# GMO ANIMAL REPLACEMENT PRODUCTS

*Critical questions and implications for our health and the environment*

**Left: pasture-raised organic cows. Right: Impossible Food's biotech lab used for creating Impossible Burger.** Source: https://psmag.com

## INTRODUCTION

The meat, eggs and dairy at the center of many plates, and the ways in which we typically produce them, are at the heart of some of the world's greatest threats to the environment, public health, workers' rights and animal welfare. Industrial produced animal products are amongst the most resource-intensive foods in our diet. They require massive water and energy inputs and generate significant greenhouse gas emissions, soil, air and water pollution. Industrial factory farming is carbon and resource intensive[1] and costs the public billions of dollars in diet-related diseases.[2,3]

There are two primary approaches to addressing these problems — one, through healthier and more sustainable ways of producing animal products, such as organic and regenerative pasture-based methods, and two, reducing consumption of animal products by moving toward plant-based diets. These alternatives to factory farmed animal products have been steadily growing in popularity and are becoming more available to consumers.

While this is great news for human health, animal welfare and the environment, an emerging wave of genetically engineered animal replacement products is raising new concerns.

## MEAT AND DAIRY ALTERNATIVES RAPIDLY ENTERING THE MARKET

In recent years, more processed plant-based alternatives to animal products, such as soy-based bacon and turkey, have entered the market and their U.S. retail sales are growing significantly.[4,5] According to a recent study, over a 52-week period ending in January 2017, U.S. retail sales of plant-based milk alternatives generated $1.5 billion in sales, with a growth rate of 3.1%, while conventional cow's milk sales were down 5%.[6] Meat substitutes generated $555 million and had a growth rate of 6.1%.[7] Other studies suggest that the meat substitutes market could be worth close to $6 billion by 2022.[8] In comparison, the global processed meat market continues to grow and is expected to reach approximately $1.6 trillion by 2022, a growth rate of around 14% between 2017-2022.[9]

Now there is a new wave of startups developing lab meat and genetically engineered protein products. In 2013, the first lab meat burger debuted,[10] kicking off newly energized venture capital fueled interest in developing these new proteins. Products in development range from lab-produced substitutes for animal products from chicken, fish, and milk to egg whites and gelatin.

Product proposals and speculation around laboratory created meat and genetically engineered meat replacements are increasingly garnering attention in the media and with investors. Companies like Memphis Meats and Finless Foods are developing what they refer to as "clean meat" or "lab meat" in which developers are attempting to grow meat from

animal cells via in vitro production. Companies including Impossible Foods and Perfect Day are genetically engineering microorganisms to produce proteins that mimic animal proteins.

Companies like these have attracted growing interest and capital from Silicon Valley investors. Memphis Meats has raised at least $22 million, with investments from Bill Gates, Cargill, DFJ Venture Capital, Richard Branson and Tyson Foods. Silicon Valley start-up Impossible Foods, maker of the Impossible Burger, with its genetically engineered "heme" protein, has raised upwards of $400 million since 2011 with investments from Bill Gates, Li Ka-shing, Temasek and Khosla Ventures. But according to Impossible Food's CEO, "it is truly astonishing how little diligence [venture capitalists] do in terms of the actual science that underlies some tech companies."[11]

*Genetically engineered animal replacement products are entering the market before they have been proven to be safe, scalable and sustainable alternatives to factory farmed animal products.*

However, are these highly processed, multi-ingredient, animal replacement products the long-term answer for better meat or vegetable based proteins? The answer is that we don't know, and what we do know raises important questions that must be considered before these products enter the market and our diets at scale.

