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The Economics of Cellular Agriculture

Sharon Raszap Skorbiansky, Jonathan McFadden, and Monica Saavoss

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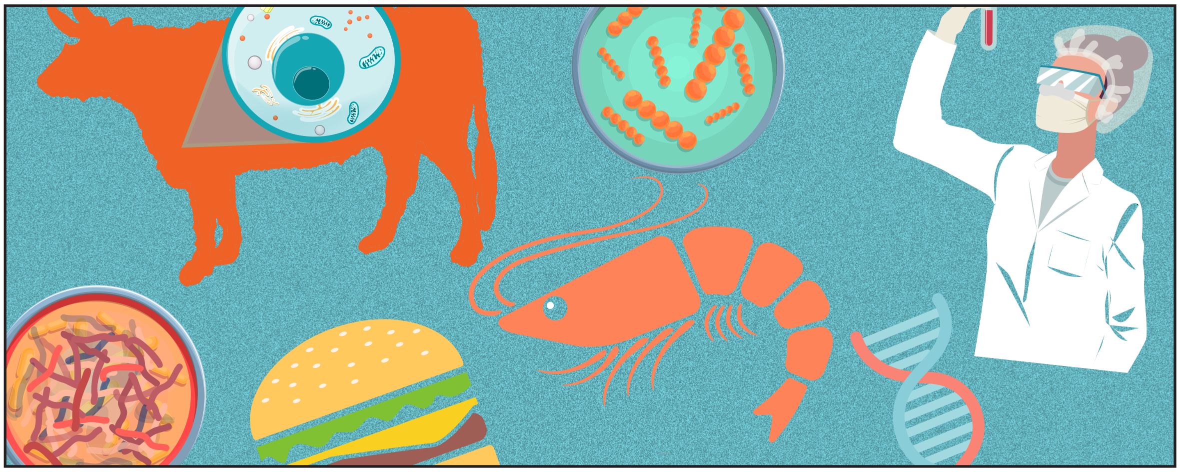

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Abstract

Cellular agriculture is the production of animal products, such as meat, seafood, milk, and eggs, with no or minimal use of animals. This system includes both precision-fermented proteins and fats (e.g., from meat, seafood, eggs, and dairy) treated by encoding genetic material into an organism and cell-cultured-meats and seafood. Between 2015 and 2023, cumulative invested capital in cell-cultured meat and seafood reached $3.1 billion. During the same period, invested capital in precision fermentation reached $2.1 billion. These increases are partially in response to growing interest in the environmental and animal welfare dimensions of conventional livestock production, concerns about disease transmission between humans and animals, and issues of global access to protein. Although novel, products using cellular agriculture have been commercialized to meet rising consumer demand for animal-free foods that are close substitutes to conventional dairy, eggs, meat, and seafood. Using data from publicly available sources, this report introduces the economics of cell-cultured and precision fermentation foods and documents the growth in the sector. Areas of emphasis are market drivers, structural aspects of the industry, the U.S. regulatory environment, government research funding, and market challenges as of 2023.

Keywords: cellular agriculture, laboratory-grown foods, cell-cultivated meat and seafood, cell-cultured meat and seafood, precision fermentation

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Meat, seafood, milk, eggs, and other animal products are a significant source of protein in the diets of U.S. consumers and the foundation of important revenue streams for U.S. farmers, the food processing sector, and other food businesses. However, some consumers in the United States and abroad are increasingly purchasing alternatives to conventional animal-sourced foods that involve minimal or no use of animals. These dietary changes have been partly facilitated by the increased availability and variety of plant-based substitutes for animal products, such as soy patties as an alternative for hamburger meat and nut-based dairy alternatives.

However, a set of novel technologies allows animal products to be made largely without livestock that are biologically similar (either at the cellular or protein-based level) to their conventional counterparts. Cell-cultured meats and seafood are created by using a sample of animal cells without the need for animal slaughter. Precision fermentation can be used to produce conventional proteins and fats by encoding genetic material into an organism like yeast or bacteria. Although the sector is in its infancy, investments in cell-cultured and precision-fermented food companies have increased substantially. USDA's Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA) have implemented processes to ensure the safety of these foods. To date, little has been written about the economics of cellular agriculture. This report fills that void by providing an overview of the policy-relevant economic dimensions of this sector, detailing market drivers, current industry structure, government regulation and investment, and market challenges.

What Did the Study Find?

While having similar end-product goals, the production process is significantly different between cell-cultured and precision fermentation-based technologies.

- Precision fermentation uses bioengineering techniques by using genetically engineered microbes as a platform to express specific products, such as proteins and fats, that are molecularly similar to animal products.
- Cellular-cultured food production relies on animal cells as a starting point. These cells divide, form cell lines, and progress through a series of bioreactors to continue multiplying until they are harvested and further developed into a final meat product.

There are at least four major drivers of the cellular agriculture industry: consumer concerns surrounding environmental considerations, animal welfare, public health and food safety, and food access.

Investments, firms, and patented methods and products have increased substantially in recent years.

- Between 2015 and 2023, cumulative invested capital in cell-cultured meat and seafood reached $3.1 billion. During the same period, invested capital in precision fermentation reached $2.1 billion.
- As of 2023, more than 200 companies had major commercial interest in cellular agriculture.
- As of 2024, more than 100 patents had been filed in this sector.

Federal regulatory changes and Federal funding, in addition to the actions of foreign governments, are accommodating growth in the sector.

- Under the current U.S. regulatory framework, the FDA conducts a voluntary scientific and regulatory consultation for companies producing cultured animal cell foods for human consumption and oversees all food facilities culturing animal cells. At harvest, oversight of foods comprised of cell-cultured livestock, poultry, and/or certain types of fish is transferred to USDA, FSIS, which regulates and inspects facilities under its purview.
- Foods produced using precision fermentation are regulated exclusively by the FDA.
- The authors' analysis of comments to a USDA, FSIS-issued Advance Notice of Proposed Rulemaking (ANPR) suggests that 83 percent of respondents believed cellular meat and poultry should be labeled differently from their conventional counterparts. The most suggested phrase by respondents for labels of foods containing cultured animal cells was "lab-raised." To date, several Government agencies have provided several million dollars in research funding.

Multiple market challenges are currently limiting product commercialization and production at scale.

- Life-cycle analyses suggest a wide range of minimum per-unit production costs of cell-cultured products.
- Economic evidence indicates a range of consumer attitudes about these products. While some consumers have negative perceptions related to naturalness, others view the animal welfare dimensions positively.
- The extent of the products' environmental impacts and their effects on consumer demand remain to be seen.

How Was the Study Conducted?

The authors analyzed data from four sources: (1) literature reviews, (2) the Good Food Institute, (3) the U.S. Patent and Trademark Office via Google Patents, and (4) Federal regulatory websites. The examination of technological capacities/functioning and market determinants drew on a review and synthesis of multiple studies. Information about private investment, number of firms, and animal product analogs were from the Good Food Institute, corroborated with publicly available data where possible. Annual patent counts and their composition were taken from Google Patents. Regulatory information comes from Federal agency websites, and analysis of comments to the ANPR relied on public data related to the Federal Register notice. The analysis of these comments involved assessment of their intents and meanings, assignment to categories, and regression analysis.

Acronyms and Glossary

Acronyms

ANPR – Advance Notice of Proposed Rulemaking

CDC – U.S. Department of Health and Human Services, Centers for Disease Control and Prevention

FAO – Food and Agriculture Organization of the United Nations

FBS – Fetal Bovine Serum

FDA – U.S. Department of Health and Human Service, Food and Drug Administration

FMIA – Federal Meat Inspection Act

FSIS – USDA, Food Safety and Inspection Service

GE – Genetically Engineered

GFI – Good Food Institute

GHG – Greenhouse Gas

GWP – Global Warming Potential

LCA – Life-Cycle Analysis

NIFA – USDA, National Institute of Food and Agriculture

NSF – National Science Foundation

PPIA – Poultry Products Inspection Act

SBIR – NSF, Small Business Innovation Research

USPTO – United States Patent and Trademark Office

WHO – World Health Organization

Glossary

Antimicrobial resistance: Drug resistance built over time by bacteria, viruses, fungi, or parasites, making antimicrobial medicines ineffective.

Antimicrobials: Medicines, including antibiotics, antivirals, antifungals, and antiparasitics, used to prevent infectious diseases in humans, animals, and plants.

Biomass fermentation: A novel fermentation method in which proteins are produced very rapidly. These proteins are not necessarily molecularly similar to existing animal proteins.

Bioreactor: A specialized container for cell growth and multiplication, which has sensors and automated processes that maintain proper temperature, pH, dissolved oxygen, carbon dioxide, turbidity, and other biochemical conditions.

Cell-culture media: A nutrient rich liquid that provides the necessary components for cell health and growth.

Cell line: A collection of cells that are genetically identical.

Cell-cultivated product: A food produced in a bioreactor as part of cellular agriculture. The terms "cultivated," "cell-cultivated," "cultured," "cell-cultured," and "cellular" are often used interchangeably.

Cell-cultured product: A food produced in a bioreactor as part of cellular agriculture. The terms "cultivated," "cell-cultivated," "cultured," "cell-cultured," and "cellular" are often used interchangeably.

Cellular agriculture: Methods of creating animal food products with minimal or no use of livestock. Cellular agriculture includes cell-culture methods and precision fermentation.

Mycelia: Networks of thread-like fungus. Several companies are working to produce high-protein, meat-like products made from mycelia that are grown in a bioreactor.

Premarket consultation: The FDA process of scientific and regulatory review to evaluate safety of a product prior to the product's commercialization.

Precision fermentation: A novel fermentation method that uses genetically engineered microbes.

The Economics of Cellular Agriculture

Introduction

Cellular agriculture refers to agricultural systems that produce animal products, such as meat, seafood, eggs, and dairy, with minimal or no use of livestock. The field emerged because of concerns related to animal welfare, climate change, eutrophication (overabundance of nutrients in water), and zoonotic disease (e.g., Saavoss, 2019; Howitt & Rausser, 2022).[1] Cell cultivation is the process of cultivating animal cells directly from other cells rather than from a live animal.[2] Fermentation refers to a broad class of food production using microbes (such as yeast or bacteria) to produce a change in the taste, texture, or nutritional content of inputs. Precision fermentation uses a genetically engineered microbe as a platform to create a specific substance such as proteins or fat. For example, a microorganism may be engineered with DNA to ferment sugar and produce a dairy protein. Such products are sometimes referred to as "acellular products" because they are made of organic molecules such as fats or proteins as opposed to "cellular products," which are made of living or once-living cells (e.g., Stephens et al., 2018; Eibl et al., 2021).[3] [4]

Acellular products have been on the market for decades, although they have been produced in far smaller quantities than would be needed for mass food production. For example, patients with diabetes were previously treated with insulin from the pancreases of pigs or cattle through the late 1970s. However, in 1978, scientists programmed bacteria with the DNA encoding the gene for human insulin so that the bacteria could produce insulin with no pig or cattle involvement (Goeddel et al., 1979). Similarly, rennet, an enzyme used for certain kinds of cheese production, was previously only available from the stomach of a cow. However, in 1990, the pharmaceutical company Pfizer debuted a fermented version of the product (called fermentation-produced chymosin) that has since largely replaced the animal-derived version (Los Angeles Times, 1990; Barbano & Rasmussen, 1992). Today, a variety of food ingredients are produced via precision fermentation, including vitamins, flavorings, and sweeteners like honey (Turrell, 2024). While commercial applications of cell-culture methods have only been sold in limited quantities at restaurants in the United States and Singapore, similar technologies have had medical applications for humans. These technologies include tissue-engineered skin, arteries, cartilage, and tracheas. While available, these medical technologies are still experimental and costly (National Institute of Biomedical Imaging and Bioengineering (NIBIB), 2022). Thus far, Singapore, the United States (see section "Federal Regulatory Environment"), and Israel have approved the sale of food made with cell-cultured animal products for human consumption.

The product markets for cell-cultured agriculture and precision fermentation are distinct from the growing market for plant-based analogs to meat products. Plant-based analogs use plant ingredients to mimic the taste, texture, and nutrition of animal products. While companies are perpetually optimizing plant ingredients to embody the desirable characteristics of the animal products they aim to mimic, the ingredients they use are plants broadly familiar to consumers, and the end product is not biosimilar to the animal products they mimic. Some plant-based analogs have been on the market for decades, such as soy-based patties or soy-based milk. However, cell-cultured and precision fermented products are created by a distinctly

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[1] Eutrophication is the process in which nutrients accumulate in bodies of water, resulting in increased growth of microorganisms that may deplete oxygen. Zoonotic diseases are infectious diseases that spread between animals and humans.

[2] The production of cell-cultivated meat begins in a laboratory. The terms "cell-cultivated meat," "cell-cultured meat," and "cellular meat" are often used interchangeably. As of the writing of this report, USDA, Food Safety and Inspection Service has approved the terms "cell-cultured" and "cell-cultivated" for use in labeling. The FDA uses the terms "human food made from cultured animal cells" or "cultured animal cell foods."

[3] Examples of acellular or fermented products include vanillin (the primary component of the extract of the vanilla bean), omega-3 fatty acid, casein (the main protein in milk), gelatin, or ovalbumin (the primary protein found in egg whites). Examples of cellular products include meat, leather, fur, or wood.

[4] A significant portion of the peer-reviewed literature uses "cellular agriculture" to include both cellular and acellular production processes. The authors follow this convention in this report.

novel technology with unique production processes, technical needs, supply chain demands, and consumer attitudes (e.g., Hassoun et al., 2022; Smith et al., 2022).

Data Sources

Apart from literature review information, the data for this report are from three primary sources: (1) intellectual property information from Google Patents, (2) public responses to USDA, Food Safety and Inspection Service's (FSIS) Advance Notice of Proposed Rulemaking (ANPR) on "Labeling of Meat or Poultry Products Comprised of or Containing Cultivated Animal Cells," and (3) The Good Food Institute's (GFI) alternative protein company database, which underlies its annual reports about the status of the industry (e.g., Cohen et al., 2022).[5]

The information on patents related to cellular agriculture is from Google Patents, a well-known online repository containing over 120 million patent publications from more than 100 patent offices worldwide. This includes full-text documents from the U.S. Patent and Trademark Office (USPTO), European Patent Office, World Intellectual Property Organization, and national patent offices from countries in North America, South America, Europe, Asia, and elsewhere (Google, 2023). Economists routinely use Google Patents for their analyses (e.g., Moser & Voena, 2012) and/or to identify trends in innovation for certain economic sectors. Using search terms, including "cultivated meat," "cellular agriculture," and "precision fermentation," this report draws on information from 114 patents filed globally since 2001. For more information, see the appendix, "Patents Analysis: Data and Methods."

Responses to the USDA, FSIS-issued ANPR on labeling of products with cultured animal cells were from the publicly available web page Regulations.gov. USDA, FSIS received nearly 1,200 comments. After removing duplicate comments (i.e., files with identical commenter names and comment text), a final set of 1,154 documents was analyzed. The ANPR posed 14 questions; this report analyzed responses to the first 2 questions—those with the broadest scope and greatest relevance to industry stakeholders. In general, the analyzed questions relate to: (1) whether products comprised of/containing cultured animal cells should be labeled differently than conventional animal products and (2) differentiating terms (if any) in the names of products made using cell-culture methods. For additional context and information, see the appendix, "ANPR Response Analysis: Data and Methods."

Report authors also used GFI's alternative protein company database (GFI, 2024). GFI is a 501-nonprofit organization that advances plant- and cell-based alternatives to animal products. The database is sourced from lists produced by international GFI affiliates, as well as information obtained from news articles, event exhibitors, venture funding documents, industry association lists, and information submitted directly to GFI. To be included in the database, a company must have an expressed interest in commercializing a good or service for the alternative protein industry and display evidence of market activity and business maturation. Companies that are out of scope (e.g., insect farms, animal feed processors), do not produce animal product substitutes (e.g., vegan baked goods), or specialize in traditional plant-based foods (e.g., tofu, tempeh, seitan, nut butters) are not included. Information in the database is corroborated with external information (e.g., company websites, LinkedIn, Crunchbase) and audited annually by each GFI affiliate office. Comprehensive and accurate data for this industry are not known to be federally collected, thus the authors drew data originating from the private sector, following past USDA, Economic Research Service (ERS) research (e.g., Fuglie et al., 2011; Greene et al., 2016; McFadden & Schimmelpfennig, 2019).[6]

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[5] Following USDA, Economic Research Service standard procedures in using industry databases, all observations in each of the databases have been scrutinized and corroborated with external sources and other information, where possible.

[6] Global consulting firms (e.g., BCG), accounting firms (e.g., Ernst & Young), and multinational banks (e.g., Barclays, JPMorgan Chase & Co.) also rely extensively on the GFI database for their market research related to the cellular agriculture and precision fermentation sector (Barclays, 2019; Dongoski et al., 2021; Morach et al., 2022; Oken et al., 2022).

