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Scaling Up Precision Fermentation of Dairy Proteins

A Chicken and Egg Problem

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Att skala upp precisionsfermentering av mejeriproteiner: Ett moment 22

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Abstract

Precision fermentation is an emerging technology for dairy protein production with potential health, animal-welfare, and sustainability benefits over traditional production methods. This paper investigates the challenges of scaling up precision fermentation of dairy proteins. Additionally, it aims to pinpoint what could trigger a potential industry transition by highlighting what is required by the current system to adopt the technology. Through an exploratory approach data has been collected inductively through semi-structured interviews with industry experts and academics. The analysis revealed doubts regarding financial feasibility of the technology, which prevails hesitancy in investing the necessary capital for scaling up, and that reaching price parity with animal-derived dairy proteins is the main catalyst for a potential transition to occur. These results suggest that companies involved in precision fermentation of dairy proteins need to strengthen the current business model by for instance adopting a circular production approach or to focus on high-value dairy proteins to minimize the distance to price parity. Through the multi level perspective, the niche, being precision fermentation of dairy proteins, is analyzed, offering a conceptual framework summary of the system-level potential and limitations of said niche, considering the current incumbent regime and landscape pressures. This study contributes to the current and limited body of literature by providing perceptions of the fundamental aspects of transforming precision fermentation of dairy proteins to commercial scale.

Key-words

Precision fermentation, dairy protein, CDMO, contract development manufacturing organization, incumbent, large corporates, foodtech, infrastructure investor, MLP, multi level perspective, transition pathways, transition studies, system level analysis, novel food

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Sammanfattning

Precisionsfermentering är en ny teknik för att producera protein som gentemot traditionella- och alternativa protein har potentiella fördelar inom hälsa, djurvälfärd och hållbarhet. Denna studie undersöker utmaningarna med att skala upp precisionsfermentering av mejeriproteiner, syftet är också att fastställa vad som kan utlösa en potentiell transformation på systemnivå och vad som krävs för att precisionsfermentering ska bli en etablerad produktionsmetod för mejeriproteiner. Med hjälp av ett induktivt tillvägagångssätt samlades data in från en grupp branschexperter och akademiker genom semistrukturerade intervjuer. Av analysen framgår det ur ett ekonomiskt perspektiv att det råder tvivel kring huruvida precisionsfermentering av mejeriproteiner skulle fungera i praktiken, vilket leder till tveksamhet inför att investera det kapital som är nödvändigt för att skala upp produktionen. Utöver det framgår det också i analysen att en viktig drivkraft för en eventuell transformation är att nå prisparitet med traditionella mejeriproteiner. Dessa resultat tyder på att företag involverade inom precisionsfermentering av mejeriproteiner måste stärka den nuvarande affärsmodellen, exemplevis genom att integrera en cirkulär produktionsstrategi eller att fokusera på specifika mejeriproteiner med högt marknadsvärde för att minimera avståndet till prisparitet. Denna studie bidrar till den nuvarande och begränsade litteraturen med insikter om de grundläggande aspekterna av att ta precisionsfermentering av mejeriproteiner till en större skala.

Nyckelord

Precisionsfermentering, mjölkprotein, CDMO, kontraktsutvecklings- och tillverkningsorganisation, etablerad aktör, stora företag, mat-tech, infrastrukturinvesterare, MLP, flernivåperspektiv, transformationsvägar, övergångsstudier, analys på systemnivå, nya livsmedel

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We would also like to thank our KTH supervisor Emrah Karakaya for his support. Except for his encouraging mindset and belief in our capabilities, he has through his commitment and academic expertise been of tremendous help in shaping our research to align with our aspirations.

Lastly, we want to express our gratitude to the industry experts and academics interviewed in this research, of which all played a pivotal role in contributing with insights and knowledge. We believe their collective contribution has established a foundation of knowledge that will be necessary for accelerating the transition to precision fermentation of dairy proteins.

Definitions and Abbreviations

Term	Description
Alternative proteins	Alternative proteins is a collective term describing protein sources outside the realm of the traditional meat and dairy industries. The following protein sources are typically the ones referred to when using the term: cultivated meat, plant based milk and dairy, precision fermented dairy proteins, plant- and fungi based proteins, and insects.
Biomass	Biomass is the collective term of the output from an upstream fermentation process. The biomass contains the target protein that has been procured through the precision fermentation process but often it is a minority component of the mass as a whole. For this reason, downstream processing is required to extract the desired molecule.
Biosimilar	Biosimilar is the term that closest resembles 'equals to' in the context of synthetic biology. When comparing for example two proteins, it is not merely enough to consider the similarities in terms of the physical molecular structure, one must also consider and compare the qualitative characteristics of two proteins, like the so-called 'bioactivity' and 'functionality' of a protein.
CAPEX	Capital Expenditures.
CDMO	Contract Development Manufacturing Organization.
CO2e	Carbon Dioxide Equivalent particle impact. This refers to the total greenhouse gas effect of an activity or product. CO2e is a unit of measurement which translates for example other gasses such as methane gas into 'how big greenhouse gas effect' measured in CO2-equivalents does said activity or product yield.
F-CDMO	Food grade CDMOs, tailored for precision fermentation of food protein production including, but not exclusively, dairy proteins.
GMO	Genetically Modified Organism.
Infrastructure Investors	Infrastructure investors are involved financing the construction, acquisition, or enhancement of tangible assets that deliver essential services.
Institutional Investors	For example, pension funds and large private equity firms that are characterized by having long-term investment strategies with comparatively lower expected returns on investments as a consequence of making lower risk investments compared to VCs and CVCs.
MLP	The Multi Level Perspective framework.
OPEX	Operational Expenditures.
R&D	Research and development.

1 Introduction

"Fermentation has an opportunity to fundamentally change the way the world eats and improve global human and environmental health and the economy" (Suescun Pozas & Bushnell, 2020).

Precision fermentation of dairy proteins is one of the more recent emergent fermentation methods for food procurement and as is stated above, offers a lot of potential for addressing future health and climate needs. Suescun Pozas and Bushnell (2020) further point out that in order for precision fermentation to succeed, investments made in this space during the upcoming years need to go into efforts of scaling up the technology. Yet, four years later, production of precision fermented dairy proteins has barely left the pilot-scale environment. Why is that? Before attempting to answer this question, it is important to establish the relevance of this topic.

Proteins are a nutritional cornerstone for us humans, with attributes that uniquely contribute to our dietary needs (Li-Chan & Lacroix, 2018; Deng et al., 2023; Willett et al., 2019). Similarly, specifically dairy proteins have certain nutritional properties, like improving iron absorption and gut health, which in the right dietary context distinguishes them in favor of, for example, plant, meat, or fungi derived protein alternatives (Battle et al., 2024; Liu et al., 2024). However, traditional dairy production increases both pandemic and antibiotic-resistance risks (Battle et al., 2024; Deng et al., 2023), and, in cases of applied factory farming practices, disregards ethical considerations for the welfare of animals (Tubb & Seba, 2021).

The dairy sector, as a socio-technical system, has been under pressure due to growing consumption patterns, climate change, animal welfare concerns, and supply chain shocks (Henkell-von Ribbentrop et al., 2024). For instance, traditional animal agriculture contributes between 11-20% to global greenhouse gas emissions (Battle et al., 2024) and global consumption patterns of proteins are expected to grow over the next few years as a consequence of an increasing global population (Deng et al., 2023), pointing to the critical need for alternative, more environmentally friendly production methods of dairy. For the world to achieve present climate, biodiversity, public health, and food security goals, it is necessary to redefine the way food is made (Deng et al., 2023; Sonnino, 2023; Webb et al., 2020; Willett et al., 2019).

Precision fermentation of dairy proteins as a niche, might offer a solution to the above-mentioned challenges (Bucca & Gerry, 2024) and is therefore the focus of this study. Although the global market size of precision fermented dairy proteins is almost non-existent today, there are some estimates that the market for fermented meat, dairy, egg, and seafood combined, will reach a size between USD 15 billion and USD 74 billion in the year 2030 (Synonym, 2023). However, the current precision fermentation manufacturing capacity is insufficient to meet demand, and costs are too high for widespread market adoption (Battle et al., 2024).

The low market share of precision fermented dairy proteins partly seems to be related to an imbalance in supply and demand. Currently, incumbent contract development manufacturing organizations (CDMOs) are the dominant manufacturing actors within the space of commercial precision fermented dairy protein production, with highly limited availability (Boukid et al., 2023). According to the *State of Global Fermentation* industry report conducted by Synonym Inc. in November 2023, the demand for precision fermented dairy protein products exceeds the capacity of CDMOs which is also confirmed by the non-governmental organization The Good Food Institute (GFI) (Battle et al., 2024). In 2023, if all companies in the industry would produce at commercial scale, the market would require almost 600 million liters of capacity, around 900% more than the total global capacity available (Synonym, 2023), which also mirrors today's situations since nothing major has happened capacity- or demand-wise.

Rising concern for both the environment and animal welfare, points to the need for an industry transition, creating favorable circumstances for innovations such as precision fermentation of dairy proteins to emerge. Yet, the availability of commercial scale production capabilities are clearly lacking. Precision fermentation as a technology is comprehensively covered by existing biotechnology literature (Hettinga & Bijl, 2022; Deng et al., 2023; Terefe, 2022), but challenges associated with scaling up the infrastructure to specifically produce dairy proteins has been understudied. The purpose of this paper is to fill this gap by identifying these challenges and to analyze potential pathways to find out what could trigger a transition.

In accordance with the aim of this study, the following are the research questions:

1. What are the perceived major challenges with scaling up precision fermentation of dairy proteins to commercial scale?
2. What could potentially trigger an industry transition and can it be achieved with today's technology?

