

Manufacturing capacity landscape and scaling strategies for fermentation-derived protein

A summary of recommended policy stakeholder actions

A <u>report</u> by the Good Food Institute and Integration Consulting takes a census of existing global fermentation-based alternative protein production capacity, assesses the decision points for determining whether to contract manufacture or self-produce, and explores salient considerations for developing a fermentation facility for the alternative protein industry. This summary highlights key insights from the analysis and outlines recommended actions for policy and governmental support of the industry.

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Overview

The range of fermentation-derived alternative protein products has expanded tremendously in the past several years. Driven by innovations in biotechnology that enable proteins, fats, and other ingredients to be produced in microbes such as yeast and bacteria, many food ingredients can now be made using animal-free methods. Further, the well-established biomass fermentation industry has seen a rapid diversification of microbial species, production methods, and consumer products. Together, these advancements have set the stage for fermentation-derived products to enjoy widespread presence in food formulations and on store shelves.

To meet the Paris Agreement's 1.5°C target, we <u>must</u> <u>considerably reduce emissions from food and</u> <u>agriculture</u>. Protein production generates <u>roughly half</u> of all food system greenhouse gas emissions, and meat demand is projected to double by 2050. <u>Transition to fermentation-derived protein has</u> <u>significant climate advantages over animal-based</u> <u>protein production.</u>

A global protein transition with more

fermentation-derived protein sources helps us reach these necessary climate goals. For governments and policymakers, fermentation-based manufacturing of food proteins is also an opportunity to foster innovation that brings novel technologies, desirable jobs, and nutritious products to market.

More and larger fermentation facilities suitable for food production are needed to accommodate rising demand and ever-improving innovations in microbial biotechnology and fermentation approaches. Scaling up production to achieve lower price points is also needed to support increased B2B and B2C demand in the coming years. Policies and support can be put into place to avoid a "valley of death," where promising innovations are unable to be commercially deployed due to a lack of funding, and to bridge the divide between R&D and commercial scales. The Good Food Institute and Integration Consulting have authored a report, summarized in this document, capturing the volume and capabilities of existing global fermentation facilities able to produce alternative proteins and food ingredients. This capacity is characterized by scale, geographic region, and availability for contract manufacturing. The report also explores the trade-offs of strategies to scale manufacturing capacity, including partnering with contract manufacturing organizations (CMOs), building greenfield sites, or retrofitting brownfield facilities and equipment as informed by expert interviews and an industry survey.

This report covers key considerations for each scaling strategy across six major decision factors—overall cost, value chain connectivity, lead times, intellectual property protection, financing, and access to a talented workforce. Further, this report identifies limitations of existing capacity and recommends strategies for scaling that serve a range of industry players and promote overall category growth.

Fermentation is a well-established platform for producing products like beverages, industrial enzymes, and fuels because humans have domesticated microbes for thousands of years and industrialized many fermentation-derived products over the past century. The report also includes an overview of available opportunities to retrofit existing fermentation facilities in parallel industries to produce alternative proteins, fats, or novel ingredients. We analyze facility types available for retrofit, their corresponding markets, and the appropriateness of the equipment they contain. In this report, facilities experiencing relatively low margins and slow growth are identified as potential sites for alternative protein production. However, much of the equipment at these facilities is ill-suited for most fermentation-derived protein manufacturing.

<u>Click here for the full report:</u> Manufacturing capacity landscape and scaling strategies for fermentation-derived protein

Key findings

There are 16 million liters of fermentation capacity available to the fermentation-derived food protein industry across the globe.

A known 89 companies provide 16 million liters of food-certified fermentation capacity and associated process equipment to the alternative protein industry. These companies are capable of producing 0.4 million tonnes of alternative protein product per year. When all potential contract manufacturing capacity from the pharmaceutical and bioindustrial sectors were included, this number rises to 2.8 million tonnes of alternative protein product. The majority (81 percent) of the identified capacity across all production scales is in North America (34 percent) and Europe (47 percent)¹

An increase in the number of fermentation-derived protein products, offtake agreements, and consumer demand will stress the current fermentation capacity. Strategic scale-up of fermentation capacity with associated increases in biological and bioprocess efficiency will be required to meet demand.

Current fermentation capabilities do not meet the needs of development projects for new protein/products.

To optimize production, new fermentation processes must be scaled from lab to demonstration to commercial processes.

Many current fermentation-derived protein companies require piloting support to make their products commercial-ready. There is a notable scarcity of pilot and demonstration scale facilities that can develop and certify a process for commercial-scale production. These smaller-scale facilities, whether at research institutions or contract development and manufacturing organizations (CDMOs), play a vital role in bringing bioproducts from lab scale through to commercialization by shortening lead times and lowering up-front capital investment compared to constructing a company-held facility.

The fermentation capacity captured in this report is roughly divided 50:50 between in-house fermentation and food-exclusive CMOs. Institutional pilot/demonstration facilities and CMOs play an important role in supporting the ecosystem by providing bioprocess experience and guidance to process development.

