong, Peter Head, Richard Horton, Georgina M. Mace, Robert Marten, Samuel S. Myers, Sania Nishtar, Steven A. Osofsky, Subhrendu K. Pattanayak, Montira J. Pongsiri, Cristina Romanelli, Agnes Soucat, Jeanette Vega & Derek Yach, *Safeguarding Human Health in The Anthropocene Epoch: Report of the Rockefeller Foundation-Lancet Commission on Planetary Health*, 386 LANCET 1973 (2015).

²⁴⁷ EAT-LANCET COMMISSION SUMMARY REPORT, *supra* note 10, at 7.

²⁴⁸ U.S. DEP’T OF AGRIC., *supra* note 91.

²⁴⁹ *Id.* at 5.

²⁵⁰ *Id.* at 2. 7 U.S.C. § 5341 requires that the U.S. Departments of Health and Human Services and of Agriculture publish a new edition of the Dietary Guidelines for Americans every five years.

²⁵¹ U.S. DEP’T OF AGRIC., *supra* note 91, at 7–8.

²⁵² *Id.* at 6–7.

One of the most contentious issues in the development of the most recent DGA was the inclusion of environmental sustainability.²⁵³ The history of this debate evinces the complicated relationship between science, politics, and business interests, which are also at play in attempts to broaden the definition of “healthy” to encompass planetary health. Although the 2010 DGAC report made little mention of sustainability,²⁵⁴ when the Advisory Committee began its review process in 2013, it decided that the topic should be a substantial part of the 2015 DGA.²⁵⁵ Although the 2015 DGAC scientific report focused on meat reduction, the Committee had discussed fifteen other questions related to sustainability, “including the benefits of grass-fed versus industrial farm-raised animals and organic versus conventionally-grown food.”²⁵⁶ Dr. Miriam Nelson, who has served on the DGAC and has advocated for greater inclusion of sustainability in the DGA, noted the increase in publication of high-quality, low-bias peer-reviewed academic studies supporting its inclusion.²⁵⁷ The DGAC advisory report submitted in February 2015 described sustainability as an essential element of food security:

An important reason for addressing sustainable diets, a new area for the DGAC, is to have alignment and consistency in dietary guidance that promotes both health and sustainability. This also recognizes the significant impact of food and beverages on environmental outcomes, from farm to plate to waste disposal, and, therefore, the need for dietary guidance to include the wider issue of sustainability. Addressing this complex challenge is essential to ensure a healthy food supply will be available for future generations.²⁵⁸

The report also recognized the importance of plant-based foods in a sustainable diet and recommended “a diet higher in plant-based foods, such as vegetables, fruits, whole grains, legumes, nuts, and seeds, and lower in calories and animal-based foods is more health promoting and is associated with less environmental impact than is the current U.S. diet.”²⁵⁹ There was widespread public support for inclusion of these sustainability-focused recommendations. According to Dr. Nelson, of the 30,000

²⁵³ Andy Bellatti, *The Woman Fighting to Make Sustainability Part of the American Diet*, Civil Eats (Feb. 1, 2016), <https://civileats.com/2016/02/01/miriam-nelson-sustainability-dietary-guidelines/> [<https://perma.cc/YE4N-8VN7>].

²⁵⁴ The report mentioned sustainability in connection to the lack of agricultural land to feed Americans the recommended quantity of fruits and vegetables. U.S. DEP’T OF AGRIC., DIETARY GUIDELINES FOR AMERICANS, 2010 57 (2010), <https://www.dietaryguidelines.gov/sites/default/files/2019-05/Dietary-Guidelines2010.pdf> [<https://perma.cc/3WKB-F55M>].

²⁵⁵ Bellatti, *supra* note 253.

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ DIETARY GUIDELINES ADVISORY COMM., U.S. DEP’TS OF AGRIC. AND HEALTH AND HUMAN SERVS., SCIENTIFIC REPORT OF THE 2015 DIETARY GUIDELINES ADVISORY COMMITTEE - ADVISORY REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES AND THE SECRETARY OF AGRICULTURE 283 (2015), <https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf> [<https://perma.cc/8NR7-6RBN>].