In the pursuit of seeking these answers, the next section will outline how recent literature describes the state of precision fermentation out of multiple perspectives. Using said literature combined with interviews with industry experts, ranging from business to academia, the analysis will be conducted using the multi-level perspective, which is described in section *3 Theoretical Framework: Multi Level Perspective*. The purpose of analyzing the findings through the lens of the multi-level framework (MLP) is to: (a) map out and define a complex industry system (b) to identify pathways from which today's system can transition into a future state.

2 Literature Review: The Current State of Precision Fermentation of Dairy Proteins

There is a substantial body of literature covering precision fermentation from a biotechnological perspective, including some on the specific niche of precision fermentation of dairy proteins and its main challenges (Deng et al., 2023; Hettinga & Bijl, 2022; Terefe, 2022). Deng et al. (2023) makes a broader assessment of the current economic viability of precision fermentation of dairy proteins, concluding that "[t]o achieve large-scale milk protein production, more efforts should be made [...]" (p.8) through substantial process improvements. However, system-level studies analyzing industry interdependencies, the broader infrastructure, and the major challenges related to scaling up precision fermentation of dairy proteins are lacking. Industry reports are currently more clearly articulating the need for industry-wide change in order to solve the issue of scaling up this niche, referencing a perceived need for available commercial production capabilities and infrastructure, financing across the entire value-chain, and multinational regulatory approval (Battle et al., 2024; Synonym, 2023).

Recent articles cover isolated areas within the system, such as consumer perception of precision fermented dairy proteins (Banovic & Grunert, 2023) and the current state of regulatory approvals and frameworks in regions such as the EU (Ronchetti et al., 2024). Research approaches that are more similar to the system-level analysis of this study, can be found in adjacent alternative protein transition literature, however, is absent for the coverage of the precision fermentation of dairy protein niche (Bulah et al., 2023; Moritz et al., 2023; Sonnino, 2023; Webb et al., 2020; Willett et al., 2019). The choice and implementation of a conceptual framework for analysis is further described in section *3 Theoretical Framework: Multi Level Perspective.*

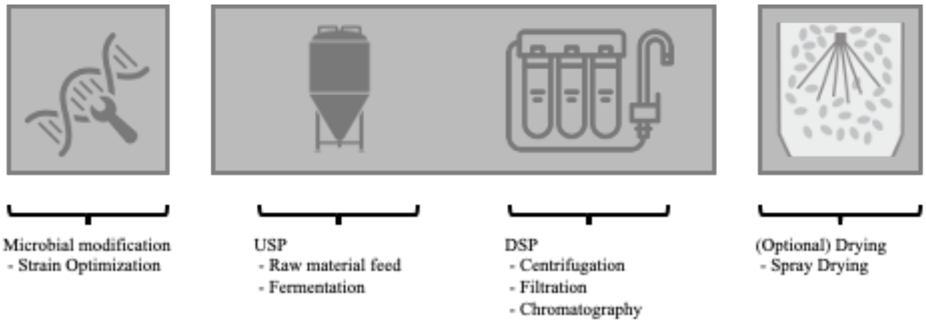
2.1 Technology Background: Scaling Up Challenges and Realities

To address the first research question, relating to challenges with scaling up, it is important to establish the technological background and legacy, state of the art, and emerging innovations within the niche that is studied. Precision fermentation is in many ways an established technology, having been used to produce insulin since the 1980s, enzymes, recombinant proteins for therapeutic use, and other pharmaceutical products (Liu et al., 2024; Bucca & Gerry, 2024). The technology is built on the concept of genetically modifying microbes (i.e., strains) so that it during fermentation secretes the target output product, here being a predetermined dairy protein such as whey, casein, or lactoferrin (Chai et al., 2022). Microbial fermentation uses organic substrates like sugars (glucose), starches, or other complex organic molecules as carbon sources for the feed (Geistlinger et al., 2024).

As is illustrated in Figure 1, the procurement process of precision fermentation consists of four main steps. First, the microbe is genetically modified, creating a microbial strain, which is now programmed to secrete the desired target protein. Second, the upstream process is initiated and consists of placing the microbe in a bioreactor (fermentor) where the fermentation process occurs. Third, the downstream process consists of filtration, extraction, and purification of the target protein followed by waste management. The fourth step, spray drying, is optional and used to isolate the product from the liquid it comes out in, turning it into a protein powder. (Stanbury et al., 2016)

Figure 1

The precision fermentation procurement process of dairy proteins (own drawing).



Selecting the right growth media and tuning the fermentation parameters, such as temperature and pH-value, are crucial for maximizing yields and maintaining product quality when scaling up (Boukid et al., 2023; Liu et al., 2024). The two key terms for productivity are titer and final recovery defined in Table 1.

Table 1

Terms used for describing production productivity.

Term	Explanation	Unit of Measurement
Titer	Titer refers to the output of target protein per liter volume in the fermentation tank, which is both a measure of the quality, or rather performance, of a strain and effectiveness of the upstream process.	g/l
Final Recovery	Final Recovery indicates how many grams of protein one ends up with, per liter of input (into the fermenter), after both the upstream process and downstream process.	g/l
Recovery Rate	To summarize, the difference between final recovery and titer, i.e., the recovery rate (%), indicates the effectiveness of the downstream processing.	%

Purification, which is done through downstream processing, remains a bottleneck for scaling up, as it is an intricate and expensive process (Boukid et al., 2023; Stanbury et al., 2016). The downstream process can consist of several different, or a mixture of multiple, tools and processes. Filtration and or centrifugation are common to use as initial processes, but to guarantee a highly purified product it is typical to utilize chromatography which is an expensive process that is difficult to optimize out of a cost perspective due to its reliance on costly consumables (Hoppenreijs et al., 2024; Stanbury et al., 2016). The challenge of scaling up can therefore be said to be both technical, as the fermentation process still produces yields that are not industrially at par with commercial requirements, and financial as the current downstream processing-methods are unfit for commodity dairy proteins, due to the pharmaceutical legacy from which the downstream processing-technologies stem and have been optimized for (Battle et al., 2024; Chai et al., 2022; Hoppenreijs et al., 2024).

2.1.1 Technology Outlook

The strain and upstream process developments are continuously improving the path to industrialization, i.e., scaling up, but few have, according to Deng et al. (2023), reached economically viable titer-levels. However, the downstream processing is considered to be the primary barrier to scaling up precision fermentation of dairy proteins. To address this, substitutions for chromatography have been researched and one potential candidate is polyphosphate salts, having shown comparable efficiency in lab-scale tests (Hoppenreijs et al., 2024). Since polyphosphates are already used in the food industry it does not require additional regulatory approval and can therefore more easily replace a current operational process such as chromatography (Hoppenreijs et al., 2024).

To significantly reduce the climate impact of the technology and as a means for reducing the raw material cost, another innovation with potential has emerged, called gas fermentation. Simply put, it is a specialized form of microbial fermentation, where the typical glucose substrate, is exchanged with a carbon-based gaseous substrate such as carbon dioxide (CO2), carbon monoxide (CO), or methane (CH4) to name a few (Marcellin et al., 2022). This could potentially both reduce the cost and carbon footprint of the precision fermented proteins (Marcellin et al., 2022).

Lastly, a key technological breakthrough which could change the cost dynamics significantly would be the successful commercial scale implementation of continuous fermentation and or continuous downstream processing (Hoppenreijs et al., 2024). The main challenges with these two processes, and even more so if fully integrated, is that the process is in many ways a closed system and therefore in a sense, a black box, so that if errors occur, it is more difficult to assess what went wrong and where, unless the sufficient sensor technology is implemented (Hoppenreijs et al., 2024). Recent literature considering the use of artificial intelligence in precision fermentation such as that from Hassoun et al. (2024), argues for it having great potential, but lacks providing concrete examples or implementation.

2.2 Product Background: Precision Fermented Dairy Proteins

Since the analysis of this study aims to address what could potentially trigger an industry transition, it is necessary to establish what the product really is and within which industry or segment it could potentially enter or even transform. While the technology stems from the pharmaceutical industry, precision fermented dairy proteins are made for the food industry and can be compared with, for example, traditional dairy proteins, meat proteins, and alternative proteins. Whether it is a substitute, complement, or completely distinct product from these segments has different implications to a potential industry transition. Thus, it is necessary to outline what the key characteristics of the product is before describing the system-level interdependencies, including considerations for regulations, consumer perception, and the financial infrastructure, among others, which are addressed in the upcoming sections 2.3 and 2.4.

Precision fermented dairy proteins are believed to have certain nutritional benefits that are superior compared to other alternative proteins (Battle et al., 2024; Liu et al., 2024). To assess potential health benefits and concerns of any food, particularly novel foods, it is necessary to consider details due to the inherent complexities related to human dietary needs. As a starting point, the broadly recognized recommended daily protein intake is around 56-80g for an average adult, however, it should surpass this level for elderly, pregnant women, and athletes (Deng et al., 2023; Willett et al., 2019). Proteins can be derived from a large range of sources such as meats, dairy, and plants and are of particular importance for the healthy development and growth of children (Li-Chan & Lacroix, 2018). Each type of protein has a different set of properties, such as taste, functionality, texture, solubility, and general nutritional value (Li-Chan & Lacroix, 2018). Specific dairy proteins provide many uniquely highly nutritional properties, like improving iron absorption and gut health which in the right dietary context distinguishes dairy proteins in favor of plant-, meat-, or fungi-derived alternatives (Battle et al., 2024; Liu et al., 2024). These statements regarding the high quality and certain superior nutritional benefits that dairy proteins provide are supported by a large body of literature (Drake et al., 2014).

