Attachment 1
Good Food Institute, Plant-Based Meat Mind Map

PLANT-BASED MEAT MIND MAPS:

AN EXPLORATION OF OPTIONS, IDEAS, AND INDUSTRY

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GFI is a 501(c)(3) nonprofit working to create a healthy, humane, and sustainable food supply. GFI is committed to democratizing scientific information that will help move our food system away from factory farming and toward better alternatives.

I. AN INTRODUCTION TO MIND MAPS: CONCEPTUALIZING GROWTH OPPORTUNITIES

A mind map provides a visual representation of critical technologies in an emerging industry to identify gaps in research and development as well as opportunities for strategic industry partnerships. This paper presents established, emerging, and speculative opportunities for plant-based meat sourcing, creation, processing, and distribution through two schematics: the plant-based meat product mind map, which surveys the types of meat analogues that have the potential to replace meat; and the plant-based meat technology mind map, which outlines areas of research and innovation that will accelerate the sector's ability to compete for market share of the meat industry.

The end goal of producing more and better plant-based meat products is to decrease consumption of animal meat products at all levels of quality and price, from steaks to processed meat. Therefore, some of the opportunities and recommendations presented here may apply to only certain types of products or manufacturing methods. For replacement to be successful, in addition to the scientific and technological opportunities discussed below, we must consider the nutritional profiles of various types of plant-based meat and their comparability to the animal products they are designed to replace. Moreover, as it advances, the industry should be transparent regarding its natural resource consumption and other environmental impacts. Though beyond the scope of this introductory paper, The Good Food Institute plans to conduct in-depth analyses of research and innovation opportunities regarding the nutritional qualities of plant-based meat and the environmental significance of its production.

II. THE CASE FOR PURSUING PLANT-BASED MEAT RESEARCH AND DEVELOPMENT

It is now widely recognized that industrialized animal agriculture takes a significant toll on our environment, sustainability, human health, and animal welfare. Additionally, the possibility that antibiotics will become useless for treating human infections due to their overuse in farm animals or that a zoonotic disease outbreak could kill tens of millions of people is a very real threat.

Nevertheless, decades of work by the health, environmental, and animal protection communities to convince people to consume less meat have not put a dent in meat consumption. In fact, meat consumption in the developed world continues to rise, and meat consumption in the developing world is growing rapidly. According to the United Nations, global meat production is projected to increase by nearly 360 million tons by 2050.

Despite rising awareness of the global impacts of our dietary choices, consumers continue to base their purchasing decisions on price, taste, and convenience. Plant-based meat still accounts for only a small percentage of the meat market. While plant-based milk commands more than 9 percent of total milk sales, plant-based meat commands less than one-quarter of 1 percent of meat sales in the U.S. Because the industry is so small, major players have not meaningfully entered, and most of the potential innovation remains unexplored. Merely bringing plant-based meat to 10 percent of the market share would create a $20 billion market in the U.S. alone, and it would have a significant positive impact on our climate, food sustainability, and global health.

That said, the wide-ranging uses of meat present a challenge for understanding where to focus research, development, and manufacturing innovations to create meat replacements. A schematic overview of the opportunities in this market—from both product and technology perspectives—can provide direction for research in food science programs, emergent or established plant-based meat companies, and the food industry as a whole. To this end, GFI has produced two industry mind maps to establish focus areas and provide insight into targeted research and innovation that may advance the industry via product development, production processes, and agricultural research.

III. PLANT-BASED MEAT PRODUCT MIND MAP

Several different animal species are bred, raised, and killed for meat, and each species is used to produce many different types of meat. While some meat is sold relatively unprocessed, a significant amount of meat is ground, minced, or processed in other ways. To effectively compete with animal-based meat products, the plant-based meat industry must expand and innovate to develop a variety of replacements that are as appetizing and affordable as conventionally produced animal meat. Fortunately, opportunities for innovation in the plant-based meat industry are even more vast than for the conventional meat industry. The conventional meat industry is inherently constrained by limitations in the diversity, anatomy, and physiology of the animals it uses, whereas plant-based meat companies can innovate beyond mere replication of the limited types of animal meat currently manufactured. In the following section, we outline categories of meat replacements that represent areas for plant-based meat product innovation that align with this premise.

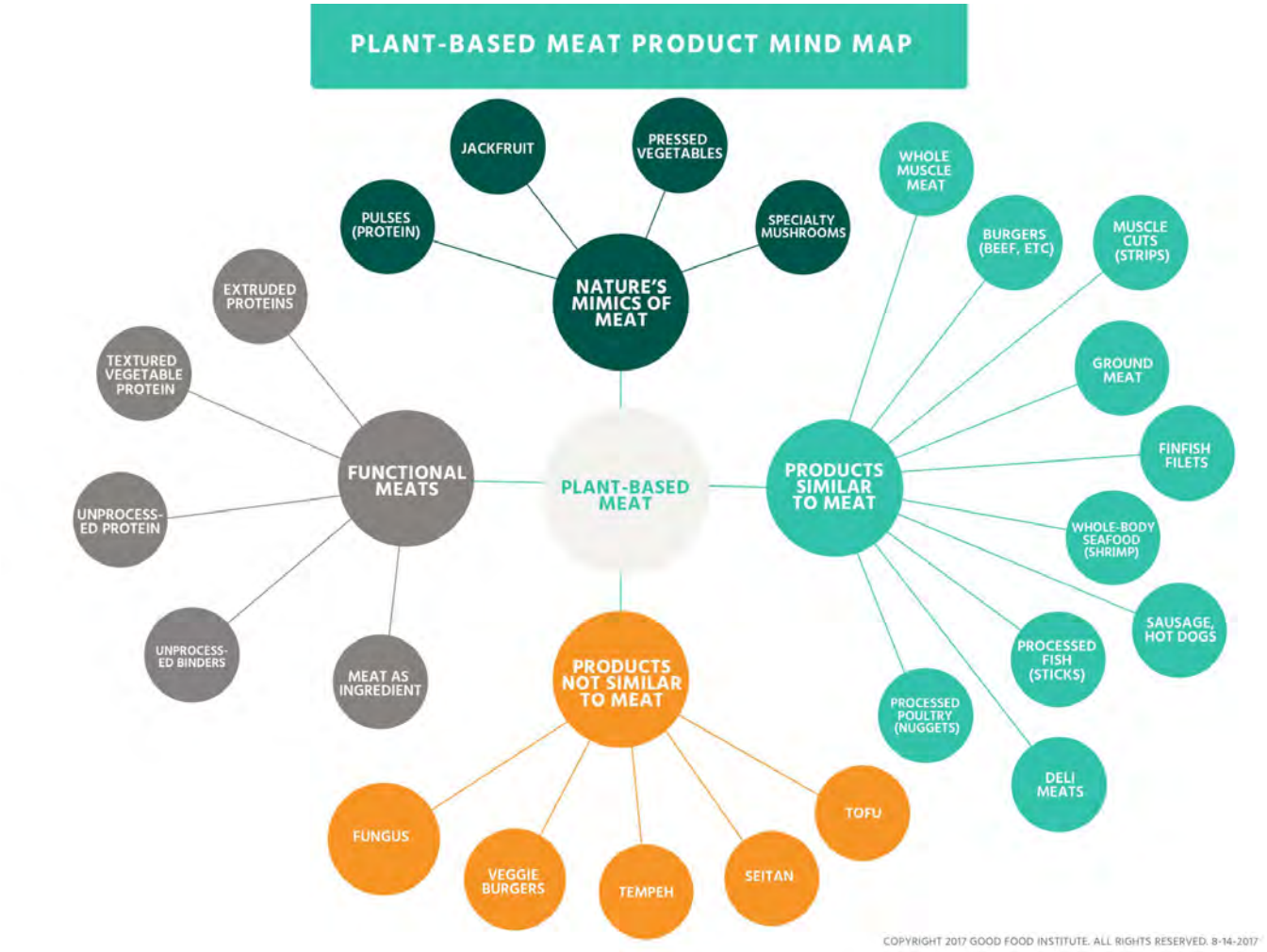

Figure 1. Plant-based meat product mind map

A. PRODUCTS SIMILAR TO MEAT

Products that attempt to replicate animal meat in texture, flavor, and aroma have been the focus of several recent and groundbreaking developments in plant-based meat. New products in this category, such as the Beyond Burger and the Impossible Burger, are built from the ground up to mimic animal meat's characteristics. This particular segment of the plant-based meat industry is redefining "meat" as a product defined by its molecular structure and composition rather than its animal origin. By emulating key characteristics of specific animal-based meat products, plant-based meat can now enjoy greater success as the meaty, center-of-the-plate entr entrée. Furthermore, where demand for plant-based meat was once driven predominantly by vegetarians, today's products—such as the Impossible Burger—which tastes, smells, and "bleeds" like a fresh beef burger, appeal to a range of "flexitarian" consumers who are generating considerable market growth for plant-based meat.

The taste profile of meat is highly complex, comprising thousands of molecules that interact chemically in subtle and not always predictable ways with other food components during the cooking process. Because of its complexity, the flavor of meat is neither trivial nor easy to replicate with alternative ingredients. To create more and better plant-based replicas, we need to study the molecular structure of animal meat and develop innovative plant-based ingredients that mimic this structure.

B. PRODUCTS NOT SIMILAR TO MEAT

Many innovative plant-based meat companies have developed products that are intended to be used directly in place of meat but are not designed to replicate every aspect of the animal-based products they replace. These include products made from whole-food ingredients, such as classic veggie burgers; products intentionally created to have a taste profile different from animal-based meat, such as plant-based sausages flavored with vegetables and fruit; and products considered to be more health-conscious, such as tofu or tempeh. These products appeal to consumers looking for foods that are not sourced from animals. Growth opportunities in this area include increasing the market presence of these products—in terms of both quantity and variety—at competitive prices, while expanding ingredients and flavor profiles to appeal to a wider range of consumers.

C. FUNCTIONAL MEAT PRODUCTS

Functional plant-based meat ingredients, such as proteins and binding agents, are not intended to taste identical to animal meat but are designed to be texturally similar and serve the same purpose as meat in prepared foods (e.g., ground crumbles made from plant ingredients, used in heat-and-serve lasagna). Since it is typically used as an ingredient, functional plant-based meat may require special formulation, just as animal meat is prepared, flavored, or tenderized for a specific purpose. Though functional plant-based meat does not alone serve a center-of-the-plate purpose, it can play a pivotal role in replacing animal meat in the expanding prepared meals market comprising various types of heat-and-serve entrees.

Innovation in this area includes creating plant-based meat ingredients that retain their shape, texture, and flavor through freezing, thawing, and cooking in a full range of prepared products. Additionally, by developing functional plant-based protein ingredients, production capacity of plant-based foods can be increased to improve the price parity of alternatives to popular heat-and-serve products, such as plant-based chicken nuggets, to serve lower-cost markets, such as schools.

D. NATURE'S MIMICS OF MEATS

Certain plant and fungal foods can also displace animal meat as the focus of a meal by providing a whole-food product with a savory taste and the mouthfeel of meat. These less processed foods, such as jackfruit, pulses, and certain mushrooms, are often naturally fibrous or high in protein. Some companies already produce "mushroom bacon," while others use jackfruit to mimic barbecue pulled pork. Innovation in this area includes developing a scaled method of growing these natural meat mimics and creating a supply chain (fresh, frozen, or shelf stable) to distribute the products. Innovation can also focus on developing better marinades and sauces to expand product variety and developing marketing strategies to encourage broader appeal and acceptance.

IV. PLANT-BASED MEAT TECHNOLOGY MIND MAP

Successful innovation in the types of plant-based meat products described above requires a corresponding development of relevant technologies. To provide ample supply and price parity with animal meat, plant-based meat production will require research and development in many interrelated areas. The plant-based meat technology mind map (figure 2) illustrates five key areas: sourcing, isolation and functionalization, formulation, processing, and distribution. These areas come with unique challenges but provide considerable opportunities for meaningful industry innovation.