²⁵⁹ *Id.* at 5.

public comments regarding the DGAC report, approximately eighty percent were related to sustainability, and almost all were in favor of the report's conclusions.²⁶⁰

In contrast to this popular support, the meat industry vehemently objected to the report's inclusion of foods' environmental impacts in the DGAC report.²⁶¹ Secretary of Agriculture Tom Vilsack and Secretary of Health and Human Services Sylvia Burwell announced that sustainability—defined as “evaluating the environmental impact of a food source”—is beyond the scope of the Dietary Guidelines, citing a mandate in the 1990 National Nutrition Monitoring and Related Research Act (NNMRA), which states that Secretaries of the Departments of Health and Human Services and Agriculture are tasked with developing and issuing “nutritional and dietary information and guidelines” “based on the preponderance of the scientific and medical knowledge” every five years.²⁶² The Secretaries took the position that “[they] [did] not believe that the 2015 DGAs are the appropriate vehicle for this important policy conversation about sustainability.”²⁶³ To further ensure that sustainability would not be included in the DGA, the Senate inserted language into the 2016 appropriations bill prohibiting any funds to be

used to release or implement the . . . [2015] Dietary Guidelines for Americans . . . unless the Secretary of Agriculture and the Secretary of Health and Human Services ensure that each revision to any nutritional or dietary information or guideline contained in the 2010 edition of the Dietary Guidelines for Americans and each new nutritional or dietary information or guideline to be included . . . is based on significant scientific agreement; and is limited in scope to nutritional and dietary information.²⁶⁴

Many nutrition experts disagree vehemently with the exclusion of sustainability from the DGA. As Miriam Nelson explained, “[y]ou can't think about long-term food security without thinking about sustainable diets. And food security has always been a central tenet [of the guidelines]—back in 1980 when they were first developed, and even before there were guidelines.”²⁶⁵ Dr. Nelson noted that the guidelines have also

²⁶⁰ Bellatti, *supra* note 253; Natalie Wood-Wright, *New U.S. Dietary Guidelines Ignore Broad Support for Food Sustainability*, JOHNS HOPKINS UNIV. (Mar. 11, 2016), <https://hub.jhu.edu/2016/03/11/dietary-guidelines-sustainability-survey/> [<https://perma.cc/5G6D-WUCU>]. “[A] survey, conducted by Greenberg Quinlan Rosner Research, polled 800 Americans and found an interest in sustainability measures that cuts across partisan political lines. Nearly 83 percent of Democrats, 72 percent of Independents, and 64 percent of Republicans agree that the dietary guidelines should take into account environmental considerations as they relate to health, nutrition, and long-term healthy food availability.” *Id.* In total, “[n]early three-quarters of adults [surveyed] believe U.S. dietary guidelines should include environmental provisions and support sustainable agriculture practices.” *Id.*

²⁶¹ Miriam Nelson stated that “[t]he [meat] industry did three things reminiscent of the tobacco industry. . . . It discredited the science, discredited the scientists, and deflected the issues.” Bellatti, *supra* note 253.

²⁶² Sec'y Tom Vilsack & Sec'y Sylvia Burwell, *2015 Dietary Guidelines: Giving You the Tools You Need to Make Healthy Choices*, U.S. DEP'T OF AGRIC. (Feb. 21, 2017), <https://www.usda.gov/media/blog/2015/10/06/2015-dietary-guidelines-giving-you-tools-you-need-make-healthy-choices> [<https://perma.cc/L55S-3XQQ>].

²⁶³ *Id.*

²⁶⁴ Consolidated Appropriations Act, 2016, Pub. L. 114-113, § 734, 129 Stat. 2242, 2280 (Dec. 28, 2015).