In a recently published article by Liu et al. (2024), the current state of the industry of food proteins is covered, comparing conventional dairy proteins to precision fermentation of dairy proteins to plant-based substitutes to name a few. What is interesting with precision fermented dairy proteins is that "[b]ecause precision fermentation proteins in most cases have the same molecular structures as their natural equivalents, they have the same allergenicity, nutrition, and functionality as well." (Liu et al., 2024, p.12). Therefore, precision fermented dairy proteins share most of the benefits and drawbacks with the mimicked conventional animal-derived ones.

2.3 Industry Dynamics: Interdependencies Between Consumer Perception, Market Acceptance, Regulation, and Sustainability

Although various products derived from precision fermentation have been approved in the US by the Food and Drug Administration (FDA), the same products are currently prohibited in the EU (Liu et al., 2024). In order to ensure further development and breakthroughs regarding scaling up, it is necessary to accelerate legislative research to provide a legal framework about the regulatory approval process since legal norms and measures have not yet been established (Deng et al., 2023). While regulatory approval is vital to reach commercial scale, precision fermented dairy proteins are also facing major challenges regarding consumer perception and acceptance (Banovic & Grunert, 2023). Liu et al. (2024) findings support this statement, claiming that consumers usually have a negative mindset towards novel technologies, assuming they do not reach the expectations of natural, healthy, and tasty foods.

In the same way that precision fermented dairy proteins face consumer perception challenges today, genetically modified organisms (GMO) technology encountered similar resistance regarding safety, risks, labeling and regulation (Augustin et al., 2023). While the concept and initial GMO technologies emerged over two decades ago, it is still relevant to consider as there is an ongoing debate whether the end-product of precision fermentation is to be categorized as genetically modified or not, particularly in the EU region (Liu et al., 2024). Regardless of labeling, consumer perception is the driving force of market acceptance, and remains one of the major challenges for precision fermented dairy proteins (Liu et al., 2024). However, this issue could be addressed by moderating consumer perception through education and exposure to official information (Augustin et al., 2023), and additional research in this area for precision fermented dairy proteins.

If precision fermentation were to in part reduce or substitute animal derived dairy this would in effect lead to the reduced use of antibiotics, which in turn diminishes pandemic risk (Deng et al., 2023), and potentially reduce animal suffering. Apart from these ethical arguments in favor of the technology, precision fermentation of dairy proteins are assessed to become more environmentally friendly than many conventional animal-derived proteins (Banovic & Grunert, 2023; Terefe, 2022). Any comparison of climate impact is multifaceted, however precision fermented dairy proteins are expected to produce less greenhouse gas emissions and through substitution of conventionally derived dairy, increase biodiversity and reduce water usage (Deng et al., 2023; Liu et al., 2024). Estimates suggest that in comparison with animal-derived counterparts, dairy protein produced through precision fermentation appears to require ten times less water, five times less energy, and 100 times less land (Bucca & Gerry, 2024).

2.4 Financial Landscape: The Role of Funding Sources and the Financial Infrastructure of Precision Fermentation

To address the financial landscape of precision fermented dairy proteins, one must consider the incumbent traditional dairy industry's influence and role. Because, innovative production methods and novel technologies within the alternative dairy space are facing major financial challenges caused by an uneven playing field compared to the incumbent dairy actors (Vallone & Lambin, 2023). According to Vallone and Lambin (2023), the incumbents received 800 to 1,200 times more in public funding than novel competing technologies in the US and EU respectively, which begs the question of whether the price of dairy products are in fact 'fair market prices'.

In order to better understand the financial needs it is important to highlight that innovations are characterized by high uncertainty, having long lead times, and are said to be collective and cumulative (Mazzucato & Semieniuk, 2017). Therefore, it is vital to bridge the many financial gaps along the long journey from research and development (R&D) to commercialization through funding, addressing each stage along the innovation's trajectory. For this reason, the financial market consists of different financial actors equipped and specialized in different areas and stages. Each type of financial actor has specific objectives, financial leverage, and is appropriate at different timings, meaning that the sources of financing varies depending on the maturity of a technology (Corsatea et al., 2014). Precision fermentation of dairy protein has to date, almost exclusively been funded by private venture capital while at the same time having come up against a real financial unbridged gap, being the inability to fund commercial production manufacturing capabilities (Battle et al., 2024).

While the role of private venture capital can not be neglected in terms of successfully bringing many breakthrough innovations to life, evidence shows that many high-growth companies have sought and received public funding in some of the early stages along the innovation trajectory (Breznitz & Ornston, 2013). This firstly indicates that the limited interest from private funding does not necessarily imply that innovative companies and business models lack market fit but is rather an indicator of risk or misalignment with private funding strategies (Corsatea et al., 2014). Secondly, public funding does not adhere to the same corporate governance requirements of for example having to report quarterly returns which potentially leads to shortsightedness and the practice of short-termism (Mazzucato & Semieniuk, 2017).

Examples of state-funded success-cases range from the emergence of renewable energy sources (Corsatea et al., 2014) to tech companies (Mazzucato & Semieniuk, 2017) which at a first glance might appear distant from precision fermentation of dairy proteins but in fact, share many industry dynamics and structural similarities. Consider for example innovations in renewable energy that received mainly public funding for the most capital-intensive and high-risk areas in order to compete with incumbent fossil fuels at its emergence (Mazzucato & Semieniuk, 2017). While public funding and public subsidies could play a crucial role for the successful scaling up of precision fermentation of dairy protein, it should be emphasized that private funding combined with consumer demand were the key success factors for the plant-based protein transition to occur (Bulah et al., 2023). The transition can be argued to have occurred in 2017, mainly due to the involvement of large incumbent food corporations (e.g., Nestlé) that started to engage through acquisitions and investments, motivated by significantly noticeable consumer demand (Bulah et al., 2023).

3 Theoretical Framework: Multi Level Perspective

The MLP is applied to identify, highlight, and analyze the interplay between the so called levels, being niche, regime, and landscape. It is used to describe socio-technical systems and potential industry transitions (Geels, 2002; Geels, 2011). A key aspect of the framework is that it views the system through an ex-ante ex-post lens, assuming that a system is dynamic, not static. The MLP framework considers three layers of perspectives from landscape to regime to niche. This analysis, inspired by prior MLP analyzes, considers one niche as the main focal point, here being precision fermentation of dairy proteins and its interactions and role within a larger system. To summarize, the landscape can put destabilizing pressures on the regime, the regime is pushed and pulled from both the landscape and niche, while the niche in the end acts as the proxy for illustrating how successful innovations or clusters of innovations and technologies can enable industrial transformations or represent cases of unsuccessfully impacting an existing regime.

Applications of the MLP in comparable niches has been done to study for example the rise of plant-based meats and milks in the US and Europe (Bulah et al., 2023; Tziva et al., 2019; Mylan et al., 2019; Hassoun et al., 2022). Bulah et al. (2023) investigates the plant-based industry transition which in its current known form began in 2006 with the initial market entries in 2009 up until today in the US, UK, and Netherlands. Similarly, Elzen et al. (2011) studies the development and transition of animal welfare in pig husbandry over a specific time period. Additionally, Mylan et al. also applies the MLP framework to study food sector transitions, in their case the societal embeddings of plant-based milks. Bulah et al. (2023), Elzen et al. (2011), and Mylan et al. (2019) apply the MLP framework in varying degrees but uniformly to dissect and highlight interdependencies between multiple levels. This approach appears also in the previously mentioned articles indicating that a suitable initial part of the analysis should be structured so as to highlight the interdependent nature of the system and underscore specific interplay within and between the niche, regime, and landscape.

There have been a set of criticisms directed at the MLP framework, seven of which are addressed by Frank Geels (2011), the founder of the MLP framework, in the article T*he Multi-Level Perspective on Sustainability Transitions: Responses to Seven Criticisms*. One of the main critiques of the MLP is that it is too general and open to interpretation of how to implement it, especially when defining what the parameters of a system or regime should entail (Geels & Schot, 2007; Geels 2011). To address this concern, Geels have provided multiple examples of historical transition case analyzes, wherein the framework is applied and described alongside each case analysis (Geels, 2001; Geels, 2009; Geels & Schot, 2007).

To ensure the drawing of boundaries align with how the framework is intended to be used and that is suitable for the field of research this thesis addresses, inspiration will be drawn for construction and structuring of the system by comparing with similar articles in the field which is described in the next paragraph. Another main criticism of the framework is that the “[...] approach places too much emphasis on technological niches as the principal locus for regime change” (Geels & Schot, 2007, p. 400). To address this, Geels and Schot (2007) propose an analysis structure through which one can avoid this risk by more explicitly and concretely considering the regime typology which consists of two primary factors, timing and nature, conceptualized as transition pathways. Said pathways, P1-P4 are the ‘transformation pathway’

(P1), ‘de-alignment and re-alignment’ pathway (P2), ‘technological substitution’ pathway (P3), and ‘reconfiguration pathway’ (P4). A fifth pathway, P5, describes the scenario wherein the most likely pathway is more like a journey from P4 to P1. Both the MLP in general, and pathway analysis more specifically, has commonly been used to describe and analyze past, already completed industry transitions, but few have applied it to study ongoing or emerging niches.

P1 or the ‘transformation pathway’ assumes there are moderate landscape pressures on the regime, creating a situation wherein the regime experiences the need for change. However, at the timing of pressure outbreak, the potential niche or niches available are underdeveloped, thus, not mature enough to break into the created opening in the regime to completely transform the system. Thus, the regime actors will pivot by “[...] modifying the direction of development paths and innovation activities.” (Geels & Schot, 2007, p.406) leading to a seemingly more incremental or gradual system change, and altering of the regime playing field. In contrast, the P3, ‘technological substitution’, pathway describes a scenario wherein a landscape factor completely shocks a system, rather than just moderately pressuring it, leading to an industry transition or rather, transformation, where the leading niche is mature enough at the timing of this event to substitute existing regime solutions, praxis, rules, or actors (Geels & Schot, 2007).