As of March 2024, 1,484 companies were listed in the GFI database for manufacturers and brands of alternative proteins. However, the vast majority were primarily plant-based food companies with no major emphasis on cellular agriculture (e.g., Morningstar Farms, Beyond Meat, Impossible Foods). After the removal of these companies, the remaining data consisted of 232 companies worldwide with commercial interest in cell-cultured or precision-fermented agriculture or with a major product line or business unit concentrating on this sector.

How Does Cellular Agriculture Work?

This section provides an elementary introduction to the technology behind precision fermentation and cell-cultured agriculture. Both discussions are intended to familiarize the reader with the broad contours of the science and engineering underlying these novel food technologies. While this section describes some of the most common methods for producing precision fermented and cell-cultured products, the process continues to evolve over time and varies across companies. The appendix "Additional Information on Cellular Agriculture" provides further details on the science underlying cellular agriculture.

Precision Fermentation-Based Foods Production

Fermentation can be broadly grouped into three categories: traditional, biomass, and precision (Augustin et al., 2024; Specht, 2023).[7] The process for producing fermented foods begins with initial ingredients and microorganisms (e.g., yeast or bacteria) that are placed in a fermenting vat (figure 1). Traditional fermentation is a process that uses intact microorganisms to process ingredients in order to change the ingredient's texture, taste, or nutritional profiles. Traditional fermentation is used in producing beer, bread, tempeh, and cheese. Biomass fermentation results in the accumulation of large quantities of microbial mass for consumption as a source of protein either directly or with limited processing. Companies, such as Colorado-based Meati or UK-based Quorn, use biomass fermentation to create products marketed as similar to animal meat in terms of taste, texture, and nutrition (see box, "Biomass Fermentation").[8] The process typically does not include genetic modification (Augustin et al., 2024; Specht, 2023).

Precision fermentation produces animal proteins by encoding novel genetic material into a host organism such as yeast or bacteria. Precision fermentation has been used for production of rennet via a genetically engineered (GE) bacteria, a complex set of enzymes traditionally extracted from the stomach of young ruminant animals like calves, goats, and lambs (Barbano & Rasmussen, 1992; Augustin et al., 2024). The company Perfect Day, for example, uses GE microorganisms as a production platform for recombinant proteins that are identical to those found in cow's milk (Perfect Day, 2022). Cow's milk is not used anywhere in the process, and the resulting product does not contain any GE material.

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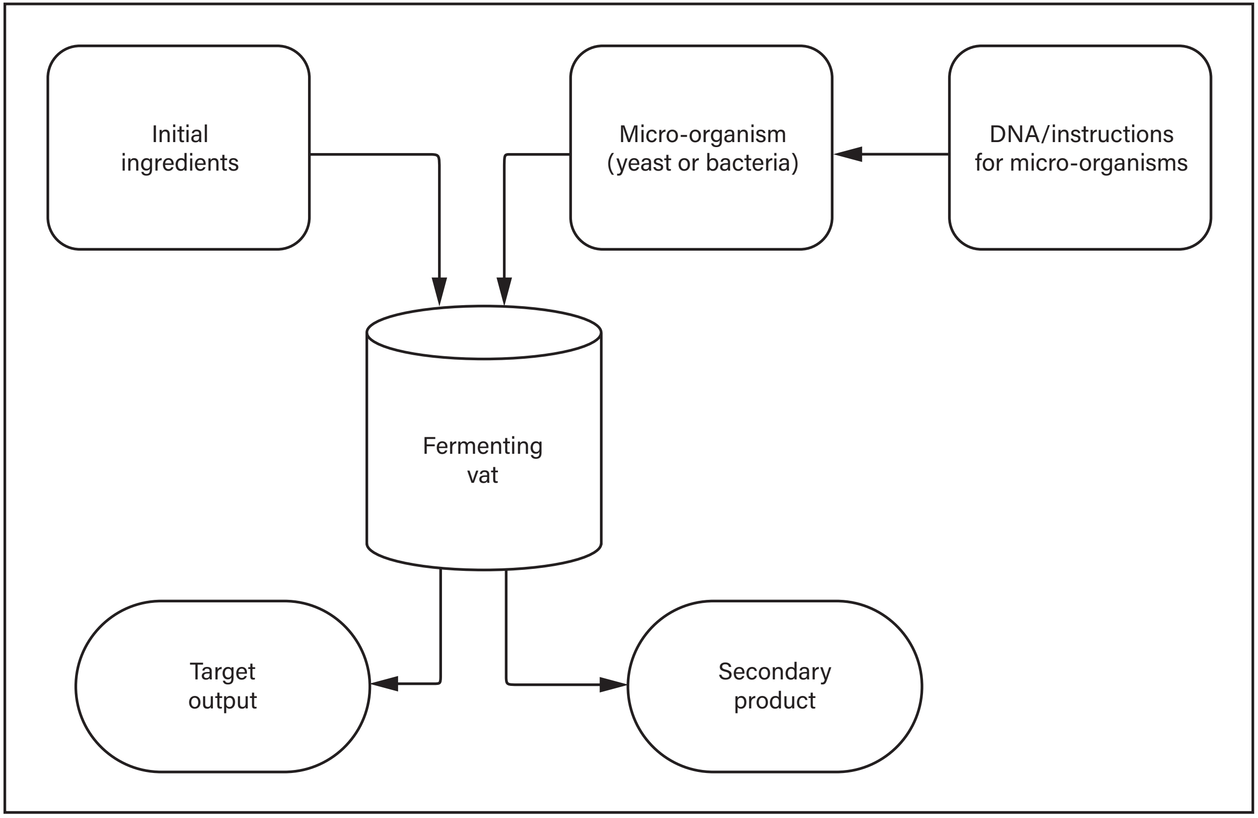
[7] Fermentation is the process that converts a carbohydrate (e.g., starch or sugar) into an alcohol or an acid. Often, the process uses bacteria or yeasts to chemically change a substance.

[8] Meati uses mycelium, the root-like structure of fungi, to create a variety of high protein products (Meati, 2022).

Figure 1
Precision fermentation production process



Note: This diagram is illustrative rather than comprehensive. The process involves providing DNA instructions to micro-organisms, which are then mixed with other ingredients in a fermenting vat.

Source: USDA, Economic Research Service.

Biomass Fermentation

Products from biomass fermentation are in some ways more similar to plant-based foods than to products of precision fermentation or to cell-cultured meat because biomass fermentation produces foods that are not molecularly similar to animal products. However, biomass fermentation shares some important similarities in the methods of production as well as the relative novelty of the types of foods produced with cellular agriculture.

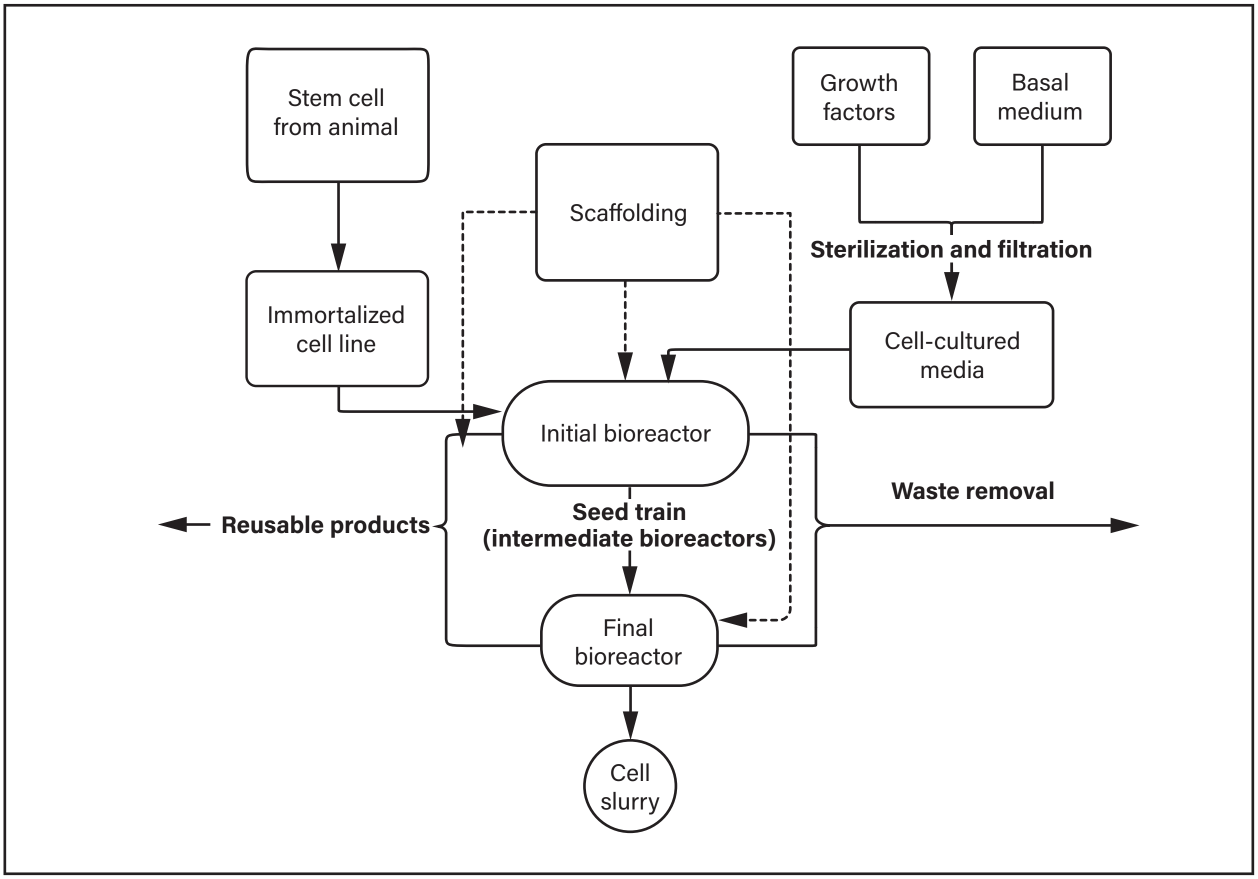
One particularly prevalent form of biomass fermentation is mycelia fermentation. Mycelia are networks of thread-like fungus. Several companies, such as Meati and Better Meat Co., are working to produce high-protein, meat-like cuts made from mycelia that are grown in a large bioreactor using biomass fermentation. There are some similarities between biomass fermentation and precision fermentation, including that both processes occur in a bioreactor rather than on a traditional farm, both produce novel foods, and both are emerging food technologies.

Cellular-Based Foods Production

Cell-culture methods differ from precision fermentation because the underlying process does not use microorganisms to process food—it involves growing animal cells directly from other cells to make meat or seafood.[9] The cell-culture production process is thus more complex than that of precision fermentation (figure 2). Many elements of this process vary greatly from company to company as well as product to product. The entire process may take 5 to 7 weeks and depends on the species, type of cells, growing conditions, scale of production, and the desired end product (Educated Choices Program, 2022). The process begins with biopsied stem cells from live animals (Post, 2012). Stem cells have the ability to develop into different types of cells such as muscle, fat, or bone.[10]

Figure 2

Cell-cultured meat and seafood production process



Note: This diagram is illustrative rather than comprehensive. A biopsied stem cell (a cell that has the ability to develop into different types of cells such as muscle, fat, or bone) goes through the process to become an immortalized cell line, giving it the ability to divide indefinitely. Along with a scaffold (a 3-dimensional structure) and media (nutrient-dense liquid needed for cell growth), the cell line is placed in several bioreactors to induce growth, creating the output, and in this case, a combination of cells and inputs called a cell slurry.

Source: USDA, Economic Research Service.

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[9] While precision fermentation is used to create egg proteins, milk proteins, and specific meat and seafood analog components, cell-cultivation is currently focused on meat and seafood products. However, researchers are also exploring cell-cultured dairy products (Yart et al., 2023).

[10] Stem cells may be either pluripotent (capable of differentiating into any type of cell) or multipotent (capable of differentiating into a limited number of cell types). These cells may come from either embryonic stem cells or adult stem cells. Embryonic stem cells have the advantage of being pluripotent but the disadvantage of being unstable and difficult to work with. Certain types of non-embryonic cells can be reprogrammed to being induced pluripotent cells. Adult stem cells have more limited capacity to differentiate into various types of cells but are more stable.

The stem cells from the animal then undergo a variety of steps. First, the cells go through immortalization, allowing the cells to continue dividing indefinitely (Pajčin, 2022; Soice & Johnston, 2021) and are used to create a cell line, a culture of cells with a uniform genetic makeup. The cell line is placed in an initial bioreactor along with a medium, nutrients to induce growth, other solutions to maintain the correct pH, and a scaffold, a three-dimensional construct to provide shape and structure. The bioreactor provides the environment required to support the growth of cells (Zhang et al., 2020; Swartz & Bomkamp, 2023). Bioreactors are specialized containers with sensors and automated processes that maintain proper temperature, pH, dissolved oxygen, carbon dioxide, turbidity, and other biochemical conditions. Cells can only survive at particular densities because they need consistent levels of turbidity, oxygen, nutrients, and temperature. Increasing the number of cells tends to change the environment, which necessitates transferring the cells to a larger bioreactor as they multiply. For this reason, starter cells are first placed in a small bioreactor and then transferred to a series of progressively larger bioreactors to keep the cell density relatively similar between bioreactors.

As the cells multiply, they are eventually fed through to incrementally larger bioreactors with appropriate media and scaffolding in each. This series of bioreactors are referred to as a seed train. The final bioreactor has an automated process for harvesting the new meat product. Whether the product is a textured cut similar to steak or a slurry of cells to be processed into a patty depends on the scaffolding as well as other features of the process. Three-dimensional bioprinting can also be utilized to create complex scaffolding for the cells.

Drivers of the Cellular Agriculture Industry

The cell-cultured and precision fermentation industry has experienced substantial growth in private investment, research funding, regulatory scrutiny, and consumer attention in less than a decade. This growth is the result of several factors, many of which link to pressing issues facing conventional animal agriculture and food supply chains in the United States and abroad. Four key factors—environmental considerations, animal welfare concerns, public health and food safety, and food access—have led to a rise in public and private interest in this sector. These factors are not unique to cellular agriculture and are also drivers of plant-based substitutes.

Environmental Considerations

The production of animal-based foods (including animal feed, direct emissions, land use change, and related supply chains) account for almost 60 percent of food production-related greenhouse gas emissions (Xu et al., 2021). The impact on land use, acidification, and eutrophication varies substantially from system to system, with beef having the largest emission footprint (Machovina et al., 2015; Poore & Nemecek, 2018). Biodiversity loss has been linked to greenhouse gas emissions, high land-use intensity from operations raising ruminant animals for meat (Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, 2019; Scherer et al., 2020), and pollution from agrochemicals (Bouwman et al., 2013; Nordborg et al., 2017). One driver of cellular agriculture is its potential environmental benefits over traditional animal husbandry. For example, emissions of nitrous oxide and methane from alternative meat production methods are low, as are the direct land use requirements. As discussed in the section "Market Challenges: Environmental Impacts," cell-cultured meat and seafood production may have environmental benefits relative to traditional animal husbandry. However, few studies exist given that these products are yet to be commercialized at scale.

Animal Welfare Concerns

Consumer interest in animal welfare is not a new phenomenon, and concerns over animal well-being are often tied to ethical considerations, including animals' health and nutrition, emotional state, and access to natural behaviors. As early as 1993 and 1994, the General Social Survey (GSS), a project of the independent National Opinion Research Center (now known as NORC at the University of Chicago), with principal funding from the National Science Foundation, asked respondents whether animals should have the same moral rights as humans (Davern et al., 2023). The data available for both years noted that 30 percent of respondents agreed or strongly agreed with equality of moral rights between humans and animals. More recently, the European Commission conducted a study to understand European Member States' attitudes toward animal welfare. It found that 94 percent of European Union citizens believe it is important to protect the welfare of farmed animals (European Commission, 2016). Similarly, a nationally representative online survey commissioned by the American Society for the Prevention of Cruelty to Animals (ASPCA) found that 83 percent of consumers would likely switch to a meat, egg, or dairy brand that guaranteed the product was sourced from farm animals raised under improved animal welfare standards (Thibault et al., 2022).

Debates over animal welfare and farming practices have increased as animal productivity has increased. However, the discussions are no longer debates among advocates and those perceived to be activists—they are a common concern for producers and consumers (Lusk & Norwood, 2011). Since 2002, 15 U.S. States have implemented policies addressing practices affecting animal welfare (Ufer, 2022). Consumer interest has led to product labels, including those supported by Government agencies (e.g., USDA certified organic), third-party verified (e.g., Certified Humane), or labels not enforced by inspection (e.g., cage-free and pasture-raised).[11] Several studies have shown the public is willing to pay a price premium for practices improving animal welfare (Chang et al., 2010; Van Loo et al., 2014; Lusk, 2019).