**EXAMPLES OF COMPANIES DEVELOPING ANIMAL REPLACEMENT PRODUCTS USING GENETICALLY ENGINEERED YEAST**

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|---|---|
|  | **Impossible Foods**<br>*Product:* Impossible Burger<br>*Status:* Sold in restaurants<br>*Investment:* $396 million[66] |
|  | **Perfect Day**<br>*Product:* Perfect Day Milk<br>*Status:* In development<br>*Investment:* $24.7 million[67] |
|  | **Clara Foods**<br>*Product:* Clara Whites egg white substitute<br>*Status:* In development<br>*Investment:* $3.5 million[68] |
|  | **Geltor**<br>*Product:* gelatin replacement<br>*Status:* In development<br>*Investment:* $2.5 million[69] |

**Companies developing genetically engineered replacement products are receiving significant capital from Silicon Valley investors.**

These products, while bold in their goals to reduce factory farming have not been fully assessed for sustainability of the resources needed (*energy, water, fossil fuels, feedstocks, chemicals, plastics, etc.*) to manufacture or engineer the 15-20 ingredients[12, 13, 14] commonly found in many of these animal replacement products. These ingredients can move quickly from lab development to marketed products without even being reported to the Food and Drug Administration. In fact, there is no tracking and little oversight of any new food ingredients on the market.[15] Given the lack of transparency about these food additives and ingredients derived from genetic engineering, it is critical to have strong pre-market oversight and clear third party data about the sustainability and long-term safety of these novel food ingredients, processing aids and materials.

**Top: Tubes containing growth medium used to culture cells. Bottom: Lab-based meat is grown using animal stem cells and cultured to grow tissue.**

## "LAB" OR "CLEAN" MEAT

Essential unanswered questions remain about the long-term sustainability and safety of lab-based meat, or what the companies are calling "clean meat." With this in vitro process, scientists grow artificial tissue by taking stem cells from animals and mass culturing them to grow tissue. The tissue is often cultured and grown in solutions with bovine serum,[16] mixes of hormones, growth factors, amino acids, vitamins and other food additives.[17]

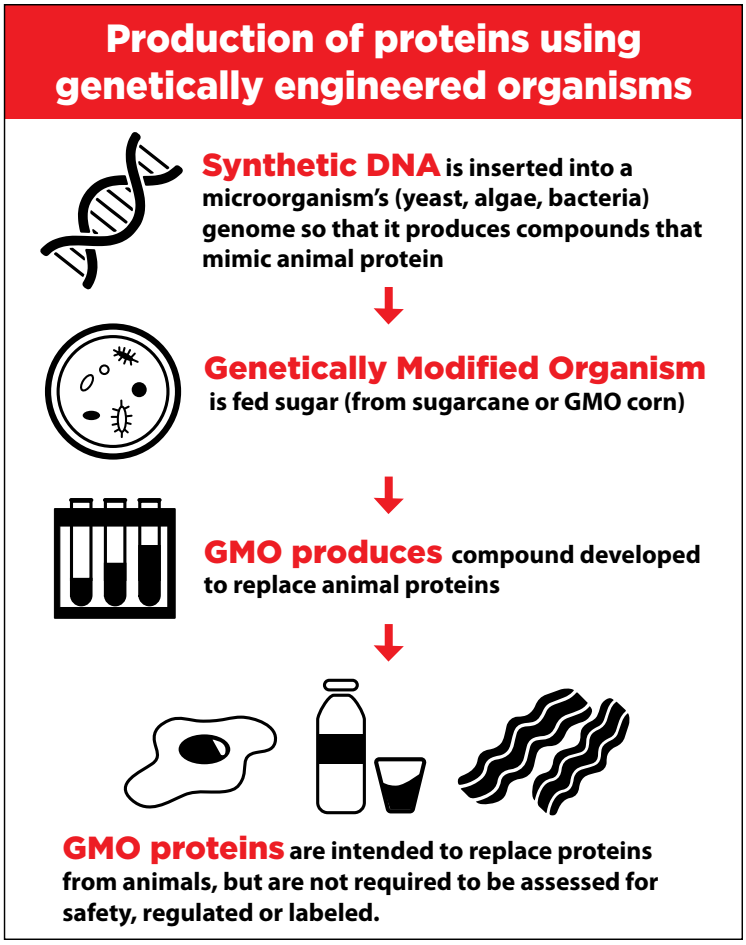
Actual data on health and environmental impacts from these "lab meat" products, many of which are still in research and development phases, are hidden as confidential business information. Questions about the safety of the chemical mixtures used to culture the tissue, and about the energy use and sustainability footprint once production is to scale are speculative. One study in 2015 suggested that while lab meat might end up using fewer agricultural inputs and land than livestock, "large-scale cultivation of in vitro meat and other

