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Opportunities and Challenges for the Introduction of New Food Proteins

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Abstract

New forms of protein are being developed at a rapid rate as older forms of protein, particularly meat and poultry, are coming under attack for nutritional, environmental, food safety, and animal welfare issues. To date, the FDA and USDA have split oversight of the new technologies that include genetic engineering and precision fermentation. Because these new products address the problems associated with traditional proteins, consumer demand appears to be overcoming fundamental fears associated with innovative foods. Currently, agencies are struggling with naming issues for the new proteins and, in some cases, possibly being forced to use costly and lengthy premarket approvals. Because of the complexity of new production methods, the speed of development, and the potential benefits, a new system of regulation may be necessary. It would consist of one of the existing agencies becoming a super regulator overseeing private companies that specialize and compete with each other and are regulated quickly and competently.

> Let the advocate of animal food, force himself to a decisive experiment on its fitness, and as Plutarch recommends, tear a living lamb with his teeth, and plunging his head into its vitals, slake his thirst with the steaming blood; when fresh from the deed of horror let him revert to the irresistible instincts of nature that would rise in judgment against it, and say, Nature formed me for such work as this. Then, and then only, would he be consistent.
>
> From Animal Rights: A History by Percy Bysshe Shelley 1792–1822

INTRODUCTION

Shelley may have been 200 years ahead of his time in his concern about animal welfare, perhaps because there was no realistic alternative for sources of protein—at least in the West. Today, US consumers, and, in fact, people around the world, are both demanding more protein and looking to sources other than live animals. In addition to food safety and nutrition, consumers are becoming concerned with environmental and animal welfare issues. Although soy protein isolate has been available for many years, innovators are now creating alternative sources of protein that are (*a*) composed of a broader range of vegetable protein concentrates containing new ingredients and produced by novel processes whereby the products mimic traditional animal proteins; (*b*) produced by genetic engineering and precision fermentation (PF) to create novel proteins; or (*c*) actual animal proteins produced without animals.

Regulatory agencies, which are most adept at addressing relatively static innovation, are struggling to keep up with the oversight of these new products, as regulations can take, on average, more than four years to develop. Two issues that have come to the forefront are (*a*) names for the new products and (*b*) food safety and nutrition issues. To date, states that have taken the lead in addressing names almost exclusively assign property rights to traditional proteins, although, as federal agencies catch up, these regulations are likely to be preempted.

For food safety issues, the FDA and USDA have recently agreed to split federal oversight of cell-based proteins, with the FDA taking the lead on the early stages of laboratory operations and the USDA taking over from there. For other types of novel processes, the FDA appears to be the lead agency. Interestingly, although cell-based meat proteins may be the most novel, this technology may not have the same potential to disrupt the traditional protein markets as PF will.

Some new products represent an entirely new way of producing food, moving production from the land to the laboratory and innovating at a pace not seen before in foods. Because of that, there may be better forms of regulatory governance than the century-old food regulatory agencies that are currently in place. Additionally, the future presents two major challenges for traditional regulatory agencies that include education through social media and precision nutrition.

TYPES OF NEW PROTEINS

Plant-based meat alternatives have been around at least since John Harvey Kellogg invented peanut-based *Protose* at the turn of the twentieth century. This was followed by Worthington Foods in 1949 creating Soyloin Steaks and Meatless Wieners (Smith 2015). Next, in the late 1960s, the first veggie burger came from a London-based natural food restaurant catering to hippies (Smith 2014). It was made of wheat gluten, sesame, soy, and oats and was a dehydrated powder that required water to make it into a patty.

Today, vegetable-based meats are made from soy protein, wheat protein, and pea protein (Specht 2018). In the future, proteins will likely be extracted from new plant sources, including fungi, canola, and algae. Whereas traditionally veggie burgers were made to mimic the look of

conventional burgers, today's technologies start with the taste and mouthfeel of meat and work backward by "coaxing plant proteins, which tend to be globular, into behaving like animal proteins, which are fibrous" (Allen 2018). These products have gone from just looking like burgers, e.g., Garden Burgers, to both looking and tasting like burgers, e.g., Beyond Meat.

One innovative source of proteins that has not been fully utilized is 3D-printed plant-based meats (Guardian 2019). There are already 3D printers that make pizza and chocolate in incredible shapes. They can also make crackers and pasta shapes using recipes from the internet that use less salt, oil, and additives. The advantage of 3D printers, particularly when used at home, will be that they can make foods for individual appetites, which should decrease food waste. It is not yet known whether this technology will be available for home use for proteins.

PF is a combination of precision biology and fermentation that has been used since the 1980s to make medicines, cosmetics, and other materials. Recently, this technique has been used in food manufacture to make the Impossible Burger. This process starts with heme taken from the roots of a soy plant. Heme is found in every living organism and is used to transport oxygen into cells. In meats, the iron in the heme protein is what influences the taste that is enhanced through cooking.