Cell-culture methods still involve the use of animals via biopsy for stem cells. Additionally, some cell-cultured companies use animal serum as a component of growth media, such as fetal bovine serum (FBS).[12] Due to animal welfare concerns and the prohibitively high costs of FBS for large-scale production, researchers have worked to develop animal-free serums or serum-free media (Messmer et al., 2022). For example, GOOD Meat (a brand from U.S. company Eat Just) received regulatory approval for serum-free, media-produced chicken in Singapore (GOOD Meat, 2023). Precision fermentation does not require the use of animals because it uses microbes to produce specific animal proteins.

Public Health and Food Safety

The main public health and food safety concerns arising from meat consumption are antimicrobial resistance in microorganisms and threats of zoonotic diseases. Antimicrobial compounds used to improve animal health, increase production, and decrease foodborne pathogens in animal-derived food production have led to questions about their contribution to the increased prevalence of antimicrobial-resistant bacteria affecting humans (Mathew et al., 2007; Oliver et al., 2011; Innes et al., 2020). Several studies have linked the rise in antimicrobial resistant organisms in animals and humans to the widespread use of antibiotics in animal agriculture (Van Boeckel et al., 2015; Talebi et al., 2019).

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[11] Interest in certified organic products is not a perfect proxy for animal welfare concerns, as consumers purchase organic products for a variety of reasons (Carlson et al., 2023). Organic consumers may desire to avoid recombinant bovine growth hormones (rBST or rBGH) or another possible prohibited chemical. However, organic livestock requirements include several animal welfare considerations, such as accommodations for the health and natural behavior of the animals, allowing year-round access to the outdoors except under specific conditions, access to clean and dry bedding, shelter, direct sunlight and fresh air, and space for exercise.

[12] Fetal bovine serum (FBS) is harvested from the fetus of a pregnant cow during slaughter. FBS is commonly harvested through cardiac puncture (i.e., needle insertion into the heart) without the use of anesthesia.

Another concern is the threat of zoonotic diseases, classes of infections that spread from animals to humans. Well-known examples include the 1918 H1N1 Spanish Influenza, the 2002–03 severe acute respiratory syndrome (SARS), the Middle East respiratory syndrome (MERS), and most recently, SARS-CoV-2 (the virus that causes Coronavirus disease 2019, or COVID-19). The expansion and industrialization of animal agriculture and the trade and consumption of wildlife have been linked to increased risk of zoonotic diseases (Jones et al., 2013; Bernstein & Dutkiewicz, 2021). Additionally, outbreaks of animal diseases, such as the highly pathogenic avian influenza (HPAI), which can be carried by wild birds and transmitted to domesticated birds, pose a major risk to animal health. HPAI spreads rapidly, is transmittable across different species of birds, and is often lethal to infected birds. Avian influenza has so far had limited human interaction, but several thousand documented cases of human infections were reported worldwide, resulting in multiple deaths (Shi et al., 2023). The U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) recognized that bird flu viruses are mutable and could gain the ability to spread easily between people (CDC, 2022). The 2022–2024 HPAI outbreak has continued to present challenges to both agricultural productivity and human health. As of July 2024, the CDC has confirmed 14 human cases of HPAI A(H5), a strain of the virus that typically affects birds but has also been found in mammals, in the United States since 2022 (CDC, 2024). As of July 2024, USDA, Animal and Plant Health Inspection Service (APHIS) has confirmed HPAI infections in 197 dairy cattle herds across 14 States and in over 100 million birds across 48 States (USDA, APHIS, 2024a; USDA, APHIS, 2024b).

Antimicrobials could be added to cell culture media to reduce contamination risk for cell-cultured products (Ong et al., 2021). However, the risks of contamination of infection in cell-cultured products are in theory lower than those from animal agriculture, as products are created in controlled environments (Ketelings et al., 2021). Furthermore, because these products are made with no or minimal use of animals, there are expected to be far fewer wild animal interactions, zoonotic diseases, and other interspecies diseases.

Food Access

Undernutrition is a persistent problem in low-income countries, partially due to a deficiency in the quantity of protein compared with the recommended consumption levels (Schönfeldt & Hall, 2012). The COVID-19 pandemic exacerbated world hunger issues (Food and Agriculture Organization of the United Nations (FAO) et al., 2022) and brought to light several vulnerabilities in the meat production industry. As USDA described in its 2021 response to Executive Order 14017 on "America's Supply Chains," the meat supply chain has several vulnerabilities. The high market concentration of meat processing facilities means that even temporary shutdowns can threaten significant supply chain disruptions. Additionally, a high market concentration in meat packing can result in price manipulation, leading to higher consumer prices (USDA, Agricultural Marketing Service (AMS), 2022). Currently, cellular agriculture products are not cost-effective nor sufficiently available to alleviate the food access issues. Yet cellular agriculture advocates and companies cite shorter production times and the industry's likely future capability of adjusting to market changes by not being tied to animal reproduction as potential ways to alleviate food access issues (GFI, 2022b).

Structural Characteristics of the Emerging Industry

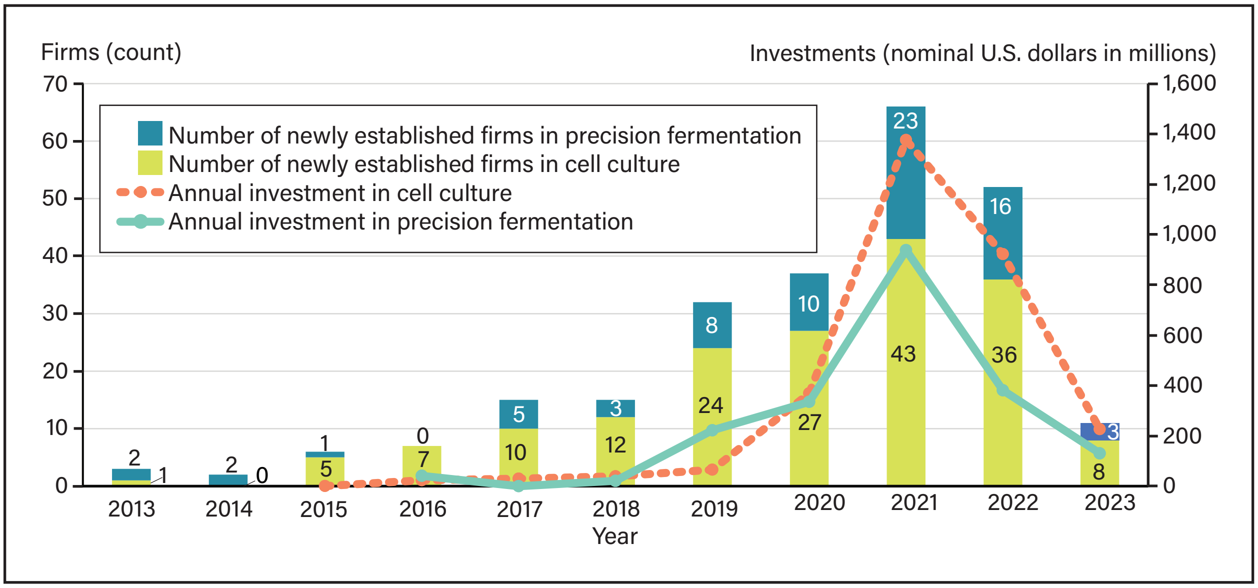
The characterization below represents the first steps toward a greater understanding of the market status of the cell-cultured and precision fermentation sector and its recent evolution.

Investments and Firms in the Cell-Cultured and Precision Fermentation Products Sector

Substantial growth in capital investments underpinning cell-cultured meat and seafood and precision fermentation has spurred increases in research and development in recent years (figure 3). From 2015 to 2023, annual invested capital in cell-cultured meat and seafood companies increased from $25,000 to an accumulated capital investment of $3.1 billion. Annual investments peaked at $1.4 billion in 2021.[13] Many investors are venture capital firms, angel groups, and accelerators/incubators. For cell-cultured meat and seafood, the three most active investors in 2022 were Big Idea Ventures (14 funding rounds), SOSV/IndieBio (9 funding rounds), and CULT Food Science (5 funding rounds). In 2022 and 2023, the industry experienced a deceleration in capital investments (GFI, 2023a). Similarly, capital investments in precision fermentation increased substantially from 2016 to 2023, from an annual investment of $41 million in 2016 to accumulated investments of $2.1 billion by 2023. Precision fermentation capital investment peaked at $940 million in 2021.

Figure 3

Global capital investments and firms within the cell-cultured meat and seafood industry and the precision fermentation industry



Note: The number of companies in 2023 may be larger than reported because companies may begin in "stealth mode," a temporary state of secrecy that companies sometimes use ahead of a product launch or initiative. Initially, Good Food Institute reported 21 companies were founded in 2021. That number grew to over 40 companies founded in 2021 as they launched out of stealth mode in 2022.

Source: USDA, Economic Research Service analysis of data from the Good Food Institute (2023b, 2023c).

Globally, from 2014 to 2023, 56 percent of cell-cultured meat and seafood investments came from the United States, and 21 percent originated from companies in Israel. Collectively, capital raised from entities in the top 10 investing countries accounted for 97 percent of investment between 2014 and 2023 (GFI, 2023a).[14] Investments in precision fermentation are highly concentrated in the United States, amassing 75 percent of capital investment between 2014 and 2023, followed by Australia (6 percent).

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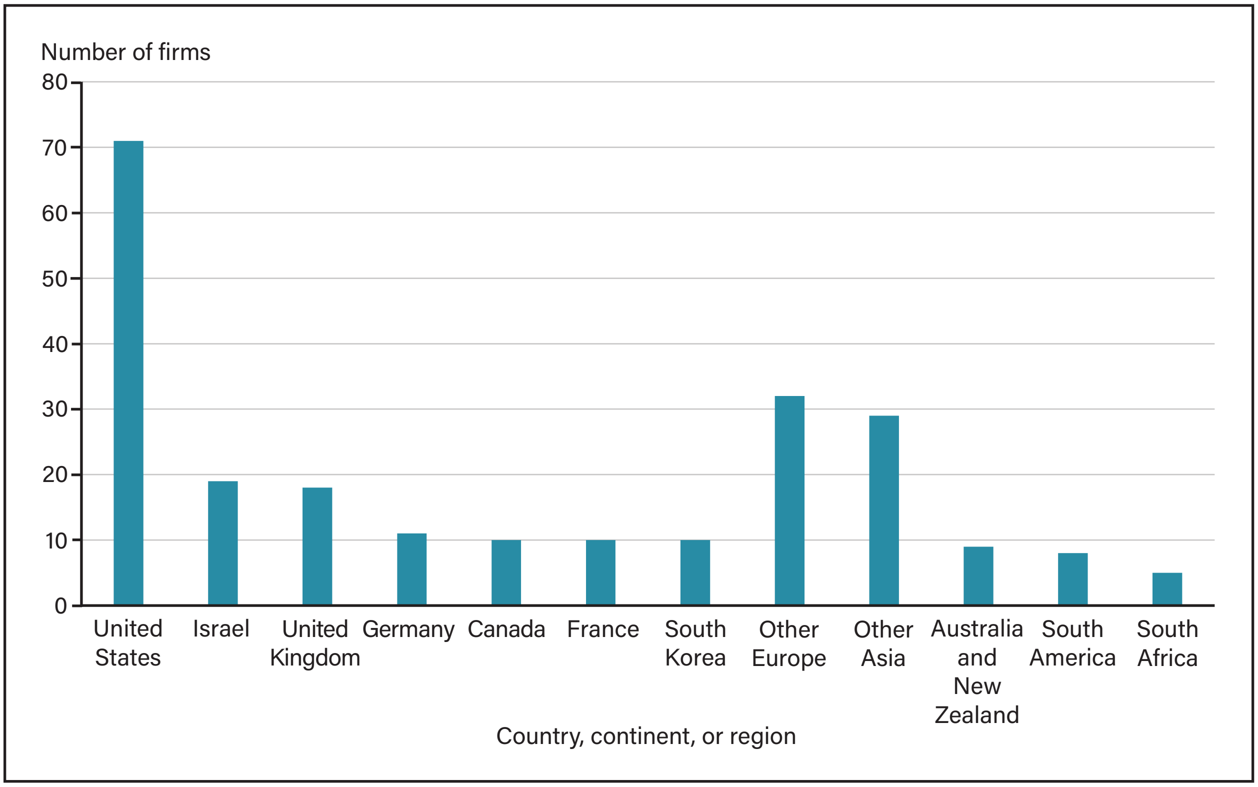
[13] Regarding capital investment, there are three items to note. (1) Invested capital is composed of accelerator and incubator funding, angel funding, seed funding, equity and product crowdfunding, early-stage venture capital, late-stage venture capital, private equity growth/expansion, capitalization, corporate venture, joint venture, convertible debt, and general debt completed deals. (2) Capital raised through a special purpose acquisition company's initial public offering (SPAC IPO) is not counted until there has been a merger with or acquisition of the target company. (3) No companies raised publicly disclosed debt (GFI, 2022c).

[14] The top 10 countries in 2023 with annual capital investments for cultivated meat and seafood were the United States, Israel, the Netherlands, the United Kingdom, Singapore, France, Australia, South Korea, China, and Spain.

As one result of this investment, significant growth occurred in the number of new companies focusing on developing cell-cultured and precision fermentation products. About 170 companies, largely based in the life sciences, have emerged in cell culture from 2011 to 2023. Over 70 companies have emerged in precision fermentation. The United States is home to the largest number of cell culture and precision fermentation companies (figure 4).

Figure 4
Headquarter locations of cellular agriculture firms



Note: Other Europe includes Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, Greece, Iceland, Ireland, Italy, the Netherlands, Portugal, Spain, Sweden, Switzerland, and Turkey. Other Asia includes Mainland China, Hong Kong, India, Japan, Malaysia, and Singapore. South America includes Argentina, Brazil, and Chile. Data included companies using cell-cultured and precision fermentation technologies.

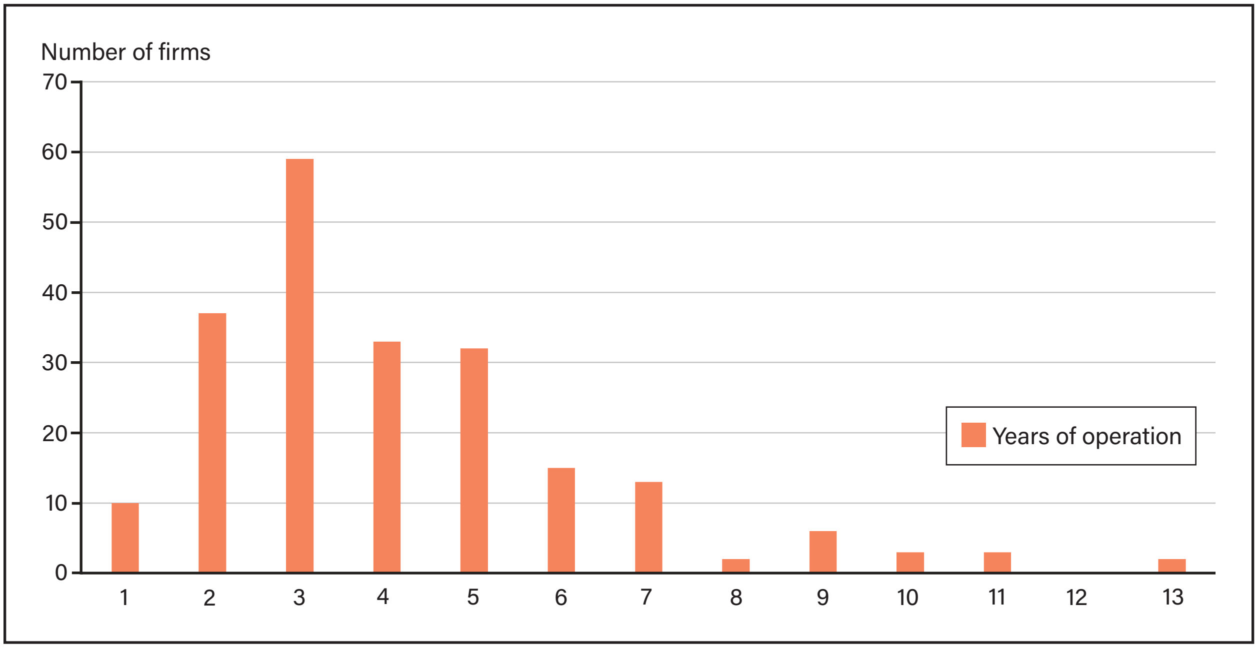
Source: USDA, Economic Research Service analysis of data from the Good Food Institute (2024) and company websites.

Sectoral Attributes: Inputs, Production Methods, and Output Variety

The vast majority of firms in the cellular agriculture industry are young because most are startups (figure 5). With few exceptions, most of these firms were established during or after 2011, though roughly 7 percent were founded prior to 2011. The modal age of the firms is 3 years, and the median age is 4 years. For firms established after 2011, the average age is 4 years. Most “incumbent” firms (those in business more than 4 years) are cell-cultured meat and seafood companies (72 percent), whereas 28 percent of firms use precision fermentation technologies. Incumbent companies using cell culture focus on beef/veal, fish, and chicken. “Entrant firms” (those in business 4 or fewer years) are also primarily cell-cultured meat and seafood companies. However, these firms tend to exhibit more diversity in animal-type analogs, with more emphasis on fish, pork, and other analogs, in addition to beef/veal. Precision fermentation companies, both incumbents and entrants, primarily focus on dairy products (GFI, 2024).