P2, the ‘de-alignment and re-alignment’ pathway, on the other hand can in short be summarized to be a pathway which shares some characteristics with both P1 and P3. It assumes there has been a significant landscape pressure event or even shock, but wherein the niche is not sufficiently developed at the timing or unfolding of said shock. The P2 pathway outlines how a regime, unequipped for responding sufficiently to the sudden landscape pressures breaks down, creates a vacuum, and readjusts or rather, de-aligns and then re-aligns. In this scenario, multiple niches play a role in filling the created gap and are thus instrumental in the re-alignment phase, rebuilding and redefining the regime (Geels & Schot, 2007,). Lastly, P4, the ‘reconfiguration pathway’ pathway, describes how niches develop to solve isolated or local problems in a regime or system, but in so doing it “[...] subsequently trigger further adjustments in the basic architecture of the regime.” (Geels & Schot, 2007, p.411). After a while, enough seemingly incremental adjustments occur so that the architecture of a regime is now so different from its ex ante state that it can only be concluded that an industry transition has occurred.

Lastly, more recent literature has pointed to the lacking consideration for the argued non-linear nature of transitions in the four pathways just described. What is meant by this is that transitions are not inevitably occurring in a linear, unstoppable fashion based on the exogenous landscape pressure and timing and nature of the regime at that time. Instead, what for example Geels et al. (2016) puts forth is that, it is natural to assume a certain dynamic back-and-forth throughout a transition based on internal regime actor interplay. Shifting forms for collaboration, interest alignment, or partnership disengagements are just a few scenarios, internal to the regime, that can unfold throughout a transition. Geels et al. (2016) argues that a further conceptual extension of the four pathways is to incorporate the factor of enactment within the regime. This is done to reformulate specifically the technological substitution and transformation pathways to consider this factor. In short, it highlight how this consideration provides grounds how a system likely can shift from one pathway to another as a consequence of enactment changes.

3.1 Potential Future Transition Pathways

Moritz et al. (2023) have effectively applied the MLP framework in a predictive manner on an existing and current developing niche within the food and alternative protein sector, by constructing definitions of three potential pathways forward, anchored in the empirical interview results and derived themes. These are then compared and contrasted with Geels original transition pathways, P1-P4, which suggest four distinctive patterns in which transitions occur. The first inductively constructed pathway by Moritz et al. (2023), the 'technocratic stagnation' pathway, "[...] identifies major obstacles for a transition [of a] system" (p.7). This pathway highlights the regime's lacking willingness to adopt or implement the niche being studied, assessing a favoritism in the current regime for incumbent solutions or other established innovations, meaning more mature alternative niches (ibid). This pathway determines that current regime actors advocate the status quo or even fail to understand and adapt to increasing landscape pressures.

In contrast, the second pathway, 'promising circumstances', instead describes a system that provides positive external conditions for the emerging niche with enough regime alignment to create a setting that is favorable to the success of a niche, provided it takes advantage of the momentum and matures in alignment with the regime actors (Moritz et al., 2023). Lastly, Moritz et al. (2023) introduces the concept of a 'rapid advancement' pathway which "[...] is characterised by the possibility of radical change" (p. 8) which, driven by a significant landscape pressure, pushes for a system wide transformation, beyond isolated or scattered industry transitions within a system. With sufficient understanding of specific emerging solutions and being able to assess the likelihood of its potential for changing the niche's maturity in a major way, one can through imagining for example, a sudden technological breakthrough, make a predictive description of how an industry transition could unfold in a 'rapid advancement' pathway trajectory.

Similar to the way Moritz et al. (2023) have operationalized the MLP framework, in the analysis section of this paper, three potential future pathways are derived inductively from the results. However, the methodology for constructing these three pathways is slightly different in this study. The point of departure is that the pathways are tailored versions of those constructed by Moritz et al. (2023). Lastly, comparisons with Geels four pathways (P1-P4) will also be made to: (a) align with more commonly used conceptual MLP tools, and (b) to establish a link to the more comprehensive body of literature on system-level analysis and utilizations of the MLP which covers past occurred industry transitions. Before outlining potential future transition pathways, the analysis section will start by mapping the system, creating somewhat of a snapshot of how it currently is in its ex-ante state. In the second section of the analysis, the potential pathway trajectories into an unknown ex-post state are described to address the second research question, assessing what could potentially trigger an industry transition. For further clarification about how the transition pathways have been operationalized, see Appendix A.

4 Methodology

The topic of challenges related to scaling up precision fermentation of dairy proteins is born out of two things. Firstly, through the very first meetings with the commissioner, a food tech startup. This organization pointed to the evident gap in an industry wide understanding of what are the root causes or rather, the main hurdles, for scaling up precision fermentation of dairy proteins on a system-level. Secondly, after an initial literature review, it became clear that there is a gap in the literature on precision fermentation of dairy proteins. This paper therefore aims to both fill the current academic knowledge gap on the topic as well as to provide a birds-eye analysis for the industry to highlight system-level challenges. The research questions are as a consequence developed from a starting in the unknown. According to Saunders et al. (2016), the exploratory study approach is particularly useful when the precise nature of a problem or phenomenon is uncertain. Given the ambiguity of the challenges related to scaling up precision fermentation of dairy proteins, an exploratory research approach was found to be the most suitable in the pursuit of finding answers to the research questions. This approach is in principle inductive, which in this context means that the most prominent source of empirical data was conducted interviews. These interviews identified topics and interdependencies between the most important actors and dynamics in the industry.

4.1 Methodological Journey

The inductive approach was utilized by conducting semi-structured interviews, producing themes and topics for further analysis. A potential risk to encounter in these cases is that one can end up with an overload of information, especially when trying to describe a non-defined or unknown gap. To address this risk, a 'problem and solution seeking' methodology was applied to focus the research and to avoid investigating redundant sidetracks. Throughout the empirical data gathering, different examples of what the major challenge of scaling up precision fermentation is. To tease out what was most important, a *problem-seeking* approach was taken to identify the root problem or root cause of said challenge. At this point, the focus shifted and a 'solution seeking' mindset was instead applied in order to find the corresponding solution. Once a promising solution was found to the root problem, the focus was shifted back to problem seeking by asking "Why has this not been done yet?". Due to time constraints and in order to maximize efficiency, this proved to be a simple, yet helpful tool to in the end identify the most urgent challenges, their root causes, and potential solutions for said problems. This iterative process finally produced the answers to both of the research questions.

In order to provide a comprehensive analysis and to systematically find the answers to the research questions, a central part of this research was to find the most well-suited theoretical framework and the best implementation of it. A considerable amount of time has been devoted to study similar research articles and to compare different frameworks, as well as different implementations of the same frameworks. Through the support of discussions with industry transition researchers (A1 and A2, see Table 2), it was in the end concluded that the multi-level perspective framework best aligns with the purpose of this research and fit well with the type of data collected. A more narrowly focused framework such as the Technological Innovation Systems (TIS), could exclude important nuances in the broader system which in a complex and intertwined system such as this, are more vital to highlight than running the risk of overinclusiveness.

There appears to be a gap in the transition literature in regards to utilizing landscape factors when applying the MLP which differentiates this study from similar research. Hopefully the inclusion of landscape factors can contribute to the broader academic body of literature interpreting and implementing the MLP. The analysis of this report has been guided by an article by Moritz et al. (2023) who studied potential future transition pathways for cultured meat in Finland and Germany. Adopting this approach enabled the mapping of the system as it currently is, but also to make claims about which pathway appears most realistic for the future, based on the interviewees' perceptions. The use of MLP to make claims about potential future transitions is also lacking to a great extent, which is an area of academia for which this study hopefully also can contribute.

4.2 Empirical Data Collection: Interviews

The primary data has been collected through open-ended interviews with a diverse range of industry and academic experts. While the interviewees are based in Singapore, the US, and Europe, which are the regions of highest potential to be market frontrunners (as well as Israel and Australia) in precision fermentation of dairy proteins (Battle et al., 2024), the insights, analysis, and findings from this paper are universally applicable. The interviews were semi-structured, meaning that a set of open-ended questions were prepared to lead the discussion to ensure the coverage of certain topics that hopefully would provide the most useful information to the study. In total, 20 interviews were conducted between February 2024 and May 2024, presented in Table 2.

Table 2

List of interviewees.

Interviewee	Role	Type of Organization
E1	*Former Business Developer*	Foodtech (Precision Fermentation)
E2	*VP Lab Planning and Operations*	Large Corporate (Real Estate Development)
E3	*COO*	Manufacturer (CDMO)
E4	*Associate Director (Investments)*	Manufacturer (F- CDMO)
E5	*Innovation Manager*	Large Corporate (Food Processing)
E6	*CEO*	Large Corporate (Dairy)
E7	*Deep Tech Analyst*	Strategy Consulting Firm
E8	*Investor and Advisor in Foodtech*	Advisor to Institutional Investors
E9	*CEO*	Manufacturer (F-CDMO)
E10	*Business Director*	Manufacturer (F-CDMO)
E11	*General Manager (Advanced Protein)*	Large Corporate (Precision Fermentation)
E12	*Head of Manufacturing*	Foodtech (Precision Fermentation)
E13	*Researcher*	Foodtech (Precision Fermentation)
E14	*Vice President Biotech*	Manufacturer (CDMO)
E15	*Principal Investigator*	Research Institute (NGO)
E16	*CEO*	Manufacturer (F-CDMO)
E17	*Product Development Manager*	Large Corporate (Food Ingredients)
E18	*Lead Scientist Precision Fermentation*	Research Institute (NGO)
A1	*PhD Candidate*	University
A2	*Professor*	University

The focus during these interviews was to gain a deep understanding of the different and most crucial parts of the precision fermentation regime and infrastructure, as well as the interdependencies within. This was done by interviewing industry experts (denoted with E) active in the regime. With each open-ended question asked, useful information was gained that helped visualize the landscape of the industry, as well as understanding interdependencies between different industry actors. The small, yet diverse, sample of industry experts served as guides, offering glimpses into unexplored areas. Indeed, the approach to interviewing industry experts with open-ended questions mirrored the essence of exploratory research (Saunders et al., 2016). It was through this process a comprehensive overview of the challenges and possible solutions for scaling up precision fermentation of dairy protein was developed. The interviewees were typically in C-suite or director level positions or in other capacities were experienced experts with decision-making power and or strategic focused job descriptions. In parallel with industry experts, interviews were conducted with academics (denoted with A) researching industry transitions. Since they did not represent an organization with direct or indirect financial dependency to the development of precision fermentation of dairy proteins, these interviews provided an unbiased view on the topic.