²⁶⁵ Bellatti, *supra* note 253.

included physical activity, which is related to, though not directly connected to, diet.²⁶⁶ “This is not about scope; it is about political pressure.”²⁶⁷ “[Dr.] Frank Hu, professor of nutrition and epidemiology and chair of the Department of Nutrition at Harvard University, served on the 2015 committee and says the omission was due to ‘political pressure’ from Congress, the meat industry, and special interest groups.”²⁶⁸ “That was a missed opportunity, because our diet has an important influence on the environment and vice versa.”²⁶⁹ Similar concerns and disappointment were expressed by Dr. Walter Willett, Professor of Epidemiology and Nutrition and Chair of the Department of Nutrition at Harvard T.H. Chan School of Public Health:

Sadly, Secretaries Vilsack and Burwell have invoked censorship on a grand scale, again demonstrating the power of the meat industry to distort national policies and priorities. The U.S. Dietary Guidelines Advisory Committee wisely considered the environmental impacts of food production because they were asked to make recommendations that would support both health and food security. Neither health nor food security are possible without a sustainable food supply. Because climate change is accelerating and is already having a multitude of adverse effects, and the footprint of our current food system is massive, we urgently need to create a national food supply that is both healthy and sustainable. For the sake of future generations, we cannot ignore this.²⁷⁰

The DGAC has been convening to develop its 2020–2025 DGA report and there have been many calls to include sustainability in the final DG. For example, in a 2019 letter to the DGAC, the Academy of Nutrition and Dietetics (the “Academy”) asserted that “the role of sustainability must be considered for each of the relevant identified topics.”²⁷¹ “A growing body of literature raises important questions about our collective ability to meet human nutritional needs given the finite natural resource available to us.”²⁷² “One of many such reports is from the EAT-Lancet Commission,

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ Emily Moon, *Should the Federal Dietary Guidelines Consider Sustainability?*, PAC. STANDARD (Mar. 6, 2019), <https://psmag.com/environment/should-the-federal-dietary-guidelines-consider-sustainability> [<https://perma.cc/B25F-5LL3>].

²⁶⁹ *Id.*

²⁷⁰ *2015 Dietary Guidelines Will Not Include a Focus on Sustainability*, HARVARD T.H. CHAN SCH. OF PUB. HEALTH (Oct. 8, 2015), https://www.hsph.harvard.edu/nutritionsource/2015/10/08/2015-dietary-guidelines-will-not-include-a-focus-on-sustainability/?utm_source=Twitter&utm_medium=Social&utm_campaign=Chan-Twitter-General [<https://perma.cc/RVW3-4F3C>].

²⁷¹ Comment Letter from Acad. of Nutrition and Dietetics to Barbara Schneeman, PhD, Chair, 2020-2025 Dietary Guidelines Advisory Comm., *Re: 2020-2025 Dietary Guidelines for Americans* (Aug. 18, 2019) <https://www.eatrightpro.org/news-center/on-the-pulse-of-public-policy/regulatory-comments/academy-submits-recommendations-for-development-of-2020-2025-dietary-guidelines-for-americans> [<https://perma.cc/4UNP-34MA>].

²⁷² *Id.* Other countries, including Canada, have incorporated sustainability into their dietary guidelines. *Dietary Guidelines—Which Countries Have Included Sustainability Within Their National Dietary Guidelines?*, MOUTHFUL, <https://themouthful.org/article-sustainable-dietary-guidelines> [<https://perma.cc/AC6N-A2BQ>] (last visited Aug. 17, 2020). For example, the Canadian Food Guide explains that, “[w]hile health is the primary focus of Canada’s Dietary Guidelines, there are potential environmental benefits to improving current patterns of eating as outlined in this report. For example, there is evidence

which recommends that dietary patterns should be viewed not only on the basis of their ability to promote health outcomes, but also on the basis of their ability to mitigate environmental externalities and their alignment with global agendas such as the United Nations Sustainable Development Goals.²⁷³ The report explains that “a large body of work has emerged on the environmental impacts of various diets, with most studies concluding that a diet rich in plant-based foods and with fewer animal source foods confers both improved health and environmental benefits.”²⁷⁴ Overall, studies indicate that plant-based diets are “win-win” because they benefit people and the planet.²⁷⁵ However, what exactly constitutes a healthy diet and sustainable food production remains subject to debate and there is no global consensus.²⁷⁶ It also remains an open question as to “whether planetary health diets may be achieved for a global population of 10 billion people by 2050.”²⁷⁷

