FROM LAB TO FORK

CRITICAL QUESTIONS ON LABORATORY-CREATED ANIMAL PRODUCT ALTERNATIVES

Friends of the Earth

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Background

For hundreds of years, people around the world have incorporated plant-based proteins like tofu into their diets. As problems with the increasingly industrial approach to livestock production have become widely known, interest in "meat and dairy alternatives" other than plant-based products has also increased. Most recently, significant investment has been made in the research and development of non-plant based products in an attempt to mimic animal-based products, ranging from animal tissue grown from animal cell cultures with animal serum, to proteins produced by genetically engineered algae and yeast.

The makers of this new wave of products claim to minimize the environmental impact of industrial factory farming by replacing animal products with synthetic products; but these engineered substances may also be resource intensive in their use of energy and water, as well as using feedstocks, like sugar and methane, and chemicals. The new animal replacement products are being marketed or promoted as "clean meat," "animal-free," "plant-based" or "climate-friendly," but with questionable substantiation.

This departure from plant-based foods includes a batch of biotech product proposals. Memphis Meats, for example, is developing "the world's first cultured meatball" and "cultured poultry,"[1] by using animal serum to grow animal cells into tissues. Other companies are using genetic engineering to manufacture ingredients that mimic animal proteins. For example, Impossible Foods has genetically engineered yeast to produce "plant blood" (leghemoglobin "heme" protein) for its "bleeding plant-based burger," and Finless Foods has genetically engineered algae to produce protein for its "algae-based shrimp." In addition, several other animal replacement proposals with ingredients derived from genetically engineered yeast include Geltor's gelatin replacement, Perfect Day's milk replacement and Clara Foods' egg white replacement.

Growing Investment

According to a recent study, over a 52-week period ending in August 2017, U.S. retail sales of plant-based milk alternatives generated $1.5 billion in sales, with a growth rate of 3.1%. Meat substitutes generated $555 million and had a growth rate of 6.1%.[2] Other studies suggest that the meat substitutes market could be worth close to $6 billion by 2022.[3] In the meantime, startups like Memphis Meats raised at least $22 million in investments from Bill Gates, Cargill, DFJ Venture Capital, Richard Branson and Tyson Foods.[4] Silicon Valley start-up Impossible Foods, maker of the Impossible Burger, has raised upwards of $300 million since 2011 from investors including Bill Gates, Li Ka-shing, Temasek, and Khosla Ventures.[5] These new investments are not directed at truly plant-based products, but are in response to the growing market demand for plant-based foods.

Highly Processed

Whether made from genetically engineered yeast or through in vitro processes, these next-generation animal replacement products are manufactured in resource-intensive factories. The products are often made with multiple processed ingredients, including gums, flavors, colors and other additives. Some products also include novel, genetically engineered ingredients like the "heme" secreted from genetically engineered yeast, which gives the Impossible Burger its "blood."

Various "processing aids" are employed to make some of these products, including organisms (like genetically engineered bacteria, yeast and algae) that produce proteins, and chemicals to extract proteins. For example, chemicals like hexane are used to extract components of a food, like proteins (from peas, soy, corn etc.) or compounds (from genetically engineered bacteria) to make xanthan gum. Currently, however, disclosure of these ingredients is not required. Other processing aids (e.g. bacteria, yeast, algae), including those that are genetically engineered to produce proteins, are also not currently required to be disclosed on package labeling. The lack of transparency makes it difficult to assess the inputs and impact of their use.

Key Concerns

This report will examine important questions and concerns about products like "lab meat" and genetically engineered animal replacement products. While several methods are used to make these second-generation animal replacement products, there are distinctions to make among them concerning disclosure requirements, safety and environmental concerns, marketing claims, and resources required. These cost/benefit parameters are important to include in a true assessment of the health and sustainability of each production technique, each product and each product category overall.