4.3 Organizing Collected Data

One important activity was to extract the most useful information from the interviews. A systematic approach was used to identify key themes and topics that each interview covered. In total, 5 different themes were identified; Technology & Production, Infrastructure, Financial Landscape, Industry Dynamics, and Sustainability, of which a majority were discussed in multiple interviews. These themes served as the foundation of the results and analysis, used as subcategories to present the results from the interviews. Table 3 was used to build the structure of the analysis. By structuring the analysis around these themes, it became clear what the major challenges are for scaling up precision fermentation of dairy proteins.

Table 3

List of interviews and covered topics.

Interviewee	Role	Type of Organization	Topics Covered
E1	*Former Business Developer*	Foodtech (Precision Fermentation)	Technology & Production Infrastructure Financial Landscape
E2	*VP Lab Planning and Operations*	Large Corporate (Real Estate Development)	Technology & Production Infrastructure
E3	*COO*	Manufacturer (CDMO)	Technology & Production Financial Landscape Industry Dynamics Sustainability
E4	*Associate Director (Investments)*	Manufacturer (F- CDMO)	Technology & Production Infrastructure Financial Landscape Industry Dynamics
E5	*Innovation Manager*	Large Corporate (Food Processing)	Technology & Production Financial Landscape Industry Dynamics Sustainability
E6	*CEO*	Large Corporate (Dairy)	Technology & Production Industry Dynamics Sustainability
E7	*Deep Tech Analyst*	Strategy Consulting Firm	Technology & Production Infrastructure Financial Landscape Industry Dynamics
E8	*Investor and Advisor in Foodtech*	Advisor to Institutional Investors	Financial Landscape Industry Dynamics Sustainability
E9	*CEO*	Manufacturer (F-CDMO)	Technology & Production Infrastructure Financial Landscape Industry Dynamics Sustainability
E10	*Business Director*	Manufacturer (F-CDMO)	Technology & Production Infrastructure Financial Landscape Industry Dynamics Sustainability
E11	*General Manager (Advanced Protein)*	Large Corporate (Precision Fermentation)	Technology & Production Infrastructure

			Financial Landscape Industry Dynamics
E12	*Head of Manufacturing*	Foodtech (Precision Fermentation)	Technology & Production Infrastructure Financial Landscape Industry Dynamics Sustainability
E13	*Researcher*	Foodtech (Precision Fermentation)	Technology & Production Infrastructure Financial Landscape
E14	*Vice President Biotech*	Manufacturer (CDMO)	Technology & Production Financial Landscape Industry Dynamics
E15	*Principal Investigator*	Research Institute (NGO)	Technology & Production Industry Dynamics
E16	*CEO*	Manufacturer (F-CDMO)	Technology & Production Infrastructure Financial Landscape Industry Dynamics Sustainability
E17	*Product Development Manager*	Large Corporate (Food Ingredients)	Financial Landscape Industry Dynamics
E18	*Lead Scientist Precision Fermentation*	Research Institute (NGO)	Technology & Production Financial Landscape Industry Dynamics
A1	*PhD Candidate*	University	Financial Landscape Protein Transition *Transition studies**
A2	*Professor*	University	*Transition studies**

Note: * 'Transition studies' was a topic of discussion with the two academic interviewees. This topic was not included in the analysis but guided the choice of conceptual framework.

5 Results

This section is outlined to summarize the insights and results from the conducted interviews, organized under the core recurring themes being *Technology and Production*, *Infrastructure, Financial Landscape, Industry Dynamics,* and *Sustainability.* Occasionally, specific points of reasoning are complemented with other sources such as literature and industry reports. In section 6 the presented results will be mapped onto the Multi Level Perspective Framework to further clarify and provide an analysis of the results.

5.1 Technology & Production

According to E13, it is a complex task going from a lab-environment to produce at commercial scale. Most of these challenges are related to the downstream processing (E11, E13, and E16), which is required to be developed and improved in order to be feasible at larger scale, particularly out of a cost perspective (E11 and E16). The current state of the art downstream processing equipment requires that lab, pilot and commercial environments match each other significantly to reduce the risks and uncertainties when scaling, for example through being consistent in the use of filter types and ratios (E13 and E16). Regardless of which protein is produced, specific production methodologies, or types of hardware being used, each production line is highly process specific (E1 and E13). This means that only if the ratios, component sizes, and inputs (like raw material, water etc) are exactly the same, two production lines are in fact potentially to be considered as 'identical' (E13). Consequently there is a constant switching cost related to any deviation going from one production line to another non-identical one. The process will also infer uncertainty which can lead to opportunity costs ranging from time and capital to production failures and product discrepancies (E13).

The description provided above paints a picture of a highly sensitive production process with no margin for error which to a certain extent is true. However, it should be noted that if most, or preferably all, variables are kept constant, scaling up is far from unpredictable. On the contrary, there are many benefits with testing and optimizing on lab- and pilot-scale since the translation of insights and process improvements are high as long as most variables are consistent. This highlights one commonly overlooked problem with the reliance on CDMOs, being the only currently viable option for outsourced, or actually any, commercial production today, is that they are hardware and competence generalists when it comes to pharmaceutical manufacturing but lack most general hardware equipment and infrastructure optimized for dairy protein production (E13 and E16).

As a consequence of the technology legacy within the pharmaceutical industry, current CDMOs are catering for said industry (E1, E3, E4, E5, E6, E9, E10, E12, and E13). For that reason, the typical precision fermentation production process is sequential (E9 and E13). Sequential production refers to the batch-wise approach to protein manufacturing (E9). This enables flexibility in terms of both low-volume or infrequent production and the ability to switch from one product to another on any given production line. In addition, the sequential process is easy to control as each step can be monitored and optimized, in part independently, from the previous or later stage. However, the extended combined production time increases the risk of contamination (E1 and E9) and incurs higher costs. In response to this, new emerging technologies are developed to enable a continuous manufacturing process, which may be more suitable for dairy protein production (E7, E9, E16 and E18).

Emerging innovations or expected technologies are continuous upstream processing, continuous downstream processing, implementing artificial intelligence (AI) for process optimization, and optimizing or constructing new hardware according to recent literature. The first two, continuous upstream processing and downstream processing, are estimated to offer a promise of significant reductions of OPEX (E9) and decrease CAPEX by a factor of ten (E7). Considering that continuous production makes monitoring and intervening at any step along the production process either difficult or impossible, considering the black box nature of the process, it is suggested that additional sensors supported by AI-powered monitoring and optimization systems will reduce the risk of failure, and optimize the production process significantly and thus reducing OPEX (E7). However, it is important to point out that today there are no proven cases to either confirm or dispute these hypotheses within any precision fermentation-related field as there is a lack of case study literature for AI and its influence on precision fermentation processes (E7). Lastly, E15 mentioned that in the pursuit of improving the sustainability impact, one should investigate the possibility of excluding water in the upstream processing phase which has been done and proven already on a lab and research scale.

Although today's precision fermentation technology, specifically the hardware, has not changed or been innovated for the last three decades (E7 and E9), it appears that the technology is still sufficient in terms of potential productivity to tackle the challenge of scaling up. According to industry experts with backgrounds ranging from foodtech startups (E1), precision fermentation production facility infrastructure builders (E4 and E9), to traditional multinational engineering corporations (E5, E10, and E11), today's technology is sufficient to scale up production capacity to commercial scale. Note that the organization of E5 does not currently have any known vested interests in the technology of precision fermentation, yet have made a similar technological assessment. However, E5 underscored that in order for precision fermentation of dairy proteins to realize its full potential it must, on a factory-level, adopt a circular business model by reusing inputs or generating additional outputs. The adoption of a circular production process in precision fermentation of dairy proteins will also strengthen the business model, highlighting that it will play a critical part in the effort of attracting capital needed to scale up is underscored by several investors and experts (E5, E6, and E12).

Although many insist on the importance of a circular factory to make precision fermentation of dairy protein feasible, from both a sustainability and economical standpoint, there are no proven or at least limited attempts having been made to practically test this hypothesis and thereby assess the concrete potential of a circular factory (E14). E14 emphasized that in order to do this, it is necessary to conduct comprehensive real life cycle analysis of the product, which is considered to be a very complex exercise. E15 supported this statement, and argued that the industry as a whole is not ready for circular factories, pointing out that before optimizing the production process, the current priority is to optimize and enhance the products, namely precision fermented dairy proteins, themselves. Advancing this argument further, E16 was determined that in the near future, it will not be possible to circularly operate precision fermentation facilities, and particularly not for dairy proteins considering today's level of maturity. This is primarily due to the fact that there are no other low-hanging fruit applications for the biomass. Currently it can neither be reused as raw material input into the same process, nor proved as an additional revenue stream since there are no established markets for valorised non-target-protein biomass (E16). However, suggested output products such as animal feed has been investigated and has potential according to E9. It should however be pointed out that according to E11, valorisation of the side streams created by the purification of dairy proteins is not as easy to do as established literature says. E11 explains that the most promising results will be yielded from designing a strain to either secrete more than one target protein, or to early on, examine and determine if a strain is producing multiple proteins with commercial potential in the very early stages of strain development, to optimize the productivity for this protein alongside the main target protein. Lastly, it should be pointed out that this approach has a 'two-outputs for the input of one' effect, yet will require for the secondary protein that has been identified to go through the same rigorous regulatory approval process as for the main target protein, even if it goes into animal feed (E9 and E11).