Rather than using soybean roots in the product, the process begins with extracting the genes that encode for soy leghemoglobin protein from soybean roots and inserting them into a specific yeast created by genetic engineering (Impossible Foods 2020). The yeast is then grown by fermentation to produce leghemoglobin as it would be found in the roots of soybeans. Finally, the soy leghemoglobin (which contains the heme) is isolated from the yeast cells and added to other micronutrients in fermentation tanks to grow soy heme, the main flavor compound in the Impossible Burger (Reiley 2019). In the end, leghemoglobin is not a GMO product, rather it is a protein produced by genetically modified yeast cells (Clinton 2017).

PF technology takes advantage of tools like CRISPR to manipulate microbial genes to produce microbes with specific attributes. Importantly, this technology can not only synthesize known organic molecules but also produce novel foods that have never existed before. Food producers, with the use of artificial intelligence and robotics, can search for the right combination of nutrition, taste, flavor, aroma, and mouthfeel (Tubb & Seba 2019). Ultimately, this process may use software databases of food molecules to produce novel foods for both large populations and subpopulations with specific nutritional needs or desires.

The PF process used to grow novel plant-based meat products is an extension of the same fermentation process that has been used for centuries to make yogurt, bread, cheese, and beer. Quorn, a fungal protein, is produced by fermentation and has been available since the mid-1980s. The primary source of rennet, which has been used as a coagulating agent in cheesemaking, was originally obtained from the mucosal lining of the stomachs of nursing calves, but its replacement, chymosin (rennin), which is the principal milk-coagulating protease in rennet, is now produced using PF. Today, human insulin used for diabetes treatment is largely produced by PF, as are vitamins and minerals. Because PF is combined with precision biology (e.g., CRISPR), the cost of producing a product like vitamins has decreased from approximately $1 million/kg in 2000 to $100/kg today (Tubb & Seba 2019). By 2025, one estimate suggests that the cost for producing meats by PF will be reduced tenfold, making them more cost competitive with conventional meats (Tubb & Seba 2019). Besides red meats, PF may also be used to produce poultry- and seafood-like products.

The last category of new proteins includes cell-based meats, poultry, and seafood, which are grown from stem cells. Using either harvested or legacy cells, these cells are fed a growth broth similar to that found in pregnant animals and grown in bioreactors. Currently, producers are looking for nonanimal-based growth broths and ways to produce them less expensively. The cells are grown in stainless-steel cylinders like those used for growing cells that produce drugs, vaccines,

antibodies, and skin replacements for burn victims. After the protein is produced, it is separated from the host cells and purified (Waschulin & Specht 2018).

When such cell-based proteins do come to market, consumers may have difficulty differentiating them from actual beef, pork, poultry, and fish. There is one important difference, however, in that they will not be from slaughtered animals, including those raised in confined conditions.

Referring to products of both PF- and cell-based proteins, the visionary George Monbiot, in his new documentary *Apocalypse Cow*, suggests that "before long, most of our food will come neither from animals nor plants, but from unicellular life. . .replacing all farming except fruits and vegetables" (Monbiot 2020).

CONSUMER DEMAND

Surveys reveal that most US consumers are willing to try new plant-based proteins. Those most likely to have tried a meatless product include vegetarians (76%), people younger than 45 (62%), men (53%), wealthier people making more than $120,000 (72%), and those with a college degree (62%) (Int. Food Inf. Counc. 2020). One projection suggests that the new beef-like proteins will replace 70% of conventional beef by 2030 (Tubb & Seba 2019).

Others suggest that this level of disruption is impossible, noting that, for this to happen, enough substitute proteins would have to be produced to make more than 2.1 trillion burgers (Eenennaam 2019). Another estimate is that cultured and plant-based proteins (including proteins from PF) will capture approximately 13% of the market share.

One obstacle is that many people may not accept alternative proteins that are "birthed" in a laboratory and grown in a food manufacturing facility. Some wish to append any laboratory food with the prefix "franken," referring to Mary Shelley's *Frankenstein*. As people learn more about how some alternative meats are produced, this is likely to become a greater concern. For example, one observer at the Memphis Meat laboratory reported watching a (stem) cell dividing followed by horror as the still living beef tissue spasmed when a small electrical shock was applied (Little 2019).

Foods created in laboratories do not seem natural and, as one food industry executive stated, "People don't want to eat technology." In fact, the trend toward laboratory-produced proteins is contrary to the recent trend toward eating foods with "clean labels," i.e., less technologically complex. These consumers prefer foods that are more natural, such as those that are organically grown with fewer pesticides and growth hormones. Proponents of these positions range from those who preach, "if you can't pronounce it, don't eat it" (Senapathy 2017) to Marion Nestle (2018), a nutritionist who states, "In their largely unprocessed forms, foods from the earth, trees, or animals are healthful by definition."