KEY QUESTIONS NEED TO BE ANSWERED BEFORE PRODUCTS ARE ALLOWED TO ENTER THE MARKET:

- Are second-generation animal replacement products truly sustainable?
- Are they a viable solution to the numerous problems surrounding industrial animal production?
- How do these products' environmental impact compare to sustainably produced plant-based meat and dairy alternatives and products from animals raised in sustainable, high-welfare production systems?
- Do they meet their marketing claims as sustainable and healthy
- Should the safety of these new products be left to individual companies to determine?
- Is there adequate independent safety assessment, regulatory oversight and transparency?
- Do these products and their claims meet consumer expectations?

Overview of lab-grown meat and genetically engineered animal replacement products

	Lab-Grown Meat	Genetically Engineered Proteins
Description of Technology	Artificial muscle tissue is produced in vitro by mass culturing stem cells from animals (in energy-intensive sterile conditions). The tissue is often cultured and grown in solutions with bovine serum,[6] mixes of hormones, growth factors, amino acids, vitamins and other food additives.[7]	Yeast, bacteria and algae are engineered to produce proteins that mimic those derived from plants and animals.[8] Extraction and other processing methods are often required to isolate protein(s).
Regulatory Requirements for Safety Assessment	The company may determine the safety of the product.	The company may determine the safety of the product.
Data on Health and Environmental Impact	Data on health and environmental impact are often hidden as "confidential business information."	Data on health and environmental impacts from production and contamination are often hidden as "confidential business information." The safety of genetically engineered "heme" protein in Impossible Burger was questioned by the FDA.

Transparency	The FDA does not require notification of new food ingredients or processes. Manufacturing processes are considered confidential business information. Ingredients used in culture mediums and other processing aids are not required to be listed on the ingredients panel.	The FDA does not require notification of new food ingredients or processes. GMO ingredients are currently not required to be labeled as such. Processing aids are currently not listed on the ingredients panel and can be considered confidential.
Marketing and Promotion Claim Examples	• Clean meat • Cultured meat • Sustainable	• Animal-free • Plant-based • Climate-friendly • Sustainable
Examples of Companies	• Memphis Meats • MosaMeats • Just, Inc. • Finless Foods	• Impossible Foods (Impossible Burger)[9] • Perfect Day (Milk substitute)[10,11] • Clara Foods (Egg white substitute)[12]
Processing Aids (not required on ingredient panel)	• Fetal bovine serum[13] • Cell culture medium • Drugs and antibiotics in medium	Genetically engineered yeast, bacteria or algae that produce proteins and other ingredients.
Environmental Impacts and Resource Use	• Use of energy, water, feedstocks and other chemical inputs. Lifecycle impacts not available. • Greenhouse gas emissions, plastics, water and sustainability footprint.	• Use of energy, water, feedstocks and other chemical inputs. Lifecycle impacts not available. • Risk of environmental contamination and escape of engineered organisms.

Critical Areas to Examine:

1. Safety & Oversight

Altering an organism at the genetic level can create unexpected changes in the organism, as well as in the compounds it produces. Animal replacement ingredients produced through genetic engineering may therefore pose unforeseen health risks.[14,15] Currently, safety assessments specific to these genetic engineering techniques are inadequate, and no mandatory regulatory oversight is in place for this swiftly moving set of new technologies used to genetically engineer organisms. Regulations under the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA) fail to address the health and environmental impact, as well as the safety, of new genetic engineering applications, editing techniques (e.g. CRISPR) and products derived from them.[16]

Research has demonstrated that some new genetic engineering techniques may result in hundreds of surprise off-target effects and genetic mutations.[17] Theoretically, such mutations could lead to unexpected production of toxic byproducts that could impact human health in unforeseen ways, such as causing allergic reactions in people who consume products with genetically engineered ingredients.[18] Concerns run high particularly with regard to engineered proteins, as they may cause novel allergies.[19]

This lack of precision, together with the potential for unintended consequences, highlights the need for these new, genetically engineered organisms and their products to be thoroughly assessed, both in terms of the technology and methods used, and on a case-by-case basis, before entering our food system and environment.