Figure 5

Years of operation for global cellular agriculture fermentation firms, 2011–23



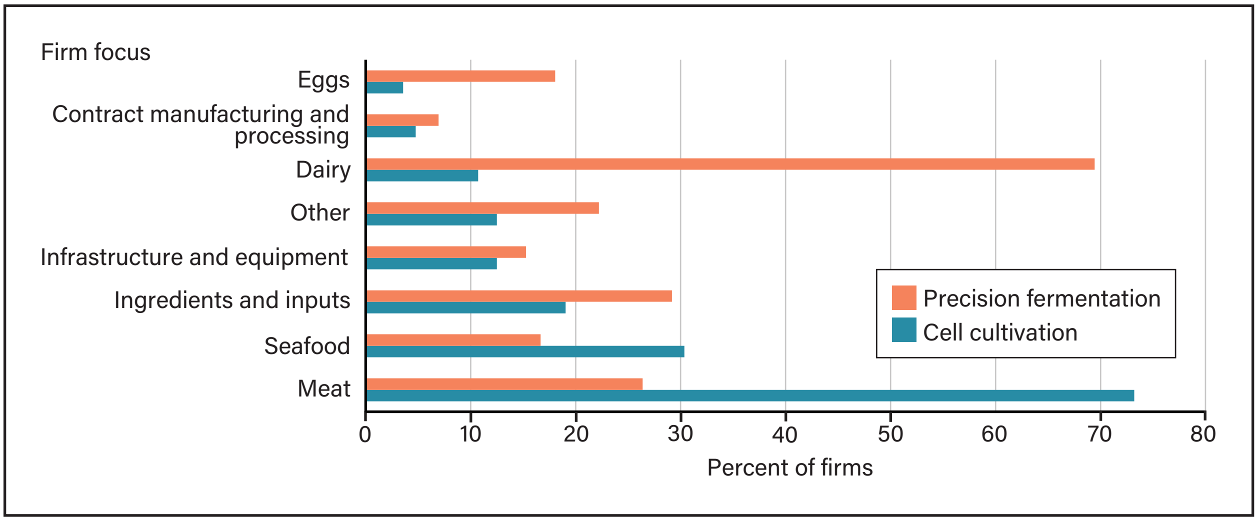
Note: Of the firms represented, 10 operated for 1 year, 37 operated for 2 years, 59 operated for 3 years, 33 operated for 4 years, 32 operated for 5 years, and 15 operated for 6 years. Collectively, these account for 81 percent of the firms in the database with a known starting year.

Source: USDA, Economic Research Service analysis of data from the Good Food Institute (2024) and company websites.

Among the earlier established firms included in the data, many are major national and international food, biotechnology, and enzyme companies, including Nestlé, Nissin Foods, Kerry, BRAIN Biotech Ag, and Molecular Devices. Most are concerned with end-production formulation and manufacturing and/or ingredient optimization, though some focus on the development of cell lines and host strains. Many of these companies, like their less-established competitors, are carrying out research and development, though the size and revenue bases of these incumbent firms may eventually afford them economies of scale and/or scope. Nestlé, for example, is working with Believer Meats (formerly known as Future Meat Technologies) on cell-cultured meat products such as chicken kebabs, while Nissin Foods has been researching cultured steak meat (GFI, 2024). The set of companies operating in this sector has a diverse portfolio of product research (figure 6). For cell-cultured companies, more than 70 percent focus on meat—more than twice the proportion of companies focusing on seafood (30 percent). By contrast, research interest for precision fermentation focuses on dairy (69 percent). Few companies research egg analogs, with 15 companies listing it as a focus, although many companies researching this product are also researching additional cell-based or precision fermentation offerings. Indeed, 30 percent of cellular agriculture companies pair their focus on products with research into ingredients, inputs and/or bioprocessing infrastructure and equipment, and contract manufacturing and/or processing (GFI, 2024). This suggests companies need to innovate not only in product markets but in the production process itself.

Figure 6

Distribution of commercial focus of global cellular agriculture firms



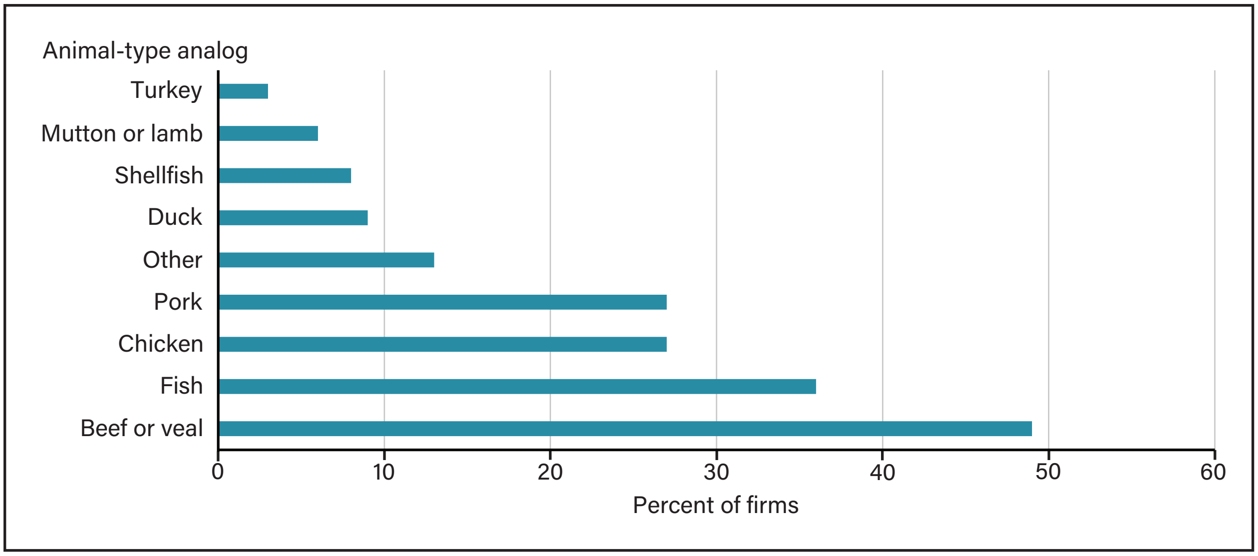
Note: To clarify, 136 firms in cellular agriculture have a commercial interest in meat products, 63 in dairy products, 58 in seafood, 50 in ingredients and inputs, 27 in infrastructure and equipment, 15 in egg products, and 12 in contract manufacturing and processing. Furthermore, 33 companies have a commercial interest in other items, a diverse category including pearls and cooking oil. The categories are not exclusive, and many firms focus on several alternative proteins.

Source: USDA, Economic Research Service analysis of data from the Good Food Institute (2024) and company websites.

The broad trends regarding company focus can be decomposed to provide a more detailed assessment of the kinds of animal food analogs companies are pursuing in laboratory development (figure 7). Of the 95 cell-cultured companies reporting information about meat and seafood analogs, 49 percent indicated beef or veal as a product under development, with fish, chicken, and pork being developed by 36, 27, and 27 percent of companies, respectively. The “other” category, which consists of exotic animals such as kangaroos, zebras, tortoises, and lions, and proteins for pet food, was represented by 13 percent of the companies. Additional analogs, such as for turkey, duck, mutton, and lamb, were far less likely to be the subject of development, with fewer than 10 percent of companies researching any of these items.

Figure 7

Distribution of animal food analogs researched and/or developed by global cell cultured firms



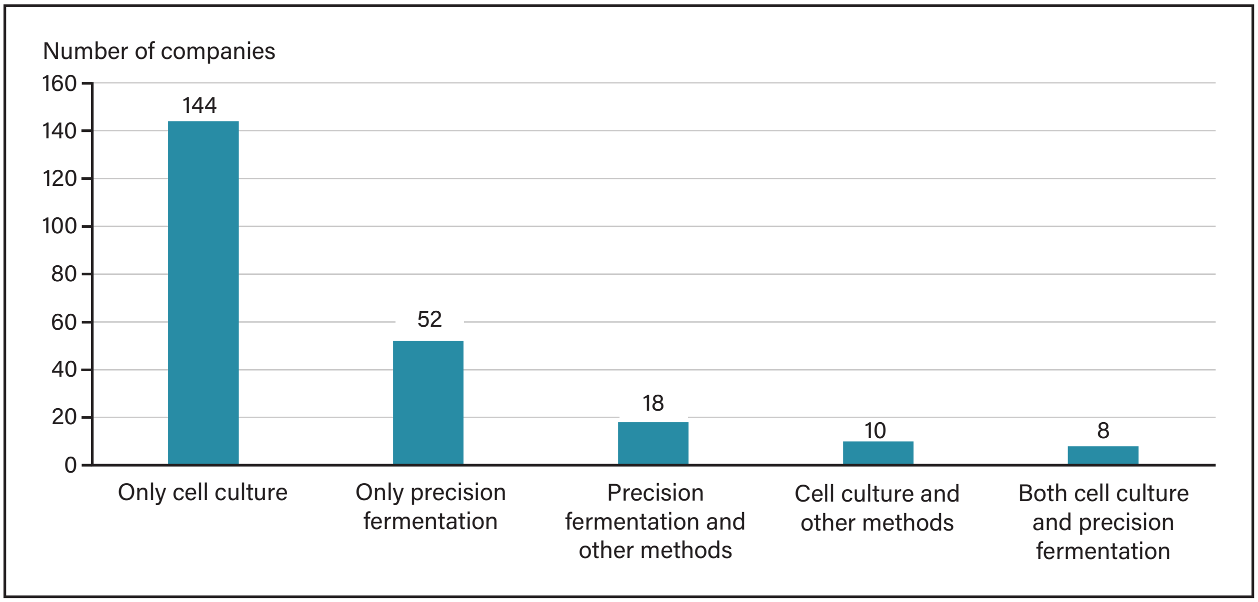
Note: Of the cell culture firms providing information about the type of animal analog (95 firms), the largest number of firms (47) reported focusing on beef/veal. “Other” is a diverse category that includes meat from exotic animals such as kangaroos, zebras, tortoises, and lions, and proteins for pet food. Note that the categories are not exclusive, and many firms list more than 1 animal-type analog.

Source: USDA, Economic Research Service analysis of data from the Good Food Institute (2024) and company websites.

The majority of firms working in cellular agriculture specialize in either cell culture or precision fermentation (figure 8). However, several firms report utilizing more than one production process. For example, 18 firms reported combining precision fermentation with other methods such as traditional fermentation, biomass fermentation, or plant-based technologies. Eight firms reported using cell culture and precision fermentation in their production process.

Figure 8

Distribution of production processes in products researched and/or developed by global cellular agriculture firms



Note: Most firms in the sector either utilized only cell culture or precision fermentation technologies. However, some firms reported being involved in other technologies as well, such as biomass fermentation or plant-based technologies.

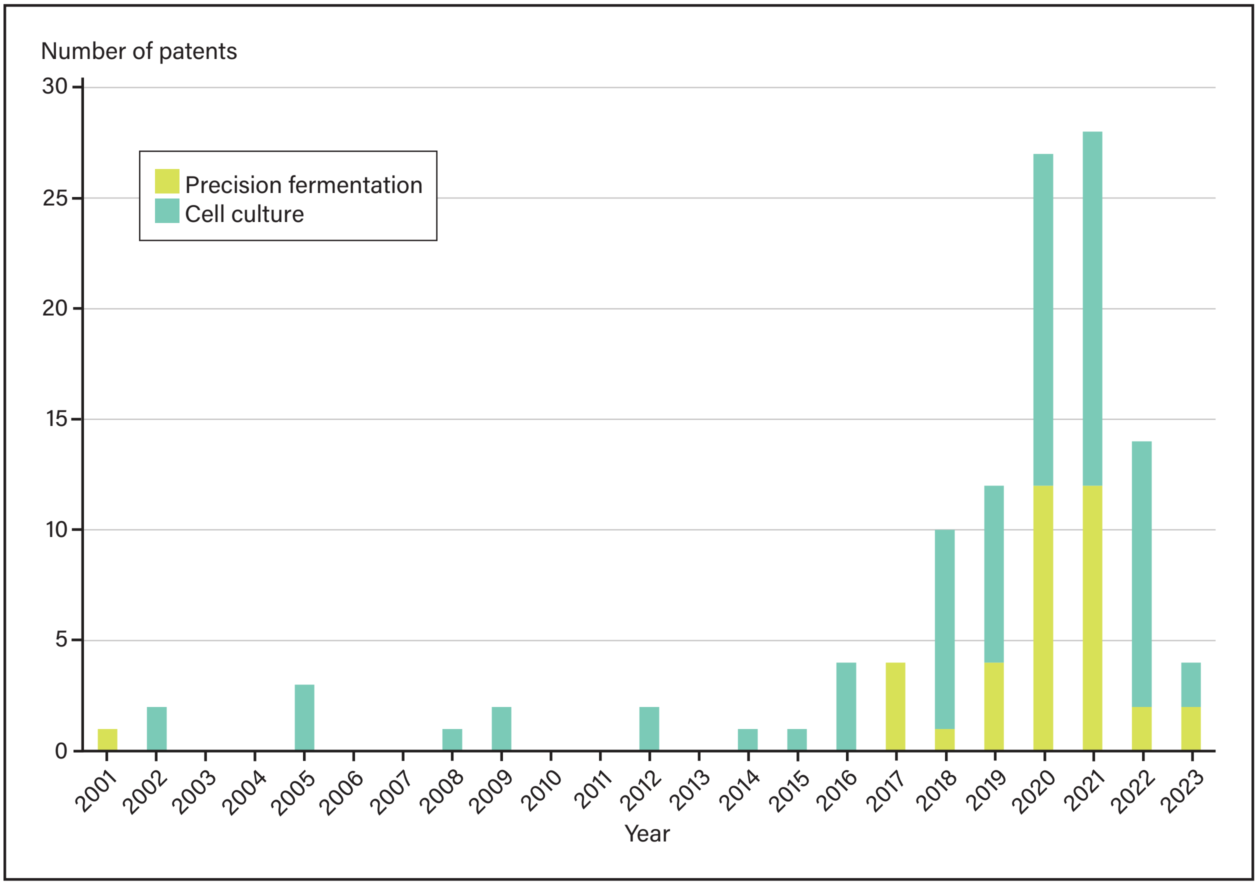
Source: USDA, Economic Research Service analysis of data from the Good Food Institute (2024) and company websites.

Research and Development: Evidence From Global Patents

Patent volume is one proxy for speed and intensity of innovation (Griliches, 1990). Fields with more patents granted and patents filed may have more active investment in innovation than fields with fewer patents. The fact that all inventors have incentives to protect their inventions with patents (such that the patent office carefully evaluates each patent for novelty) makes patents a highly legible and informative criterion by which to measure innovation. However, using patents as a proxy for innovation is imperfect for several reasons. First, patents make innovations public, which is sometimes not in the interest of a company with a novel idea that might want to keep an innovation as a trade secret. Companies may prefer this because patents expire and because enforcing a patent requires costly lawsuits. Therefore, patent stocks could undercount total scientific innovation in any given field. A second limitation of using patents as a proxy for innovation is that many patents are relevant but not directly or solely targeted toward cellular agriculture. For example, a lab that grows cell cultures for pharmaceutical purposes might file patent applications that are highly relevant for cultured meat but have no intention of using it for that purpose. Similarly, a lab might specialize in general purpose cell culture technologies that would be applicable to both conventional meat products and meat analogs.

Based on Google Patents searches (see appendix, "Patents Analysis: Data and Methods"), 114 patents have been filed since the early 2000s (figure 9). Of these, 78 were related to cell-cultured technologies and 38 were related to precision fermentation. Two patents included both cell-cultured and precision fermentation technologies. The earliest patent in the dataset was filed in 2001, entitled "Method for producing tissue engineered meat for consumption." The patent described the broad outline for how cellular agriculture might work. The majority of patents, however, were filed in 2018 or later. Since most patents were more recently filed, many (95) were pending in status. An additional 43 patents were active, and only 3 patents were expired. Withdrawn patents were excluded from the analysis.

Figure 9
Distribution of patents related to cellular agriculture, by year of approval



Note: N=114 (78 = cell-cultured technologies; 38 = precision fermentation), with 2 patents including both cell-cultured and precision fermentation technologies. All patents depicted have an active, pending, or expired status and were filed in the United States. See appendix, “Patents Analysis: Data and Methods,” for more information.

Source: USDA, Economic Research Service analysis of data from Google Patents.

Government Regulation and Research Funding: United States and Abroad

Currently, cell-cultured meat and seafood products are not available at grocery stores. In the United States and Singapore, cell-cultured products were sold in limited quantities at selected restaurants. However, some precision fermentation products are commercially available.[15] As these technologies continue to evolve in the United States and abroad, governments’ interaction with cellular agriculture globally has increased regarding regulation, funding, and legislation (FAO, 2022).