5.2 Infrastructure

The current state of the precision fermentation infrastructure for food proteins is fragmented. Consider a spectrum ranging from lab-scale testing facilities to pilot scale, to a small to medium commercial scale, to finally, large scale commercial operating factory. Mapping out the infrastructure landscape and dynamics requires consideration for a multitude of factors. Today, lab- and pilot scale facilities exist and operate to a fairly large extent (E16). Currently, the only actors occupying the small to medium scale space are CDMOs (E4 and E9). The large scale commercial plants, referring to facilities with millions of liters of fermentation capacity, do not exist but have great promise for both economies of scale, but perhaps more acutely are actually needed to start bridging the perceived supply gap (E4). The infrastructure gap lies in the middle of the medium to large scale where there is little or no infrastructure in place, and there is a significant threshold to overcome in order to build new infrastructure.

According to E12, a common question among investors and stakeholders is; *Is there a way to prove commercial viability in a 'cheap' way before making a full-size investment?*According to E2, this results in a fundamental problem as there are more or less no landlords equipped to or existing production sites to repurpose as medium scale commercial precision fermentation production sites. In addition, there is a lack of experience and thus lack of willingness to invest in medium scale precision fermentation production sites within the existing pool of landlords in the United States (E2). Conversely, there are no clear solutions for how to repurpose such a site, if the precision fermentation-production tenant were to default (E2). This means that built-in structural components such as space for fermenters, indoor roads, cranes, waste management systems, and air filtration systems to name a few, need to be fully torn down and remade or the site is 'overdimensioned' for other future use cases (E2).

To clarify the issue, E2 provided an example of a medium sized site: A site in the small- to medium scale for precision fermentation production requires high ceilings, wide buildings and easy-access everywhere in addition to sufficient air filtration systems. The buildings of the appropriate size in terms of width and height are today commonly used for temporary warehousing or packaging. Currently, the demand for more sophisticated facilities of said size is non-existent, thus requiring a landlord, when the lease expires or in the case where the tenant is unable to pay rent and defaults, to completely redo and repurpose the building and site for completely different purposes which requires significant investment. According to E2, this creates one of two scenarios, or a combination of the two. Either the landlord requires a large upfront direct investment into the facility of the tenant in question, or rent is significantly higher to mitigate the landlord's risk. The most common scenario is, however, a combination of a significant upfront investment paired with higher-than-wished-for rent. It is worth to again underscore the need of larger scale production capacity to really prove or disprove the commercial scalability of precision fermentation of dairy proteins (E16). But for this, one can today only rely on CDMOs. Therefore, today, there are really only three possible options for operationalizing commercial production (E12), summarized in Table 4.

Table 4

Methods of operationalizing commercial production.

Method	Ownership	Technology Status
Greenfield	Insource, co-owned, or outsourced	Current or new technology
Brownfield	Insource, co-owned, or outsourced	Current or new technology
CDMO	Outsourced	Current technology and facilities tailored for pharmaceutical grade production

Greenfield refers to building a new manufacturing site with the latest equipment for the specific production of precision fermentation of dairy proteins, or sometimes even more specifically, for the specific production of a single target dairy protein. In order to scale up precision fermentation of dairy proteins, most industry experts agree that greenfield is the best way forward (E1, E4, E5, E7, E9, E12, and E13).

Brownfield production can be done in different ways. For the purposes of precision fermented dairy proteins it is useful to consider the following levels of brownfield levels. The most complex brownfield model entails repurposing an entire plant, like transforming a precision fermentation plant made for enzyme production being one of the more theoretically feasible options and converting a beer or wine brewery being a more complex and difficult endeavor (Leman et al., 2023; E4 and E5). A more feasible brownfield model with less complexity is that of repurposing parts of the equipment such as drainage solutions, fermenters when possible, and standardized downstream processing equipment like centrifuges or microfilters (Leman et al., 2023; Stanbury et al., 2016). Lastly, the least complex and most basic model for brownfield is that of merely repurposing a production site. This can entail repurposing a factory site ranging from an 'empty shell' of the correct dimensions, to containing correct water and electricity wiring, to being fully equipped with correct inside road infrastructure, cranes, and shipping station for handling inbound raw materials and outbound product shipments (E2 and E3).

Technologically there are many challenges and uncertainties related to higher levels of repurposing the parts and equipment in levels 3 and 2 (E13) but for level 1 there seems to be a higher degree of certainty as to the feasibility (E3 and E4). One of the main arguments other than the potential cost-saving for a brownfield site is time-to-operationalization. However, in the US the time to get the proper permitting for the purpose of operating a precision fermentation production site of food proteins is apparently one of the more time-consuming and non-differing bottlenecks which kills said argument (E4). Furthermore, there is an infrequent and somewhat random supply and scarcity among all, but especially the higher level brownfields, as a consequence of the fact that brownfield requires an existing plant to be made redundant or 'open for sale'. This leads to an uncertain waiting and scouting period (E4 and E12) before one can even do the necessary in-depth assessment of a site's suitability which even further prolongs the lead time to production. Considering the uncertainties related to higher brownfield levels and the consensus among industry experts about the feasibility of level 1, it is natural to conclude that this level is what one should seek out if aiming to utilize a brownfield approach.

CDMO-production is the last option and currently, only viable one for commercial production of precision fermented dairy proteins (E12, E13, and E16). As has already been established, today's CDMOs are typically optimized for pharmaceutical purposes, which causes a mismatch based on the requirements of dairy protein production (E2, E3, E4, E13, and E16). E3 emphasized that current CDMOs often surpass the needs of dairy protein production, resulting in unnecessarily expensive processes and costs. These costs are partly attributed to specific production requirements, such as stringent air quality standards, and partly to the operational practices of these production facilities (E5, E12, and E13). While supporting the statement that current CDMOs have excessively high standards for other than pharmaceutical purposes, E16 additionally claimed they lack important knowledge that is needed to successfully run precision fermentation production optimized for dairy protein. Among other things, this knowledge gap is related to the selection of filtering methods in the downstream processing as well as the selection of raw materials (E16).

The current and total capacity of CDMOs constitute only a small fraction of the demand and in particular the expected demand for precision fermentation of proteins (E11), making the market heavily unbalanced (Synonym, 2023). Some claim the supply-demand imbalance is even more skewed than reported based on the analysis that less than 10% of the available capacity among CDMOs is actually equipped for the purpose of food (including dairy) proteins (E9).

In light of these challenges, partnering with established CDMOs offers a pragmatic solution for companies seeking to enter the precision fermentation space. By leveraging the capabilities of CDMOs, companies can avoid the logistical and financial burdens associated with building their own production plants, while still gaining access to the market for precision-fermented dairy proteins (E1, E12, and E13). However, once a company has entered the space of precision fermentation and successfully developed a product at lab scale, many of the challenges for scaling up the production even with the support and experience of current CDMOs remain (E1, E4, E9, E12, E13, and E16).

While still in an emerging stage and not operationable, there are a few actors that have embraced the concept of greenfield and are currently building new production facilities optimized for food ingredients, some of which even specifically for dairy proteins (E9). As these actors will operate (business-wise) just like any other CDMO but distinctly differentiates in terms of purpose (being optimized for food ingredients) they are referred to as food grade contract development manufacturing organizations (F-CDMOs).

5.3 Financial Landscape

As previously mentioned, precision fermentation is not a novel production method in the market. Since the FDA over four decades ago approved insulin, the first biosynthetic drug, the market of precision fermentation-produced products has reached a size of USD 100 billion (Bobier et al., 2024). However, the application of precision fermentation to dairy protein is fairly novel, and considered to be an innovation.

While pharmaceuticals and dairy proteins have multiple things in common and that both are serving the consumer market, they strictly separate from each other from a financial point of view. The market dynamics of pharmaceuticals is based on low volumes and high margins which is the opposite of traditional dairy proteins which are part of the food market wherein the business model is characterized by high volumes and low margins (E11; Bobier et al., 2024). Given that current CDMOs are optimized for the production of pharmaceuticals and consequently designed around the business model of low volumes and high margins, there is clearly a business model-mismatch between manufacturing incumbents (CDMOs) and dairy protein production (E3, E4, E11, and E16).

That current utilization of precision fermentation to produce dairy protein is expensive, does not necessarily imply that precision fermentation itself is a production method related to high costs. In fact, it is emphasized by Bobier et al. (2024) that the construction of more efficient production facilities, combined with more optimized strains, could lead to achieving price parity or even surpass the production costs of incumbent methods. Given that price parity will be reached, the market size for biomanufactured food ingredients (of which precision fermented food ingredients constitutes a substantial part) have the potential to reach USD 100 billion by the year of 2040 according to Bobier et al. (2024). Nonetheless, the utilization of precision fermentation to produce dairy protein or any food ingredients remain expensive in comparison to established methods.

It should further be noted that price parity, in particular regarding dairy proteins, is argued to be unattainable (E11 and E16). Although the organizations of E11 and E16 would gain financially by an increased demand for precision fermented dairy proteins, they firmly believe that price parity will never be reached due to the low production costs related to incumbent animal-derived methods. However, E11 argued that the pursuit of reaching price parity might be flawed and may in fact not constitute a hindrance for scaling up. To concretize, in comparison to animal-derived products, consumers pay a premium of 30-100% for end-products derived from plant-based protein (E11 and E17), which famously lack many quality and nutritional aspects of which dairy proteins have (E11 and E16). Yet, due to the competition with animal-derived products, the majority of dairy proteins are dismissed as potential products for precision fermentation at larger scale because of the still very low market price that dairy proteins are set to (E11 and E16). Therefore, seen from a financial perspective, many experts emphasized that certain dairy proteins are more promising than others due to their high-value character and use cases, such as lactoferrin, since they more closely adhere to the high value, low volume price dynamic typical of precision fermented products (E5, E6, E11, and E16).