There are a few reasons to be skeptical of the "natural" statement. As shown in **Table 1**, beef is made of many "unpronounceable" ingredients and the ingredients in the two main competitors for beef burgers can be listed in "pronounceable" forms. Also, nothing on earth, including plants, animals, and fish, has evolved specifically to be healthful for another living thing to eat. Quite the reverse, as the competition is to avoid being eaten so that replication can take place (with a few notable exceptions). In fact, numerous plants and animals are poisonous to humans. As Kabat (2016, p. 116) noted,

> Just because something is natural it does not mean that it is good and just because something is unnatural it does not mean that it is bad. Arsenic, cobra poison, nuclear radiation, earthquakes and the Ebola virus can all be found in nature, whereas vaccines, spectacles, and artificial hips are all man-made.

In fact, virtually every single food we eat today has been, in some way, manufactured. As Tom Standage (2009, p. 27) points out, "The simple truth is that farming is profoundly

Table 1 Beef burgers versus new protein components

Impossible Burgers[a]	Beyond Meat Burgers[a]	Beef burger
Water, soy protein concentrate, coconut oil, sunflower oil, natural flavors; 2% or less of potato protein, methylcellulose, yeast extract, cultured dextrose, food starch modified, soy leghemoglobin, salt, soy protein isolate, mixed tocopherols (vitamin E), zinc gluconate, thiamine hydrochloride (vitamin B1), sodium ascorbate, (vitamin C), niacin, pyridoxine hydrochloride (vitamin B6), riboflavin (vitamin B2), vitamin B12	Water, pea protein isolate, expeller-pressed canola oil, contains 2% or less of the following: cellulose from bamboo, methylcellulose, potato starch, natural flavor, maltodextrin, yeast extract, salt, sunflower oil, vegetable glycerin dried yeast, gum arabic, citrus extract (to protect quality) ascorbic acid (to maintain color, beet juice extract (for color), acetic acid, succinic acid, modified food starch, annatto (for color)	Water (63%), additives allowed in meat (and poultry): BHA, BHT, tocopherols, carrageenan, whey protein concentrate, food starch, cellulose, bromelin, citric acid, corn syrup, lecithin, mono- and di-glycerides, ficin, gelatin, glycerine hydrolyzed protein, modified food starch, monosodium glutamate, papain, sodium or potassium salts of tripolyphosphate, hexametaphosphate, acid pyrophosphate, orthophosphates, BHA, BHT, sodium caseinate, sodium erythorbate, sodium nitrate, sugar, dried whey[b] Some contaminants and residues in meat: PCDDs, PCDFs, PCBs, PBDEs, PFOS, PFOA, pesticides, toxic metals, and veterinary drugs[c]

[a]Data from Capritto (2019).
[b]Data from USDA (2020).
[c]Data from Kim (2012).
Abbreviations: PBDEs, polybrominated diphenyl ethers; PCBs, polychlorinated biphenyls; PCDDs, polychlorinated dibenzo-*p*-dioxins; PCDFs, polychlorinated dibenzofurans; PFOA, perfluorooctanoic acid; PFOS, perfluorooctane sulfonate.

unnatural. . .and. . .all domesticated plants and animals are man-made technologies." He goes on to say, "Corn, cows, and chickens as we know them do not occur in nature, and they would not exist today without human intervention. Even carrots are man-made" (Standage 2009, p. 27). Because most of us are far removed from farms and ranches, we have very little idea of how food is grown, much less the history of domesticating food to fit our needs and preferences.

Despite the popular proscriptions against food technology, many people are trying alternative proteins out of curiosity and a concern for their health, but other factors are coming into play. Beyond nutritional concerns, particularly about red and processed meat, they are now also concerned with issues such as the effect of production processes on the environment, food security, animal welfare, food safety, nutrition, and, particularly because of the recent COVID-19 worldwide pandemic, zoonotic issues.

ENVIRONMENTAL ISSUES

Concern about the effect that meat, poultry, and seafood production have on the environment is growing. The issues include the effects of greenhouse gases, land use, water use, and land and water degradation.

For greenhouse gas, livestock is responsible for approximately 15% of greenhouse gases (FAO 2020). Methane results from, e.g., animal burps and settling ponds, and traps 84 times more heat than carbon dioxide over a 20-year period (Torgovnick 2018). Carbon dioxide, however, will continue to accumulate forever. Nitrous oxide is 300 times more potent than carbon dioxide, and it remains in the atmosphere for more than 100 years (Young 2018). Alternatively, cell-based meat

is anticipated to require more energy than is needed to produce ruminant animals (Eenennaam 2019).