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[15] One example is Brave Robot ice cream, which uses Perfect Day proteins created through precision fermentation of a fungal species encoded with the DNA sequence for whey protein.

Federal Regulatory Environment

The novelty of cellular agriculture, combined with existing animal product regulations and the interest in or opposition to marketplace release by companies and organizations, creates a challenging regulatory environment. In 2020, the Singapore Food Agency (SFA) granted approval to cultured chicken for sale from Eat Just, Inc. (SFA, 2022). The product is sold in select restaurants and stores in Singapore. In Israel, the Health Ministry granted a "no questions" letter to produce cultivated beef steaks (Shaked & Morgan, 2024). In the United States, two agencies—USDA, FSIS and the FDA—have joint oversight authority over food production, inspection, and labeling. The FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Fair Packaging and Labeling Act. USDA, FSIS is responsible for implementing and enforcing the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (table 1).

Table 1

Relevant legislative acts and U.S. Food and Drug Administration and USDA, Food Safety and Inspection Service actions

Year	Act or regulation	Description
1906	Federal Meat Inspection Act (FMIA, 21 U.S.C. 601, et seq.) Implemented by USDA, Food Safety and Inspection Service (FSIS)	Authorized the Secretary of Agriculture to implement mandatory pre- and post-mortem inspection of livestock; establish sanitary standards for slaughterhouses and meat processing plants; condemn meat unfit for human consumption; authorize ongoing monitoring and inspection of operations; ensure accurate labeling.
1938	Federal Food, Drug, and Cosmetic Act (21 U.S. 301, et seq.) Implemented by the U.S. Food and Drug Administration (FDA)	Gives authority to the FDA to oversee safety of food, drugs, medical devices, and cosmetics.
1944	Public Health Service Act (42 U.S. 201, et seq.) Implemented by the FDA	Authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States.
1957	Poultry Products Inspection Act (PPIA; 21 U.S.C. 451, et seq.) Implemented by USDA, FSIS	Requires inspection of domesticated birds when slaughtered and processed for human consumption; prevention of adulterated or misbranded poultry from being sold as food, and ensures slaughter and processing is done under sanitary conditions.
1966	Fair Packaging and Labeling Act (15 U.S. 1451, et seq.) Implemented by the FDA	Requires all foods, drugs, devices, and cosmetics produced or distributed for retail sales to be labeled.
1970	Egg Products Inspection Act (21 U.S.C. 1031, et seq.) Implemented by USDA, FSIS	Regulation by the Secretary of Agriculture and Secretary of Health and Human Services must ensure eggs and egg products are wholesome, not adulterated, properly labeled, packaged to protect health and welfare of consumers. Inspection of shell egg handlers to control disposition of certain types of loss and undergrade eggs. Mandates permitted amount of not desirable eggs for sale and disposal of not desirable eggs.
2018	Use of Cellular Agriculture to Manufacture Products Derived from Livestock and Poultry Stem Cells (USDA, FSIS, non-rulemaking, Docket No. FSIS-2018-0036)	USDA, FSIS and the FDA hosted a joint public meeting to discuss the regulation and inspection, processing and labeling of products made from livestock and poultry tissue grown using cellular agriculture.
2019	Formal agreement between the FDA and USDA, FSIS	USDA, FSIS and the FDA formal agreement to describe intended roles of the agencies with respect to oversight of human food produced from animal cell culture technology, derived from cell lines of USDA-amenable species and required to bear a USDA mark of inspection.

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Year	Act or regulation	Description
2021	Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells (USDA, FSIS, Advance Notice of Proposed Rulemaking, Docket No. FSIS-2020-0036)	USDA, FSIS requests comments pertaining to labeling of meat and poultry products comprised or containing cultured cells derived from animals subject to Federal Meat Inspection Act (FMIA) or Poultry Products Inspection Act (PPIA).
2022	The FDA completes first voluntary premarket consultation	The FDA concluded that UPSIDE Foods harvested cell material is safe for use as food and does not contain substances or microorganisms that would adulterate food.
2023	USDA, FSIS Directive 7800	Provides instructions to USDA, FSIS inspection program personnel (IPP) on roles and responsibilities for inspecting/verifying activities in harvesting/processing cell-cultured meat or poultry food products for human consumption, and on requesting information from the FDA related to the production of cell-cultured meat or poultry products.
2023	USDA, FSIS Notice 31-23	Provides instructions to USDA, FSIS IPP on how to collect cell-cultured meat and poultry food products and send samples to relevant laboratory for microbiological, chemical residue, speciation testing, and pathology. It provides instructions to Enforcement, Investigations and Analysis officers on how to collect food contact surface and environmental swab samples at cell-cultured meat and poultry food product establishments and submit the samples to the appropriate laboratory for testing.

Source: USDA, Economic Research Service synthesis of legislation and regulation history.

In 2018, USDA, FSIS and the FDA hosted an informational joint public meeting to discuss each agency's relevant expertise in regulation, inspection, processing, and labeling of human foods made from cultured animal cells and to collect public comments. The joint meeting was partly in response to a significant amount of correspondence submitted to USDA, FSIS, especially concerning the United States Cattlemen's Association petition to USDA, FSIS to prohibit the use of "meat" and "beef" labels and marketing for products manufactured using animal cell culture technology (USDA, FSIS, 2018).

In 2019, the two agencies signed a formal agreement detailing joint oversight over human food production from cell-cultivation (figure 10). Precision fermentation products do not fall under this agreement and would be regulated exclusively under the FDA. For example, Perfect Day, which makes precision-fermented whey protein, submitted a generally recognized as safe (GRAS) notice to the FDA for its product in 2019 and received a "no questions" letter from the FDA in 2020.

The current agreement on cell-cultured products notes that the FDA is the first stop for any company or facility seeking to produce cellular agricultural food products. The FDA conducts all voluntary premarket analyses and regulates the process of culturing cells, including, as applicable, initial cell collection, proliferation and differentiation, and initiation and maintenance of cell banks. The voluntary premarket consultation process involves a regulatory and scientific consultation between the FDA and a particular company being evaluated. At harvest, the FDA shares all publicly available pertinent information with USDA, FSIS for facilities under the agency's purview. As required by regulation, USDA, FSIS regulates and inspects all meat, poultry, fish of the order Siluriformes,[16] and egg products-producing facilities. As an example, in November 2022, the FDA evaluated cell-cultured chicken cells from UPSIDE Foods, a California-based food technology company, and determined that the agency had no questions regarding the conclusion that the food is as safe as comparable foods produced by other methods (Fasano, 2022) (table 1). After voluntary premarket consultation, the FDA transferred UPSIDE Food's information to USDA, FSIS.

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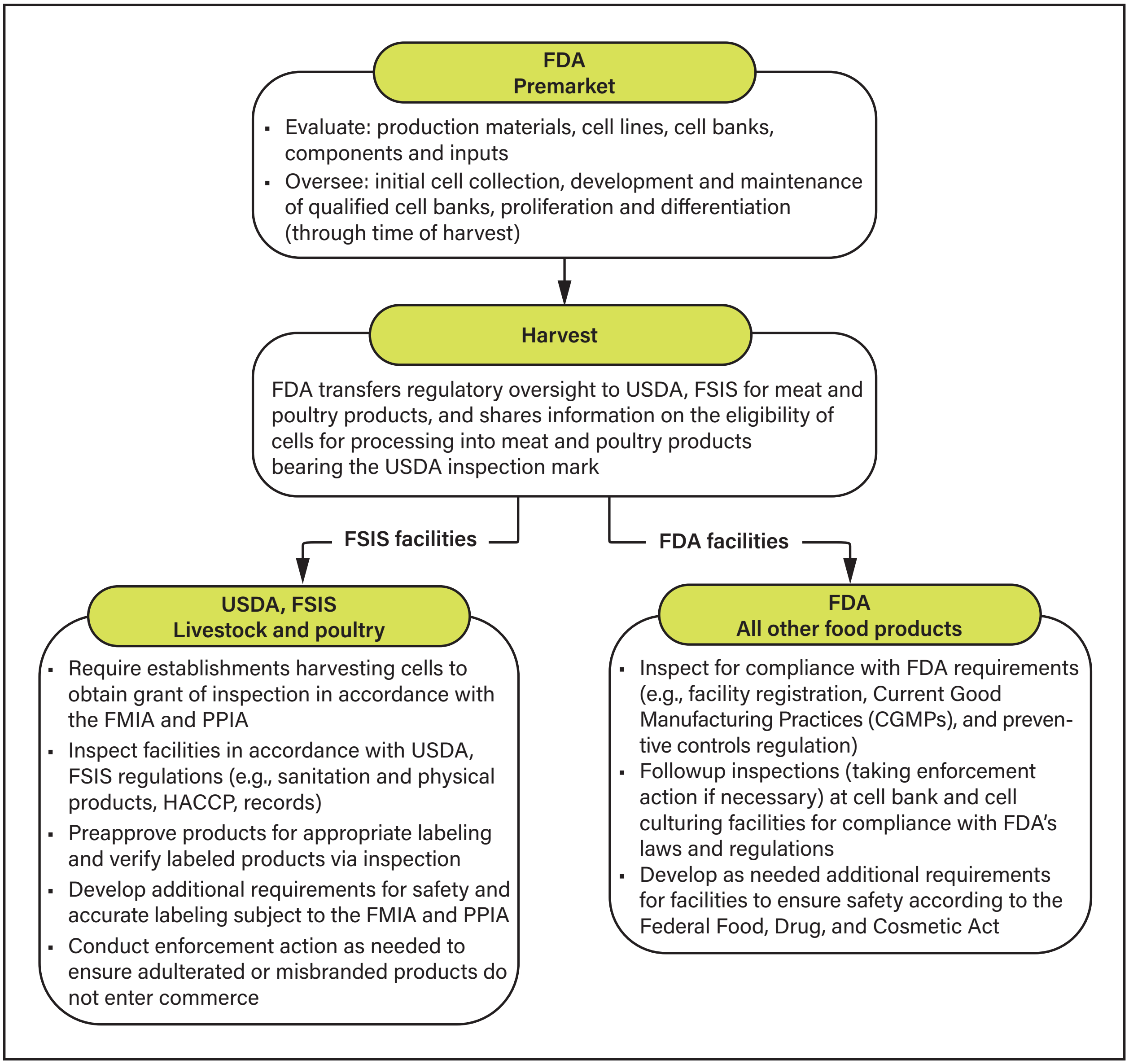
[16] Siluriformes are a group of freshwater fish, which include catfishes.

Figure 10

Formal agreement regarding cell-cultured foods on intended roles of the Food and Drug Administration and USDA, Food Safety and Inspection Service



FDA
Premarket

- Evaluate: production materials, cell lines, cell banks, components and inputs
- Oversee: initial cell collection, development and maintenance of qualified cell banks, proliferation and differentiation (through time of harvest)

Harvest

FDA transfers regulatory oversight to USDA, FSIS for meat and poultry products, and shares information on the eligibility of cells for processing into meat and poultry products bearing the USDA inspection mark

USDA, FSIS
Livestock and poultry

- Require establishments harvesting cells to obtain grant of inspection in accordance with the FMIA and PPIA
- Inspect facilities in accordance with USDA, FSIS regulations (e.g., sanitation and physical products, HACCP, records)
- Preapprove products for appropriate labeling and verify labeled products via inspection
- Develop additional requirements for safety and accurate labeling subject to the FMIA and PPIA
- Conduct enforcement action as needed to ensure adulterated or misbranded products do not enter commerce

FDA
All other food products

- Inspect for compliance with FDA requirements (e.g., facility registration, Current Good Manufacturing Practices (CGMPs), and preventive controls regulation)
- Followup inspections (taking enforcement action if necessary) at cell bank and cell culturing facilities for compliance with FDA's laws and regulations
- Develop as needed additional requirements for facilities to ensure safety according to the Federal Food, Drug, and Cosmetic Act

FDA = U.S. Department of Health and Human Services, Food and Drug Administration; USDA, FSIS = USDA, Food Safety and Inspection Service; FMIA = Federal Meat Inspection Act; PPIA = Poultry Products Inspection Act; HACCP = Hazard Analysis Critical Control Point.

Note: The FDA and USDA, FSIS have signed a formal agreement clarifying the regulatory environment of cellular foods (table 1). All voluntary premarket consultation is overseen by the FDA. At harvest, the FDA transfers regulatory oversight to USDA, FSIS for meat and poultry products.

Source: USDA, Economic Research Service synthesis of formal agreement wording.

In 2023, USDA, FSIS published a directive providing guidance to the agency's inspection and program personnel (IPP) about their roles and responsibilities when inspecting and verifying activities in establishments harvesting or processing cell-cultured meat or poultry food products for human consumption. Additionally, the directive provided information on requesting information and records from the FDA on the production of cell-cultured meat and poultry products (USDA, FSIS, 2023a). USDA, FSIS also published a notice in 2023 on the cell-cultured meat and poultry products sampling program (USDA, FSIS, 2023b). For example, IPP are instructed on the collection of raw product samples to be tested for a variety of purposes, such as detection of Salmonella, chemical residues, and pathology.

An ongoing debate is whether words such as “meat” or “steak” can be used alongside these products (see section “Federal and State Legislation.”) USDA defines meat as “the flesh of animals (including fish and birds) used as food, that can be part of a healthful diet” (USDA, 2019). FMIA defines meat as the part of livestock muscle that is skeletal or from the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels that normally accompany the muscle tissue and are not separated from it in the process of dressing. USDA, FSIS has previously amended the definition of meat, for example, to include a meat product resulting from advanced meat/bone separation machinery (USDA, FSIS, 2004). New methods of producing meat and poultry products have sometimes required new labeling requirements. In 1995, USDA, FSIS evaluated the need to establish new labeling requirements for mechanically separated poultry due to the product—resulting from the mechanical process—being “paste-like in form and similar to a cake batter in consistency, and (not being) the same as chicken or turkey removed from carcasses or parts of carcasses by hand” (USDA, FSIS, 1995). Conversely, regarding advanced meat recovery, in 2004, the agency found meat products resulting from advanced meat/bone separation machinery comparable to meat. As of the writing of this report, no final guidance exists on labeling and terminology of cell-cultured products. However, USDA, FSIS has approved the terms “cell-cultured” and “cell-cultivated” for labeling of the cell-cultured chicken products that have entered commerce.

Advance Notice of Proposed Rulemaking (ANPR) Issued in 2021

To gather information on labeling, a USDA, FSIS Advance Notice of Proposed Rulemaking (ANPR) requested public comment regarding the labeling of meat and poultry products “comprised of or containing cultured cells derived from animals” subject to the FMIA or PPIA (USDA, FSIS, 2021). The ANPR issued 14 questions for comment, including whether the product names of meat or poultry foods comprised of or containing cultured animal cells should indicate differentiation from slaughtered meat or poultry. The ANPR also sought recommended names from respondents that preferred differentiation. (For more information, see the appendix “ANPR Response Analysis: Data and Methods” section.) Although participants self-select into the Federal Register request for comments (i.e., the set of comments cannot be considered a random sample of the U.S. public’s views), an analysis of these comments provide an important lens into the labeling beliefs of those with a clear interest in the topic—commercial, scientific, academic, administrative, or solely personal.

Individual respondents submitted 92 percent of the comments (table 2). Results show that 83 percent of respondents believed cellular meat and poultry should be differentiated from slaughtered meat, while 15 percent did not. Additionally, about 5 percent of responses suggested that conventional meat products also be labeled. For example, one comment read, “I think cultured/lab-grown meat should count as meat and should have a label identifying it as cultured meat. In the same vein, meat that comes from an animal should be labeled as slaughtered meat.”

Table 2

Counts of responses to question, "Should the product name of a meat or poultry product comprised of or containing cultured animal cells differentiate the product from slaughtered meat or poultry by informing consumers the product was made using animal cell culture technology?"

Commenter	Response			
	No	Yes	Nonresponse	Proposed label for conventional meat products
Individual commentators	168	877	20	60
Group commentators (total)	5	81	3	2
Government	0	8	1	0
Organization	5	55	1	2
Company	0	17	1	0
Total comments	173	958	23	62

Note: Nonresponses indicate comments for which the respondent did not directly answer the yes/no question. The last column indicates the number of comments that indicated there should be a label for conventional meat products (e.g., slaughtered meat).

Source: USDA, Economic Research Service analysis of all comments USDA, Food Safety and Inspection Service received from the Advance Notice of Proposed Rulemaking, Docket No. FSIS-2020-0036.

To understand the difference between individual and group preferences, the authors estimated a simple probit model. The model was specified as

$$RESPONSE_i = \alpha + \beta \cdot commentertype_i + \varepsilon_i$$

where $RESPONSE_i$ is equal to 1 if respondent *i* answered yes to the question "Should the product name of a meat or poultry product comprised of or containing cultured animal cells differentiate the product from slaughtered meat or poultry by informing consumers the product was made using animal cell culture technology?" and 0 if the respondent answered no. The binary commenter type variable in the equation indicates whether the respondent was answering the question on behalf of themselves as an individual or on behalf of a group (which includes government, organization, and company responses). Results from the noncausal probit model indicated that individuals were less likely to suggest differential labeling (table 3). Specifically, being an individual commenter relative to being a group commenter was associated with a decreased probability of answering that there should be labeling differentiation by 10 percent. In other words, group commenters that answered this question were somewhat more likely to prefer differential labeling. Note that few respondents chose to not answer. In total, 20 individual respondents did not answer, and 4 group respondents did not answer.