NEW FOOD INGREDIENTS, PROCESSING AND TECHNOLOGIES

The safety and true sustainability of these new techniques and products, as well as the resources and inputs necessary to produce them, have not been thoroughly assessed and require closer examination. New food ingredients, processing aids, and products can move quickly from lab development to marketed products, without even being reported to the FDA. In fact, there is no tracking and little oversight of any new food ingredients on the market.[20] Without strong oversight and clear third-party data, the long-term safety and sustainability of these novel food ingredients cannot be ensured or even understood.

The FDA does not have a viable process for evaluating the safety of novel food products, ingredients or food additives that are genetically engineered. In the U.S., new food additives, including those that are genetically engineered, are allowed to enter the market through the voluntary "Generally Recognized as Safe" (GRAS) process. This allows a manufacturer to decide for itself, without FDA input or disclosure, and using only company data, whether or not a product is safe.

GRAS has been criticized for allowing the food industry to bypass critical safety checks for new ingredients.[21] In 1958, GRAS was established to require companies to demonstrate that new ingredients were safe. There was an exemption for "time tested substances" [22] that had already been common in diets and were known to be safe, like salt or vinegar. In 1997, the FDA changed this rule. Now, companies are not required to notify the public or the FDA about new food ingredients, additives or processing aids. The inadequate GRAS process applies to all food additives, which means that ingredients that have not been reported or publicly evaluated, such as genetically engineered proteins and food additives, are escaping evaluation. The GRAS designation does not require mandatory risk assessment, which can obscure health and environmental impacts.

Grassfed Organic Burger Ingredients

- Lean organic grass feed beef

Ingredients that may be found in a Meat-Replacement product

- Soy protein concentrate*
- Maltdextrin*
- Natural flavors including “smoke”
- Hydrolyzed corn or soy protein*
- Caramel color
- Pea protein isolate
- Leghemoglobin (soy)*
- Gum Arabic
- Cellulose
- Soy protein isolate*
- Carrageenan
- Autolyzed yeast extract*
- Oleoresin paprika (color)
- Potassium chloride
- Xanthan gum*

* Ingredients which may be derived from genetic engineering

CASE STUDY: THE IMPOSSIBLE BURGER

Although Impossible Foods did voluntarily disclose the use of "heme" derived from genetic engineering to the FDA, documents obtained from the FDA through the Freedom of Information Act (FOIA) indicated that Impossible Foods, maker of the Impossible Burger, was informed by FDA officials that it had not provided adequate proof of safety for a key genetically engineered ingredient, the "soy leghemeglobin" (SLH), or "heme" protein, that gives the burger its meat-like taste and color. [23] This novel protein had never previously been introduced to the human diet. Documents also showed that the manufacturing SLH with genetically engineered yeast resulted in 46 unexpected additional engineered proteins. Some of these surprise proteins are unidentified and none were assessed for safety in the dossier provided to the FDA. Impossible Foods presented that SLH is "substantially similar" to real heme found in the root of a soy plant, but not identical.[24]

The FOIA-procured documents state that the "FDA believes that the arguments presented, individually and collectively, do not establish the safety of SLH for consumption, nor do they point to a general recognition of safety." The company was warned by FDA officials that this ingredient would not meet the basic FDA GRAS status. Despite this warning, Impossible Foods put a product (the Impossible Burger) with this ingredient on the market for public consumption.[25] In addition, despite the concerns of the FDA, Impossible Foods touted the color properties of the engineered "heme," but did not seek FDA approval for the "heme" as a color additive. [26]

2. Transparency

Environmental and health risk assessments of new food ingredients, processing materials or products are often not publically accessible, because most of the related data are produced by companies that do not have to disclose information. This means that any impact on health or the environment is obscured by confidential business information (CBI) protections. CBI obstructs external review, independent of industry-funded research interests. It can also impede transparency around a company's decision-making process regarding safety and whether or not to bring a product to market.