Land use for growing ruminant food animals includes rangeland, pastures, and cropland, and involves more than 40% of all land (Merrill & Leatherby 2018). Approximately 165 square meters of land are needed to produce 1/5 of a pound of beef (Ritchie 2017).

However, ruminant animals are often grazing on marginal land and eating and converting otherwise inedible crop residues into animal protein (Eenennaam 2019). There may be innovative ways to feed animals and fish raised in aquaculture by using insects, which will reduce the use of land for feed.

Concerns about the production of animals for meat are not new. For example, nearly 50 years ago Francis Moore Lappé's (1971, p. 1) best-selling *Diet for a Small Planet* argued that a vegetarian diet was needed to feed the planet:

> I learned that for every 7 pounds of grain and soybeans fed to livestock we get on the average only 1 pound back in meat on our plates. Of all the animals we eat, cattle are the poorest converters of grain to meat: it takes 16 pounds of grain and soybeans to produce just 1 pound of beef in the United States today.

Water is also a concern, with beef needing 1,847 gallons of water and chickens using 518 gallons of water to produce a pound of meat, whereas only 34 gallons are needed to produce a pound of broccoli (Boehrer 2018). Nearly one-third of all freshwater used in agriculture is for livestock production, with 98% of that used for watering grass, forage, and feed that cattle consume during their lifetime (Dieter et al. 2018). As wealth in countries like China and Brazil increases, the demand for more calories from meat is also likely to increase (Gerbens-Leenes et al. 2013). Water usage is particularly important in water-starved states, with, for example, California using 9% (between 101 and 250 million gallons per day) of its water availability for livestock (USGS 2015).

Animal agriculture is also polluting surface and groundwater via manure on croplands and pastures and animal feeding operations, especially concentrated animal feeding operations. Manure run-off into streams, rivers, and the ocean results in algal blooms that, as they die and decompose, allow bacteria to grow using the dissolved oxygen (Macklin 2017). This creates a dead zone of low or depleted oxygen, also called hypoxia. Algae blooms may also produce toxins that can kill shellfish, fish, marine mammals, turtles, and birds (Macklin 2017).

FOOD SECURITY

In ten years, the world consumption of livestock products is estimated by the World Health Organization to increase from 36.4 k/(m·y) (kilograms of meat per person per year) to 45.3 k/(m·y), i.e., an increase of nearly 25% by 2030 (WHO 2020). The demand for milk is anticipated to increase by nearly 15%. By 2050, the World Resources Report projects that food production overall will need to increase by 50% to feed 10 billion people (Searchinger et al. 2018).

NUTRITION AND ANIMAL PROTEIN

One important concern regarding alternative proteins is whether they contain adequate amounts of the eight essential amino acids needed for human health. This may not be a major issue, as revealed in **Figure 1**.

Each bar in **Figure 1** represents how much of a specific amino acid is present in a group of foods. A bar height of 100% means that the daily needs of a human for each essential amino

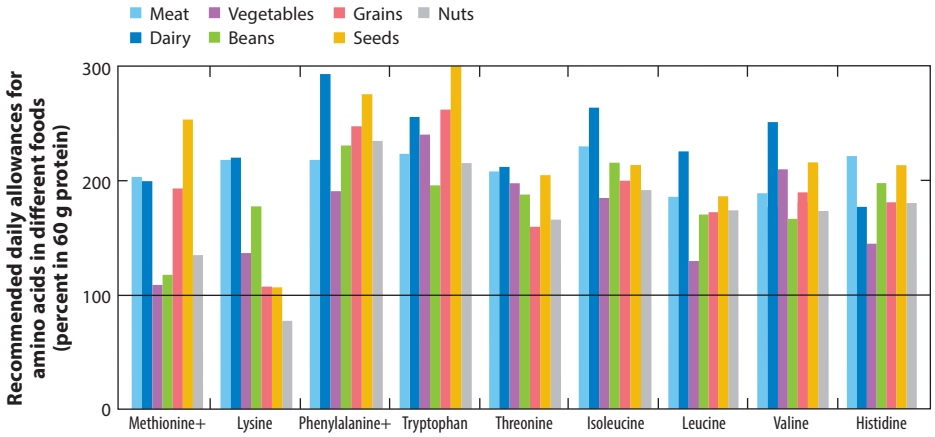

Figure 1

Recommended daily allowances for amino acids in different foods. Adapted from Davis (2018).

acid are met. As the chart reveals, even a vegetarian diet can fully meet the needs for the essential amino acids if it is appropriately varied. As for other nutritional concerns, including levels of sodium, saturated fat, fiber, vitamins, minerals, etc., it is important to note that, although the nutrient content of today's alternative protein sources may be similar to or less than that found in conventional proteins, it can be modified according to the ever-evolving recommendations of nutrition experts. This adaptability may be important as consumers adopt individualized diets, i.e., personalized nutrition.