Considering that viable production opportunities are unnecessarily expensive, and the large estimate for the market size in 2040, there is evidently a lucrative opportunity for growth. One might assume that significant commercialization efforts are made by investments being directed toward research and development of new production facilities optimized for high-value dairy products. However, after interviewing several industry experts, it became evident that this is not the case. Especially does it not hold in terms of attempts to commercialize and build large scale production facilities (E4, E5 and E9). Even though it appears attractive to get involved in precision fermentation to produce high-value dairy proteins, E7 said that there is still some uncertainty regarding the feasibility from a financial perspective. While concerns about the financial feasibility are at current scale (lab and pilot), some of the interviewees underscored the importance of noting that the potential of the technology lies in extreme economies of scale since CAPEX do not linearly increase with the size of the production facility (E4, E7, E9 and E18). Furthermore, according to E9, a facility at commercial scale does not require a substantially larger amount of employees than a lab/pilot facility does.

On one hand, there is a strong belief in the potential of utilizing precision fermentation to produce dairy proteins (E5), however on the other hand, many investors hesitate to invest due to the lack of involvement of large corporates, since they are considered to be of greatest importance to accelerate the scaling-up process (E4, E10, and E11). The importance of large corporates has been showcased before, specifically in transitions within the food industry at the timing of plant-based emergence. According to A2, large corporates played a significant role in the technology transition back in 2017, when the transition of plant-based protein is said to have occurred. The large corporates demonstrate significant interest in the application of precision fermentation to produce dairy proteins (E16), but are waiting for the technology to be proven profitable, leaving the spot for others to take the lead in investing in production sites of commercial scale before making similar commitments themselves (E5, E9, and E10). While the demand for capital is substantial in the pursuit of scaling up precision fermentation of dairy proteins, institutional investors and banks tend to allocate funds to businesses already operating at commercial scale and characterized as being in a mature stage (E8), which is further supported by Corsatea et al "[b]anks are reluctant to make large investments in technologies that have not passed both the technological and commercialization phase." (2014, p.142).

Another obstacle is that investors as well as large corporates must commit to long-term agreements due to long lead-times. However, both are hesitant, arguing that such a project is too risky and takes too long for return on investment (E9). The mentality of especially earlier stage Venture Capital (VC) and Corporate Venture Capital (CVC) investors completely aligns with Mazzacuto and Semieniuk (2017), pointing to an increasing short-termism among private investors, partly caused by increasing internal adherence to corporate governance structures that prioritize quarterly or annual returns. According to E4, raising capital for building production facilities usually requires attracting infrastructure investors, who typically seek safe investments with modest but close to guaranteed return. This is a requirement which is of course difficult to meet given that the technology and infrastructure to date is unproven from a profitability at commercial scale standpoint. Just like in 2017, when large corporates accelerated the transition to plant-based proteins, through significant investments in the space (Bulah et al., 2023), E8 emphasized that it will most likely be a joint venture among multiple different CVC entities that accelerates the commercialization of precision fermentation-produced protein. E5, E9, E10 and E11 also implied that since the large corporates already have the necessary capital, competence and infrastructure, they are collectively a vital actor for the transition to occur. E5, representing one such large corporate, highlighted the importance of having proved the business model of such infrastructure before the large corporates take action. E5 said this can be done by generating higher margins or volumes.

E8 emphasized the importance of private funding since public funding is lacking for enabling scaling up. Considering the lack of public funds throughout the emergence and advancement of plant-based products during the same stage of maturity as precision fermentation of dairy proteins currently is, there is doubt about public funds bridging the current financial gap (A2). While a considerable amount of literature points to the importance of public funding, E8 said that many countries lack useful public funding tools, which could be one of the reasons why these countries are behind when it comes to foodtech in general. E8 suggested that the world should learn from countries like Singapore and Israel, where public financing through financial vehicles such as sovereign funds are acting catalysts for emerging technologies to reach commercial maturity.

5.4 Industry Dynamics

The industry dynamics within the precision fermentation of dairy proteins are multifaceted, shaped by both financial considerations, biotechnological innovations, and strategic infrastructure challenges. The identity of this industry is not entirely set, many ask whether the main startup actors consider themselves to be food or synthetic biology companies. According to E9, way too many of today's companies are too research heavy and are 'secretly' synthetic biology companies, merely posing as food companies, which is an aspect which might have contributed to the current inertia in scaling up to commercial production (E9).

The regulatory environment further illuminates interesting and important insights into what the growth potential and scalability of this technology is. E14 asserted that one of the greatest challenges with scaling up precision fermentation of dairy proteins is regulatory approval, and emphasized that politicians will be and are a critical part of the transformation. E16 also implied that the regulatory environment presents a current obstacle, and in particular for precision fermentation of dairy protein since it is labeled as a GMO. The EU has significantly more stringent rules and regulations for the introduction of novel foods which might prolong the time-to-market, this might however, accelerate the adoption once approved at a higher rate than in other regulatory environments that are more open from the start like the US and Singapore (E6 and E14). In short, the US and EU regulations represent two of the majority regulatory frameworks for new food products to enter the market. In the US, a so-called Generally Recognized as Safe (GRAS) status is given to novel foods before entering the food system (FDA, 2019). This is distinctly different from the European Food Safety Authority's (EFSA) regulatory framework (Lähteenmäki-Uutela, 2021). Precision fermented foods need to go through the EU Novel Food Regulation which either approves or denies novel foods from entering the market (Lähteenmäki-Uutela, 2021). The GRAS framework simply recognizes that a food is not prohibited, but it does in fact not directly approve any novel food products from entering the marketplace. Consequently the EFSA regulatory practice is more stringent and clear while the GRAS allows for more rapid approval. According to one industry expert, recent advancements in redefining the regulatory boundaries for precision fermented foods is under development in the EU which presents an opportunity for future more rapid approval processes. This could speed up the time to market not only in the EU but also in other regions wherein similar novel food approval frameworks are applied (E18).

The traditional dairy industry being in many ways the closest neighbor to precision fermentation of dairy proteins, is made up of a heterogeneous group of actors ranging from obvious skeptics, mainly US-based, to those who embrace the technology when, suitable and as long as it meets business and sustainability criteria (E6). For traditional dairy, precision fermentation is interesting for a variety of reasons. Firstly, it can complement or augment the current product portfolio instead of cannibalizing existing products (E6). The dairy industry appears more open and takes the precision fermentation industry more seriously, viewing its actors as potential allies or competitors rather than "low-quality substitutes" as in the case with plant-based options (E6).

Large corporates are keen to get involved in precision fermentation of dairy proteins, as they know that precision fermentation is the future of food (E17). As previously mentioned, the involvement of large corporates is vital to scale up precision fermentation of dairy proteins (E5, E8, E9, E10 and E11). As for the industry dynamics, their engagement enables clear go-to-market pathways and opportunities since they have the necessary sales channels and capability to place end products on retail shelves (E11). According to E11, large corporates recognize significant potential with certain high-value precision fermented dairy proteins, specifically those with unique nutritional benefits that could serve niche markets (E6). E16 and E17 are of the same opinion, and argued that the optimal market for precision fermented dairy proteins is the health and wellness market. E6, representing a large dairy corporate, claimed they had conducted an analysis of precision fermentation of dairy proteins, and concluded that its most promising application lies in procuring niche or completely novel proteins with specific properties, which aligns with the more explicit opinions of E11, E16 and E17. Leveraging this insight, they embarked on a joint venture with a world leading company within biomanufacturing to develop a niche dairy protein tailored to a new segment, serving as a complement to their current products (E6). By targeting a distinct demographic not served by existing products, the company avoids direct competition and instead expands its product portfolio.

However, despite the potential for growth and innovation in this sector, capacity constraints pose a significant challenge (E11 and E15). The demand for precision-fermented proteins exceeds current production capabilities, creating an opportunity for CDMOs to dictate pricing (E4 and E11). Clients, eager to secure access to precision-fermented proteins, are willing to pay a premium to fill the utilization gaps of CDMOs, further driving up costs within the industry (E4). It is important to underscore the international nature of this industry which is a defining characteristic. Although the overwhelming leaders in foodtech, precision fermentation of dairy proteins included, are based in the US, Singapore and Israel (E8) the global competence within precision fermentation is found also across North America, Australia, and Europe (E9 and E12) making this a global industry despite its currently small size.

Precision fermentation of food proteins is an emerging technology and area of manufacturing, especially at commercial scale. At its current state it is undeniable that the technology and operations require skilled labor (E1, E2, E3, and E12). Access to competence is scarce, and labor is concentrated in biotechnology hubs that are typically located in high cost areas driving up everything from labor costs to rent, real estate, and land space. Just as finding the optimal location for a greenfield or brownfield site out of a supply-chain or facility point of view, access to competence is an essential aspect that must be both considered and met to successfully build and operate production infrastructure.

5.5 Sustainability

Among the industry experts and academics interviewed, it is noteworthy that none have expressed extreme opinions of any direction. Even though some of the interviewees could be considered to belong to two different sides in this aspect, emerging technology and incumbent technology, there are overlapping opinions. There is, however, some disparity between some of the existing literature and the interviewees. While certain literature emphasize that cows are one of the most inefficient manufacturing systems to produce protein (Tubb & Seba, 2021), E3 argues that cows are actually highly sustainable and effective in regards to their circular nature, were its inputs such as hay and grain can be grown using the output (the cow's manure). Nonetheless, E3 said that despite this circular nature of farming, fewer and fewer farmers are operating in such a manner, which of course indicates it may not be as sustainable from a financial perspective.