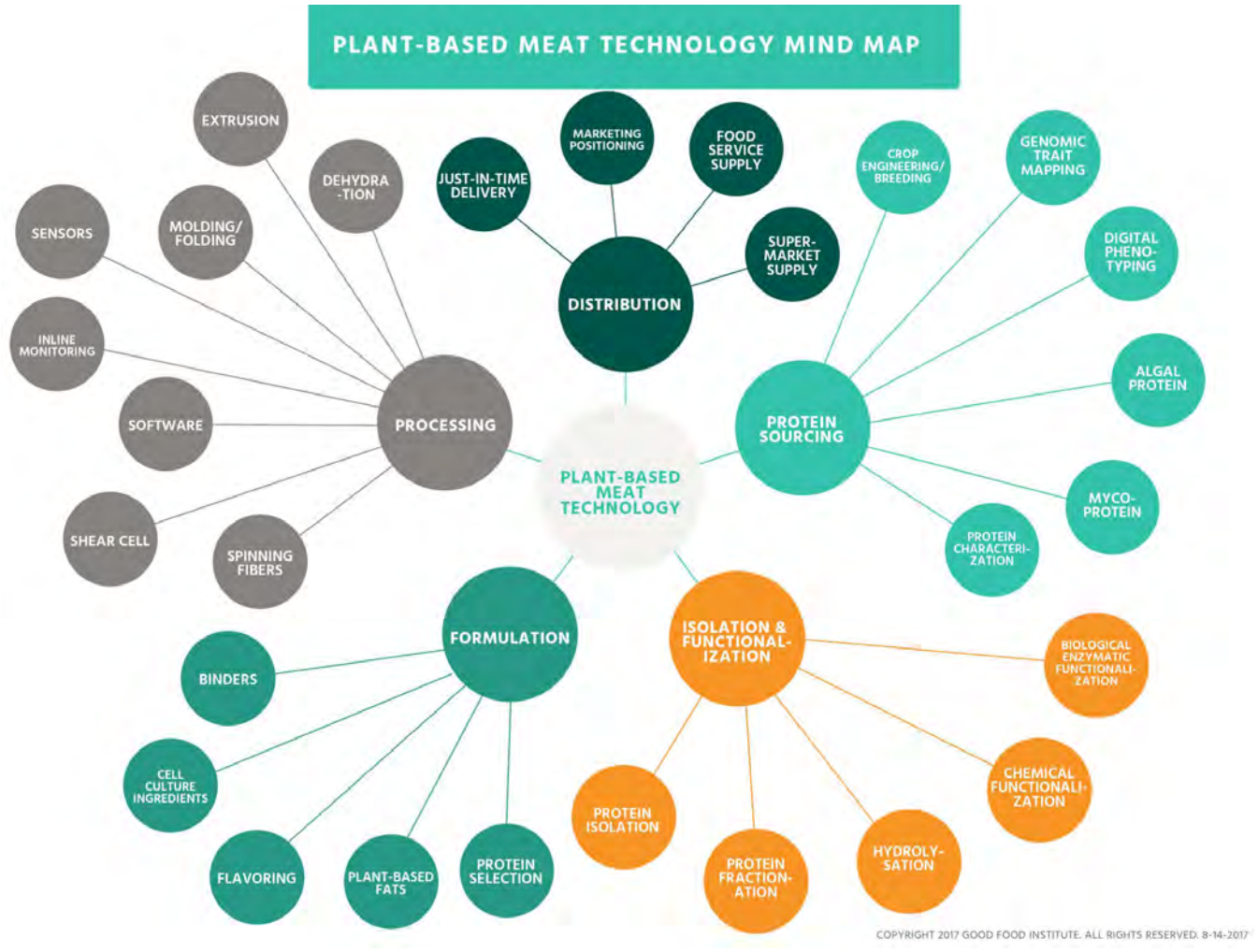

Figure 2. Plant-based meat technology mind map

A. PROTEIN SOURCING

The vast majority of commercially available plant-based protein ingredients comes from only 2 percent of the 150 plant species on which today's global food supply depends. A significant pool of potential plant protein sources is thus available for exploration, and this does not even take into account the almost 250,000 additional plant species not used in agriculture today. Innovation opportunities in this area include expanding and diversifying our use of plant protein sources, determining which sources are best suited to particular plant-based meat products, and ensuring that the proteins from these novel sources are optimized specifically for plant-based meat rather than plant-based foods in general. The methods of protein production described below could potentially provide protein supplies that are both lower cost and more nutritious.

With the identification and utilization of novel plant protein sources comes an opportunity to cultivate innovative farming practices. Concerted breeding or strain improvement efforts can provide underexploited plant protein crops with gains in yield, robustness, and disease resistance similar to what has been achieved for decades with commodity crops, such as corn and soy. This can decrease the cost of these novel protein sources and increase yield, making them more attractive to farmers seeking new crop opportunities.

There is also room for more sophisticated breeding or enhancement to develop strains that are uniquely suited to plant-based meat applications. For instance, specifically breeding plants for high levels of proteins that can be easily isolated will improve efficiency in obtaining purified proteins from the whole plant. Surprisingly, though they are still the most commonly used protein sources for plant-based meat, wheat and soy have historically been bred for starch or oil rather than protein. Efforts to optimize protein sources for plant-based meat can be rapidly accelerated using whole-genome sequencing and digital phenotyping to map desirable traits onto specific genomic loci. This facilitates targeted breeding and drastically reduces the number of generations required to obtain improved strains.

Fungus-based protein is also a promising area for expansion and opportunity. Optimized strains of a wide variety of mushrooms and other fungi could be cultivated in growing rooms or bioreactors for large-scale production.

B. ISOLATION AND FUNCTIONALIZATION

Once a source of plant protein is identified, the plant must be harvested, milled, and processed to obtain a more purified and concentrated protein that can support mass production. Plant-based meat typically relies upon plant-protein concentrates or isolates as raw materials. The inherent characteristics of the proteins, such as size and amino acid composition, determine how well the protein concentrate or isolate will function in the final product. The quality and performance of plant-based meat would be greatly advanced by implementing environmentally friendly methods for protein conditioning, which increase the desirable functional traits of a protein, such as gelation capacity, solubility, and fat adsorption. For instance, biological (enzymatic), chemical, and physical methods can be used to hydrolyze (break down) proteins to increase solubility or crosslink them to increase gelation. Additionally, fractionation (separation) can be used to select proteins that exhibit a desirable set of characteristics. For example, high molecular-weight proteins may perform better in texturization, while slightly hydrophobic proteins may increase fat-holding capacity. Systematic research aimed at identifying which functional traits of proteins are most desirable for particular types of plant-based meats would inform best practices for protein conditioning.

Several studies have found that the results of enzymatic functionalization can vary depending on the protein source because the effects of enzymatic treatment are specific to the sequence composition of each plant's dominant storage proteins. We need a more exhaustive analysis of the response of various plant proteins to specific sets of enzymes and conditions (pH, enzyme concentration, substrate concentration, temperature, exposure time, etc.). These data may enable greater predictive capability for developing optimal protein conditioning regimens to produce desired functional traits.

C. FORMULATION

Proteins are not the only components of meat; meat is also composed of water, fat, and polysaccharides. Thus, procuring a plant protein fraction with optimal functional properties is merely the start of formulating the final, edible meat alternative. The process of formulation involves establishing the correct mix of ingredients to create the desired taste, texture, smell, and structure of a new plant-based meat product. A first step toward successful formulation is to combine a molecular analysis of animal meat with an understanding of the texturization capability of plant proteins to match the texture and flavor components of specific meat products. Many functional characteristics beyond flavor and texture are also important, such as maintaining integrity during cooking. For this, novel binders that exhibit greater resistance to thermal degradation can be explored.

Proteins with high water-holding capacity can bolster the water content of plant-based meat to improve the juiciness of the end product. Likewise, for non-extruded plant-based meat products, proteins that exhibit greater fat-holding capacity can increase fat content by molecularly entrapping the fat. But for extruded products, the inclusion of fats can be technically challenging because fats disrupt the mechanical shear exerted during extrusion. Fat encapsulation or topical fat coating after extrusion may allow fat content to be increased, thus improving mouthfeel and flavor, without interfering with the protein structure. For all these approaches, antioxidants may be needed to stabilize the fats and protect them from rancidity.

Finally, formulation includes the culinary art of flavor selection. Plant-based proteins—especially hydrolyzed proteins, which are more soluble and thus exhibit greater functionality—are often prone to bitter or "beany" off-flavors. This could be addressed by creating new bitter-blocking agents as part of a larger opportunity for developing new flavoring components, particularly those derived from natural sources, and specifically designed to address the challenges of working with plant-based proteins. The selection and incorporation of flavoring in the production process is vital for creating plant-based meat that replicates the flavors of animal meat. Formulation must also consider the nutritional qualities of the plant-based meat product as compared to those of animal-based products. Given the complexity of formulation, the process must include both culinary experts and food scientists.

D. PROCESSING

After successful formulation, the mixture must be shaped into an appropriate form. Methods for transforming plant-protein mixtures into meat substitutes include a variety of manufacturing processes, such as stretching, kneading, shear-cell processing, press forming, folding, layering, and extrusion. Each of these processes can produce unique forms and textures of plant-based meat and affect the nutritional quality of the final product. Furthermore, different plant proteins perform differently in each of these manufacturing processes due to their unique compositions and functional properties. Therefore, understanding how particular plant proteins and combinations of plant proteins from various sources react to specific production techniques is crucial for manufacturing accurate replacements for animal meat.

Like all manufacturing systems, plant-based meat production requires methods for evaluating and controlling quality. Currently, technology to help evaluate and improve the consistency of plant-based meat production is in the early stages of research. Real-time production-system monitoring may be enhanced by inline morphology sensors designed to detect the internal structure of the product during processing. Quality control systems of this kind would reduce waste and increase consistency of the final product. Offline diagnostic tools, such as neutron scattering methods for fiber evaluation, can aid in making more realistic plant-based meat in the R&D phase.

In addition to sensors and analyzers, innovation in software would improve plant-based meat processing. Software tools to model and predict the performance of plant-based proteins would provide understanding and help control the undesirable variability currently observed in plant-based meat production and guide development of new processing methods.

A significant portion of animal meat is processed into sausages, cold cuts, hot dogs, and similar products. For these foods, extrusion is the most common method for developing shape and texture. Many of these popular types of meat can be reproduced with plant proteins and fats using essentially the same production methods. But improvements in processing methods and machinery are necessary to better mimic the taste and texture of more sophisticated or highly structured types of animal meat products.

E. DISTRIBUTION

Plant-based meat is also distinct from animal meat with respect to marketing, positioning, distribution, and production. Some types of plant-based meat can be sold fresh or frozen, while others can be freeze-dried for later use and do not require the intensive cold supply chain needed for most animal meat. Additionally, plant-based meat production may be more flexible and responsive to market demands, as it is not dependent on upstream processes like breeding and slaughter. These distinctions could potentially result in significantly less waste. Schools with variable schedules or hospitals with variable numbers of patients could quickly adjust their orders for plant-based meat, placing less hardship on producers, who may simply throttle output since no animals are waiting in trucks to be slaughtered. Many industries use this just-in-time inventory model to lower costs and reduce waste throughout their supply chains. Similar innovations in supermarket distribution and other marketing methods could revolutionize the availability and accessibility of plant-based meat, thus expanding consumer acceptance.

V. OPPORTUNITIES FOR INVOLVEMENT

Opportunities abound for academic researchers, established food conglomerates, and entrepreneurs to contribute to the growing market for plant-based meat, whether through building supply chains for novel protein sources, improving production methods, or designing new products.

The areas outlined above represent not only tremendously profitable market opportunities but also a substantial opportunity to address urgent challenges in our global food supply. By addressing needs along the supply chain, the quality, cost, and availability of plant-based meat products will improve dramatically, positioning them as economically viable and sustainable alternatives to animal meat. For this to happen expeditiously, both private and public sector funding for research and development are critically needed.

As a leader in the advancement of policy, innovation, and industrial development to move the food system away from conventional animal agriculture, GFI is actively investigating and pursuing key strategies to expand the field and catalyze further development of the plant-based meat industry to create a more healthy, humane, and sustainable food supply. See GFI.org for more information.

ABOUT THE GOOD FOOD INSTITUTE

The Good Food Institute is a 501(c)(3) nonprofit organization whose mission is to build a healthy, humane, and sustainable food system through markets and food technology. GFI is accelerating the market expansion of affordable and appetizing "clean meat" and plant-based alternatives to conventional animal products. GFI is taking ethics off the table for consumers by making the sustainable and humane choice the default choice.

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Liz Specht, Ph.D., is a Senior Scientist at The Good Food Institute. Liz works to identify and address areas of need for plant-based and clean meat scientific innovation and works with funding agencies to prioritize research that moves this field forward. Liz holds a bachelor's degree in chemical and biomolecular engineering from Johns Hopkins University, a doctorate in biological sciences from the University of California, San Diego, and postdoctoral research experience from the University of Colorado Boulder. Liz is a Fellow with the University of Colorado at Boulder's Sustainability Innovation Lab and has a decade of academic research experience in synthetic biology, recombinant protein expression, and development of genetic engineering tools.

Note: This report is intended to provide a snapshot overview of the current state of technology in the plant-based meat industry. However, due to the nature of the industry, some technological advances may be the intellectual property of the companies that developed them and thus are not covered in this report. Furthermore, this report should be considered a living document, subject to frequent revision and updates as new information becomes available. Please refer to the first page for the date of last revision.

Attachment 2
Good Food Institute, Clean Meat Mind Map

THE GOOD FOOD INSTITUTE

MAPPING EMERGING INDUSTRIES:

OPPORTUNITIES IN CLEAN MEAT

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AN INTRODUCTION TO MIND MAPS: MAPPING EMERGING INDUSTRIES

A mind map allows the viewer to visualize critical technologies in an emerging industry and identify gaps in research and development as well as opportunities for strategic industry partnerships. This mind map illuminates opportunities for technology development in one of the most promising food tech industries: clean meat. As will be explored in more detail in a forthcoming white paper on the industry, some of these areas are best addressed by academic research, others are best suited for innovation within nimble startups, and others would be best addressed by established companies in related fields like cell therapy or industrial biotechnology.