For decades, there have been questions regarding the nutritional aspects of red and processed meat, particularly about their saturated fat content. Currently, there appears to be no consensus. For example, data from an NIH-AARP study published in the *British Medical Journal* revealed that red meat consumption is associated with an increased risk of dying from eight chronic diseases, including diabetes, heart disease, and cancer (Etemadi et al. 2017). In response to whether consumers should continue to eat red meat, physician David Katz (2019) stated,

> Don't. Not if you would like to reduce your risk of dying prematurely from any cause. Not if you would like to avoid heart disease. Not if you would like to avoid cancer. Not if you would like to avoid diabetes.

However, physician Mark Hyman (2020) maintains that fat speeds up metabolism and that the unintended consequences of the low-fat revolution resulted in our current obesity crisis. Journalists such as Gary Taubes and Nina Teicholz have joined the scientific debate, with Teicholz (2018) reporting:

> The U.S. government's nutrition advice since 1980 has mainly been to increase consumption of carbohydrates and avoid fats. Despite following this advice for nearly four decades, Americans are sicker and fatter than ever. Such a record of failure should have discredited the nutrition establishment. Yet defenders of the nutrition status quo continue to mislead the public and put Americans' health at risk.

Somewhat in agreement with Hyman and Teicholz, a new study suggests that there is not enough of a risk to tell people to limit the amount of meat they eat (Johnston et al. 2020).

Regarding the nutritional value of new alternative proteins, Capritto (2019) compared the Impossible Burger with conventional beef and found that they are similar in nutritional content

Table 2 Nutritional content of ground beef versus Impossible Burger

3.5 ounces lean ground beef	4-ounce Impossible Burger 2.0
217 calories	240 calories
12 g fat (5 g saturated)	14 g fat (8 sat)
90 mg cholesterol	0 g cholesterol
70 mg sodium	370 mg sodium
0 g carbohydrate	9 g carbohydrate
0 g fiber	3 g fiber
26 g protein	19 g protein

Data from Capritto (2019).

(**Table 2**). Ultimately, this comparison may be less relevant in the future, as cell-based and PF-produced protein technologies continue to produce better products. Depending on consumer demands based on tastes and personal nutrition needs, these technologies may be capable of infinite sensory and nutritional variations.

FOOD SAFETY AND ZOONOTIC DISEASE

Food safety is a continuing concern for conventional meat. Scharff (2013) reported that the estimated annual costs in the United States for food safety are $77.7 billion, resulting from 48 million foodborne illnesses, 28,000 hospitalizations, and 3,000 deaths. Using 2014 CDC data, 28% of foodborne illnesses caused by bacteria, chemicals, parasites, and viruses are associated with land animals (beef, game, pork, and poultry) (Painter et al. 2014), with nearly half (45%) of those cases resulting in hospitalizations (Scanes 2018).

There are also concerns regarding the presence of antibiotics (Aarestrup et al. 2000) and hormones, although the USDA's results reveal that the chances of consuming antibiotics through animal foods are extremely low (Brown 2017). It is also not clear that animal hormones have any effect on humans according to the FDA (Storrs 2011).

Both animal slaughter and animal waste can result in antibiotic-resistant bacteria entering the human food supply, as can swimming in infected waters. It may also result from contact with farm animals (as well as pets) (CDC 2020). Zoonotic diseases, i.e., diseases transferred from animals to humans, are becoming more of a concern since the fast-spreading coronavirus. Approximately 60% of all human diseases and 75% of all emerging infectious diseases are zoonotic (Bryner 2012). Most zoonotic human infections are from livestock, including pigs, chickens, cattle, goats, sheep, and camels (Bryner 2012). Pathogenic microbes transmitted by cattle include bacterial pathogens (42%,) parasites (29%), viruses (22%), and fungi (5%) as well as disease-causing prions (2%) (McDaniel et al. 2014).

ANIMAL WELFARE

In his book *Sapiens*: *A Brief History of Humankind*, animal-rights activist Yuval Noah Harari provides an alarming description of the way livestock animals are treated from birth to death (Harari 2015). Most people tend to ignore animal welfare unless it is animals they care about, such as cats, dogs, whales, elephants, and horses, all of which, in fact, are eaten in various parts of the world. In most surveys, more than half of consumers claim to be concerned about farm animal welfare and nearly half want to ban slaughterhouses, but most never find out whether the chicken, pork, or

beef they are consuming comes from mistreated animals (Norwood & Murray 2018). However, that may be changing, as a 2017 survey revealed that 58% of consumers agree or strongly agree that they are becoming more concerned about the welfare of farm animals (Granderson 2017). Animal welfare will likely become a greater concern when there are better substitutes for animal flesh. For some flexitarians, that may be a tipping point.