To address the critical need for “globally agreed scientific targets for healthy diets and sustainable food production,” the EAT-Lancet Commission “convened 37 leading scientists from 16 countries in various disciplines including human health, agriculture, political sciences, and environmental sustainability to develop such targets.”²⁷⁸ The report recommends a substantial dietary shift to achieve healthy diets by 2050 which includes “a more than doubling in the consumption of healthy foods such as fruits, vegetables, legumes and nuts, and a greater than 50% reduction in global consumption of less healthy foods such as added sugars and red meat.”²⁷⁹ As the recent EAT-Lancet Report emphasized, “[f]ood is the single strongest lever to optimize human health and environmental sustainability on Earth”²⁸⁰ and meat reduction in industrialized countries presents the most significant opportunity to improve planetary health.

Another recent study published by the Proceedings of the National Academy of Sciences also evaluated the connection between dietary and planetary health and concluded that “[d]ietary choices—the types and amounts of foods that individuals consume—are a major determinant of human health and environmental sustainability.”²⁸¹ The study evaluated “human health and environmental impacts of 15 different food groups: chicken, dairy, eggs, fish, fruits, legumes, nuts, olive oil . . . potatoes, processed red meat, refined grain cereals, sugar-sweetened beverages (SSBs), unprocessed red meat, vegetables, and whole grain cereals.”²⁸² Specifically, the study examined the “food-dependent linkages between and among 5 different diet-

supporting a lesser environmental impact of patterns of eating higher in plant-based foods and lower in animal-based foods. The potential benefits include helping to conserve soil, water and air.” HEALTH CANADA, CANADA’S DIETARY GUIDELINES FOR HEALTH PROFESSIONALS AND POLICY MAKERS 15 (2019), <https://food-guide.canada.ca/static/assets/pdf/CDG-EN-2018.pdf> [https://perma.cc/X8KA-P4DA].

²⁷³ *Id.*; accord EAT-LANCET COMMISSION SUMMARY REPORT, *supra* note 10.

²⁷⁴ EAT-LANCET COMMISSION SUMMARY REPORT, *supra* note 10, at 7.

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.* at 5.

²⁷⁹ *Id.* at 12.

²⁸⁰ *Id.* at 5.

²⁸¹ Michael Clark, Marco Springmann, Jason Hill & David Tilman, *Multiple Health and Environmental Impacts of Foods*, 116 PROCEEDINGS OF THE NAT’L ACAD. OF SCI. 23357, 23357 (2019).

²⁸² *Id.*

dependent health outcomes in adults—type II diabetes, stroke, coronary heart disease, colorectal cancer, and mortality—and 5 different environmental impacts of producing the foods”—GHG emissions, land use, scarcity-weighted water use, acidification, and eutrophication.²⁸³ The study found that “foods with the lowest environmental impacts often have the largest health benefits (lowest relative risks of disease or mortality), and that the foods with the largest environmental impacts—unprocessed and processed red meat—often have the largest negative impacts on human health.”²⁸⁴

The findings demonstrated that “the same dietary changes that could help reduce the risk of diet-related noncommunicable diseases could also help meet international sustainability goals.”²⁸⁵ Thus, “focusing diets on foods consistently associated with decreased disease risk would likely also reduce diet-related environmental impacts.”²⁸⁶ Understandings about the connections between human and planetary health could “help consumers, food corporations, and food policies, potentially increasing the likelihood of meeting international sustainability targets such as the United Nations’ Sustainable Development Goals and Paris Climate Agreement.”²⁸⁷