¹ Note that this analysis did not examine capacity devoted to fermentation-derived animal feed products due to the regulatory framework and standards differences between food and feed production.

The fermentation-derived alternative protein industry scale-up challenge presents a unique financing situation.

Fermentation for alternative proteins and ingredients entails a diverse family of products that originate from many different microbes, fermentation approaches, and bioprocess designs. From a biotech standpoint, this makes fermentation-derived alternative proteins an attractive investment for venture capital. Scale-up efforts will require investment in long-operation infrastructure to produce over many years of operational lifespan, requiring an institutional investor who is comfortable with long-term returns. Currently, fermentation-derived alternative producers sit at the intersection of these two situations, and a clear demonstration of successful scale-up will help demonstrate derisking and facilitate increased investment.

Retrofit facilities and equipment opportunities exist in commercial fermentation for ethanol production.

Fermentation for ethanol production—whether for beer, biofuel, or wine—utilizes standard equipment and relatively simple downstream processing. It also has low margins and slower industry growth than other parallel fermentation industries such as pharmaceuticals and enzyme production. As a result, there are potential opportunities within the beer, wine, and biofuel industries for retrofitting.

These facilities are located near fermentation value chains, provide proper utility (power, water, wastewater) access, and are right-sized structures. However, much of the equipment at these facilities would require significant modification and optimization to be suited for most fermentation-derived protein manufacturing, especially considering the anaerobic nature of ethanol fermentation. If the proper resources were dedicated to developing retrofit hardware and identifying microbes well-suited for anaerobic or semi-aerobic reactor vessels, additional existing fermentation facilities and equipment could be co-opted for retrofitting. Research efforts could be funded to make progress in this space.

Key policy recommendations

Fund R&D, scale-up, and commercialization efforts in fermentationderived proteins to create a thriving biomanufacturing industry. The fermentation-derived alternative protein industry can leverage governmental efforts to expand and mature capabilities in biotechnology and biomanufacturing. Support and funding for fermentation-derived protein manufacturing align with governmental efforts such as the "Bold Goals for U.S. Biotechnology and Biomanufacturing" strategy articulated in a recent report from the White House Office of Science & Technology Policy. Significantly scaling the biomanufacturing of proteins, fats, and other food ingredients through microbial fermentation aligns with the U.S. government's ambitious goals to rapidly mature domestic biomanufacturing industries. Government support can bolster new technologies that provide a precompetitive resource for biotechnology and engineering. This can significantly derisk infrastructure investments in the space and lower the barrier to industry ecosystem maturation:

- The industry needs to innovate and generate technology that supports sustainable, efficient, and safe bioprocessing of fermentation-derived proteins. These efforts should be funded and supported from lab to commercial scale. In doing so, this will address a major U.S. Department of Energy (DoE) Bold Goal (3.3): "Develop bioprocessing approaches that enable scale-up of biotechnology-based protein production while maintaining or improving quality, and thoughtfully matching large-scale waste feedstocks to efforts in synthetic biology and bioprocess engineering."
- Leverage DoE public-private partnerships to build out a network of scale-up facilities and bioprocess technologies for alternative protein fermentation and increased collaboration with national lab facilities such as ABPDU (Advanced Biofuels and Bioproducts Process Development Unit at Lawrence Berkeley National Lab, Emeryville, CA).
- Governments can create, maintain, and fund supportive ecosystem frameworks that allow for lower-cost R&D, resource sharing, workforce development, and at-cost services within innovation hubs or consortiums such as the Agile BioFoundry supported by the U.S. DoE.
- The scaling of the fermentation-derived protein industry will lead to an expanded industry that benefits from economies of scale and increased innovation in sustainability and novel food systems. Funding and support for this scaling and innovation will address a major U.S. Department of Agriculture Bold Goal (2.1): "To support development of new food and feed sources" by supporting an overarching R&D need: "Identify and conduct feasibility studies for high-volume, low-cost protein and fat sources that could be used in food or feed, including products resulting from precision fermentation and coproducts or waste streams from other industries."

Support and fund fermentation-derived alternative protein manufacturing to meet climate goals. **Expanding the fermentation-derived alternative protein industry can help governments achieve their commitments to address climate change.** Fermentation-derived protein production is a promising platform for sustainable protein production. As protein consumption increases worldwide to support nutrition for a growing population, fermentation-derived protein represents an efficient, sustainable, and scalable solution to decrease the greenhouse gas emissions associated with animal-sourced foods.

Establish innovative funding mechanisms to support domestic producers looking to scale up fermentationderived products.