POTENTIAL BENEFITS OF ALTERNATIVE PROTEINS

An additional benefit of alternative proteins is that it may be possible to produce them in small factories adjacent to where they will be consumed, like vertical farms for produce, or even at home with 3D printers. Because these are rapidly evolving technologies, it is difficult to project whether the environmental, safety, and nutritional aspects of the different kinds of alternative proteins will be better or worse than conventional proteins.

There is a tremendous amount of uncertainty and variability among the types of future protein production processes, such that only two sources addressing their potential benefits are included here. The first is from *RethinkX*, a think tank that makes predictions about the future of technology-driven disruption (Tubb & Seba 2019), and the second is an article by Poore & Nemecek (2018).

Below are bullet points from the *RethinkX* report that provide a glimpse into the possibilities of market disruption by alternative proteins and the potential benefits of that disruption.

- "We are on the cusp of the deepest, fastest, most consequential disruption in food and agricultural production since the first domestication of plants and animals ten thousand years ago" (Tubb & Seba 2019, p. 6).
- "This will result in a far more distributed, localized food-production system that is more stable and resilient than the one it replaces. The new production system will be shielded from volume and price volatility due to the vagaries of seasonality, weather, drought, disease and other natural, economic, and political factors" (Tubbs & Seba 2019, p. 7).
- The nutritional benefits (of alternative meats) could have a profound impact on health, in a reduction in both foodborne illness and conditions such as heart disease, obesity, cancer, and diabetes that are estimated to cost the US $1.7 trillion every year (Tubbs & Seba 2019).
- Environmental benefits will (also) be profound, with net greenhouse gas emissions from the cattle falling 60% by 2030 (Tubbs & Seba 2019, p. 51). Other issues such as international deforestation, species extinction, water scarcity, and aquatic pollution from animal waste, hormones, and antibiotics will be ameliorated as well. By 2035, land previously used to produce animal foods in the United States could become a major carbon sink (Tubbs & Seba 2019).
- The volume of crops needed to feed cattle in the United States "will fall by 50%, from 155 million tons in 2018 to 80 million tons in 2030" (Tubbs & Seba 2019, p. 44).
- "By 2030, at least half of the demand for oil from the US agriculture industry—currently running at about 150 million barrels of oil equivalent a year—will disappear. . ." (Tubbs & Seba 2019, p. 8).
- By 2035, 60% of the land currently used for livestock and feed production will be freed for other uses (Tubbs & Seba 2019, p. 48).
- "Water consumption in cattle production and associated feed cropland irrigation will fall by 50% by 2030. . ." (Tubbs & Seba 2019, p. 50).

By comparison, Poore & Nemecek (2018) reported that eliminating animal products and replacing them with alternative proteins could:

- Reduce food's use of land by 76% (including a 19% reduction in arable land)
- Cut greenhouse gas emissions by 49%
- Reduce acidification by 50
- Reduce eutrophication (oxygen deprivation in water) by 49%
- Reduce withdrawals of fresh water by 19%

These are perhaps crude estimates; however, there is one benefit that is unchallengeable: With alternative proteins, there will be no issues with animal welfare.

REGULATORY GOVERNANCE

The primary issue for the governance of alternative proteins, as a new, rapidly evolving technology, is to ensure that risks and benefits are carefully weighed in real-time as issues evolve. Rather than absolute risk, for which there is no logical set point, governance should be based on relative risk. For new products, the governance question should be risk relative to substitutes, which can be other alternative proteins or conventional ones. If the new product is not riskier than conventional products and offers beneficial improvements, there should be no reason to prevent it from being on the market. With food safety issues like microbial pathogen contamination during slaughter and the dissemination of zoonotic diseases, there may be compelling reasons to allow alternative proteins on the market.

Immediate issues for alternative proteins are how they are named and food safety concerns. The first challenge for new proteins has been what to name them. Not waiting for federal solutions, states are passing laws to prohibit the use of terms like meat, burger, hot dog, sausage, or jerky for plant- or cell-based meats (Pitz 2020). Some of those laws in turn have been challenged, both successfully and unsuccessfully, in the courts as violating free speech.

Interestingly, the argument made by conventional meat processors is that consumers would be confused by alternative meat producers using these terms. In fact, the FDA proposed a rule in 2019 that said that no product could use the word milk on a product that was not produced by "lacteal secretion. . ." from "milking one or more healthy cows" (Riggs 2019).

The challenge to the name "almond milk" was based on the Standard of Identity for milk. These standards were created in 1938 to ensure that recipes used in packaged foods were identical to foods that were like "mothers used to make." Today, about half of all foods are governed by these standards. They are still being created because it is easier for incumbent manufacturers to organize and lobby for these rules than for new entrants to argue against them. It is not clear how incumbents will react to cell-based milk that is produced outside of animals.