The study also found that “foods with intermediate environmental impacts or that are not significantly associated with health outcomes, such as refined grain cereals . . . could also contribute to meeting international health-focused or environmental-focused sustainability targets if they are used to *replace* foods that are less healthy or have higher environmental impacts such as unprocessed red meat and processed red meat.”²⁸⁸ This hits on the purpose of plant-based meat and dairy alternatives—to serve as replacements for conventional meat, poultry, and dairy to help meet international health and environmental goals. The challenge though, is reconciling the sustainability and comparative health benefits with the categorization of the Beyond Burger and Impossible Burger (used as examples because they are the leading plant-based meat alternatives) as highly or ultra-processed. The *Proceedings of the National Academy of Sciences study excluded* ultra-processed foods “because no dose–response metaanalyses [sic] had examined the association between consumption of these foods and health outcomes.”²⁸⁹ The authors did note, however, that some studies have shown a link between the consumption of ultra-processed foods and increased disease risk.²⁹⁰

According to Professor Nestle, “[t]he cutting-edge issues in dietary advice” include reducing meat consumption and producing food sustainably, thus, “[g]uidelines that avoid these issues will be years behind the times.”²⁹¹ Unfortunately, the USDA confirmed that sustainability is not among the topics that will be addressed.²⁹² The agency explained its decision to focus on “topics based on their importance to public

²⁸³ *Id.*

²⁸⁴ *Id.* at 23359.

²⁸⁵ *Id.* at 23360.

²⁸⁶ *Id.*

²⁸⁷ *Id.* at 23357.

²⁸⁸ *Id.* at 23360–61 (emphasis added).

²⁸⁹ *Id.* at 23361.

²⁹⁰ *Id.*

²⁹¹ Laura Reiley, *How the Trump Administration Limited the Scope of the USDA’s 2020 Dietary Guidelines*, WASH. POST (Aug. 30, 2019), <https://www.washingtonpost.com/business/2019/08/30/how-trump-administration-limited-scope-usdas-dietary-guidelines/> [<https://perma.cc/ED8A-Q2PV>].

²⁹² *Id.*

health, potential impact on federal nutrition programs, and to avoid duplication of federal efforts.”²⁹³ Rather, it announced that the DGAC “will limit its review and advice to dietary guidance for human nutrition on the topics and scientific questions specified by the Departments.”²⁹⁴ Despite the limitation placed on the DGAC, by identifying broader goals and taking consumer perception into account, FDA could take a leadership role in aligning planetary and dietary health in defining “healthy.” To do so, FDA should allow food manufacturers to truthfully communicate that a product is “healthy” for people and the planet by requiring disclosure statements with the use of the term, as is already required for the nutrient content claim.

Touting the planetary health benefits of plant-based alternatives compared to conventional animal products is an attribute that has already, and will continue to be, a critical marketing strategy for the alt-protein industry. In 2018, both Impossible Foods and Beyond Meat received the United Nations’ environmental planetary health Champion of the Earth Award.²⁹⁵ Life cycle assessments, which are methodologies for assessing environmental impacts associated with all the stages of the life-cycle of a product, have demonstrated the benefits of Beyond Meat’s and Impossible Foods’ products.²⁹⁶ The Center for Sustainable Systems at University of Michigan was commissioned by Beyond Meat to conduct a “cradle-to-distribution” life cycle assessment of the Beyond Burger.²⁹⁷ The study evaluated environmental impacts by comparing “greenhouse gas emissions, cumulative energy demand (energy use), water use, and land use . . . with those from typical beef production in the U.S.”²⁹⁸ The report concluded that “[b]ased on a comparative assessment of the current Beyond Burger production system with the 2017 beef LCA . . . the Beyond Burger generates 90% less greenhouse gas emissions, requires 46% less energy, has > 99% less impact on water scarcity and 93% less impact on land use than a ¼ pound of U.S. beef.”²⁹⁹

The Impossible Burger LCA was similarly impressive. “Compared to conventional ground beef, the Impossible Burger reduces environmental impacts across every

²⁹³ *Id.*

²⁹⁴ U.S. DEP’T OF AGRIC., CHARTER FOR THE 2020 DIETARY GUIDELINES ADVISORY COMMITTEE 1 (2020), <https://www.dietaryguidelines.gov/sites/default/files/2019-03/DietaryGuidelinesAdvisoryCommitteeCharter-10-05-18.pdf> [<https://perma.cc/88YW-QBX9>].