Table 3

Results from probit regression analysis

	Coefficient	Marginal effect
Individual respondent	-0.586*** (0.2216)	-0.103*** (0.0274)
Constant	1.576*** (0.2167)	-
Total observations	1,131	1,131

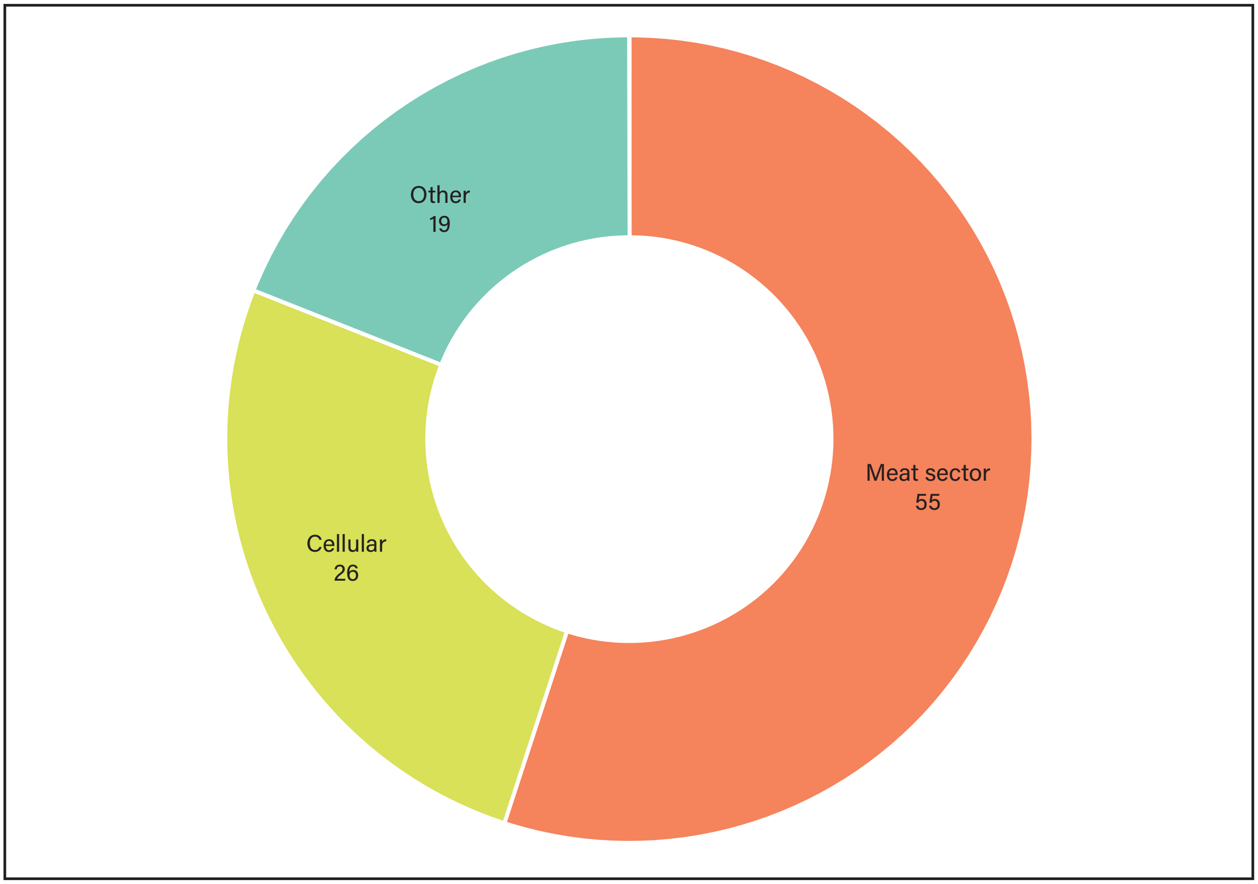
Note: Coefficient and marginal effects estimates are from a probit regression analyzing the noncausal relationship between preferences for differential labeling and whether the respondent was an individual or group. Asterisks denote statistical significance: *** p < 0.01. Numbers in parentheses represent standard errors.

Source: USDA, Economic Research Service analysis of all comments USDA, Food Safety and Inspection Service received from the Advance Notice of Proposed Rulemaking, Docket No. FSIS-2020-0036.

The affiliation breakdown of companies and organizations that commented on the Federal Register notice is shown in figure 11. Over half the responding companies and organizations were affiliated with the traditional meat sector (e.g., farm bureaus and cattle associations). All commenters in this category answered that cellular meat should be differentiated from slaughtered meat. All but one company/organization explicitly connected to cellular agriculture also believed there should be a differentiated label. Finally, the "other" category was comprised of a more diverse group, spanning pet food companies, universities, and food industry associations. About 27 percent of the "other" category believed cellular meat and poultry should not have a differentiated label (figure 11).

Figure 11

Distribution of affiliation of companies or organizations responding to the Advance Notice of Proposed Rulemaking, Docket No. FSIS-2020-0036, by percentage



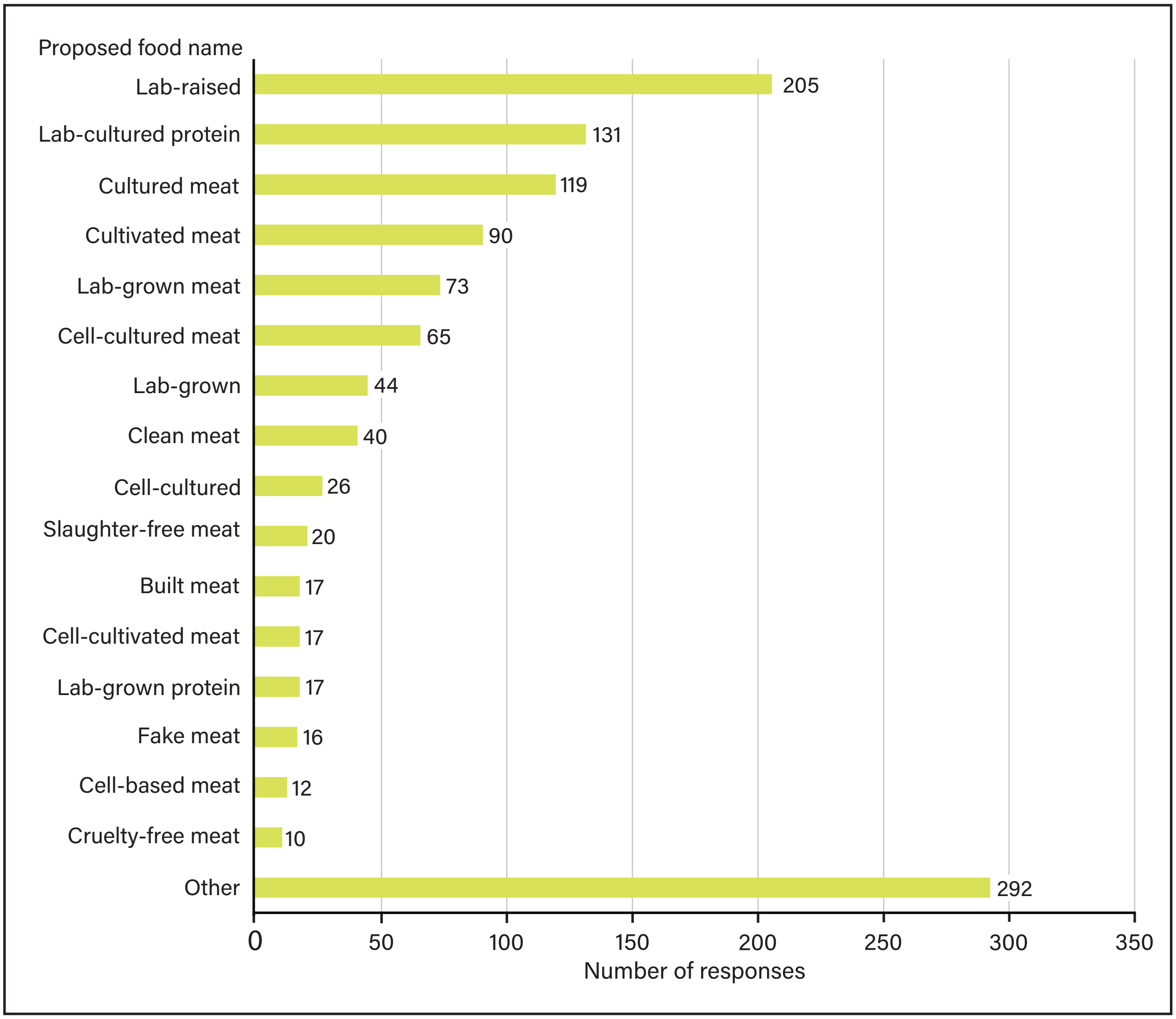
Note: The majority of company/organizations responding to the Advance Notice of Proposed Rulemaking (ANPR) had affiliations with the meat industry.

Source: USDA, Economic Research Service analysis of all comments that USDA, Food Safety and Inspection Service (FSIS) received from the ANPR, Docket No. FSIS-2020-0036.

In response to the question regarding product names for foods comprised of or containing cell-cultured animal cells, the most provided term was lab-raised (205 counts), lab-cultured protein (131 counts), cultured meat (119 counts), cultivated meat (90 counts), and lab-grown meat (73 counts) (figure 12). In total, 625 suggested terms contained the word meat, and 569 did not. However, it is not possible to know (unless explicitly stated in the comment) that a respondent providing the term "cultured" did not intend for it to be combined with the word "meat." See box, "Nomenclature of Cellular Agriculture Products," for a discussion on consumer surveys on labeling.

Figure 12

Distribution of responses to the Advance Notice of Proposed Rulemaking, Docket No. FSIS-2020-0036



Note: The figure shows the distribution of terms provided by respondents answering the question, "What term(s), if any, should be in the product name of a food comprised of or containing cultured animal cells to convey the nature or source of the food to consumers? (e.g., "cell cultured" or "cell cultivated")."

Source: USDA, Economic Research Service analysis of all comments that USDA, Food Safety and Inspection Service received from the Advance Notice of Proposed Rulemaking, Docket No. FSIS-2020-0036.

Nomenclature of Cellular Agriculture Products

USDA, Food Safety and Inspection Service (FSIS) has solicited public comments on preferred terminology for cellular meat and poultry (see "Advance Notice of Proposed Rulemaking (ANPR) Issued in 2021"), and States have passed legislation on labeling for cellular meat (see "Federal and State Legislation"). Questions on terminology are important because labels inform consumers about products they may be interested in purchasing or consuming. For example, individuals allergic to particular animal meats will likely be allergic to cell-cultured meat derived from the same animals because the two are biosimilar. Additionally, while it is unclear whether the United States will require separate mandatory labeling, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have jointly agreed to use the term "cell-based foods" as a working terminology while they assess the technology for the Codex Alimentarius, the international food standards and guidelines for international food trade (FAO & WHO, 2022).

Due to the novelty, different stakeholders have used diverse terms to describe cell-cultured foods. Authorities have used terms such as cell-based, cell-cultured, cell-cultivated, cultured, and cultivated (FAO, 2022). According to a focus group of cell-cultured food companies, about 75 percent prefer the modifier term "cultivated" (Cohen et al., 2021) added to the word "meat." There is no consensus in academic research or media on the terminology, but the most commonly used term between 2013 and 2022 for both was "cultured" (FAO, 2022). The language may also interact with consumers' perception of the product. For example, a term such as "clean meat" may trigger a positive perception, and "lab-grown" meat may trigger a negative perception (Bryant & Barnett, 2019). However, these perceptions are not necessarily stable from consumer to consumer, and research has shown them to differ by country (Bryant & Krelling, 2021; Bryant et al., 2019; Possidonio et al., 2021). Singapore's Agency for Science, Technology, and Research published articles in local media with their preferred term, "cultured meat," which may have helped consumers become more familiar with the terminology (FAO, 2022).

Recent Federally Funded Research

In the United States, Federal funding has been disbursed by the USDA, National Institute of Food and Agriculture (NIFA), National Science Foundation (NSF), NSF's Small Business Innovation Research (SBIR),[17] and by the State of California.[18] To date, for cell-culture technology, USDA, NIFA has awarded $92,000 (USDA, NIFA, 2012). NSF has awarded $512,000 to fund multiple projects (NSF, 2021a; NSF, 2021b) and $3.5 million to the University of California, Davis, to develop cellular agriculture and conduct a techno-economic and life-cycle analysis of cultured meat production (NSF, 2020). SBIR (funded by the U.S. Department of Energy) has awarded $500,000 (SBIR, 2020). For precision fermentation technology, SBIR (funded by NSF) has awarded $1 million (SBIR, 2019; SBIR, 2021).

Additionally, awards have funded university-housed centers to study various cellular and precision fermented food issues, including food production and consumer acceptance. In 2021, USDA, NIFA awarded $10 million to establish the National Institute for Cellular Agriculture at Tufts University (USDA, NIFA, 2021).

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[17] SBIR receives funding from 11 Federal agencies: USDA, Department of Commerce, Department of Defense, Department of Energy, Department of Education, Health and Human Services, Department of Homeland Security, Department of Transportation, Environmental Protection Agency, National Aeronautics and Space Administration, and the National Science Foundation. Agencies designate research and development topics in their solicitations and accept proposals from small businesses.

[18] This section describes funding for the current cellular agriculture sector. This R&D, however, builds on decades of funding into cell and tissue culture research for human medical purposes.

NSF awarded $20,000 to the Tufts Center for Cellular Agriculture and Cultured Meat also in 2021 (NSF, 2021c). The State of California appropriated $1 million to the University of California, Berkeley Alternative Meats Lab (State of California, 2021). The next year, the State of California budgeted a $5 million one-time allocation to support research and development of cell-cultured and plant-based meat at the University of California campuses in Berkeley, Davis, and Los Angeles, California (Wolf, 2022).

Federal and State Legislation

At least 16 States have introduced legislation pertaining to the labeling of cell-cultured meat.[19] In March 2024, the State of Florida passed legislation to prohibit "manufacturing, sale, holding, or distribution of cultivated meat."[20] However, bans on cellular agriculture could be invalidated under preemption, depending on guidance by USDA and the FDA (Sylvester et. al., 2020). Preemption provides that State laws must yield to Federal law.[21] The preemption doctrine, derived from the Constitution's Supremacy Clause, states that Federal law is "the supreme Law of the Land," and as such, Federal law supersedes any State laws in conflict (Adkins et al., 2023). Federal statutes most relevant to preemption include the Food Safety Modernization Act of 2011,[22] PPIA, and FMIA (Sylvester et. al., 2020). For example, States are prohibited from imposing additional or different requirements within the scope of the FMIA on USDA-regulated meat facilities.

Funding by Non-U.S. Governments

Governments worldwide are funding research and development of cellular agriculture, including through public-private partnerships via research accelerators and grants, and government-led research. As an example of a partnership with the private sector, the Office of the Principal Scientific Adviser to the Government of India and the New and Emerging Strategic Technologies Division within India's Ministry of External Affairs collaborated in 2020 with an India-based collaborative group called the Science Policy Forum to bring researchers together on emerging topics, including "synthetic meat" (Science Policy Forum, 2020). In Japan, the New Energy and Industrial Technology Development Organization (NEDO), a public national research and development agency, granted 200 million yen (about $1.5 million as of March 2023) to accelerate development and mass production of cell-cultured meat from a range of animal cell types and to reduce the production costs of various types of meat (IntegriCulture, 2022). The Swine and Poultry Unit of Brazil's Agricultural Research Corporation (Embrapa, an affiliate of the country's Ministry of Agriculture), an agency established by the Government to develop technological solutions to sustainable pork and poultry meat production, is developing a cell-cultured chicken breast filet prototype (Feddern et al., 2022). Additional information can be sought from GFI, which annually publishes a list of federal funds by country (GFI, 2023a).

Market Challenges

The cellular agricultural sector faces several market challenges, despite wide-ranging determinants and drivers of market growth; significant recent expansions in research, development, and other market activity; and governmental regulatory accommodation and funding opportunities.

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[19] Alabama, Arkansas, Colorado, Georgia, Kentucky, Louisiana, Maine, Mississippi, Missouri, Montana, North Dakota, Oklahoma, South Carolina, South Dakota, Texas, and Wyoming.

[20] Florida HB 435 and SB 586.

[21] U.S. Constitution, Article IV, Clause 2.

[22] FDA Food Safety Modernization Act, Pub. L. No. 111–353, 124 Stat. 3885 (2011) (codified in 21 U.S.C. § 301 (2018)). This law amended the 1938 Federal Food, Drug, and Cosmetic Act, providing the FDA with new regulatory authority on food safety.