THE CASE FOR PURSUING CLEAN MEAT RESEARCH AND DEVELOPMENT

In March 2017, the National Academy of Sciences released a report, "Preparing for Future Products of Biotechnology." The report, which was researched and written by more than a dozen top scientists and peer reviewed by an additional 17, was produced at the request of the White House with a focus on identifying the products that are likely to be produced by biotechnology in the next 10 years. In the report, clean meat is flagged as an area of high growth potential.

While the plant-based meat sector continues to make impressive strides toward parity with conventional meat in taste and texture, clean meat allows consumers to maintain their dietary preferences for animal meat while removing many of the inefficiencies and harms of current meat production. Clean meat production requires far less land and water than conventional meat, will produce exponentially less climate change, and eliminates the severe environmental repercussions of animal waste and contamination via runoff. It also requires no antibiotics, produces no bacterial contamination, and will not harm animals.

Clean meat will likely find an early market entry point as a high-value ingredient in products that are predominantly plant-based. The taste profile of meat is highly complex, comprising thousands of molecules that interact chemically in subtle, not always predictable ways with other components of food during the cooking process. As a result, the flavor of meat is not trivial to replicate or reconstitute from alternative ingredients, and adding clean meat to the mix can solve this problem without introducing the external harms of conventional animal agriculture.

Furthermore, critical technologies that are developed along the way will likely serve as lucrative intellectual property licensing opportunities for other high-value industries that rely on large-scale cell culture. Thus, investment of human and financial capital into this field is likely to pay dividends in many areas, several of which may occur on shorter timescales than the development of full-fledged, price-competitive clean meat production.

LAUNCHING AN INDUSTRY: CRITICAL AREAS OF RESEARCH AND DEVELOPMENT

The clean meat industry mind map (Figure 1) illustrates five main areas for development: cell lines, cell culture media, scaffolding and structuring, bioreactors, and supply chain and distribution. While they are displayed as discrete areas to facilitate visualization, each of these areas is closely intertwined. Thus, rapid development of the industry as a whole requires concerted communication among researchers and companies that are conducting development in different areas of this conceptual map.

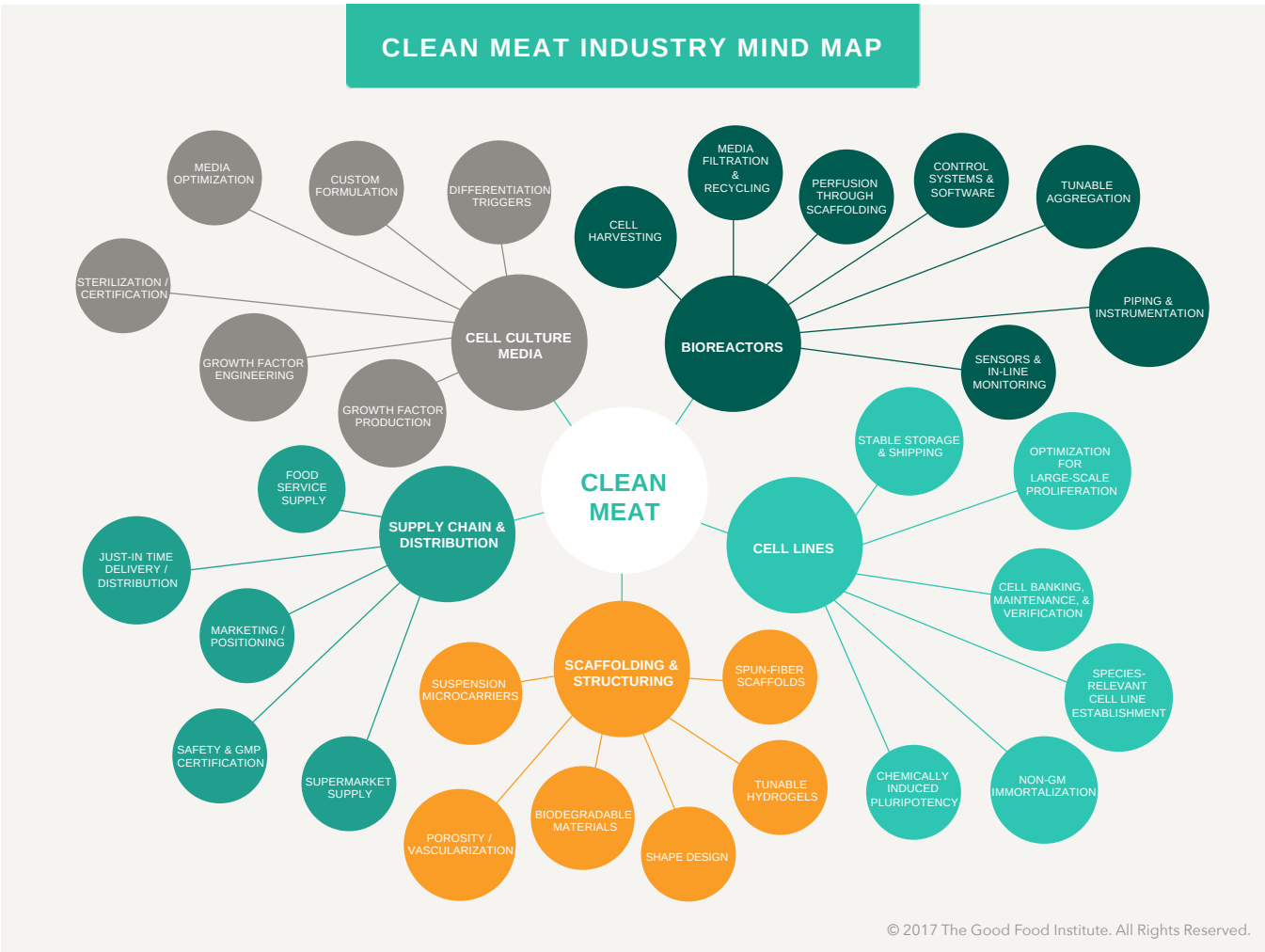

Figure 1. A conceptual mind map illustrating the primary elements for development and production of clean meat at large scale.

CELL LINES

Clean meat production begins with obtaining cell lines for the desired animal species. Generating a cell line means isolating a population of cells that is stable and immortalized. In other words, the cell line must behave in a consistent and predictable way through many generations, while maintaining an unlimited capacity to divide.

In some cases, "primary cells" directly isolated from an organism can spontaneously immortalize, meaning that they develop the ability to reproduce indefinitely without human interference. However, more stable lines may be produced through targeted modifications. Due to regulatory concerns in some countries, methods that do not rely on genetic modification may be preferred. Adult cells can also be reverted to stem cells, which are capable of proliferating indefinitely and differentiating into multiple cell types. Genetic modification has been the standard method for inducing these stem cells, but other so-called "footprint-free" methods should be explored for the clean meat field. Other modifications or adaptations – such as the ability to grow in suspension, divide more quickly, or differentiate in response to unique environmental cues – may also be introduced in the cell lines.

Once a stable, immortalized cell line exists, in theory it can be used indefinitely for production. However, even the most stable cell lines may eventually exhibit instability. Commercial cell banks store the original cell lines, provide validation services to ensure consistency, and will need to develop appropriate storage and shipping strategies for the volumes of cells needed by the clean meat field.

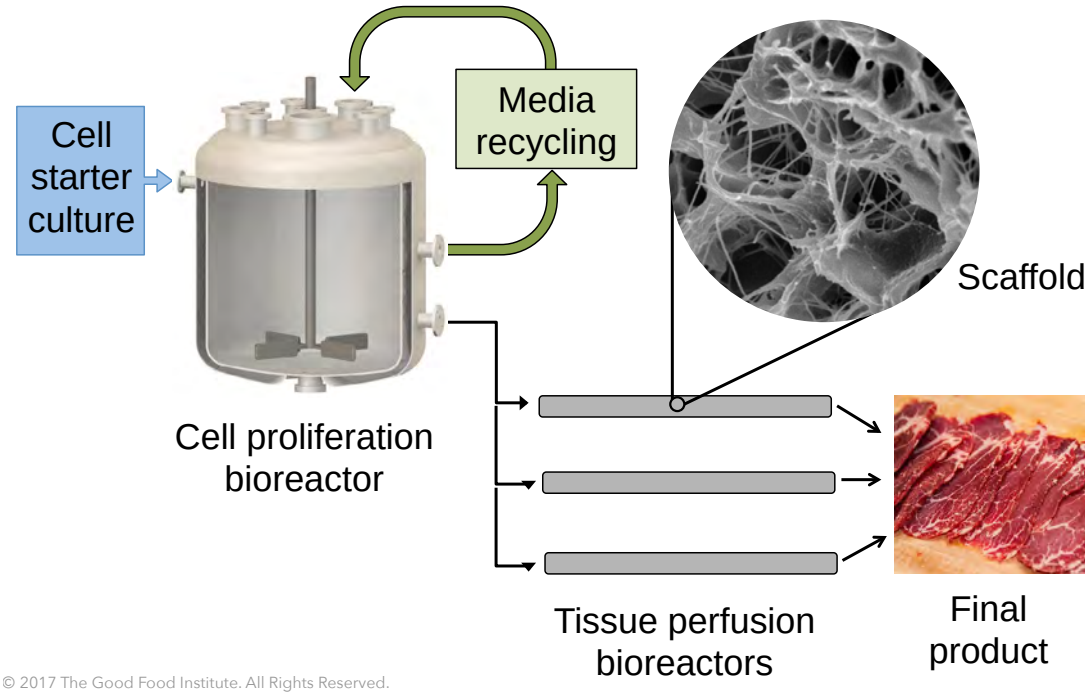

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Figure 2. Schematic illustrating one conception of the process of clean meat production at scale. The first stage is proliferation of the cells, followed by a differentiation and maturation stage where cells are seeded onto scaffolds and allowed to mature into the cell types required for meat. Each of these stages presents its own design requirements for the media, scaffolding, and bioreactors.

CELL CULTURE MEDIA

Just like cells inside an organism, cells in culture require nutrients to grow. Cell culture media is a nutrient solution containing salts, pH buffers, and the building blocks of cellular structures like proteins and fats. It also contains molecules called growth factors, which are signaling molecules that direct the cells to behave in certain ways. For example, specific differentiation factors guide cells towards becoming muscle or fat or blood cells. Traditionally these factors were obtained from animal serum, but serum has already been largely phased out of cellular therapeutics and regenerative medicine. Hundreds of serum-free formulations already exist; however, they are currently too costly for commercially viable clean meat production. Customized serum-free formulations will have to be optimized for clean meat-relevant cell lines with cost as a key parameter.

Several approaches can substantially reduce the cost of media. Growth factors can be engineered for higher stability and potency, or even replaced by peptide or small molecule mimics that are far less expensive. A synthetic biology approach could be used to reengineer cellular signaling pathways to respond to benign triggers like sugars or light, thus eliminating the need for complex growth factors altogether. Finally, sourcing, sterilizing, and certification requirements may be less stringent for food applications than for biomedicine, opening another avenue for significantly reducing media costs.

SCAFFOLDING AND STRUCTURING

Scaffolds provide a support structure for cellular adherence. In the simplest case, microcarriers within a stirred bioreactor may act as scaffolds during cell proliferation. For more complex, structured products, the scaffold requirements are much more demanding and must be integrated within the final product. The material must be edible or biodegradable, as well as low-cost and made from abundant sources.

These complex products require co-culture of multiple cell types and/or differentiation while embedded within a three-dimensional scaffold. To accommodate three-dimensional growth, the scaffolds must exhibit porosity for perfusing nutrient media. Alternatively, they must support vascularization of the tissue itself, i.e., the formation of a network of vessels to allow nutrients to permeate the tissue. Several production methods, including 3D printing and spun-fiber platforms, allow fine-tuning of pore size and microstructures within the scaffold.

Scaffold materials can also assist with the cellular differentiation process. Cells differentiate in response to external molecular signals from the growth media or neighboring cells, but they are also responsive to the biomechanical properties of their environment. Materials like engineered hydrogels allow fine-tuning of parameters like stiffness, cell adherence, and even controlled release of growth factors. These cues can direct cells to differentiate into various cell types along defined regions, helping to achieve the segmented flakiness of a fish filet or the marbling found in a steak.

BIOREACTORS

Bioreactors are the machines in which every other element in clean meat production is contained: where cells proliferate, and where the transition from cells into meat occurs. As with media, clean meat bioreactors will have unique design requirements depending on the stage of production.

The proliferation bioreactors will likely be stirred tank reactors, which are already well developed for mammalian cell proliferation. Some of these systems use cells in suspension while others rely on microcarriers. Cell aggregates are also frequently used for stem cell growth, and some systems allow the formation and dissolution of such aggregates to be controlled by conditions like temperature. Regardless of the proliferation platform, the cells must be harvested efficiently for transfer into the next phase of production. For the differentiation and maturation stage, perfusion bioreactors are needed that will flow media through cell-seeded scaffolds. These bioreactors will need to be developed in close collaboration with scaffold developers.