The problem created by standards for new entrants is that they end up with new names or adjectives like "imitation," raising marketing costs and becoming a barrier to entry. This point is not lost on incumbent processors. For example, plant-based ice cream must be called "frozen dairy dessert" because it does not contain enough milk fat to be named ice cream. But, as a European rapporteur noted, "One person's imitation food is another's innovation—and stigmatizing products that are made with nontraditional ingredients risks putting the brakes on innovation. . ." (Halliday 2011). For all other alternative meats except cell-based meat, the FDA will enforce naming conventions under federal food standards laws. Because of the agreement between the FDA and USDA, the USDA will enforce naming for cell-based meat. Under USDA rules, names must be preapproved.

Food safety issues are addressed by the FDA for all products except cell-based meat and poultry, which are split between the USDA and FDA. The FDA also retains seafood except for catfish, which is governed by the USDA. Food safety concerns for alternative proteins include:

- the safety of the starting cells, particularly from novel sources or those that have been genetically engineered
- contamination during the growth phases of cell and PF proteins, including the growth broth for cell-based meat
- potential contamination of the fermentation tank
- waste disposal
- safe handling of products after production

All these risks are related to either pathogen contamination or allergenicity.

Depending on the novelty of the products, they may be designated as generally recognized as safe (GRAS) without notification to the FDA or GRAS with FDA notification, or they may need a food additive premarket approval. If a claim is made that categorizes the product as a drug, it must go through the premarket drug approval process. The immediate issues surrounding everything but GRAS without approvals are speed and the cost of taking the product to market, which are disincentives to innovate.

GRAS approval allows a company to make its own determinations as to whether the ingredient is safe and either notify or not notify the FDA. If the FDA is not notified, the time to bring the product to market is approximately 60 weeks, whereas if the FDA is notified, it takes approximately 116 weeks. The cost for either is approximately $375,000. In contrast, a food additive petition takes between 250 and 324 weeks and costs approximately $830,000 (Burdock 2017). If there are product claims that are medical in nature, a drug petition is required that costs between $314 million and $2.8 billion (Terry 2020). There are wide variations in both the time and costs of these processes.

The FDA approved soy leghemoglobin, the protein-based color additive that makes the Impossible Burger blood appear real and imparts ground beef flavor, by the premarket approval process (FDA 2019a). That process included submitting the following to the FDA: "(1) The history of consumption of soy, soy leghemoglobin protein, and *P. pastoris*; (2) the safety of *P. pastoris* as a production strain; (3) 14-day and 28-day feeding studies with soy leghemoglobin preparation in rats; (4) mutagenicity and genotoxicity studies of soy leghemoglobin preparation; and (5) an allergenicity assessment of soy leghemoglobin and *P. pastoris* proteins in the soy leghemoglobin preparation" (FDA 2019b). Interestingly, the FDA had no issues with the Impossible Burger until customers in supermarkets noticed the pink color from the leghemoglobin.

Beyond cost and time, there are several additional issues with the current regulatory approval system. One is that technology changes exponentially, but social, economic, and legal systems change incrementally (Thierer 2016). Another is that government systems tend to become more precautionary as complexity grows because of the overwhelming political penalties for approving something that later turns out to be unsafe. A situation involving multiple levels of government that have veto power over market access would further complicate the approval process. The split between the FDA and USDA for cell-based meat is one such example. This creates what economists call "the tragedy of the anticommons," where any one of numerous regulators each have the right to exclude people from using a scarce resource (Heller 1998). The result is slowing or stopping production or distribution and inhibiting innovation based on narrow and often precautionary concerns.

Compared to regulators, consumers make much more nuanced and comprehensive food choices based on taste, convenience, price, food safety, nutrition, animal welfare, zoonotic diseases, and brand names. Consumers make these decisions based on habit and the information

they have feeding into their individual risk–benefit calculations. Although they do not have the same information as a federal regulatory agency, they have much more information about their own concerns than a narrowly focused regulator. With the information revolution, particularly the Internet, they have access to more information than at any time in history (Shirky 2008). As the production of alternative proteins becomes more diffuse and more complicated with rapid innovation going in unpredictable directions, it will become increasingly challenging for a top-down approach to keep up with consumer preferences.

Congress has a long history of passing laws in response to one-time problems, giving the FDA expanded authority for expansive regulations. As former Office of Information and Regulatory Affairs Administrator Wendy Graham has noted, "One anecdote and you get a regulation, two anecdotes and you get a law." For example, in 1937, the deaths caused by sulfanilamide led to the 1938 Food, Drug and Cosmetic Act, expanding the FDA's authority over medical devices and cosmetics and allowing the FDA to postpone drugs from coming onto the market. Most FDA legislation over the past 120 years has been to keep the FDA at the center of product innovation for foods, drugs, and medical devices (Williams et al. 2016).