Costs: Development, Commercialization, and Distribution

Precision-fermented dairy products are already on the market in the United States and, like their plant-based counterparts, sell for a premium over animal-based counterparts. For example, the company Perfect Day partners with other companies that sell products like ice cream and milk featuring their precision fermentation animal-free whey protein.[23] Precision fermented protein products are increasingly available in U.S. markets, while cell-cultured meat and seafood products are not, partially due to the ability for precision fermentation to occur in larger bioreactors with fewer requirements for gas exchange, turbulence, and other environmental factors. To achieve price parity, companies in the precision fermentation sector will have to increase scale, decrease feedstock cost, and increase protein yield (GFI, 2023b). Voutilainen et al. (2021) performed a techno-economic analysis on recombinant protein and determined the process to be price competitive with selling prices of plant-based commercial products, egg whites, and casein powders, with a minimum selling price between $10.37 and $13.10 per kg.[24] However, these calculations represented wholesale protein prices and were not inclusive of additional formulations to reach a final product.

Cell-cultured food products commercially available are limited to restaurant settings. For example, Upside Foods' cell-cultured chicken was offered at a San Francisco restaurant from 2023 to 2024. Starting in 2023, Good Meat partnered with a Singapore restaurant to sell a cultured chicken salad for roughly $14 (U.S. dollars) (Yu, 2023).[25] While Good Meat has not published updated costs for its product, the company has stated it is selling at a loss (Yu, 2023). Currently, Good Meat's volume is limited, and the company may not have the ability to take advantage of potential economies of scale. Projections of how much cell-cultured meat will eventually cost vary widely as the technology matures and companies are able to take full advantage of economies of scale, economies of scope, and/or other benefits.

Several techno-economic analyses suggest low-end cost estimates for cell-cultured products spanning a wide range, including $1.95 per kilogram (kg) (Risner et al., 2020), $6.43 per kg (Vergeer et al., 2021), $7.87 per kg (Ashizawa et al., 2022), and $37.00 per kg (Humbird, 2021). These analyses are based on a combination of current technologies and assumptions about future innovation and economies of scale, and they vary widely in assumptions about technical and economic issues. For example, Ashizawa et al. (2022), in a low-end cost scenario, assumed insect cells rather than chicken, pig, or cow cells were used because insect cells share some of the same desirable properties as cells from traditional meat animals but multiply faster. In contrast, other reports did not distinguish between species and intended to serve as a general cost estimate for cell-cultured products.

Three of these four studies also included higher end ranges that assumed particularly expensive input prices, methods, or technologies. While both the high- and low-end estimates in these reports were speculative, the higher end estimates in Vergeer et al. (2021) ($1,708 per kg, ranging from $150 per kg to $22,423 per kg), Risner et al. (2020) ($437,000 per kg), and Ashizawa et al. (2022) ($4,193 per kg) were all substantially higher than the $14 chicken salad that Good Meat sold in Singapore, albeit at a loss (Yu, 2023).

Humbird identified several key barriers to making cell-cultured meat cost effective. First, the bioreactors used in cell-cultured meat were initially designed for cultivating small quantities of cells at a time. To scale these bioreactors, engineering to enable high growth rate, metabolic efficiency, and reduced cell damage will be necessary. Second, media components, such as amino acids and protein growth factors, are not currently produced in industrial quantities, and so the costs may remain high in large quantities. The analysis also

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[23] Specifically, these products include Brave Robot ice cream, Bored Cow flavored milks, Natreve protein powder, and California Performance Co. protein powder.

[24] Voutilainen et al. (2021) estimated an average minimum selling price of recombinant protein to be between 7,956 and 10,049 euros per ton, with an average of 9,000 euros. The average exchange rate in 2021 was 1 euro to 1.183 U.S. dollar. In comparison, the average minimum selling price for plant-based protein was 7,400 euros per ton and for egg and milk protein ingredients was 10,500 euros per ton.

[25] Meati, the mycelium-fermented meat analog, retailed between $8 and $10 for 7–10-ounce packages as of mid-2023.

noted that clean room costs limit the size of a single facility, which limits the advantages of certain economies of scale. Humbird considered both a fed batch (one which continuously adds nutrients to the bioreactor but does not extract waste until cells are harvested) and a perfusion system (one which continuously adds nutrients and removes waste at a fixed rate), and concluded that the perfusion system would result in an even higher product cost at $51 per kg relative to the estimated $37 per kg from a fed batch system. (See appendix, "Additional Information on Cellular Agriculture," for more information about bioreactor types.)

While the Humbird (2021) analysis produced cost estimates by scaling up currently available technologies, Vergeer et al. (2021) took a scenario analysis approach (i.e., estimated costs conditional on various technological and economic realities). These scenarios started with a high media usage, current prices, current standard levels of cell density, production runtime, and cell volume. Each additional scenario considered a specific area of costs savings, either by using an input such as a medium more efficiently, or by prices of inputs such as growth factors declining, which occurred either through economies of scale or innovations in using lower cost products.

Vergeer et al. (2021) noted that a typical cell-cultured meat facility might contain 130 bioreactors and produce around 10 kilotons (22 million pounds) of raw cells per year. The final product weight will depend on whether and how the cells are blended with plant-based products, as is common in chicken nuggets and similar foods. For comparison, the USDA, World Agricultural Outlook Board (WAOB), *World Agricultural Supply and Demand Estimates* indicated the total supply of red meat and poultry in the United States to be 114 billion pounds in 2022 (USDA, WAOB, 2023). USDA, FSIS lists 5,824 meat and poultry slaughter and processing facilities (USDA, FSIS, 2023c), which includes a heterogeneous assortment of slaughter and nonslaughter facilities, some processing a concentrated amount of meat. The estimate does not include facilities used to raise the livestock. Assuming each facility produces 22 million pounds of raw cells per year, it would take over 5,000 facilities to produce the current amount of animal-based meat supplied in the United States annually. While this may be comparable to the total number of facilities used for animal slaughter and processing, these facilities would take time to build, and companies would likely experiment with one facility (or a small number) at a time before expanding. It is plausible that these facilities could compete with those used for traditional animal products in the long run, though building, testing, and improving on the equipment and infrastructure for these products would take a substantial period of time before the cell-cultured products could meaningfully compete with animal products.

Innovation, by its very nature, is unpredictable, and companies' particular methods for reducing costs may not be obvious. These different techno-economic analyses make different assumptions on how much innovation the sector will experience, which is both difficult to predict and dependent on private company information. These studies also generally make price comparisons with current animal meat products, which are the potentially relevant comparators for cell-cultured products once at scale. However, while the market is small, companies may be able to sustain a significantly higher price for cultured meat as a novelty niche product.

Consumer Acceptance

As cellular agriculture is still in its nascence, studies on consumers' acceptance of the products rely heavily on surveys and choice experiments. These may be subject to hypothetical bias, giving unrealistic (negative or positive) valuations to products that the consumer has not had the opportunity to purchase or experience. While current literature is an indicator of the interest and acceptance for the technology, a combination of price, taste, and texture, none of which are known to consumers today, will likely determine acceptance.

Overall, studies have found mixed attitudes. One U.S. survey found that 65 percent of respondents were willing to try "in vitro" meat, but only 33 percent were willing to eat it regularly or as a replacement for farmed meat (Wilks & Phillips, 2017). A hypothetical choice experiment reported that 11 percent of participants chose the "cultured meat burger" over conventional or plant-based burger alternatives, and preferences increased with lower prices and higher perceived market shares (Slade, 2018). Bryant et al. (2019) reported that 30 percent of U.S. consumers were very or extremely likely to purchase "clean" meat, and 47 percent were somewhat or moderately likely to make the purchase. The inconsistency in descriptions and measures of acceptance reported in the literature complicates researchers' ability to understand whether perceptions have changed and to compare results across studies (Bryant & Barnett, 2018). Also of note is that framing, the way the cell-cultured and precision fermented agricultural product is described or labeled, may impact consumers' acceptance (Siegrist et al., 2018; Hallman et al., 2020; Asioli et al., 2022; Califano et al., 2023).

Potential consumers have both concerns and appeal/interest factors regarding cell-cultured meats, although few appear to be important drivers of behavior (Bryant & Barnett, 2018). Wilks and Phillips (2017) examined barriers to engagement with the technology and found most respondents had taste or appeal concerns (79 percent), but few respondents had ethical (24 percent) and price (20 percent) concerns regarding the technology. Other potential challenges facing consumer acceptance of cell-cultured meat and precision fermented products include the perception of unnaturalness (Marcu et al., 2015; Laestadius, 2015; Siegrist et al., 2018), food safety (Siegrist & Sütterlin, 2017), health (Verbeke et al., 2015), and disinclinations to try new foods (Espinosa & Treich, 2023). A recent systematic literature review found that public awareness, perceived naturalness, and food-related risk perception were the most important factors influencing the acceptance or rejection of cell-cultured meat (Pakseresht et al., 2022). However, as the technology develops, consumer perceptions are likely to change. The provision of additional information may also affect acceptance, such as information on the environmental and animal welfare benefits of meat alternatives (Van Loo et al., 2020).

Pockets of the population may also have higher or lower incentives to purchase these products. Consumers who eat meat but have animal welfare concerns can purchase meat with one or more labels that signal farmers' production practices relating to livestock treatment. A survey of U.S. grocery shoppers found that 86 percent purchased at least one product with labels such as "cage or crate-free," "free-range," or "pasture-raised." Among consumers who purchased products with these labels, 89 percent did so with the belief that these labels indicated higher welfare of farm animals (Thibault et al., 2022). Cellular agriculture products are likely to appeal to this portion of market demand.

Additionally, demand for cellular agriculture may interact with religious diets. In nationally representative samples in the United States, India, and China, Bryant (2020) surveyed the populations for interest in cell-cultivated beef, poultry, pork, and lamb/goat meat. His results showed differences in interest by meat type and religious affiliation. The majority of Jewish and Buddhist respondents considered purchasing cell-cultivated beef (70 and 81 percent, respectively), poultry (70 and 61 percent), pork (61 and 73 percent), and lamb/goat (61 and 66 percent).[26] [27] Jewish respondents were indifferent between purchasing cell-cultivated and traditional pork. Interest in the purchase of cell-cultured products was more dependent on meat type for Muslim and Hindu respondents. A majority of Muslim respondents found cell-cultured beef (58 percent) and lamb/goat (68 percent) meat appealing, but only 28 percent of Muslim respondents stated they would

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[26] The Jewish dietary laws (kashrut) specify what can and cannot be eaten. Kashrut allows for meat from only certain animals. Additionally, meat from mammals and dairy products cannot be combined. There appears to be a consensus between most Jewish rabbis and kosher certification agencies that cell-cultivated meat and seafood from kosher animals can be considered kosher (Bleich, 2013; Kenigsberg & Zivotofsky, 2020). Furthermore, Israel's chief rabbi determined in 2023 that cultured meat is both kosher (Aleph Farms, 2023) and "parve" (meaning neutral) if it does not call itself meat (Lau, 2023). Foods designated as parve are those that do not contain meat or dairy. However, they can be mixed with meat and dairy, and they include foods such as fruits and vegetables, eggs, fish, or poultry.

[27] Few studies have been published on the permissibility of cell-cultivated meat in Buddhism (Kwon Ven Jahun & Park, 2023; Bryant, 2020). As Buddhism's first precept is to refrain from killing, of question is whether the use of immortalized cells in production could carry ethical and religious considerations if the animal was bred deliberately for that purpose (Kwon Ven Jahun & Park, 2023).

consider cell-cultured pork to be appealing.[28] Only 19 and 20 percent of Hindu respondents found cell-cultured beef and pork appealing, though over 60 percent found cell-cultured lamb/goat and poultry appealing.[29] As the technology evolves, its relationship with different religious dietary preferences and laws will continue to develop.

Environmental Impacts

Much uncertainty surrounds the net environmental impacts of the cell-cultured and precision fermentation industry due to its limited commercial offerings and lack of scale. This uncertainty includes the complex logistics required to sustain a demand base widely diffused across the United States should it develop. Analysis of supply chain sustainability for precommercialized products invariably rests on assumptions about the products' life cycle, current market conditions, and their trajectories into the near future.

For precision fermentation technology, Perfect Day commissioned an International Organization for Standardization (ISO)-compliant and third-party-reviewed life-cycle assessment for its whey protein. The assessment found Perfect Day whey protein to have between 91 and 97 percent lower greenhouse gas emissions, to consume between 96 and 99 percent less blue water (water from lakes, rivers, and aquifers), and use between 29 and 60 percent less energy than total protein from milk derived from animal sources. Utilities use (e.g., coal and natural gas from the U.S. electric grid) were the largest contributor of greenhouse gas emissions, contributing 40 percent of such emissions from Perfect Day whey protein (WSP Global, 2021).

Given the scope of variables involved in cell-cultivation, including feedstock and materials sourcing; electricity, water, and other resource use; harvest, storage, transportation, and distribution chains; and waste from production and consumption, it is only generally possible for researchers to provide a range of environmental impact estimates (e.g., Tuomisto, 2022). Comparisons of impact assessments are challenging due to a wide variation from study to study in functional units (i.e., unit of output), system boundaries, production methods, and methodologies (table 4). The substantial differences in the type and number of environmental measures are of greatest importance. While some research has primarily focused on fundamental measures like total energy, direct land use, and basic climate change indicators in cell-cultured meat (e.g., Tuomisto & Teixeira de Mattos, 2011; Mattick et al., 2015), other analyses have considered water use and pollution, land use change, deforestation, ozone depletion and harmful solar radiation, small-particle air pollution, and other factors (e.g., Smetana et al., 2015; Järviö et al., 2021; Kobayashi et al., 2022).

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[28] Islamic dietary laws specify what can and cannot be eaten and allow for meat from certain animals. Cell-cultivated meat may qualify as "halal" (permissible to eat under the dietary laws) if the cells used for production are biopsied from a halal-slaughtered animal and no blood or animal-based serum was used in the production process (Hamdan et al., 2018). Halal slaughter requires that an animal's trachea, esophagus, carotid artery, and jugular vein are cut in a single swipe. Cell-cultivated meat from a "haram" (forbidden) animal would be unlikely to be approved under Islamic dietary laws (Kashim et al., 2023).

[29] Hinduism may not accept cell-cultivated beef because cows are considered sacred (Mattick et al., 2015).

Table 4

Analyses quantifying the environmental impacts of cultured food production

	Study					
	Tuomisto and Teixeira de Mattos (2011)	**Smetana et al. (2015)**	**Mattick et al. (2015)**	**Järviö et al. (2021)**	**Kobayashi et al. (2022)**	**Humpenöder et al. (2022)**
Functional unit	1,000 kg cultured meat, with 30% mass dry matter and 19% mass protein	1 kg of ready-to-eat protein	1 kg of cell biomass	1 kg of cell-cultured ovalbumin with 8% moisture and 92% protein content; 1 kg of protein	1 kg of plant cell culture biomass in the form of dried powder	NA
Production mode	Cell-culture	Cell-culture	Cell-culture	Precision fermentation	Biomass fermentation	Biomass fermentation
Sector	Cultured meat	Cultured meat	Cultured meat	Cultured egg white protein powder	Cultured plant-based powder	Cultured microbial protein
Cell source	Animal embryonic stem cells	NA	Chinese hamster ovary cells	Genetically engineered *Trichoderma reesei* fungus	Tobacco and cloudberry plant cells	NA
Feedstock	Cyanobacteria hydrolysate	Cyanobacteria hydrolysate	Peptides and amino acids from soy hydrolysis and glucose from corn starch	Glucose (carbon source) and other nutrients for growth	Sucrose sourced from sugarcane	Sucrose sourced from sugarcane
System boundaries	Input production to factory gate	Cradle (input production) to plate (consumer use)	Cradle (input production) to factory gate	Cradle (input production) to factory gate	Input production to factory gate	NA
Production scale	Hypothetical large-scale system	Laboratory scale	Small scale (e.g., "brewery" size)	Hypothetical industrial scale system	Pilot scale	Hypothetical large-scale production/ substitution
Production location(s)	Spain, California, Thailand	NA	NA	Finland, Germany, Poland	Finland	Global in scope
Method	Attributional, anticipatory LCA	Attributional, anticipatory LCA	Attributional, anticipatory LCA	Attributional, anticipatory LCA	Attributional, anticipatory LCA	Global partial equilibrium model of land-use sector

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	Study					
	Tuomisto and Teixeira de Mattos (2011)	Smetana et al. (2015)	Mattick et al. (2015)	Järviö et al. (2021)	Kobayashi et al. (2022)	Humpenöder et al. (2022)
Environmental impacts considered	Greenhouse gas, total energy use, direct land use, GWP, direct and indirect water use	Ozone depletion; climate change; human toxicity; photochemical oxidant; particulate matter pollution; ionizing radiation; terrestrial acidification; freshwater eutrophication; terrestrial, freshwater, and marine ecotoxicity; direct and indirect land use; metal and fossil depletion	Total energy use, direct land use, GWP, eutrophication potential	Direct land use; GWP; freshwater and marine eutrophication; terrestrial acidification; water scarcity; ionizing radiation; ozone depletion; human toxicity	GWP; direct land use; freshwater and marine eutrophication; terrestrial acidification; ozone depletion; water consumption	Deforestation; carbon dioxide, methane, and nitrous oxide emissions; land-use change; water use; nitrogen fixation

kg = kilograms; LCA = life-cycle assessment; NA = not applicable; GWP = global warming potential.