²⁹⁵ Press Release, United Nations Env’t Programme, Celebrating Bold Environmental Leadership and a Plastic-Free Future (Oct. 3, 2018), <https://www.unenvironment.org/news-and-stories/press-release/celebrating-bold-environmental-leadership-and-plastic-free-future> [<https://perma.cc/QDG9-UFW9>].

²⁹⁶ MARTIN C. HELLER & GREGORY A. KEOLEIAN, CTR FOR SUSTAINABLE SYS. AT UNIV. OF MICH., BEYOND MEAT’S BEYOND BURGER LIFE CYCLE ASSESSMENT: A DETAILED COMPARISON BETWEEN A PLANT-BASED AND AN ANIMAL-BASED PROTEIN SOURCE 7 (2018), <http://css.umich.edu/sites/default/files/publication/CSS18-10.pdf> [<https://perma.cc/M23A-57L6>]; SOFIA KHAN, JON DETTLING, CRISTOBAL LOYOLA, JOSHUA HESTER & REBEKAH MOSES, QUANTIS AND IMPOSSIBLE FOODS, ENVIRONMENTAL LIFE CYCLE ANALYSIS: IMPOSSIBLE BURGER 2.0 (2019), <https://impossiblefoods.com/mission/lca-update-2019/> [<https://perma.cc/3E5Z-28YW>].

²⁹⁷ “[T]he chosen functional unit for comparison was defined as 4 oz. (quarter pound, 0.113 kg) uncooked burger patty delivered to retail outlets. This is the marketed patty size of the Beyond Burger and a standard consumer product size for beef patties. System boundaries included upstream ingredient and raw material supply (including farm production of agricultural crops), processing and packaging operations, cold storage, distribution to point of sale, and disposal of packaging materials. Retail and consumer stages, including potential losses at those stages, were excluded, as they were considered equivalent in both product systems.” HELLER & KEOLEIAN, *supra* note 296, at 7.

²⁹⁸ *Id.*

²⁹⁹ *Id.*

impact category studied in [Quantis's] report—87% less water, 96% less land, 89% fewer GHG emissions, and 92% less aquatic pollutants.”³⁰⁰ Because cows require large quantities of crops as feed, about 80 percent less herbicide is required to produce the Impossible Burger than an average animal-based burger.³⁰¹ These findings signal the potential significant environmental benefits if meat eaters substitute animal products for plant-based versions. Critical to this equation will be the use of the plant-based meat as replacements—an issue that certainly merits study and consideration in the development of “healthy” guidance. As discussed, while they have the potential to be useful for eaters “transitioning” from animal products, it is not a given that plant-based burgers will convince people either to consume less animal meat overall, or to shift to a whole-foods, plant-based diet to reduce their risk of diet-related diseases or environmental impact. As these plant-based meat products are more widely consumed, research should track their impact on human and planetary health and their role as animal meat replacement or supplement.

V. CONCLUSION

The media narratives regarding alt-proteins often miss the point of these products—they are not silver bullets that can promise everything—taste, convenience, health, sustainability, animal welfare, and affordability. At least, not yet, and perhaps not ever. There is a danger with this narrative that cuts both ways—that all alt-proteins will benefit from a health halo that does not in fact improve public health or environmental outcomes, or that alt-proteins will become tainted by the negative characterization of these products as heavily processed “fake” foods. Herein lies the challenge of simultaneously marketing products similar to conventional meat, yet different, and better than those counterparts. By virtue of the name “burger” and “meat,” consumers infer similarities—how the product is to be used, for instance; however, evaluating the differences can be difficult to discern and evaluate. Labeling must be utilized to inform consumers in a meaningful and non-misleading way.