This lack of transparency makes several of the safety and sustainability parameters described above difficult to assess. Companies can essentially determine the safety of these novel ingredients, technology applications and products without being required to disclose how those decisions were made or even that a new food ingredient is headed to market.

3. Truth in Marketing

PROMOTIONAL CLAIMS

Some animal replacement product companies, like Perfect Day,[27] Clara Foods[28] and Impossible Foods,[29] have begun to make "sustainability" claims based on limited evidence or proprietary studies. Many of these novel products are coming to market with sustainability claims. The Impossible Burger is marketed as "sustainable," and Perfect Day claims to be "earth friendly," despite the lack of data on energy consumption, emissions, or dependency on industrial feedstocks like genetically engineered corn used to feed the genetically engineered yeast that produce key ingredients. Clara Foods markets its egg whites as "purely from plants,"[30] despite key proteins being derived from genetically engineered yeast. These are just a few of the confusing promotional claims being made. When making claims about the environmental sustainability of these and similar products, companies should base them on a publicly available, full life-cycle assessment.

INGREDIENT DISCLOSURE AND LABELING

Many companies making ingredients derived from genetic engineering, including for plant or animal replacement products, are not clear with the public about the manufacturing techniques that they use, nor are they required to be.

Impossible Foods initially claimed that its "heme" protein from engineered yeast was "identical to"[31] that which the company is trying to emulate from animals, but this does not match the official documentation on the biochemical structures provided to the FDA. In fact, documents obtained from the FDA showed that Impossible Burger inadvertently contains 46 additional engineered proteins. It is not clear how they will or will not be disclosed on the label. [32] Processing aids, including those that are genetically engineered, are not required to be disclosed on the ingredient label.

4. Environmental Sustainability

Second-generation, lab-created animal replacement products have entered the market before being demonstrated to be safe, affordable, and sustainable solutions to food animal production challenges. Overall life-cycle analyses of the various animal protein replacement products in development or on the market have not been done. We do not yet understand the net resource use or the impacts of manufacturing these novel food products, especially at scale.

RESOURCE AND WASTE IMPLICATIONS

Making genetically engineered animal replacement products and lab meat involves complex manufacturing and processing. Unfortunately, while proponents claim that these methods may use fewer resources or may be sustainable, the resource inputs for genetically engineered animal replacement products and lab meat have not been fully evaluated. These resources include the energy, water, fossil fuels, chemicals, plastics and feedstocks used to manufacture the 15-20 ingredients[33, 34, 35] that commonly make up these products. Before claims of sustainability can be corroborated, waste production also needs to be assessed, including greenhouse gas emissions, water, plastic and nutrient management, along with disposal of genetically engineered organisms and the materials used in the process.

One study in 2015 suggested that while lab meat might end up using fewer agricultural inputs and land than livestock, the overall energy consumed to produce lab-grown meat might be equivalent to or more than that used to produce animal-derived meats.[36]

FEEDSTOCK IMPLICATIONS

One hidden environmental cost to these second-generation protein foods is the feedstocks required to produce them; these include sugarcane, corn and natural gas. Although the industry is in its infancy, the envisioned "synthetic bio-economy,"[37] once at scale, would require expanding production of these feedstocks,

largely produced through environmentally devastating, chemical-intensive industrial monocultures, as with GMO corn or sugar, or with natural gas (which is produced with techniques like hydraulic fracturing or "fracking"). As an example, increasing demand for sugarcane could exacerbate the current destruction of critical savannah and rain forest ecosystems in Africa, Southeast Asia and Latin America (including some of Brazil's most eco-sensitive areas of land).[38,39] Industrial feedstock production requires large amounts of synthetic fertilizers (which pollute the water and the air), as well as toxic pesticides and herbicides, such as chlorpyrifos, glyphosate and atrazine, [40, 41, 42] which are linked to cancer and associated with developmental and reproductive harm.