Both proliferation and maturation bioreactor systems will need to incorporate a media recycling system to minimize inputs and waste. This system will require analytical sensors to measure concentrations of critical media components in real time and introduce fresh components as needed. Likewise, the system will need to be capable of filtering out waste products, maintaining pH and osmotic homeostasis, and maintaining real-time quality control systems. An interdisciplinary approach with intimate knowledge of cellular metabolism as well as sensors, software, piping and instrumentation, and quality control will be necessary for success on this front.

SUPPLY CHAIN AND DISTRIBUTION

As with any large industry, establishing a robust and specialized supply chain is critical for efficient product production and delivery. The most significant inputs to the system will be the primary "ingredients" of cell culture media and scaffold material. Production of both of these will likely be outsourced rather than produced in-house by clean meat companies. For each input and for the clean meat products themselves, rigorous systems must be in place to ensure safety, good manufacturing practices, and product consistency. Developing suitable transportation methods for these inputs also represents a growth area. Once the end product has been manufactured, companies will tap into larger marketing and distribution networks to make it to the hands of consumers – through foodservice and restaurants, grocers and supermarkets, or manufacturers of plant-based meats that are creating hybrid products.

TECHNOLOGICAL REQUIREMENTS FOR A VARIETY OF CLEAN MEAT PRODUCTS

Depending on the target product, clean meat producers may not require significant development in all of the above technological areas. The first products that come to market may be hybrid products wherein clean meat is included as a part of plant-based products that essentially require only cell lines, media, and proliferative bioreactors to come to fruition. The next commercial products will likely be ground meat mimics, where scaffolding can be minimal; more complex structures requiring vascularization or perfusion bioreactors are not necessarily required. Finally, more structured tissues – like those mimicking steaks or chicken breasts – will require research and development in all of the areas outlined above. Thus, a consideration of target product(s) should drive the research and development focus.

OPPORTUNITIES FOR INVOLVEMENT

Because of the novelty of this industry, opportunities for involvement exist across the entire spectrum of research, development, and commercialization.

While the majority of research and development for the explicit purpose of commercializing clean meat is occurring in start-up companies, the importance of involving established industry partners should not be underestimated – both for upstream involvement (development and production) and for downstream opportunities (such as distribution and market access). In addition, academic researchers can provide crucial technological advances for ongoing incorporation into production platforms for the next generation of clean meat production – with an eye constantly towards improving cost and efficiency.

Additionally, there is significant opportunity for researchers currently working in related fields to shift their focus towards clean meat as a novel application with immense commercial potential. Already, relevant research - both within academia and by industry leaders - has been conducted within the biomedical field -- for example, related to immortalized cell lines, xeno-free media, and co-cultures of complex tissues -- that is simply waiting to be applied to clean meat production.

As a leader in the advancement of technology and industrial development to move our food system away from conventional animal agriculture, The Good Food Institute's Science & Technology team is actively investigating and pursuing key strategies to expand the field and accelerate the commercialization of clean meat in order to create a more healthy, humane, and sustainable food supply.

See GFI.org for more information.

ABOUT THE GOOD FOOD INSTITUTE

The Good Food Institute is a 501(c)(3) nonprofit organization whose mission is to build a healthy, humane, and sustainable food system through markets and food technology. GFI is accelerating the market expansion of affordable and appetizing "clean meat" and plant-based alternatives to conventional animal products. GFI is taking ethics off the table for consumers by making the sustainable and humane choice the default choice.

ABOUT THE AUTHORS

Liz Specht, Ph.D., is a Senior Scientist at The Good Food Institute. Liz works to identify and address areas of need for plant-based and clean meat scientific innovation and works with funding agencies to prioritize research that moves this field forward. Liz holds a bachelor's degree in chemical and biomolecular engineering from Johns Hopkins University, a doctorate in biological sciences from the University of California, San Diego, and postdoctoral research experience from the University of Colorado Boulder. Liz is a Fellow with the University of Colorado at Boulder's Sustainability Innovation Lab and has a decade of academic research experience in synthetic biology, recombinant protein expression, and development of genetic engineering tools.

Christie Lagally is a Senior Scientist at the Good Food Institute. Christie works on GFI's efforts to establish technology readiness assessments for clean meat and plant-based meat and supports technology development for new research projects and product development. Christie holds bachelor's and master's degrees in mechanical engineering and has worked as a mechanical engineer on diverse projects, including space- and ground-based telescopes, natural gas engines, roller coasters, and commercial aircraft. Throughout her career, Christie has focused her areas of expertise in multidisciplinary technology development, manufacturing, automation, mathematical modeling and programming, mechanical engineering R&D, and technical and business management.

Note: This report is intended to provide a snapshot overview of the current state of technology in the clean meat industry. However, due to the nature of the industry, some technological advances may be the intellectual property of the companies that developed them and thus are not covered in this report. Furthermore, this report should be considered a living document, subject to frequent revision and updates as new information becomes available. Please refer to the first page for the date of last revision.

Attachment 3
2016 correspondence between USDA and FDA about labeling plant-based bacon

Emerick, Margaret-Hannah

From: Hammond, Seyra
Sent: Tuesday, May 03, 2016 11:18 AM
To: 'Mark.Wheeler@fsis.usda.gov'
Cc: Szybist, Lynn
Subject: RE: Misbranding

Hello Mark,

Your question was assigned to me for response.

We appreciate your concern regarding the labeling of this product. However, based on recent discussions with our legal counsel regarding similarly labeled products, we do not believe there would be adequate support for enforcement action regarding the name of this product. While the PDP states "Benevolent Bacon," this is asterisked to another statement on the PDP that states "Vegan, Plant Based Substitute for Pork Bacon." The PDP also states "Plant-Based." FDA reviews labels as a whole. Without any evidence (such as consumer studies) to demonstrate that consumers would be misled, we would likely not object to the use of certain terms like "bacon" if they are appropriately qualified or if the label otherwise clearly and accurately discloses the nature of the product.

I hope that this is helpful. Please let me know if you have further questions.

Regards,

Seyra Hammond
Consumer Safety Officer
Food Labeling and Standards Staff-Labeling Regulations Implementation Team
Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

From: Wheeler, Mark - FSIS [mailto:Mark.Wheeler@fsis.usda.gov]
Sent: Monday, April 18, 2016 12:28 PM
To: Szybist, Lynn
Cc: Murphy-Jenkins, Rosalyn - FSIS; Canavan, Jeff - FSIS
Subject: Misbranding
Importance: High

Good afternoon, Lynn.

A FSIS compliance officer pick up a product labeled as bacon that is meatless. See the attached labels. Aside from the phrase "Vegan – Plant Based Substitute" at the bottom of the label, there is no indication that this product is meatless. In addition, there are numerous references on the label to unqualified bacon and reference to meat. Would you agree that this product is misbranded? Would this product need to follow labeling similar to the Boca products?

Mark Wheeler
Mark Wheeler, Labeling and Program Delivery Staff
Patriots Plaza III, 8-143B
355 E Street SW
Washington, DC 20024-3221

(301) - 504-0878

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Attachment 4
Good Food Institute, Petition to FDA

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Recognize the Use of Well-Established Common and Usual Compound Nomenclatures for Food	))))	Docket No. _____

Submitted by the

Good Food Institute

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Nicole Negowetti
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Nigel Barrella
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March 2, 2017

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[by electronic submission]
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
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CITIZEN PETITION

The Good Food Institute[1] ("GFI") submits this petition under sections 403(i), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")[2] to request that the Commissioner of Food and Drugs issue regulations clarifying how foods may be named by reference to the names of other foods. Many products named in this fashion are already on the market, with many more likely to be developed in the future. The requested clarification would be consistent with current FDA regulations and policies, would reflect consumer understanding and the current realities of products in the marketplace, and would serve to foster continued innovation. Further, promulgating a general regulation regarding the nomenclature of these products will avert perceived regulatory uncertainty surrounding such product names, and will promote honesty and fair dealing in the interest of consumers.[3]

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[1] The Good Food Institute is a 501(c)(3) nonprofit organization that is working toward a healthy, humane, and sustainable food supply, by publicly advocating for and encouraging research into alternatives to conventional animal foods.

[2] 21 U.S.C. §§ 343(i), 321(n), 371(a).

[3] 21 C.F.R. § 130.5(b). GFI further asserts that it is prepared to substantiate the information in this petition by evidence in a public hearing, if such a hearing becomes necessary. 21 C.F.R. § 130.5(c).

I. Action Requested

GFI requests that FDA issue a regulation clarifying that new foods may be named by reference to other "traditional" foods in a manner that makes clear to consumers their distinct origins or properties. As described herein, the practice of using such names is well-established in the marketplace, and consumers easily understand and accept such common or usual names for a wide variety of products. Specifically, GFI requests that FDA amend 21 C.F.R. § 102.5, to add the following language after part (d):

> (e) The common or usual name of a food may be —
>
> (1) the common or usual name of another food preceded by a qualifying word or phrase that identifies (i) an alternative plant or animal source that replaces the main characterizing ingredient(s) or component(s) of such other food, or (ii) the absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance, that is ordinarily present in such other food; or
>
> (2) any other word or phrase comprised of two or more terms, which may be separated by hyphens or spaces; but if such name includes the common or usual name of any other food, it must effectively notify consumers that the product is distinct from such other food.
>
> The use of such a name does not violate section 403 of the act or regulations of this chapter solely because it includes the common or usual name of another food (including a food for which a standard of identity is established) if the entire name serves to notify a reasonable consumer that the product differs from such other food.

GFI further requests that FDA, in the interim while undertaking the proposed rulemaking, publish guidance for industry clarifying that such product names may generally be used, consistent with the proposed regulation and the contents of this petition.

II. Statement of Grounds

A. Statement of Factual Grounds

1. Consumers are increasingly seeking out new variations on familiar foods.

The American food supply today consists of a greater variety of foods than ever before. The diverse array of food products now on the market can cater to the needs and tastes of most any consumer, and the plethora of options available to consumers continues to grow year after year.[4]

The increasingly diverse varieties of food in the marketplace are available because consumers are demanding them, for several reasons. Changing consumer preferences may partly reflect changing demographics and greater awareness (and availability) of the variety of foods from different parts of the world. Additionally, a large and growing share of consumers are becoming more discerning of the food they buy, selecting certain foods over others for reasons of health, environmental and ethical concerns, or personal taste.[5]

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[4] US Department of Agriculture, Agricultural Research Service, Nutrient Data Laboratory, USDA National Nutrient Database for Standard Reference Dataset for What We Eat In America, NHANES (Survey-SR), October 2015, available at https://www.ars.usda.gov/Services/docs.htm?docid=25662 (noting the addition of 265 "new foods" to the latest NHANES survey database); US Department of Agriculture, Economic Research Service, New Products, October 12, 2016, available at https://www.ers.usda.gov/topics/food-markets-prices/processing-marketing/new-products/ (describing the upward trend of new food product introductions per year since the early 1990s).

[5] The "new foods" added to the 2013–2014 NHANES database "include mainly commercially processed foods such as several gluten-free products, milk substitutes, sauces and condiments such as sriracha, pesto and wasabi, Greek yogurt, breakfast cereals, low-sodium meat products, whole grain pastas and baked products, and several beverages including bottled tea and coffee,

As part of this trend, consumers have become accustomed to seeing various qualifiers and claims in food labeling and advertising: organic, low-fat, reduced fat, fat-free, reduced calorie, low-carb, gluten-free, wheat-free, dairy-free, soy-free, no artificial colors, non-GMO, grown without pesticides, raised without antibiotics, no added sugars — the list goes on. Some of these qualifiers are subject to definitions under the law and regulations administered by FDA and USDA; others are constrained only by the general requirement that they not be false or misleading.

FDA and Congress have responded to these changes in the marketplace and in consumer demand by providing frameworks for new labeling claims (whether mandatory or voluntary), while also giving producers flexibility in formulating new products to suit these changes in consumer demand. One significant example of this trend is FDA's regulation relating to nutrient content claims, promulgated after the passage of the Nutrition Labeling and Education Act of 1990 (NLEA).[6] In that regulation, 21 C.F.R. § 130.10, FDA permitted modified versions of foods to be labeled with a "nutrient content claim and a standardized term," even if they did not comport with the standard of identity for the standardized term. This allowed new products with reduced levels of nutrients of concern to consumers (e.g. fat, sodium, calories) to be labeled in a clear manner that references standardized food terms (e.g. ice cream), leading to products with names like "low-fat ice cream" or "reduced calorie salad dressing."

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coconut water, malt beverages, hard cider, fruit-flavored drinks, fortified fruit juices and fruit and/or vegetable smoothies." USDA NHANES survey, note 4, above.

[6] Public Law 101-535.

Since the early 1990s, the list of nutrients or ingredients of interest to consumers has grown significantly. For example, the prevalence of common food allergies has apparently increased for unknown reasons,[7] and more consumers now seek foods free of specific allergens. Congress has responded by amending the FDCA to require labeling disclosures of common allergens,[8] and food producers have responded by making available varieties of (and alternatives to) traditional foods that do not contain common allergens such as wheat, milk, peanuts, egg, or soy. Similarly, the prevalence and identification of celiac disease appears to be increasing;[9] consumers with celiac disease are advised to avoid gluten, and many other consumers avoid gluten due to non-celiac gluten sensitivity or for other reasons. FDA has responded by defining the term "gluten-free,"[10] and food producers have responded by creating new varieties of traditional foods that do not contain gluten and are labeled "gluten-free."