While there may be consumer confusion about the healthfulness or sustainability of these products, the products currently on the market (and menu) are not intended to be the pinnacle of health. Yet, there are significant, tangible, and measurable benefits of these innovations. They are incremental steps towards a more healthful diet—defined broadly. Even given his reservations about the health of the products, Whole Foods CEO John Mackey says there is at least one good dietary argument for plant-based meat: “A lot of people say . . . that [plant-based] meat is a transition food, meaning it’s a way for [people] to begin to reeducate [their] palates’; it’s a good first step in weaning people off of meat products.”³⁰² As Michele Simon, executive director of the Plant Based Foods Association, explained, “It’s clear the American palate has been trained on a diet of animal foods. . . . For the average person, it will be difficult to trade

³⁰⁰ KHAN ET AL., *supra* note 296; *accord* SOFIA KHAN ET AL., COMPARATIVE ENVIRONMENTAL LCA OF THE IMPOSSIBLE BURGER WITH CONVENTIONAL GROUND BEEF BURGER 3 (2019), <https://impossiblefoods.com/mission/lca-update-2019/> (follow “Read the Report” hyperlink to download report) (last accessed Aug. 16, 2020).

³⁰¹ Pat Brown, *How Our Commitment to Consumers and Our Planet Led Us to Use GM Soy*, MEDIUM (May 16, 2019), <https://medium.com/impossible-foods/how-our-commitment-to-consumers-and-our-planet-led-us-to-use-gm-soy23f880c93408#:~:text=And%20crucially%20for%20critics%20of,a%20cow%20to%20produce%20beef> [<https://perma.cc/KXS7-M6CT>].

³⁰² Scipioni, *supra* note 43.

hamburgers for salad, and this next generation of companies is trying to reach the hard-core meat eaters.”³⁰³ “‘So the reason why these plant-based meats have taken the world by storm is that they taste very similar to regular meats, whereas if you get a [healthy] black bean burger with flax seeds and sweet potatoes in it, that’s going to taste great to me,’ says Mackey, but not to most people.”³⁰⁴

In terms of health, processing does matter for a variety of reasons. For instance, are antibiotics or hormones used? Are increased pesticides or herbicides necessary for the production of the food? Are ingredients demonstrated to be safe? Are there undisclosed processing aids that could be risky? Is the nutritional value of otherwise healthy ingredients compromised by processing? Such desire for more information is made clear by increasing consumer demand for “natural,” “non-GMO,” and “clean” products and how those claims are equated with health. FDA should be responsive to these trends, conduct research, and issue guidance to recommend and promote best practice to benefit both food manufacturers and consumers.

As discussed, information that is likely to be most useful for the public allows consumers to compare the attributes of the “alternatives” to their counterparts. Thus, if someone is deciding between the plant-based burgers vs. conventional, how do they compare? Of course, the nutritional facts panel and new menu labeling present nutritional information, but as discussed above, credence attributes are undetectable by consumers. For example, how is one to know whether the plant-based burger is more environmentally sustainable than a conventional burger vs. a grass-fed “all-natural” burger? A revised definition of “healthy” as well as guidance from FDA for substantiation of sustainability claims, in coordination with USDA and FTC, can help consumers better understand and evaluate the role of alt-proteins in a planetary health diet. The potential role of plant-based meat to reduce one’s environmental impact is enormous and may, in fact, “be the only pragmatic way to reverse climate change.”³⁰⁵ To best communicate this information, the time has come for a broader conception of “health” in FDA’s definition and Dietary Guidelines for Americans that includes not just nutrition, but also long-term planetary health.

³⁰³ Tugend, *supra* note 33.

³⁰⁴ Scipioni, *supra* note 43.

³⁰⁵ Tugend, *supra* note 33 (quoting Jeff Anhang, Environmental and Social Specialist at the World Bank Group).