bioengineered products could represent a new phase of industrialization with inherently complex and challenging trade-offs." The study also suggested that overall energy required to produce lab-based meat could end up being similar to or more than that used to produce animal-derived meats.[18] Questions about animal welfare also remain uncertain, as the technology relies on fetal bovine serum,[19] and how the inputs and final products will be assessed and regulated remains to be determined.

*This issue brief lays out a series of critical questions and information about animal replacement products derived from genetic engineering, including implications for health and the environment.*

## GENETICALLY ENGINEERED PROTEINS

Many companies making animal replacement proteins are employing genetic engineering techniques to engineer organisms such as yeast, algae or bacteria to produce compounds that mimic those derived from plants and animals.[20] Some companies, Like Perfect Day, claim to be using synthetic biology techniques, a subset of genetic engineering. Synthetic biology is a newer dimension of modern biotechnology and type of genetic engineering "that combines science, technology and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organism and biological systems."[21]




Example of process to create genetically engineered compounds marketed to replace animal proteins.

In addition to swapping genes from one species to another, as in traditional genetic engineering (transgenics), synthetic biologists can add, delete, silence or completely rewrite an organism's DNA.[22] They can use GMO yeast, algae and other organisms as "living factories" to produce fuels, industrial chemicals, bioplastics, pharmaceuticals and food. However, although scientists are able to make these genetic changes to organisms, the processes, outcomes and unintended consequences are not fully understood or controlled.

Companies including Impossible Foods,[23] Perfect Day[24,25] and Clara Foods[26] are developing new animal replacement food products with ingredients derived from genetically engineered organisms such as yeast. These GMOs are engineered to produce proteins, colors, flavors and other ingredients that mimic those found in real animal products. For example, Impossible Food, Perfect Day and Clara Food's genetically engineered yeasts are designed to produce proteins. Impossible Food's genetically engineered "heme" also gives the Impossible Burger its blood-like red color, although it has not been assessed or regulated as a color additive. However, some of these products are being misleadingly marketed as "sustainable" and "purely from plants,"[27] despite being derived from genetically engineered yeast.

Genetically engineered animal replacement products, and associated food additives, are entering the market before being demonstrated as safe and sustainable alternatives to factory farmed animal products. It is also unclear whether any environmental impacts will be amplified once the products are produced at a larger scale. Because altering organisms at the genetic level can create unexpected changes in the compounds they produce, genetically engineered animal replacement ingredients could also pose novel health risks.[28,29,30]

## CRITICAL AREAS TO EXAMINE

### ❶ Are they regulated?

In the U.S., new genetically engineered ingredients and food additives are allowed to enter the market via the *voluntary* "generally recognized as safe" (GRAS) process. This


**All products containing ingredients derived from genetic engineering are not currently required to have on-package labeling.**

allows a manufacturer to decide for itself, without Food and Drug Administration (FDA) input, whether or not a product is safe. Companies claim that this self-determination of safety does not require notice to the public or the FDA, and may apply to food products regardless of conflicts of interest or whether the products are new or not widely studied. The inadequate GRAS process applies to all food additives, which means that genetically engineered proteins and food additives are escaping detailed and critical evaluation.