Note: Ovalbumin is the primary protein found in egg whites. Microbial proteins are single-celled proteins produced in a bioreactor from substances like fungi, bacteria, or algae. Animal embryonic stem cells are stem cells (i.e., undifferentiated cells with the ability to become tissue cells with specific functions) from the embryos of animals. An attributional, anticipatory life-cycle assessment (LCA) is a method used to assess environmental impacts across all stages of the process needed to produce an anticipated product; "attributional" indicates that allocations are used to subdivide impacts of the process across byproducts. Cyanobacteria hydrolysate is a medium that provides nutrients and energy for cell production; a similar medium can be formed from peptides and amino acids resulting from chemical reactions involving soy (Mattick et al., 2015). Glucose and sucrose are forms of sugar. Global warming potential (GWP) is a measure of how much energy the emissions of 1 ton of a gas will absorb over a given period of time, relative to the emissions of 1 ton of carbon dioxide. Ionizing radiation is a form of energy that can penetrate the human body, with the potential to cause harmful effects at high exposure levels. Photochemical oxidants are air pollutants that result from the action of sunlight on nitrous oxides and certain chemical compounds in the atmosphere containing carbon and hydrogen (i.e., reactive hydrocarbons). Particulate matter pollution refers to a mix of solid particles and liquid droplets in the air, including dust, dirt, soot, and smoke. Terrestrial acidification, mainly caused by atmospheric deposition of acidifying compounds (e.g., acid rain), results in lower soil pH, which can decrease plant performance and lead to biodiversity loss. Freshwater and marine eutrophication is a process in which nutrients (e.g., nitrogen, phosphorus) accumulate in freshwater, seas, and oceans, which leads to an overabundance of plants and algae. Toxicity refers to the detrimental effects of chemical emissions on the health of humans (human toxicity) and ecosystems (ecotoxicity).

Source: USDA, Economic Research Service analysis.

Despite the heterogeneity and case-study nature of the analyses, a synthesis of the existing studies suggests mixed results. Broad consensus exists that energy consumption, and particularly electricity use, is the input with the greatest (potential) negative environmental impact. At present, cell-cultured meat production is a highly energy-intensive process. To the extent that bioreactors are not increasingly powered by renewable energy sources, various scenarios indicate that global warming effects from cell-cultured meat production could exceed those of conventional meat. Cell-cultured meat production is dependent on conventional energy sources that emit long-lasting carbon dioxide. In contrast, conventional livestock emit methane, a far more potent but short-lived greenhouse gas. Replacing conventional power sources with renewable sources such as solar power would lead to a decreased footprint (Lynch & Pierrehumbert, 2019). Nevertheless, this finding is uncertain. Relative impacts will depend on the global extent of energy decarbonization, production efficiency, and the trajectories of per capita (conventional and cultured) meat consumption.

Along several other important environmental dimensions, however, the projected impacts of cell-cultured foods are relatively low or minimal. Emissions of nitrous oxide and methane from cell-cultured meat production are small, as is the potential for overaccumulation of nutrients (e.g., nitrogen, phosphorous) in freshwater and marine waters. The direct land use requirements are also low, especially in scenarios modeling bioreactor plants as having the same scale as urban breweries. In one study of fermentation-derived microbial protein, Humpenöder et al. (2022) found that substituting 20 percent of global per capita protein from ruminant meat (e.g., beef, bison, mutton) with microbial protein by 2050 would offset increases in global pasture area, reduce annual deforestation and associated carbon dioxide emissions by 50 percent, and lower global methane emissions. Moreover, an analysis by Smetana et al. (2015) of cell-cultured meat production indicated a relatively low potential for toxic effects from chemical emissions in land-based and freshwater ecosystems (i.e., ecotoxicity).

Conclusion

Since the early 2000s, scientists in the public, private, and nonprofit sectors have been actively researching methods for producing food products that are physically and chemically equivalent to livestock- and poultry-produced foods (i.e., meat, dairy, eggs) but that minimally rely (if at all) on animals. This report reviewed the economics and scientific literature, presented descriptive analysis of trends in this emerging sector, and analyzed responses to regulatory inquiries and patents as one measure of companies' research and development. In 2023, more than 200 private firms within the industry existed worldwide, and cumulative invested capital in the cell-culture and precision fermentation industries exceeded $5 billion. As of 2024, more than 100 patents have been filed pertaining to cellular agriculture. U.S. food regulatory agencies (U.S. Food and Drug Administration, and USDA, Food Safety and Inspection Service) have been developing regulatory frameworks to accommodate and ensure the safety of cell-cultured meat and seafood products. As a result of sustained research, development, and marketing efforts, cell-cultured chicken meat has been commercialized in Singapore and the United States, while precision fermentation-derived dairy proteins have been commercially available more broadly.

Despite this rapid technological innovation and market evolution, the absence of significant commercial-scale production of cellular agricultural products implies that substantial uncertainty continues to affect most aspects of the industry. Open questions remain concerning the design of bioreactors and important elements of the production process, including cell source, growth medium, and energy requirements, as well as the optimal size and configuration of production/processing plants. Some analysts suggest that cultured foods will be prohibitively expensive without further technological breakthroughs (e.g., Humbird, 2021; Hubalek et al., 2022; Martins et al., 2024), though increased efficiency and the possibility of scale and/or scope economies could reduce these costs. The extent to which commercial-scale production will be profitable in the short run will depend on, among other things, consumer willingness to pay for these products at sufficient premiums. Current consumer attitudes regarding the industry and its products are mixed, although research presumes that consumer demand will shift—upward or downward—as the technology develops and consumers gain the opportunity to familiarize themselves with these foods. Environmental impacts are also largely unknown. Increasing public- and private-sector interest in improved sustainability suggests that these impacts will be scrutinized by interested companies, policymakers, and other market participants as uncertainty begins to resolve.

Several important dimensions of related markets—largely beyond the scope of this report—could greatly impact the cellular agriculture sector. For example, increasing availability and quality of noncultured plant-based meat, dairy, and egg products could pose a competitive challenge (Raszap Skorbiansky & Saavoss, 2023). Increased competition from plant-based meat substitutes could stimulate additional innovation and product commercialization in the cellular agriculture industry. Conversely, this competition could result in lower market shares of cell-cultured products if consumers find noncultivated plant-based counterparts more appealing. Along similar lines, innovations in conventional livestock production systems, such as cattle feed ration changes that drastically reduce methane emissions, genetic engineering that reduces the need for body modification (e.g., de-horning), and/or new legal requirements pertaining to animal housing, could influence demand for cultured products from consumers most concerned with greenhouse gas emissions and/or animal welfare. Additional changes in the structure and organization of the U.S. livestock sector, especially those involving the scale or efficiency of production or processing and that alter the returns to livestock farming, could induce supply effects that ultimately impact cellular agriculture. Any of these developments could have a major impact on the price of cell-cultured and precision fermentation products, which would affect quantities sold to consumers.

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Appendix

Additional Information on Cell-Culture Technology

The process of producing cell-cultured meat and seafood begins with biopsied stem cells from live animals (Post, 2012). Stem cells have the ability to develop into different types of cells, such as muscle, fat, or bone. The stem cells then can go through a process called immortalization, which allows the cells to divide continuously (Pajčin, 2022; Soice & Johnston, 2021). These cells are used to create a culture of cells with a uniform genetic makeup (i.e., cell line); cultures from these immortalized cell lines can divide indefinitely for future use. This process of turning cells from animals into usable cell lines can take several months to well over a year. To grow, the starter cells must be placed in a media solution that provides nutrients such as glucose, inorganic salts, water-soluble vitamins, and amino acids (O'Neill et al., 2020). These nutrients must be incorporated into a certain solution so the correct pH level is maintained. Eventually, the cells will also need insulin, transferrin, selenium, lipids, antioxidants, and other growth factors for long-term health and proliferation. These growth-factors have historically been provided by fetal bovine serum (FBS).[30] However, the industry is developing alternatives because FBS is animal-derived and expensive. Some companies, such as Eat Just, have created animal-free serum, and other companies are following suit. Similarly, other companies, such as IntegriCulture, have developed processes that do not use immortalized cells or the addition of growth factors to the cell-culture media (IntegriCulture, 2023).

To create the environment required to support the growth of cells, the cells and media are placed in a sequence of bioreactors (Zhang et al., 2020; Swartz & Bomkamp, 2023). Bioreactors are containers in which proper temperature, pH, dissolved oxygen, carbon dioxide, turbidity, and other biochemical conditions are maintained automatically. Cells can only survive at particular densities because they need a consistent environment (e.g., oxygen, nutrients, temperature, and turbidity). Starter cells are placed initially in a small bioreactor and then moved to increasingly larger bioreactors to keep the cell density similar across bioreactors.

Bioreactors can be operated under a fed-batch process or a perfusion process (Humbird, 2020; Swartz & Bomkamp, 2023). A fed-batch process continuously adds nutrients to the bioreactor throughout the growth process but does not extract any waste until the cells are harvested. Perfusion processes, in contrast, continuously add fresh nutrients to the bioreactors and remove waste at a fixed rate by cycling media through a cell retention device, such as a filter or centrifuge, and holding the cells in place with a fixed substrate.[31] The fixed substrate often plays a key role in cell differentiation (Swartz, 2021). In principle, elements of the removed media may be recycled back into the process after filtration. Both types of processes have pros and cons. Perfusion processes allow for higher cell densities (by removing waste that is growth-inhibiting) but require smaller bioreactors (due to size constraints of the cell retention device), leading to lower output than fed-batch processes (Humbird, 2020).

The starter cells and the media are placed in the first bioreactor to multiply for a larger pool of starter cells. These cells are then distributed on a scaffolding, a three-dimensional structure that provides shape and structure to the cells and facilitates oxygen and nutrient exchange. The scaffolding works with the cell culture media to allow cells to differentiate toward particular cell types. The type of scaffolding needed depends on the target product. As with animal-derived products, cell-cultured companies strive to create meat and seafood products in a range of textures, ranging from less to more differentiated. Hot dogs are a less differen-

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[30] FBS is the liquid remnant of coagulated blood from calf fetuses, which are typically sourced at slaughterhouses. FBS contains a range of adhesion and growth factors, in addition to nutrients (van der Valk, 2022).

[31] In chemistry, a substrate is a molecule that is acted upon by an enzyme, which itself is just a protein that accelerates a chemical reaction. The production of cheese curds, for example, is a chemical reaction in which rennet (an enzyme) is added to milk. The milk contains the substrate, casein (a protein), needed for the chemical reaction.

tiated meat, mainly made from ground meat products. Cuts of meat, such as a steak, require the most variation in textures and are more technologically difficult and expensive to produce (Swartz & Bomkamp, 2023).

Scaffolding can be made of a variety of materials, including natural, synthetic, or composite media (Bomkamp et al., 2021; Seah et al., 2022). Specific examples include textured vegetable protein, carrageenan, cellulose, and fungal mycelium.[32] In other cases, animal-derived materials may be used for scaffolding, such as gelatin, silk, or chitosan (a carbohydrate which is sometimes derived from crustaceans). However, as with FBS, companies are using animal-derived components primarily for exploratory purposes and plan to switch to nonanimal derived alternatives. Scaffolding can either be an edible part of the finished product or a component that dissolves (either chemically or mechanically) before the cells are harvested. Scaffolding can be made using a variety of techniques, including 3D bioprinting, stereolithography, and electrospinning.

As the cells continue to multiply, they are placed in larger bioreactors with suitable media and scaffolding. Harvest of the product is carried out automatically in the last bioreactor. The ultimate product could be a group of cells to be formed into a meat patty or a steak-like cut, though this mainly depends on the scaffolding used throughout the process.

Patents Analysis: Data and Methods

The authors searched for patents relating to products within the cell-cultured and precision fermentation industry using three search procedures and three inclusion criteria. The search was conducted between February and March 2024. The first procedure involved searching for patents that are currently or were previously assigned to a company from a list of known companies working in cellular agriculture (Good Food Institute (GFI), 2024). The list specifies whether each company is engaging in precision fermentation or cell culture and are the same database underlying figures 4–8. Next, the authors used the search terms “synthetic meat,” “cultivated meat,” “cultured meat,” “cellular meat,” “lab grown meat,” and “clean meat” in a review of Google Patents. Finally, they consulted a list of cellular meat patents compiled by Ark Biotech (2022) and added any patents that previous searches did not find and that met the inclusion criteria. The Google Patents search procedure for precision fermentation was limited to a search for patents with an assignee for a company identified by GFI as working in precision fermentation. Once a patent was identified, the authors also examined patent citations and related applications. This was mainly because search terms for “fermentation” yielded an unmanageable number of results that were not directly related to animal protein alternatives.

Three inclusion criteria were applied for patents. First, the patent must have been directly relevant to cellular agriculture. The patent was evaluated as relevant if it was either: (a) in the general field of precision fermentation science or cell cultivation and was assigned to a company known to be in the alternative protein sector; or (b) explicitly mentioned the purpose of use for creating alternatives to animal proteins. Second, the patent must have had an active, pending, or expired status. International or abandoned patents were not included. Third, the patent must have been filed in the United States.

Some patents were borderline cases. For example, the company Ajinomoto makes both plant-based and cell-cultured foods. The company filed a patent for a method for producing the amino acids L-lysine and L-threonine. These amino acids are used in the production of cell-cultured meat but are also used in other contexts, such as direct supplements to humans and animals. In this instance, the patent was included in the analysis.

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[32] Carrageenan is a chemical compound found naturally in certain edible seaweed and is commonly used in the food industry as an additive to thicken, preserve, and stabilize food and beverages. Cellulose, a carbohydrate, is the chief constituent of cell walls in plants.

ANPR Response Analysis: Data and Methods

USDA, Food Safety and Inspection Service (FSIS) published the Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register in August 2021. The Federal Register allows the public to access and comment on Government documents. The ANPR contained 14 questions, although most comments included answers only to the first 2 questions. The authors analyzed responses to the ANPR's first question, "Should the product name of a meat or poultry product comprised of or containing cultured animal cells differentiate the product from slaughtered meat or poultry by informing consumers the product was made using animal cell culture technology?" The second question was, "What term(s), if any, should be in the product name of a food comprised of or containing cultured animal cells to convey the nature or source of the food to consumers? (e.g., ''cell cultured'' or ''cell cultivated.'')"

The ANPR received 1,179 responses. Removing all answers with known repeated comments (same commenter name and comment) provided 1,154 comments for analysis. As with nearly all text analyses, this analysis of Federal Register comments required interpretation and classification of subjective statements. While the questions are clear-cut (e.g., whether USDA, FSIS should create a label to differentiate cellular foods could evoke a "yes"), comments often provided unclear answers that left room for interpretation (see table A.1).

Table A.1

Method for coding responses from the USDA, FSIS Advance Notice of Proposed Rulemaking

Number	Example comment	Question 1: Should it be differentiated?	Question 2: What should be the term/label used?
1	Cell-cultured meat should just be labeled meat.	No	-
2	Cell-cultivated meat should have a different label than slaughtered meat.	Yes	-
3	Cell-cultured meat should be labeled "cellular meat."	Yes	Cellular meat
4	I think cell-cultured meat should be labeled as such.	Yes	Cell-cultured meat
5	I'm excited about cellular meat.	No response	-
6	I believe this type of meat should have a label, for example, "cell-cultured."	Yes	Cell-cultured meat
7	I think it should be called "cell-cultured."	Yes	Cell-cultured
8	This technology should not exist.	Yes	-
9	I think it should be called "cell culture."	Yes	Cell-cultured

Source: USDA, Economic Research Service.

For question 1, the authors provided a value of yes, no, or no response. For question 2, they recorded all suggested terminology, including whether the comment noted a belief that slaughtered meat should also receive a separate label. The ANPR provided examples of labels (“cell cultured” and “cell cultivated”) and also used the words “cultured animal cells” and “animal cell culture technology.” Therefore, if a comment simply stated a term, the authors did not assume it was advising its use. Additionally, several comments used terminology without a clear indication whether the commenter believed it should be the term used. The authors only recorded the label name if it was clear that the commenter was advocating its use (see example comments 1–5 in table A.1). If it was clear that the commenter meant for the word “meat” to be used, it was added to the label (see example comment 6). If it was not clear, the word “meat” was left out (see example comment 7). If a comment suggested the commenter was against the technology, the authors assumed if that technology did come to exist, the commenter would want a label differentiating it (example 8 in table A.1). Finally, the authors classified “aggregate” comments with comparable terminology (see example comment 9).