Yet another significant (and growing) group of consumers has sought to reduce or eliminate certain animal products — especially dairy products — from their diet. Some of these consumers are avoiding allergens as described above (as milk is among the most

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[7] K.D. Jackson et al. *Trends in Allergic Conditions among Children: United States, 1997–2011*. National Center for Health Statistics Data Brief (CDC), May 2013, *available at* https://www.cdc.gov/nchs/data/databriefs/db121.pdf.

[8] *See* Food Allergen Labeling and Consumer Protection Act of 2004, Pub. Law 108-282; 21 U.S.C. §§ 343(w), 321(qq).

[9] *See, e.g.* J.F. Ludvigsson et al. *Increasing Incidence of Celiac Disease in a North American Population*, 108 AM. J. GASTROENTEROL. 818 (2013), available at http://www.nature.com/ajg/journal/v108/n5/full/ajg201360a.html.

[10] FDA, "Final Rule: Gluten-Free Labeling of Foods" 78 Fed. Reg. 47154 (Aug. 5, 2013).

common food allergies). Additionally, many consumers avoid dairy products due to lactose intolerance.[11] Still other consumers have reduced or eliminated their consumption of dairy for reasons of health, due to environmental or ethical concerns, or for mere personal taste. This trend has been most visible in recent years with a sharp increase in the consumption of alternatives to traditional fluid dairy milk. From 2011–2015, sales of almond milk grew 250%, surpassing the next most popular alternative (soy milk) and reaching nearly $900 million in annual sales in 2015.[12] Other plant-based alternatives to traditional dairy products (such as yogurt, cheese, and ice cream) are becoming more common as well, as just one part of a larger thriving plant-based food industry that has been growing so rapidly in response to consumer demand.

In sum, the growth in "new foods" described above, as well as many others has been ongoing since at least the 1990s and shows no signs of slowing.[13] Whether due to changes in demographics, or due to health, environmental, or ethical concerns of consumers, or merely due to changes in taste, the American food supply will continue to grow more diverse with a greater variety of products. GFI therefore submits this petition, requesting FDA to clarify that food producers may label and name their new products in

[11] Demographic shifts in the American population may contribute to an increasing incidence of lactose intolerance; FDA, citing NIH estimates, has noted that "up to 75% of all adult African Americans and Native Americans and 90% of Asian Americans are lactose intolerant." FDA, Problems Digesting Dairy Products?, October 2009, available at http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143705.pdf.

[12] Nielsen Insights, *Americans Are Nuts for Almond Milk* (Mar. 31, 2016), available at http://www.nielsen.com/us/en/insights/news/2016/americans-are-nuts-for-almond-milk.html.

[13] See note 4 above.

a clear, commonsense manner consistent with consumer expectations, with the law applied fairly and equally to each.

2. **Many products on the market are already named in a manner consistent with the standard GFI proposes**.

The new food products described above — whether brought from other parts of the world or newly invented — often resemble familiar products that are considered traditional in the American diet. Consumers often name them by reference to such familiar and "traditional" products by adding a qualifying term in front of the name of the traditional product (as GFI proposes). Example of this practice are too many to list comprehensively, but in this section, GFI discusses numerous examples, some of which pre-date the FDCA itself. And more specifically, this section focuses on well-known food products that incorporate the most closely regulated food names — those with established standards of identity.

To start, consider bread, a food as old as civilization. Historically, bread has been made from the ground meal or flour of a variety of plant species, usually (but not always) leavened with yeast. Virtually every culture around the world has its own versions of this dietary staple — countless variations with different ingredients and methods of preparation that have been developing for centuries.

But in the United States, FDA has specifically defined "bread" as a product primarily consisting of (non-durum) wheat flour, and requires that it be leavened with

yeast and baked.[14] "Nonwheat flours, nonwheat meals, nonwheat grits, . . . and nonwheat starches" may be used, but only "if the total quantity is not more than 3 parts for each 100 parts by weight of [wheat] flour used."[15] Additionally, "bread" must weigh half a pound or more.[16] Does this regulation mean that other types of bread (e.g. unleavened or nonwheat varieties from around the world, cooked by different methods, in different shapes and sizes) cannot be called bread?

The answer, of course, is no. Almost any American consumer is aware of the existence of rye bread, cornbread, and potato bread — just a few examples of breads commonly eaten in the United States (especially in certain regions or communities). Consumers know that bread can take different forms, such as flatbreads like pita bread or matzo. Some consumers seek out "multigrain" breads precisely because they contain a variety of nonwheat grains.[17] Still other consumers with celiac disease or gluten sensitivity seek out gluten-free breads, a variety of which are now on the market, along with gluten-free rolls and buns.[18] No consumers purchasing these diverse offerings are deceived or confused by the fact that they are labeled "____ bread" even if the products do not conform to the standard of identity for "bread." The qualifying term immediately

[14] 21 C.F.R. § 136.110(a), (c)(1), (c)(3); 21 C.F.R. § 137.105 (defining "flour" as a product made from "wheat, other than durum wheat and red durum wheat.").

[15] 21 C.F.R. § 136.110(c)(11).

[16] 21 C.F.R. § 136.3(a).

[17] A purchaser of "12-grain bread" might be unpleasantly surprised if the product *did* conform to the general standard of identity for "bread" (because in that case, the 11 nonwheat grains would, in total, constitute less than 3% of the total flour used).

[18] Rolls and buns must follow the same standard as "bread" except as to weight.

preceding "bread," denoting alternative grain sources or other origins or properties, provides enough clarity that the product is different from (unqualified) "bread."

Consider also another staple in many cultures — noodles. As with bread, FDA has defined noodles as "ribbon-shaped" products made exclusively from wheat flours (including durum, the variety of wheat typically used in pasta), and requires that they contain egg products.[19] (Per FDA's identity standards, ordinary pasta and similar products that do not contain eggs are "macaroni products.")[20] But many cultures, in East Asia and Southeast Asia for example, eat noodles made from rice, sometimes broad and flat rather than ribbon-shaped, and such noodles hardly ever contain egg. Other noodles of the world are made from different grains (e.g. Japanese *soba* noodles, made from buckwheat) or are made from wheat but without egg (e.g. ramen noodles). Are these products wrong to call themselves "noodles" in light of FDA's standard of identity? Of course not: they are rice noodles, ramen noodles, bean thread noodles, and so on. Again, the qualifying term — the "____" in "____ noodles" — notifies any reasonable consumer

[19] 21 C.F.R. § 139.150(a), (b).

[20] This antiquated term (established in 1944 under the heading "alimentary pastes", 9 Fed. Reg. 14881) demonstrates how far some standards of identity have fallen behind the evolution of the English language and consumer expectations: Americans today simply call it "pasta" and understand "macaroni" to refer exclusively to small tubular pasta varieties (meanings that reflect the Italian *pasta* and *maccheroni*). The standardized term is frankly confusing to the modern consumer, and the regulatory meaning cannot even be found in many modern dictionaries. Thus, some pasta producers have chosen to identify their products with the universally-understood term "pasta" rather than "macaroni products." This may technically violate FDA regulations, but justifiably so: pasta is simply the true common or usual name of these products, notwithstanding the outdated standard of identity.

that the product is distinct from what FDA may define as "noodles" (to the extent the reasonable consumer knows about FDA's definition of "noodles" from 1944).[21]

To give another example of similar compound names in action, "butter" has a standard of identity defined by statute — a product of more than 80% milkfat.[22] In spite of this, FDA defined standards for "peanut butter" and "fruit butters" (such as apple butter), products that do not contain butter.[23] And outside of FDA's identity standards, other "nut butters," such as almond butter or cashew butter, are now common in the market (for those allergic to peanuts, or who just prefer the taste), and consumers readily understand that these products are not (dairy) butter or other "____ butters."

It is in a similar vein that another global food — soy milk or soymilk — came to the United States in the mid-20th Century from areas of the world where cow's milk was often not traditionally consumed. And although the (unqualified) term "milk" has a standard of identity that refers exclusively to cow's milk,[24] consumers have long understood that various compound terms of the form "_____ milk" or "milk of _____" refer to distinct products unrelated to cow's milk. (Goat milk, buffalo milk, coconut milk, almond milk, or milk of magnesia, to name a few.) These compound constructions are so thoroughly lexicalized that they often appear in dictionaries as part of the first or

[21] Similarly, many wheat-free pasta products are now on the market (e.g. "gluten-free pasta," "brown rice pasta"), and these products often incorporate the names of standardized "macaroni products" (e.g. "gluten-free spaghetti"). 21 C.F.R. § 139.110(b)–(d).

[22] 21 U.S.C. § 321a.

[23] 21 C.F.R. § 150.110; 21 C.F.R. § 164.150.

[24] 21 C.F.R. § 131.110.

second definition of the word "milk,"[25] and the overwhelming majority of consumers refer to these products by these names.[26] The government itself (including FDA) has played its role in this linguistic trend, using the common names of products like soy milk and other dairy alternatives in public statements and documents.[27]

These linguistic patterns are hardly limited to the English language or the U.S. market — various languages from around the world use the same semantic constructions to describe the same products.[28] And almond milk is similarly well-established —

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[25] *See, e.g.* Merriam-Webster Online, Definition of MILK, available at https://www.merriam-webster.com/dictionary/milk (accessed January 26, 2017): "1 b . . . (2): a food product produced from seeds or fruit that resembles and is used similarly to cow's milk <coconut *milk*> <soy *milk*>. 2: a liquid resembling milk in appearance[.]"

[26] Google statistics show that since 2004, consumer searches in the United States for the terms "soy milk" and "almond milk" have outnumbered searches for alternative names ("soy drink," "soy beverage," etc.) by more than 30-to-1. https://goo.gl/DLhGz0.

[27] *See, e.g.* FDA, *Health Claims; Soy Protein and Coronary Heart Disease* 63 Fed. Reg. 62977, 62978 (Nov. 10, 1998) (referring to "soy milk, soy yogurt, and soy cheese."); USDA, *Enhancing Retailer Standards in the Supplemental Nutrition Assistance Program (SNAP)* 81 Fed. Reg. 90675, 90693–94 (Dec. 15, 2016) (referring to "soy yogurt," "soy milk," "soy cheese," "almond milk," and "rice milk."); DHHS & USDA, *2015–2020 Dietary Guidelines for Americans* at p. 23 (describing dairy alternatives from soy and other plants, marketed as plant "milks").

[28] In China, the country of soy milk's origin, 豆奶 (Mandarin *dòu nǎi*, literally "bean milk") is used as one possible name of the product, although the name 豆浆 (*dòu jiāng*, loosely translated as "bean slurry") is more common in most places. The former name (literally "bean milk") is especially common in Taiwan. The Japanese 豆乳 (*tonyu*) has the same literal meaning of "bean milk," and the Korean 두유 (*duyu*) has a similar linguistic origin. This construction has extended to Western countries where the product appeared later in history — the French and Spanish *lait de soja* and *leche de soja* (literally "milk of soy") and the German *Sojamilch* ("soymilk") are a few examples. Often these alternative meanings of "milk" are thoroughly lexicalized and refer to other milky liquids, including other cow's milk alternatives. *See, e.g.* "leche" in DICCIONARIO DE LENGUA ESPAÑOLA, available at http://dle.rae.es/?id=N2tsDWF, accessed January 26, 2017 (definition 3, translating as "white juice obtained from some plants, fruits, or seeds. *Milk of coconut, of almonds.*") The European Union has generally disapproved of the use of such terms in food labeling since 2007 (later adding exceptions for almond and coconut milks), but Google

though it has had the recent astronomical rise in popularity described above, it was common (and named similarly) in Western and Middle Eastern kitchens *centuries* ago.[29] Clearly, names of this form have deep historical and linguistic roots.

Further, these age-old foods with names of the form "____ milk" are now as familiar and clear to consumers as rye bread, rice noodles, or cashew butter. Consumers choose these products precisely because they are not cow's milk, whether due to allergies, other ingredient sensitivities or health concerns, ethical concerns, environmental concerns, or simple taste preference. And although some have claimed that including the word "milk" may confuse consumers (leading them to think the product contains cow's milk), consumer research has demonstrated that practically all consumers who have heard of these products (including those who do not consume them) are aware of their basic nature as cow's milk alternatives that do not contain cow's milk.[30]

Non-wheat breads, non-wheat noodles, non-dairy butters, and non-dairy milks are merely a few of the instances in which established products on the market incorporate the

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statistics reveal that the EU has failed in its effort to regulate natural language: use of these names persists and predominates over alternative names. See https://goo.gl/9CLoKg.

[29] For example, the 14th-Century French recipe book *Le Viandier de Taillevent* contains numerous references to *lait d'almendes* (or in Modern French, *lait d'amande* — milk of almond). 23 LE VIANDIER DE TAILLEVENT (1892 transcription of the oldest surviving manuscript, circa 1326–1395), available at https://books.google.com/books?id=D_EYAAAAYAAJ&pg=PA23.