Currently, safety assessments specific to these genetic engineering techniques are inadequate, and no mandatory regulatory oversight for these new genetically engineered organisms is currently in place. Regulations under the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA) and FDA fail to mandate that all new genetically engineered foods and crops, including ones made with gene-editing tools like CRISPR, be regulated and assessed for health and environmental impacts.[31]

## ❷ Have they been shown to be safe for human health and the environment?

### *Health*

Companies like Impossible Foods are using the voluntary GRAS process which does not provide sufficient oversight or health assessments for food additives. For example, according to documents obtained via a Freedom of Information Act request, FDA told Impossible Foods, "the arguments present, individually and collectively, do not establish the safety of soy leghemoglobin for consumption, nor do they point to a general recognition of safety.[32] The company had failed to test the genetically engineered protein in question, which had never been in the human diet, and it admitted that the product included 46 unexpected and unassessed additional proteins as a result of the genetic engineering process.[33]

The company was warned by FDA officials that the "heme" would not meet the basic FDA GRAS status. Despite this warning and lack of safety tests, Impossible Foods put the genetically engineered product on the market for public consumption.[34] This case also raises concerns about the other food ingredients and products[35] produced via genetic engineering that are rapidly entering the market.

Research has demonstrated that some genetic engineering techniques, like CRISPR, can result in hundreds of surprise mutations.[36] Mutations could lead to unexpected production of toxic byproducts or cause unintended impacts on human health, such as allergic reactions, in people who consume these products.[37] This lack of precision and potential unintended consequences highlights the need for these new genetically engineered organisms and their products to at least be thoroughly assessed both as a technology and on a case-by-case basis ahead of entry into our food system and environment.

### *Environment*

Studies are not conclusive about the potential environmental benefits of genetically engineered animal replacement products.[38] And the GRAS process does not provide an assessment of the environmental impact of these products. One hidden environmental cost to food derived from genetic engineering is the feedstock required to produce them; these include sugarcane, corn and natural gas. Although the industry is in its infancy, the envisioned "synthetic bioeconomy,"[39] once at scale, would require expanding production of these feedstocks, largely produced via environmentally devastating chemical-intensive industrial monocultures, or in the case of natural gas, via fracking. Industrial crop production requires large amounts of synthetic fertilizers, which contribute to water pollution, and toxic pesticides and herbicides such as chlorpyrifos, glyphosate and atrazine[40, 41, 42] which are linked to cancer and developmental and reproductive harm.

*Animal replacement products derived from genetic engineering and synthetic biology techniques would take us on a path away from the proven solutions provided by a sustainable, regenerative, humane, just and transparent food system.*

**In order to produce the genetically engineered animal replacement product, the genetically engineered organism is fermented in tanks with sugar from sugarcane or GMO corn.**

Some animal replacement product companies, like Perfect Day,[43] Clara Foods[44] and Impossible Foods,[45] have led with "sustainability" claims based on limited evidence or proprietary studies. Impossible Foods claims its product is "made entirely from plants, with a much smaller environmental footprint than meat from animals."[46] Due to their very small (microscopic) size and their capacity to become airborne, engineered organisms like yeast or microalgae will inevitably escape from any industrial cultivation facility — complete containment is not feasible.[47] Because they reproduce and many can cross breed with related organisms or even, in the case of microbes, "swap genes" with unrelated species via horizontal gene transfer,[48] the escape of genetically engineered

organisms could have pronounced negative ecological consequences. These include genetic contamination of wild species, disruption of natural ecosystems and ensuing potential health risks.[49]

When making claims about the environmental sustainability of their products, companies should have to provide independent, third-party documentation of a full, independent lifecyle assessment of environmental impacts, as well as the footprint of the production facilities themselves.