CONTAMINATION QUESTIONS

Genetically engineered yeast, algae and bacteria are manufactured in incubating vats; given the prolific nature of these organisms, complete containment is difficult, if not impossible. Due to their microscopic size, organisms like microalgae will inevitably escape from any industrial cultivation facility — and potentially become airborne or spread via water.[43] Because such organisms reproduce (and some can cross breed with related organisms or even, in the case of microbes, "swap genes" with unrelated species through horizontal gene transfer)[44] the escape of genetically engineered organisms could have negative ecological consequences. These include genetic contamination of wild species and disruption of natural ecosystems.[45]

5. Consumer Data

Market data shows that 68 percent of consumers want to know where their food comes from and how it is produced.[46] Consumer polls show that 57 percent of consumers do not want to eat genetically engineered food,[47] and that approximately 95 percent of consumers agree that GMO food should be labeled as such.[48] As the demand for "natural" food increases, survey data indicates that many consumers assume the designation of "natural" to mean that no artificial or genetically engineered substances are among the ingredients.[49]

Additional surveys record that 88 percent of Americans support mandatory labeling of foods containing GMOs, and 91 percent agree with the statement that people have the right to know if they are purchasing or eating food and products containing GMOs.[50] Currently, the government does not require GMO ingredients to be labeled as such, nor does it require disclosure of genetically engineered processing aids.

6. Comparison to Demonstrated Benefit from Sustainable Crop and Animal Farm Practices

Determination of safety or any potential benefits of these products should include analyses of the impact on human health and the environment (full lifecycle assessment). Analyses should also consider consumer expectations of sustainable products, including ingredients and claims. Those parameters should be measured against animal replacement products that are truly plant-based, and products from animals raised through regenerative, high-welfare farming practices.

Evidence demonstrates that eating less and better meat and eating more truly plant-based products produced with organic and regenerative farming practices has many health, animal welfare and environmental benefits.

Nutrition from whole plants (such as legumes and other protein-rich plants) produced through ecological farming practices do not carry any of the risks associated with genetically engineered or other lab-produced proteins; [51] therefore, they should be considered the preferred alternative to animal products resulting from unsustainable, inhumane[52] and destructive factory-farmed methods. In addition, innovative animal farming practices, such as well-managed, high-welfare pasture-based systems, fit within a regenerative, humane,

just and ecologically sustainable food production model and have well-documented environmental, animal welfare, economic, social and public health benefits that consumers are already demanding.[53] For example, studies have shown that organic and pasture-based methods of production result in cleaner water,[54] promote healthier soils that can sequester more carbon,[55,56] release fewer toxins and improve biodiversity[57] and pollinator habitat.[58]

Conclusion

Second-generation, lab-created animal protein replacement products are not yet proven to be safe or sustainable by regulators or via transparent, independent third-party assessments. Rather, there are increasing concerns and questions that remain unanswered, and existing analyses show that these products may be problems masquerading as solutions.

New food ingredients, especially those derived from emerging technologies, should be required to be assessed for safety before being allowed to be used in food or going to market. Safety concerns have already been raised regarding these products, which are not considerations for plant and animal-based foods produced through regenerative organic farming.[59] Whether these new lab-created animal replacement products will be widely accepted by an increasingly discerning public that demands "real" food, along with transparency and sustainability in the food system, remains to be seen.

Companies making animal replacement products using genetic engineering and in vitro processes are making a range of claims to position their products as more sustainable than their animal product counterparts. If highly processed engineered foods, manufactured in laboratories with new, unassessed food ingredients and processes are going to replace even some of the existing animal protein from farm-based systems, then these novel food ingredients need to be carefully vetted. We recognize and applaud those looking for ways to shift away from unsustainable and inhumane factory farming, but we must carefully evaluate the benefits, and identify and mitigate the costs and inadvertent consequences, of alternatives. The true cost of second-generation animal replacement proteins has not been fully assessed, but should be before these products enter the market and our food supply at scale.

FOR MORE INFORMATION SEE:

- GMOs 2.0: Synthetic biology https://foe.org/projects/synthetic-biology/
- Challenging factory farming and shifting diets https://foe.org/projects/animal-agriculture/

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