[30] Soyfoods Association of North America, *Summary of Research on Consumer Awareness of Soymilk and Dairy Milk*, appended to this petition as Attachment A. In this 814-consumer survey conducted in 2006, the share of consumers who answered that they believe "cow's milk" is an ingredient in "soymilk" was less than 0.5%, with approximately 3% reporting "milk" as an ingredient.

common or usual name of another food to clearly and directly describe what the product is, despite being a very different product.[31] This structure, the addition of one word to another to form an entirely different word with a new meaning, is not just a matter of how marketing works — it is simply a matter of how language works. GFI submits this petition asking that FDA acknowledge and accept this fact and practice, not only for the products described above, but for others that may become part of the American diet in the future. As described in detail below, doing so would be consistent with the FDCA and with FDA policy and past practice. It would also be consistent with FDA's responsibilities under the Constitution: to regulate the market neutrally and with due respect to the First Amendment rights of food producers to label their products in a clear manner that consumers understand and accept.

B. Statement of Legal Grounds

1. GFI's proposed regulation is consistent with the FDCA and with FDA policy and practices.

GFI is asking FDA to establish a framework that formally recognizes the reality of the marketplace regarding the compound naming of foods that incorporate the common names of other foods in a way consumers clearly understand. In a way, what GFI requests is a regulation that clarifies existing law and practice; not only has FDA allowed

[31] And for good measure, here are a few more: herbal teas (like peppermint, chamomile, or ginger teas) that contain no tea; coconut water, which is not water; turkey bacon, which is not bacon; coconut cream and non-dairy creamer, neither of which contain cream; root beer, which contains no beer; English muffins, which are not muffins; shellfish, which are not fish; jellyfish, which are neither jelly nor fish; and rice cakes, which seem particularly unworthy of being called "cake."

products with such names to remain on the market, but the standard proposed by GFI is also consistent with FDA's longstanding interpretation of the FDCA and its regulations.

Even though the proposed regulation would do nothing more than clarify existing law and practice, such clarification would be helpful to industry and the public. The full meaning of the law and regulations is not always apparent to those who simply read the general language found in the United States Code or the Code of Federal Regulations, because the meaning of these provisions develops over time through interpretation by FDA and the courts, as well as through the agency's practices and policies. To put it bluntly, this is an area of law that is sometimes misunderstood or misapplied by some. For example, the Act's standard-of-identity provision is sometimes misread to completely preclude the use of standardized terms in non-standardized food names, and the Act's prohibition on unlabeled "imitation" foods is misread to cover any similar-looking food that can be used in place of another. Such misapprehensions of the law are clearly incorrect, but the fact that they persist can still do real harm to competitive industry and the public.

Such harm is not merely speculative, but concrete and apparent. For example, misguided statements of the law are often put forth by some members of industry in an anticompetitive effort to increase regulatory burdens on other members of industry. The most visible example of this today is a campaign by dairy producers against plant-based dairy alternatives — particularly soy milk and almond milk, which (as described above)

have become particularly popular and mainstream in recent years.[32] These dairy industry campaigns against regulatory flexibility for new products have spanned decades,[33] and have only intensified as demand for soy milk, almond milk, and other dairy alternatives has grown.[34] Recently, members of Congress from dairy-producing states were enlisted to argue on behalf of the dairy industry's distortions of the law,[35] and one Senator has even proposed to amend the FDCA in service of the dairy industry's anticompetitive goals.[36] These efforts spawn confusion and uncertainty for producers — many of which are startups and small businesses particularly sensitive to perceived regulatory risk.

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[32] Due to the attention these products have received, this petition will frequently use them as examples to illustrate how the proposed general language would apply.

[33] See, e.g. *Nat'l Milk Producers Fed. v. Harris*, 653 F.2d 339, 343 (8th Cir. 1981) (unsuccessful challenge to FDA's interpretation of the Act's "imitation" provisions); Letter from National Milk Producers Federation to CFSAN, February 14, 2000, available at http://www.fda.gov/ohrms/dockets/dailys/04/may04/050404/97p-0078-c00166-vol2.pdf; Comments of National Milk Producers Federation, July 28, 2010, available at https://www.regulations.gov/document?D=FDA-2010-N-0210-0092; Comments of National Milk Producers Federation, May 5, 2014, available at https://www.regulations.gov/document?D=FDA-2009-D-0430-0074.

[34] However, the dairy industry does not speak with one voice on this issue. For example, Dean Foods, the largest processor and distributor of fluid milk in the country, wrote to FDA in 2000 that "the term 'soymilk' has been widely recognized in our industry as the commonly used name for natural beverages made out of soybeans, water and other vegetable based ingredients for a number of years. We recognize this term to be accurately descriptive, meaningful and widely understood . . . . We have not found this term to be misleading to ourselves or our customers, [and w]e have not received any complaints from customers or consumers regarding this issue." Comment from Dean Foods Company, March 8, 2000, available at https://www.regulations.gov/document?D=FDA-1997-P-0016-0024. This comment, and many others like it, regards a 1997 citizen petition requesting that FDA establish a standard for "soymilk." GFI believes that this step is currently unnecessary because the name has already been clearly established by common usage, per 21 C.F.R. § 102.5(d).

[35] See Letter to Commissioner Califf from Congressman Peter Welch (D-Vt.) et al., Dec. 16, 2016, available at http://www.nmpf.org/files/Welch-Simpson%20Letter.pdf.

[36] DAIRY PRIDE Act, S. 130, 115th Cong. (2017), proposed by Senator Baldwin (D-Wisc.)

These misapprehensions of the law also manifest themselves in the courts. Some lawsuits have been filed alleging that soy milk and almond milk products are improperly named, and though such frivolous contentions have (so far) generally been dismissed at the pleading stage,[37] more such lawsuits have recently been filed.[38] Defending against these lawsuits creates costs for the producers of these products, and these costs may ultimately be passed on to the consumer. And these meritless lawsuits, just like perceived regulatory risk, can have a chilling effect that may dissuade businesses (especially small ones) from labeling their products in a clear, accurate manner that consumers understand. FDA's clarification of the law would pre-empt meritless lawsuits like these, to the benefit of producers and consumers alike.

To see how GFI's proposed language is consistent with the FDCA, and how it embodies FDA's policies and practices, this petition now reviews the (arguably) relevant provisions of the Act, and how they have been interpreted by FDA, and their applicability to names of the form GFI has proposed. This includes an analysis of (1) the Act's protection of standards of identity for certain foods; (2) the Act's requirement that products bear their common or usual name; and (3) the Act's provision regarding "imitation" foods.

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[37] See Order, *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013). These opinions are appended to this petition as Attachment B.

[38] *Kelley v. WWF Operating Co.*, 17-cv-117 (E.D. Cal., filed Jan. 24, 2017); *Painter v. Blue Diamond Growers*, BC 647816 (Los Angeles Super. Ct., filed Jan. 23, 2017).

Standards of Identity

When considering food names that incorporate the names of standardized food, section 403(g) of the Act[39] is sometimes seen to serve as the starting point of the analysis. That section states that a food is misbranded if it "purports to be or is represented as a food for which a definition and standard of identity has been prescribed . . . unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard[.]" For the various nonconforming articles described in detail above, the question, then, is whether a food name that merely includes the name of a standardized food necessarily "purports to be or is represented as" the standardized food.

The clear answer, as FDA and courts[40] have long recognized, is no. By their own terms, standards of identity only govern *unqualified* food names. Thus, this provision creates no barrier to qualified uses of standardized terms, because the use of a qualifier will generally indicate that the food does not purport to be the standardized food. So peanut butter does not purport to be "butter," rice noodles do not purport to be "noodles," and potato bread does not purport to be "bread," at least insofar as these terms are defined by regulation (as opposed to ordinary language).

Once again, take "milk" as an example. Despite the recent objections to qualified uses of the word "milk" described above, FDA has already recognized that its identity

[39] 21 U.S.C. § 343(g).

[40] See e.g. *62 Cases of Jam v. United States*, 340 U.S. 593, 600 (1951) ("Congress used the words 'purport' and 'represent'—terms suggesting the idea of counterfeit.")

standard applies only to the unqualified term — indeed, FDA has recognized this fact for as long as the term has been standardized. In the very same regulation establishing the standard of identity for "milk," FDA addressed its applicability to "flavored milk products" (e.g. chocolate milk).[41] On that topic, FDA stated, "[s]ince flavored milks, such as chocolate milk, *do not purport to be and are not represented as milk*, their distribution as nonstandardized foods could be continued after the establishment of an identity standard for milk."[42] Similarly, FDA formerly prescribed a standard for a food known as "ice milk"[43] (what is today called "low-fat ice cream") without any question that this product purported to be milk. And of course, buttermilk and milks from other animals (e.g. goat milk) have long existed on the market as nonstandardized foods, without any reasonable suggestion that they purport to be or are represented as "milk," as defined by regulation. By the same token, section 403(g) of the Act presents no problem for names like "soy milk" or "almond milk," as such products simply do not purport to be "milk."[44]

More generally, FDA noted long ago that the "existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in

[41] 38 Fed. Reg. 27924, 27925 (Oct. 10, 1973).

[42] *Id*. (emphasis added.) The Commissioner nonetheless found it "reasonable" to include provisions for such products in the standard of identity itself.

[43] 25 Fed. Reg. 7125 (Jul. 27, 1960).

[44] See *Gitson*, at 3–4 ("the standardization of milk simply means that a company cannot *pass off* a product as 'milk' if it does not meet the regulatory definition of milk. . . . Soymilk, in short, does not 'purport[] to be' from a cow within the meaning of section 343(g).")

connection with the name of a nonstandardized food, as 'in some cases it may be necessary to include a standardized name in the name of the substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling.'"[45] Regarding "substitute foods" specifically, FDA explained more fully in 1983:

> in some cases, it may be reasonable and appropriate to include the name of a standardize[d] food or other traditional food in the name of a substitute food in order to provide the consumer with an accurate description. When this is done, the name of the food must be modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute. The modification of the traditional or standardized food's name must be descriptive of all differences that are not apparent to the consumer. Thus, the procedure for naming these foods will depend on the nature of the substitute food and the manner and extent to which it differs from the food it simulates.[46]

General principles like these were reflective of FDA's shift away from prescribing standards of identity for new foods, and towards regulating most foods under general principles governing common or usual names.[47] These principles chiefly govern the food naming patterns that are the subject of this petition, and we examine them next.

Common or Usual Names

Under section 403(i) of the Act, if a food does not represent itself as a standardized food, it must bear "the common or usual name of the food, if any there

[45] 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

[46] 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

[47] *See e.g. id.* (withdrawing a proposal to establish standards of identity for milk, cheese, and cream substitutes). The fact that FDA has not established a standard of identity for any new food since 2002 ("white chocolate," 67 Fed. Reg. 62177) is reflective of FDA's change in approach.

be[.]"[48] The most natural reading of this provision is that food producers must simply label their products in accordance with what consumers commonly or usually call them.[49]

In clarifying this requirement, FDA has issued a regulation establishing general principles governing common or usual names.[50] (It is this regulation, 21 C.F.R. § 102.5, that GFI proposes amending.) The regulation, consistent with the ordinary meaning of section 403(i) described above, notes that the "common or usual name of a food may be established by common usage[.]"[51] In the more general case (e.g. when there is no such established common usage), the regulation states that the common or usual name of a food "shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients."[52] The regulation also states that the common or usual name "may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name."[53]

For the purposes of naming variations on other foods, this last provision is unfortunately somewhat vague and open to subjective interpretation. What names are

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[48] 21 U.S.C. § 343(i).

[49] Additionally, the language "if any there be" implies that some foods may *not* have a common or usual name, and that in such a case, there is no such obligation to identify the food under any particular name.

[50] Broadly speaking, this regulation is entitled to judicial deference under the *Chevron* doctrine, but only to the extent that it is a reasonable interpretation of the legal requirement of the Act. If, for example, FDA's regulation could be interpreted to prohibit the use of a name that consumers commonly use to identify a product, such an interpretation may not be entitled to judicial deference, particularly in light of the First Amendment concerns described later in this petition.

[51] 21 C.F.R. § 102.5(d).

[52] 21 C.F.R. § 102.5(a).

[53] *Id.*

"confusingly similar"? What names are "not reasonably encompassed within" another name? Without clarification of FDA's practices and policies, the vagueness of this provision leads to reasonable concerns about the risk of arbitrary (or even discriminatory) enforcement against some food products but not others.

Fortunately, FDA's stated policies and actual practices have added some clarity to these provisions. As we saw above, since the 1970s FDA has taken the position that it is sometimes "necessary" to include one name within another "in order to provide the consumer with accurate, descriptive, and fully informative labeling."[54] In the case of "substitute" foods, it is "reasonable and appropriate" to do so, as long as "the name of the food [is] modified such that the nature of the substitute food is clearly described and is clearly distinguished from the food which it resembles and for which it is intended to substitute."[55]

This policy faced opposition from some in industry — most notably the dairy industry, which was opposed to any use of dairy terms in the names of modified dairy products (most commonly, products with decreased milkfat content). But to the extent there was debate over naming such products,[56] it was largely settled with the passage of the NLEA in 1990 and FDA's subsequent promulgation of regulations under that law.[57] As a result of this change, food producers have been allowed to label food products with

[54] 44 Fed. Reg. 3964, 3965 (Jan. 19, 1979), quoting 38 Fed. Reg. 20702, 20703 (Aug. 2, 1973).