**Although majority of consumers want to know how their food is produced, companies may not be transparent about the use of new ingredients derived from genetic engineering.**

### ❸ Will consumers accept them?

Market data shows that 68 percent of consumers want to know where their food comes from and how it is produced.[50] However, most companies making these new genetically engineered animal replacement products are not transparent with consumers regarding their use of genetic engineering techniques, nor are they required to be under current GMO labeling proposals.[51]

These genetically engineered products are not labeled as genetically engineered, and some are instead marketed as "plant-based," despite being derived from genetically engineered organisms such as yeast that is grown in industrial vats. Companies like Impossible Foods may claim that their genetically engineered protein is "identical to"[52] that which they are trying to emulate, but they admit to the FDA that the protein is only "substantially similar to proteins…(found) in the form of meat and other vegetables.[53]

Polls show that 57 percent of consumers do not want to eat genetically engineered food,[54] and approximately 95 percent of consumers agree that GMO food should be labeled as such.[55]

Given the lack of transparency prevalent among these companies and the fact that consumers are demanding more real food with simple, truly natural, non-GMO, organic and sustainable ingredients, it is unclear whether consumers will accept these new products.

### ❹ What alternatives exist?

Spending billions to manufacture genetically engineered protein and meat replacement products in labs and factories as an alternative to farms is a theory of production change that requires further proof and assessment before it can or should be regarded as a sustainable solution. That assessment should include analyses of impacts on human health and the environment (full lifecycle assessment) and consumer acceptance.

In the meantime, evidence continues to grow that eating less meat and shifting to animal products produced with organic and regenerative farming practices has many health, animal welfare and environmental benefits. The world simply cannot meet its climate targets unless high meat-consuming nations like the U.S. substantially cut emissions associated with meat- and dairy-intensive diets. Plant proteins produced via ecological farming practices can help replace unsustainable, inhumane and destructive factory-farmed animal products without the risks posed by genetically engineered proteins. 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. For example, many studies have shown that organic and pasture-based methods of production result in cleaner water,[56] promote healthier soils that can sequester more carbon,[57,58] release fewer toxins and improve biodiversity[59] and pollinator habitat than conventional agriculture.[60]

The growing popularity of plant-based diets also demonstrates that animal products, whether real or synthetic, do not need to be at the center of our plates.[61] In addition, the success of non-GMO and organic plant-based meat and dairy replacement products on the market demonstrates that substitutes for animal products can gain consumer acceptance without resorting to untested and unregulated genetic engineering methods.

Instead of investing in potentially risky new food technologies, we should be investing in transparent, proven, beneficial alternatives to factory farmed animal proteins, such as truly plant-based protein, regenerative agriculture and organic food that market data demonstrates consumers are actually demanding.[62]

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## Organic & Regenerative Methods

- ✔ **Helps keep small farmers in business**
- ✔ **Can help protect water resources**
- ✔ **Not reliant on chemical-intensive GMO monocultures for feed**
- ✔ **Animals are not given hormones or routine antibiotics**
- ✔ **Can sequester carbon and contribute to climate resiliency**
- ✔ **Can foster biodiversity and pollinator health**
- ✔ **Workers and consumers are protected from harmful pesticides**
- ✔ **Produces food rich with the nutrients we need to thrive**

**The science is clear that by eating more organic plant-based proteins and smaller quantities of certified sustainable and high-welfare meat and dairy, we can improve our health, support animal welfare and reduce our impact on the planet.**

## CONCLUSION

The new genetic engineering applications discussed in this brief have not been 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 technologies may be problems masquerading as solutions.

Truly sustainable, plant-based proteins produced via regenerative, organic farming carry none of these concerns and present many co-benefits for our health and environment.[63] They are also more likely to be accepted by an increasingly discerning public that demands real food, along with transparency and sustainability in the food system. The science is clear that by eating more organic plant-based proteins and smaller quantities of certified sustainable and high-welfare meat and dairy, we can improve our health, support animal welfare and reduce our impact on the planet.[64,65] Animal replacement products derived from genetic engineering techniques take us on a path away from the proven solutions provided by a sustainable, regenerative, humane, just and transparent food system.

### 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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