Financially derisk infrastructure investments to drive fermentation capacity that enables the bioeconomy. Fermentation-derived producers encounter uncertainty during scale-up that is not supported by traditional funding mechanisms. Government support directed toward promising companies and innovations in the "valley of death" would secure domestic innovations and bring them to commercialization in the U.S., rather than losing manufacturing and facility deals to overseas competitors. Bioprocess development is often a nonlinear pathway with unexpected challenges. Early R&D is often supported by research partnerships, grants, and seed funding. Demonstrated commercial-ready bioprocesses are attractive candidates for institutional-level investment funding and subsequent revenue generation. There are few mechanisms in place between those phases to solve key biotechnology, engineering, or process challenges that would facilitate the expansion of fermentation-enabled protein products. This disconnect creates a "valley of death" where promising bioprocess and fermentation-derived proteins are not able to reach commercialization before they can overcome development and scaling challenges. Funding mechanisms, especially non-dilutive grants or loans targeted specifically at solving "valley of death" development issues, would ensure that these promising technologies and products make it to the marketplace and that manufacturing remains in the U.S., where the technology was developed.

The ability to construct the necessary fermentation facilities to meet ingredient demand will require significant capital investments that could be derisked by governments and municipalities that are enthusiastic to incentivize biomanufacturing within their borders. Financing costs and unfavorable remittance schedules can significantly affect manufacturers of commodity products with variable or low margins. Governments can provide grants, financing, or tax structures that allow these companies to grow and bring a skilled workforce and high-tech production to their jurisdictions. Recognize that different pathways to securing manufacturing capacity will lead to different outcomes across the industry. New-build construction and facility retrofitting have a general trade-off between lead time and production efficiency. Manufacturers (or future CMOs) working toward operational facilities can often achieve a shorter lead time to commissioning if they choose to retrofit an existing facility. However, based on the original purpose of these facilities and the resulting design idiosyncrasies, achieving process efficiency that approaches a new-build facility with a fit-for-purpose design may be challenging. Some fermentation bioprocesses, such as biomass fermentation, are more amenable to retrofitting than precision fermentation facilities that require extensive fit-for-purpose downstream processing. Hybrid approaches including retrofitting a portion of a larger facility and associated equipment in addition to allocating space for future bioprocessing lines may allow for faster facility development while planning for enhanced bioprocess efficiency with later additions. Familiarization with the industry will help policymakers support mechanisms for different manufacturers within the industry.

Identify and catalog national and regional fermentation capacity to help forecast current and future gaps. Policymakers should encourage self-reporting of fermentation capacity (contract manufacturers and in-house capabilities) to public databases. Not all global fermentation capacity dedicated to alternative proteins and other ingredients could be captured in our analysis due to a lack of data transparency and no centralized repository. Identifying the overall capacity, capability, and scale of each fermentation facility in a nation or region can elucidate mismatches between the current state or anticipated future needs of local industry and its current facilities. Regions with an enthusiastic and thriving startup ecosystem will require pilot- and demonstration-scale facilities to develop the bioprocesses required to bring these products to market. Further along, regions with many certified products ready at commercial scale will need larger facilities to meet the demand for manufacture. Government monitoring of this capacity balance can start with a local, regional, and global awareness of fermentation facility capacity that can be easily facilitated by registration with a fermentation facility database such as Capacitor.bio, BioP2P, or Pilots4U.

Integrate efforts for clean energy and manufacturing capacity to reduce costs. **Fermentation-derived products require energy for their manufacture. Subsidized clean energy will reduce OPEX and incentivize capital projects.** Facilities are built to balance capital costs and operational costs, so providing opportunities and financial incentives for clean energy integration will drive down operational costs and increase the sustainability of the facilities. Support institutional pilot and demonstration facilities to advance the entire fermentation ecosystem. **Pilot and demonstration facilities are key for generating the solutions and workforce that the industry requires.** Fermentation for a commercial product requires process optimization and volumetric scale-up of upstream (production) and downstream (purification) bioprocesses at increasing volumes to reach market-ready quantities. This optimization occurs when increasingly greater volumes are produced at lab, pilot, and demonstration scales. Institutional facilities that provide these services are often located at government-supported research facilities or within universities. These facilities play a vital role in bioprocess scale-up while also training a skilled workforce, prototyping process equipment in collaboration with industrial suppliers, and educating biotech startups on the commercialization pathway. Governments should continue to support existing pilot facilities while supporting the development of new pilot- and demonstration-scale facilities that can act as a catalyst for the fermentation-derived protein industry.

About the author

Adam is a lead scientist in fermentation at GFI and is focused on the development of biomass fermentation and precision fermentation biotechnology for food protein. He earned a BS in molecular genetics from the University of Rochester and a PhD from Drexel University College of Medicine in molecular biology. Adam's postdoctoral studies concentrated on fungal genetics and systems biology. During his time in biotech, Adam implemented gene expression analyses in microbial, agtech, and human health studies to better characterize these systems and offer a deeper understanding of strain development and process improvement.

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About GFI

The Good Food Institute is a 501(c)(3) nonprofit working internationally to make alternative proteins like plant-based and cultivated meat delicious, affordable, and accessible. GFI advances open-access research, mobilizes resources and talent, and empowers partners across the food system to create a sustainable, secure, and just protein supply.

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