[55] 48 Fed. Reg. 37666, 37667 (Aug. 19, 1983).

[56] FDA established standards for some such products, but was not always consistent in its positions on other unstandardized products.

[57] 21 C.F.R. § 130.10.

nutrient-content qualifiers modifying the names of traditional foods. These names can be surprising at first, like "fat-free cheddar" (cheese without milkfat) or "fat-free ice cream" (ice cream without cream), often outright contradicting what consumers would ordinarily expect from these products. And the contradictions are not limited to the qualifying terms: FDA also allowed such food products to deviate from the standards of identity for the standardized foods in ways besides the clearly-identified changes in nutrient content. FDA permitted deviations from "non-ingredient provisions" such as "moisture content, food solids content requirements, or processing conditions."[58] Additionally, FDA permitted the addition of any "safe and suitable ingredients" "used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness," even if the addition of such ingredients to the standardized food would ordinarily violate the standard of identity.[59]

As FDA explained at the time of this change, the qualifying nutrient-content language, together with "accompanying label statements[ ] and nutrition labeling, will enable consumers to distinguish traditional foods from modified versions of these foods . . . ."[60] This language demonstrates FDA's position that if qualifying language in

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[58] 21 C.F.R. § 130.10(c).

[59] 21 C.F.R. § 130.10(d)(1). However, ingredients "specifically prohibited by the standard" are not permitted in the modified foods. 21 C.F.R. § 130.10(d)(3).

[60] 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993). The introduction of nutrition labeling by the NLEA was especially important — if a consumer is confused by what exactly "fat-free ice cream" is (because the ingredients of this product can vary drastically from brand to brand), the consumer has access not just to a list of all the ingredients, but also to detailed nutritional information about the product. The "Nutrition Facts" panel has become familiar to consumers over the past two decades, and consumer consciousness of this information has significantly decreased consumer reliance on expectations that food products conform to recipes specified in identity standards.

the product name, together with other information on the label, effectively enables consumers to distinguish the modified food from the traditional food, consumers will not be confused or otherwise deceived by the product, notwithstanding the inclusion of the name of a traditional food that it resembles. The language that GFI proposes in this petition follows this standard.

This general principle applies just as well to cashew butter, rice noodles, and soymilk, as it does to "fat-free [cream-free] ice cream." Indeed, the first three terms are (if anything) *clearer* than the last, as they provide much more information as to what *is* in the product, as opposed to what is not. More analogous still would be products like gluten-free bread — as above, if a consumer is confused by what exactly "bread" is without gluten (or wheat), the ingredients list and Nutrition Facts are no more than a panel away.

Imitation

Finally, it is necessary to discuss how GFI's proposed regulation is consistent with the law and FDA policies governing "imitation" labeling, as some food products (like soymilk) are sometimes argued to be "imitations."[61] Section 403(c) of the Act deems any product misbranded if it is "an imitation of another food, unless its label bears . . . the word 'imitation' and, immediately thereafter, the name of the food imitated."[62] By

[61] See, e.g. Comments of National Milk Producers Federation, May 5, 2014, available at https://www.regulations.gov/document?D=FDA-2009-D-0430-0074.

[62] 21 U.S.C § 343(c).

regulation, FDA has clarified that a food "shall be deemed to be an imitation . . . if it is a substitute for and resembles another food but is nutritionally inferior to that food."[63]

FDA described this regulation as "fully consistent" with early court cases interpreting section 403(c), which "discussed factors of resemblance, substitution, and inferiority in concluding that the products involved were imitations."[64] These early cases discussed "substitution and resemblance" in terms of taste, smell, appearance, color, texture and body, as well as its intended uses and method of manufacture, packaging, sale.[65] (Elsewhere in its regulations, FDA uses the catchall term "organoleptically" — pertaining to all senses, including sight, taste, touch, and smell — to determine whether a food is a "substitute for" another food in deeming it an "imitation.")[66] Further, in establishing its regulation regarding imitation foods, FDA made clear that new food products (clearly identified as such) would not be deemed imitations, favorably citing cases "holding that a vegetable oil substitute for cream, which looks like, tastes like, and is intended to replace cream, is not an 'imitation cream' but rather a separate and distinct product that should bear its own common or usual name."[67]

In light of these narrow criteria for what makes a food an "imitation" of another food, specified in FDA's regulatory decisions and early court cases, only convincing

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[63] 21 C.F.R. § 101.3(e)(1).

[64] 38 Fed. Reg. 20702, 20702 (Aug. 2, 1973).

[65] *United States v. 651 Cases . . . Chil-Zert*, 114 F. Supp. 430, 432 (N.D.N.Y. 1953).

[66] 21 C.F.R. § 101.13(d).

[67] 38 Fed. Reg. at 20702, citing *Coffee-Rich, Inc. v. Kan. State Bd. of Health*, 388 P.2d 582 (Kan. 1964), *Coffee Rich, Inc. v. Mich. Dept. of Agriculture*, 135 N.W.2d 594 (Mich. 1965).

counterfeit products (which are also nutritionally inferior) fall into the category of "imitation" foods. Partly due to this exacting standard, and partly due to the more recent trends in "common or usual" nomenclature described in this petition, the "imitation" label is practically never seen on any products today.

Arguments that products like soymilk or almond milk are "imitations" of cow's milk rely too much on FDA's language "substitute[s] for and resembles another food," without evaluating this language in terms of the court decisions this language codifies (or even FDA's own use of the term "organoleptically"). A basic flaw in such arguments is that they appear to construe "resembles" too narrowly in a visual sense — essentially, they argue that because soymilk *looks* like cow's milk and is used in similar ways, it is an imitation. For one thing, this completely ignores other "organoleptic" factors (like taste, smell, and texture) that are manifestly different to anyone who has compared such products. Another obvious flaw in this argument is that, if taken at face value, it would prove too much: rye bread would be "imitation bread" and gluten-free spaghetti would be "imitation spaghetti," because both products look very much like their wheat counterparts and are used in the same way. Even goat milk would not escape this fate — it has significantly less Vitamin B_{12} than milk from cows — and would therefore need to bear the name "imitation milk." This would be nonsense. The Act's "imitation" provision has, since at least the 1960s, been understood to target nutritionally-inferior, cheap

counterfeit products — and not distinct food products that clearly identify themselves as such.[68]

For the reasons stated above, the standard described by GFI is consistent with FDA's recent policy and practices regarding the naming of new food products.[69] The language GFI proposes would allow labels to state clearly, as qualifiers to other common names, "alternative plant or animal source[s] that replace[ ] the main characterizing ingredient(s) or component(s) of" these other foods — be it goat milk or almond milk, rye bread or cornbread, rice noodles or buckwheat noodles. In the modern marketplace, consumers are very familiar with products like these that advertise alternative plant and animal sources. Products may also state, as clear qualifiers to other common names, the "absence of a primary characterizing plant or animal source, or of a nutrient, allergen, or other well-known characterizing substance" — like gluten-free bread, dairy-free ice

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[68] On this point, some are apparently attempting to relitigate bygone unsuccessful challenges to FDA's narrow definition of "imitation." *Nat'l Milk Producers Fed. v. Harris*, 653 F.2d 339, 343 (8th Cir. 1981) (citing *Fed. of Homemakers v. Schmidt*, 539 F.2d 740 (D.C. Cir. 1976)).

[69] GFI recognizes that, in 2008 and 2012, FDA issued warning letters expressing an opinion that "soy milk" is not an appropriate name simply because "milk" is a standardized term. *See* Warning Letter to Fong Kee Tofu Co., March 7, 2012, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm295239.htm; Warning Letter to Lifesoy, Inc., August 8, 2008, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048184.htm. But FDA has maintained (and courts have agreed) that such letters are "informal and advisory." *Holistic Candlers and Consumers Assn. v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012). As such, courts have not deferred to interpretations in such letters. *See, e.g. Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) (declining to recognize these warning letters as FDA's considered, reasoned policy); *cf. Nat'l Mining Assn v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014) (noting lack of deference to interpretive rules and statements of policy) (citing *United States v. Mead Corp.*, 533 U.S. 218 (2001)). For the reasons stated in this petition, GFI does not believe that FDA would, after careful consideration, formally adopt the line of reasoning stated briefly and informally in these warning letters.

cream, or wheat-free soy sauce.[70] As FDA has stated for qualifiers like "fat-free," these qualifiers effectively serve to notify consumers that these products differ from their traditional counterparts, and other information on the label enables consumers to inform themselves exactly how such products differ, including nutritionally. For the same reasons, the regulation also generally allows for any other compound name, provided it clearly notifies consumers that the product differs from the standardized or traditional food.

Finally, although the principles described in this petition are firmly rooted in established FDA policy and the practice of the agency, GFI is motivated to file this petition because others vocally disagree and, as noted earlier, have recently urged FDA to take a different course, specifically regarding plant-based dairy alternatives. As described below, this is constitutionally perilous territory: if FDA (or Congress) were to heed such calls and target new (and old) non-dairy alternative products for selective enforcement, it would violate the First Amendment rights of the producers of these

[70] GFI is also aware of 21 C.F.R. § 105.62, governing "food [that] purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by reason of being offered as food suitable as a substitute for another food having an allergenic property[.]" At first blush, this regulation seems to provide some support for GFI's more general language, as it requires (and deems sufficient) "qualification of the name of the food . . . to reveal clearly the specific plant or animal [sources]." But it also contains onerous provisions, like requiring such products to label the "*proportion* of each ingredient" and the "specific plant or animal" source of *each* ingredient. A broad reading would imply that all foods that bear claims like "soy-free," "wheat-free," or "dairy-free," as well as many substitute foods, would be subject to these burdensome and heightened labeling requirements. Because it is unclear what (if any) relevance this provision has today in view of developments since its initial promulgation in 1941 (6 Fed. Reg. 5921) — such as mandatory allergen labeling and the NLEA — GFI has chosen not to discuss this provision extensively in this petition. GFI instead simply notes that this language, similar to GFI's proposal, has previously been used by FDA.

products to label and describe their products in a truthful and clear manner consistent with consumer expectations.[71]

2. Restrictions on commercial speech are subject to judicial scrutiny under *Central Hudson*, and proposed restrictions against dairy alternatives do not withstand such scrutiny.

Forbidding producers and sellers of products like soymilk or almond milk[72] from using such names would be a restriction on protected commercial speech, and would be subject to judicial scrutiny under the First Amendment. The constitutionality of such restrictions is determined under the Supreme Court's four-prong *Central Hudson* test:[73] if commercial speech (1) concerns lawful activity and is not misleading; and (2) the government asserts a substantial interest in restricting such speech; then (3) the government regulation must directly advance that interest and (4) not be more extensive than necessary to serve that interest. As described below, attempts to restrict food producers from using names of traditional products to describe new products would fail to satisfy this standard and would therefore violate the First Amendment.

Those who propose banning names like "soymilk" and "almond milk" frequently refer to such names as "misleading," simply because the products do not contain cow's

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[71] Further, in light of the First Amendment concerns described in this petition, courts would likely construe the Act and FDA's regulations as narrowly as possible to avoid these serious constitutional questions. See, e.g. *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172–73 (2001). This consideration would strongly favor the interpretation of the Act and regulations described above.

[72] GFI uses these products throughout this section for illustrative purposes because these products have been most visibly targeted by the dairy industry. However, the analysis is much the same for any other product conforming to the standard proposed by GFI.

[73] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

milk. Under the first prong of *Central Hudson*, regulations of false or misleading speech do not require extensive constitutional analysis, but the meaning of "misleading" in this context is narrowly delineated. Only when speech is *inherently* misleading will it fall outside of the protection of the First Amendment.[74] Otherwise, if speech is only *potentially* misleading, *Central Hudson* scrutiny applies in full, and the government may restrict such speech only in a manner that directly and narrowly serves its interest in preventing deception (or any other demonstrated substantial interest).[75] Further, the *government* carries the burden of demonstrating that such an interest in preventing deception is "substantial" and directly and narrowly served by the speech restriction.[76]

The government would not meet the very high bar of demonstrating that common names such as soymilk or almond milk are inherently misleading.[77] These products have long carried these names, and as described extensively in this petition, names such as these (constructed by adding a qualifying term in front of the name of another food) are used extensively in the marketplace for many products (as well as in natural language) without any apparent confusion. And courts that have considered the issue have concluded, as a matter of law, that no reasonable consumer would be misled by these

[74] See *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (citing, *inter alia*, *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

[75] *Id.* at 655–56.

[76] *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1217 (D.C. Cir. 2012) (citing *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993)).