A BETTER SYSTEM

Ultimately, to the extent possible, consumers should be provided with sufficient information on risks and benefits so that each consumer can make their own choices. Consumers now make decisions on most of the matters they care about: taste, convenience, price, nutrition, and animal welfare. As better personal health monitoring devices become available, along with improved biomarkers to signal changes in, for example, low-density lipoproteins, consumers will be in a better position to monitor their individual nutritional needs. When that happens, foods that are now homogeneous, mass-marketed commodities will be differentiated into specialized formulations for subpopulations, making centralized regulatory oversight nearly impossible. Novel proteins will be much more easily differentiated than traditional proteins.

Where consumer risk–benefit decisions, such as for food safety determinations, are not possible for individuals, such decisions must move to a higher-level organization, but that need not be a federal regulator.

Gillian Hadfield (2017) describes a different alternative, one that is currently in place in the United Kingdom for medical devices, where instead of government civil servants establishing rules for achieving goals set by governments, private companies specialize in specific areas of regulation and work for a fee. The private regulators would be hired by food firms and these companies would, in turn, need to be approved by a super regulator (such as the FDA or USDA) (Hadfield 2017). For example, the Flavor and Extract Manufacturers Association that has been in existence since 1959 evaluates member companies' products for GRAS status (FEMA 2020). There are many advantages to having private regulators. Private regulators would compete with other private regulators and would receive feedback from customers, consumers, and their oversight regulators. They would compete on the basis of price, quality, and timeliness of approvals (Williams et al. 2015). If they do not perform well, and, in fact, fail to continually improve, they will be driven out of business by better competitors, or courts when they are sued, or they would lose their license due to malfeasance. A system of continual feedback to which they must respond and incentives to weigh benefits and risks equally would be completely different from our century-old system of federal regulators.

The new job of the federal regulator, i.e., the super regulator, would be to approve licenses and establish performance goals for the private regulators as well as continually monitor them for malfeasance, reducing the requirement for specialized industry knowledge. This system, moving

decisions down closer to users, gets us closer to what Adam Thierer (Thierer 2016, p. 5.) refers to as "permissionless innovation," i.e., "the general freedom to experiment with new and better ways of doing things." He quotes Larry Downes as saying that it "advances policies that encourage private experimentation and investment, such as exempting emerging technologies, whenever possible, from restrictions and taxes. . ." (Thierer 2016, p. 9). In the case of new technologies, particularly ones with huge potential benefits to replace problematic existing ones, the default should be allowing the technologies to proceed unless there are demonstrable risks or costs weighed against the potential benefits.

FUTURE ISSUES FOR NEW PROTEINS

There are two additional challenges for regulating all-new food technologies: social media and personalized (precision) nutrition. There is a growing generation gap related to the innovation and consumer acceptance of novel foods. Today, considerable consumer education regarding novel foods is accomplished through social media rather print media and classroom home economics, as it would have been fifty years ago. The evidence shows that each new generation, Gen Z and Millennials in this instance, are more accepting of technology than older generations. Part of this may be due to living in a world where technology changes faster, but, for foods specifically, younger generations are more aware of social issues that may have a direct impact on their lives. This implies that explanations of government decisions that involve consumer misconceptions should also be presented in social media.

Increasing knowledge about human heterogeneity will drive changes in human nutrition and medicine is another area that will affect consumer decision making. Ultimately, foods and medicine may be delivered in a joint food matrix that can be grown or processed to meet individual nutritional and medical needs. Foods grown or processed for specific subpopulations or individuals may not be mass-market homogeneous products produced centrally by large firms but rather heterogeneous products that are the subject of continuous, rapid innovation. They may also be produced in smaller vertical farms or local factories. In some cases, they may even be produced in home 3D printers to meet the needs and desires of individual consumers. Should this occur, the older, slower, static models of anticipatory federal regulations and inspections will be out of date.

DISCUSSION

With obesity and diabetes predicted to increase, some states suffering from droughts or water shortages, greenhouse gases continuing to accumulate, and concerns about animal welfare, many consumers will likely get past their aversion to foods created in laboratories and grown in food production facilities. It may become common to have many foods that are a product of the hand of man.

Government regulators can be either a help or hindrance to the development of new technologies. Presently, governments can avoid names that confuse consumers interested in foods containing protein substitutes. Government regulators can also avoid, where there is not likely to be a food safety concern, premarket approval systems that typically take years and millions of dollars to complete.

Furthermore, governments should not overreact to one-time food safety events by creating new regulatory structures that bind future innovation to the current lethargic innovation, particularly with some of the pressing public health and environmental issues before us. Instead, perhaps it is time to consider a more flexible, competitive system that meets the demands of the twenty-first century through innovative regulatory governance.

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