[77] See *Pearson*, 164 F.3d at 655 (describing "inherently misleading" standard in terms of "awesome impact" leaving consumers "bound to be misled.")

product names.[78] Furthermore, consumer research on the understanding of the name "soymilk" has demonstrated that the proportion of consumers confused by the name is nearly zero.[79] It is unclear whether the government would be able to demonstrate that the term even has substantial *potential* to mislead, given the results of such research and how courts have addressed the issue. However, because this petition concerns the prospective nomenclature of a variety of products, we may assume for the sake of argument that the naming of at least *some* such products may have the conceivable potential to be misleading.

But even if the government could demonstrate that such names have substantial potential to mislead consumers, an outright ban on such names would still need to satisfy the final two prongs of *Central Hudson*. To do so, the restriction of such names must "directly advance" the interest in preventing consumer deception or confusion to a "material degree,"[80] and must be no more extensive than necessary to serve that interest. In the case of soymilk and almond milk, forbidding such names, which an overwhelming majority consumers already understand and use to refer to such products, could not

[78] See Order, *Gitson v. Trader Joe's Co.*, 13-cv-01333, Doc. 139 (N.D. Cal., Dec. 1, 2015); *Ang v. WhiteWave Foods Co.*, 2013 WL 6492353 (N.D. Cal., Dec. 10, 2013) ("The first words in these products' names should be obvious to even the least discerning of consumers. . . . [Claiming that] a reasonable consumer might confuse plant-based beverages such as soymilk or almond milk for dairy milk . . . stretches the bounds of credulity. Under Plaintiff's logic, a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper.") These opinions are appended to this petition as Attachment B.

[79] Soyfoods Association of North America, *Summary of Research on Consumer Awareness of Soymilk and Dairy Milk*, appended to this petition as Attachment A.

[80] *R.J. Reynolds*, 696 F.3d at 1218 (citations omitted).

possibly "directly and materially" serve an interest in preventing deception or confusion. (Labeling with an alternative name, like "soy beverage," might *itself* be confusing to consumers who are used to calling it "soymilk.") Although in general, banning a potentially confusing name outright may directly avoid potential confusion, banning the use of an already well-established name would result in *more* consumer confusion, and so would hardly serve the government's interest in *preventing* confusion.

Yet even in cases where the government could show that banning a potentially confusing name would "directly and materially" avoid deception, the government would still need to satisfy the last part of the *Central Hudson* test. It is here that restrictions on GFI's proposed naming pattern would *always* fail to withstand scrutiny: such restrictions are emphatically *not* necessary to serve any interest in preventing confusion or deception, and are not narrowly tailored to that end. The government has many alternative tools at its disposal for combating whatever potential deception it might claim; in fact, many of these tools are already in place. The FDCA requires food labels to bear a full list of ingredients that can instantly dispel most any question a confused consumer may have, such as whether there is any wheat in gluten-free bread, or whether there is any egg in rice noodles, or whether there is any cow's milk in soymilk. Similarly, nutritional labeling is already required, which allows consumers to compare these foods to their traditional counterparts in yet another way.[81]

[81] This was the very same logic FDA used in addressing objections to nutrient-content qualified names like "fat-free ice cream." 58 Fed. Reg. 2431, 2439 (Jan. 6, 1993).

In the case of soymilk and almond milk, these measures are more than sufficient to fully inform consumers, as courts have recognized.[82] And even if they were not, the government has no shortage of other, more narrowly-tailored options available. For example, the government could potentially require products to label themselves with additional statements that describe significant differences that are alleged to be a source of potential confusion (e.g. requiring soymilk and almond milk products to bear "dairy-free" declarations — as most already do.)[83] In sum, there are many alternative narrowly-drawn ways to dispel potential deception, and "[i]f the First Amendment means anything, it means that regulating speech must be a last — not first — resort."[84] The government would bear a heavy burden in demonstrating that these alternative approaches (especially those already in effect) are insufficient to advance its interests before courts would permit an outright speech ban[85] — and this, GFI submits, the government would be unable to do for any of the names under GFI's proposed standard.

Proponents of a ban on the names "soymilk" and "almond milk" also argue alternatively that consumers may suffer some sort of nutritional injury if they purchase

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[82] See *Gitson* and *Ang* (Attachment B).

[83] However, GFI notes that even less-restrictive measures like this would be difficult to justify constitutionally, in light of the negligible risk of consumer confusion and the mandatory ingredient and nutritional labeling already required by the FDCA.

[84] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

[85] See *Pearson*, 164 F.3d at 659–60 (describing First Amendment preference for disclaimers and disclosures over suppression.)

and consume these products believing them to be nutritionally equivalent to cow's milk.[86] But no reasonable consumer would assume that two distinct products have identical nutritional content,[87] so this speculative risk cannot possibly justify a ban on such names.[88] Under *Central Hudson*, the government would first face the (likely impossible) task of showing that a significant number of consumers hold a belief that these distinct products are totally nutritionally equivalent. And even assuming the government could demonstrate that this presents a real, substantial, and material risk, the government has available other tools for addressing it, all of which are more narrowly drawn than an outright speech ban. In fact, mandatory nutritional labeling already suffices to inform consumers not just *that* the products are distinct, but exactly *how* they are distinct nutritionally — and this comprehensive disclosure is more than enough to protect against any supposed risk of deception.[89] Just as above, this argument in favor of an outright ban on such names would fail to stand up to *Central Hudson* scrutiny.[90]

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[86] See Comment from National Milk Producers Federation, July 28, 2010, available at https://www.regulations.gov/document?D=FDA-2010-N-0210-0092.

[87] "[A] reasonable consumer (indeed, even an unsophisticated consumer) would not assume that two distinct products have the same nutritional content; if the consumer cared about the nutritional content, she would consult the label." *Gitson*, at 3.

[88] Further, a logical extension of this argument would require a ban on labeling goat or sheep or buffalo milk with the word "milk," as all of these products have different nutritional profiles from cow's milk. And the same is true for rye bread vis-à-vis wheat bread, rice noodles vis-à-vis wheat noodles, and so on.

[89] See *Gitson*, at 3 (quoted above, note 87). And as above, in addition to already-mandatory comprehensive nutritional labeling, courts would also consider whether any other possible measures for disclosure would be more narrowly-drawn and therefore preferable to an outright speech ban. See *Pearson*, 164 F.3d at 659–60.

[90] Note also that, before the passage of NLEA and FDA's subsequent regulations, federal courts used similar reasoning in analyzing state bans on the use of dairy names by other products,

For these reasons, proposals to ban common names for dairy alternatives would run afoul of the First Amendment, failing to withstand scrutiny under *Central Hudson*. Additionally, such proposals infringe the First Amendment for other reasons, discussed next.

3. Attempts to restrict or ban common names for dairy alternatives would be subject to heightened scrutiny.

Although restrictions on commercial speech are generally subject to *Central Hudson* "intermediate" scrutiny, recent developments in the law indicate that, in some cases, such restrictions will require an even greater level of judicial scrutiny. Proposals that particularly target dairy alternatives with a ban on their commonly-used names would fall into this category, and would not withstand heightened judicial scrutiny.

The Supreme Court has recently made clear that "content-based" burdens or restrictions are subject to "heightened" judicial scrutiny, even in the commercial context.[91] The Court has not clarified exactly what form this "heightened" scrutiny takes, though it has noted that ordinarily, it is "all but dispositive to conclude that a law is content-based."[92] Further, even some restrictions that *appear* on their face to be content-neutral "will be considered content-based regulations of speech: laws that cannot be

striking down such restrictions under the First Amendment. See, e.g. *Lever Bros. Co. v. Maurer*, 712 F. Supp. 645, 651–52 (S.D. Ohio 1989); *Anderson, Clayton & Co. v. Washington St. Dept. of Agriculture*, 402 F. Supp. 1253, 1257–58 (W.D. Wash 1975).

[91] *Sorrell v. IMS Health*, 31 S. Ct. 2653, 2664–65 (2011).

[92] *United States v. Caronia*, 703 F.3d 149, 164 (2d Cir. 2012), quoting *Sorrell*, 31 S. Ct. at 2667.

'justified without reference to the content of the regulated speech' or that were adopted by the government 'because of disagreement with the message [the speech] conveys.'"[93]

Restricting the common names of dairy alternatives, such as soymilk, would be a content-based restriction on speech, because such restrictions cannot be justified without reference to the content of such speech — to wit, the fact that such names reference dairy products specifically. Such content-based restrictions are "presumptively invalid,"[94] and the government would need to put forth compelling evidence-based justifications to overcome this heavy presumption.

To avoid this heightened level of scrutiny, the government would need to develop and apply any proposed restriction in a content-neutral manner.[95] In order for a restriction of this sort to be truly content-neutral, it would need to apply with equal force to *any* product name that encompasses another, and not merely non-dairy alternatives to dairy products. The government, for example, could potentially ban *any* product from bearing the name of another unless it satisfies the definition of such other product. But the government could not do so without contradicting established FDA policies regarding the naming of foods with nutrient-content claims (e.g. "fat-free cheddar cheese"), or established commonsense practice regarding other product names that incorporate standardized terms (such as rye bread or rice noodles).

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[93] *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015) (citation omitted).

[94] *Sorrell*, 131 S. Ct. at 2667 (quoting *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992)).

[95] The current legislative proposal for such restrictions is not content-neutral; it exclusively singles out dairy terms for protection. DAIRY PRIDE Act, S.130, 115th Cong. § 3 (2017).

Nor could the government, in this context, rely on the content-neutral justification that it is merely targeting "potentially misleading" names of any sort, because many other products with similar names have *greater* potential to mislead or confuse consumers than products like soymilk or almond milk (which declare their basic nature — "soy" and "almond" — clearly and up-front). Take multigrain bread, for instance. There is no standard for such product, and a "5-grain bread" could conceivably be 98% white flour, with the other four grains constituting the remaining 2% — not the significant share consumers might expect.[96] Or rice noodles, the name of which does not declare up-front whether it contains egg or wheat, as required of "noodles" under FDA's standard of identity.[97] And so on. The government could offer no content-neutral justification for banning outright the names of "soymilk" or "almond milk," while allowing other products named in similar fashion to keep their names.

This highlights yet another reason a ban on such non-dairy names would be subject to heightened judicial scrutiny: courts would likely determine that such a restriction is a content-based *and* speaker-based restriction, targeting producers of plant-based alternative products specifically. For one thing, it would be a speaker-based restriction because it would forbid only producers of such products (though not consumers, academics, or even the government itself) from using such names to describe

[96] Ironically, as noted earlier, such a product would satisfy the standard of identity for "bread" — and would be all the more misleading for it!

[97] Also, unenriched rice flour contains lesser amounts of some nutrients (like protein and iron) than wheat flour does. This mirrors the situation of unfortified soymilk *vis-à-vis* cow's milk.

these products.[98] But it would also not escape judicial notice that these restrictions have been publicly and loudly demanded by the dairy industry for many years in an effort to protect its market share. This historical fact would infect any subsequent government action with the stench of favoritism — using the power of the state to benefit one politically powerful group at the expense of its competitors — and could lead a reviewing court to conclude that such government action is an attempt to burden "disfavored speech by disfavored speakers."[99] As the cases cited herein demonstrate, courts are particularly likely to strike down speech restrictions in such circumstances.

Simply put, proposed restrictions on the names of dairy alternatives cannot be justified in a content-neutral way, and even if they could be, such restrictions would fail to withstand *Central Hudson* scrutiny. FDA should resist the dairy industry's calls for anticompetitive regulation, and instead adopt GFI's neutral regulation that allows not just dairy alternatives, but *any* alternative products, to use clear and concise compound names noting alternative sources, properties, or origins, which consumers readily understand. This framework is not merely a good idea — under our Constitution, the freedom to use such names must generally be maintained.

[98] See *Caronia*, 703 F.3d at 165; *Sorrell*, 131 S. Ct. at 2663.

[99] *Sorrell*, 131 S. Ct. at 2663.

III. Conclusion and request for action

For the reasons described above, and consistent with FDA policy and practice as well as the First Amendment, GFI respectfully asks that FDA adopt the proposed regulation to clarify that FDA will generally allow the use of compound food names whenever a reasonable consumer would understand that such a modified food name denotes a distinct product.

IV. Environmental Impact

Preparation of an environmental assessment (EA) or an environmental impact statement (EIS) is not ordinarily required for the "issuance, amendment, or repeal of a food standard," 21 C.F.R. § 25.32(a).

V. Economic Impact

Pursuant to 21 C.F.R. § 10.30, information on economic impact will be submitted only if requested by the Commissioner following review of this petition.

* * *

VI. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes (1) all information and views on which the petition relies and (2) any representative data and information known to the petitioner that are unfavorable to the petition.

Sincerely,

Bruce Friedrich
Executive Director
The Good Food Institute

Nicole Negowetti
Policy Director
The Good Food Institute

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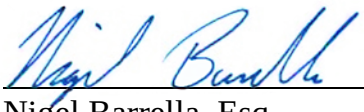
By:



Nigel Barrella, Esq.

Attachments:

A. Soyfoods Association of North America, Summary of Consumer Research
B. Orders from Federal Court Cases: *Gitson* and *Ang*