Tubb and Seba state in their industry report from 2021 that modern foods generated through precision fermentation will be approximately 10 times more efficient than cows in converting feed into end products. That translates to a substantial decrease in demand for feedstock (10-25 times less), water (10 times less), energy (five times less), and land (100 times less). Statistics like this makes it easy to draw conclusions that producing dairy protein through precision fermentation is vastly superior to incumbent methods in terms of its climate impact. However, E6 had a more modest view on the sustainability advantages of precision fermentation, highlighting that through analysis made in collaboration with a world leading company in precision fermentation technology, they concluded that precision fermentation is not particularly compelling from a CO2e perspective. According to E6, innovations in the traditional dairy sector over the next five years will significantly decrease the current level of CO2e footprint, and likely go below the CO2e impact of even future precision fermentation production processes. Nonetheless, E6 acknowledged the potential benefits from a land-use perspective, where precision fermentation of dairy proteins appears to require less land. E5 and E16 confirmed this view by emphasizing that the reduction in land requirement is one of the most significant advantages of using precision fermentation.

The reduction in land usage is particularly interesting for countries and urban areas with a desire to increase self-sustainability (E5 and E16). Using Singapore as an example, a country with minimal available land and a close to non-existing agriculture and with a 30 by 30 goal (30% of all the food consumed should be domestically produced by 2030) (E15), E5 highlighted the potential of using precision fermentation to decrease import and become more self-sustainable. But the reality is nuanced and there are many things to take into account when analyzing sustainability. One must for example consider the input raw materials used for precision fermentation. If a majority of the inputs are imported, the net impact from a self-sustainable point of view, might be small (E5 and E16). In fact, E16 claimed that the 30 by 30 goal will never be reached due to this issue, as raw material will remain Singapore reliant on imports. One of the major benefits that has been emphasized regarding precision fermented dairy proteins, through a sustainable perspective, is the exclusion of animals, but in order to claim such benefits, the selection of raw material is extremely important, in which many current CDMOs fail (E16).

For the transition to precision fermentation of dairy proteins to occur, consumer demand plays a crucial role (E17). E17 further claimed that demand is probably the major hurdle in scaling up, not because of the nature of precision fermented dairy proteins, but rather due to the nature of consumer behavior which is characterized by skepticism towards new technologies in food. A2 emphasized that from a commercial point of view, whether something is sustainable or not is purely decided by the consumer. This implies that the actual definition or a 'true' measure of sustainability is less important than consumers' perception of sustainability. E8 and E18 highlighted the importance of trends and how they can lead to coerced pressure for transition, where climate change could drive the adoption of precision fermentation to produce dairy protein. But then again, the consumers' perception of what is sustainable from a climate change perspective, is what will ultimately accelerate or slow down a transition (A2 and E17).

6 Multi Level Perspective Analysis

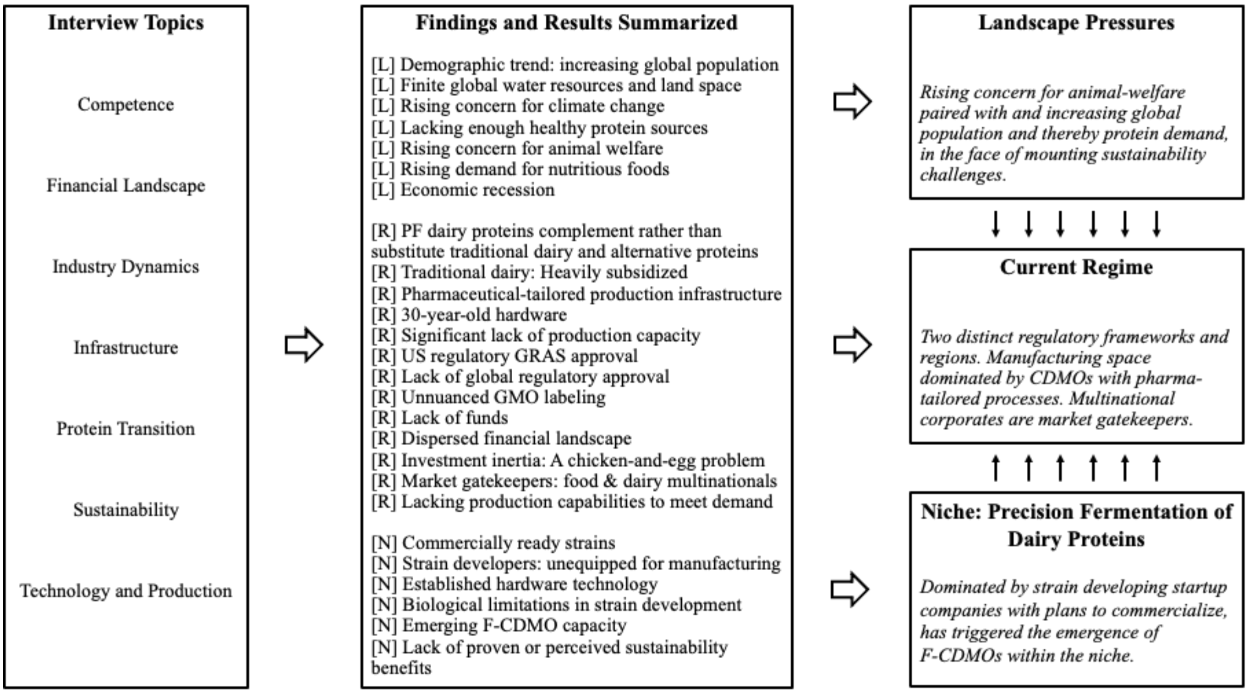
The multi level perspective (MLP) framework is typically utilized to describe either: (a) a specific niche's breakthrough or failure to enter into a regime, or, (b) analyze a specific regime which has been challenged by one or multiple emerging niches. In this study, the former operationalization of the framework is applied, meaning that the system to be analyzed is described out of the perspective of the niche. More concretely, considering the potential success or failure of the niche 'precision fermentation of dairy proteins' to break through into the incumbent regime and thus creating an industry transition under the pressures and influences of relevant landscape factors, a system is conceptually formed and analyzed. The purpose of the utilization of the MLP framework in this analysis is twofold. Firstly, in Part I, the MLP is used to map out the ex-ante state of the system as it is today and describe its characteristics. Secondly, in Part II, potential transition pathways to an ex-post state are described, which serve as proxies for scenario descriptions of potential future systems, underscoring the conceptual point from which the MLP framework stands, describing systems as dynamic.

6.1 Part I: Mapping the System Through a Multi Level Perspective Lens

Modeled after the analysis approaches of Geels & Schot (2007), Elzen et al. (2011), and Moritz et al. (2023), the findings, insights, and collected data are organized into landscape, regime, and niche levels, and the dynamic interactions within and between the levels are described. Drawing upon Geels (2002) analysis of the emergence of steamships and the industry transition that followed, the framework's usefulness is best illustrated through the description of interlinkages and interplay between the landscape, regime, and niche. Similar to Geels (2002), a specific niche, here being precision fermentation of dairy proteins, is studied through the MLP lens. However, there is a key point of differentiation from, for example Geels & Schot (2007) and Elzen et al. (2011), in the analysis approaches in that the system being analyzed in this study is current rather than historical, which more closely resembles the operationalization approach of Moritz et al. (2023). Figure 2 aims to establish a clear link between the results and MLP analysis, consider this figure an introduction to this section.

Figure 2

Summary of the main topics and perceived key actors and activities organized in the landscape, regime, and niche categories. In essence, a visual MLP representation of the current system (adapted from Moritz et al., 2023).



6.1.1 Path Dependencies and Landscape Pressures

Although this analysis is of an existing and current system, it is helpful to establish some of the significant path dependencies that influence today's system and emergence of the niche. In 2014, the company Perfect Day was founded with the mission to procure dairy proteins using precision fermentation, marking the starting point of the emergent niche that is precision fermentation of dairy proteins (Watson, 2023b). The main novelty of the innovation at the time was deriving food proteins, specifically biosimilar dairy proteins, from an existing technological process, being precision fermentation. Thereafter a niche segment consisting of primarily startup companies emerged. These actors were and are united in having a core competence and focus on strain engineering, i.e. developing a microbial strain to secrete a target protein, with the desired molecular structure and functional attributes, and optimize its biological productivity. The idea of Perfect Day at the time being that one can use the incrementally improved precision fermentation hardware technology, used within the pharmaceutical industry, to produce proteins biosimilar to "[...] milk because we've figured out how to scale this technology." (*Myths vs Facts about Our Non Animal Whey Protein*, n.d.). The following decade unfolded with an increasing number of startup companies entering the niche, targeting different dairy and milk proteins.

Not only does the growing population put pressure on the amount of protein produced, but it also increases land scarcity, which puts pressure on land usage. This implies that the production of protein must increase while the method for producing it should require less land. If it is as E5 emphasized and E6 also acknowledged, that land usage could be one of the greatest potentials with precision fermentation, the combination of land scarcity and increased demand for protein could definitely be viewed as a pressure on the regime that could trigger an opening for such technology.

Increasing global population paired with a rising concern for sustainability are landscape factors which significantly puts pressure on the system which opened the stage for alternative proteins more broadly (Deng et al., 2023) . The alternative protein space is heterogeneous and the three main categories being cultivated meat, precision fermented-proteins, and plant-based have faced different barriers along the way. Leaving potential substitutes within the alternative protein space aside, the emergence of precision fermentation of dairy protein has ridden on a wave of aligned landscape pressures, creating an opportunity for niche development. The positive economic climate further spurred continuous investments into the niche, creating somewhat of an innovation safe haven until the start of the global economic recession, beginning in 2023.

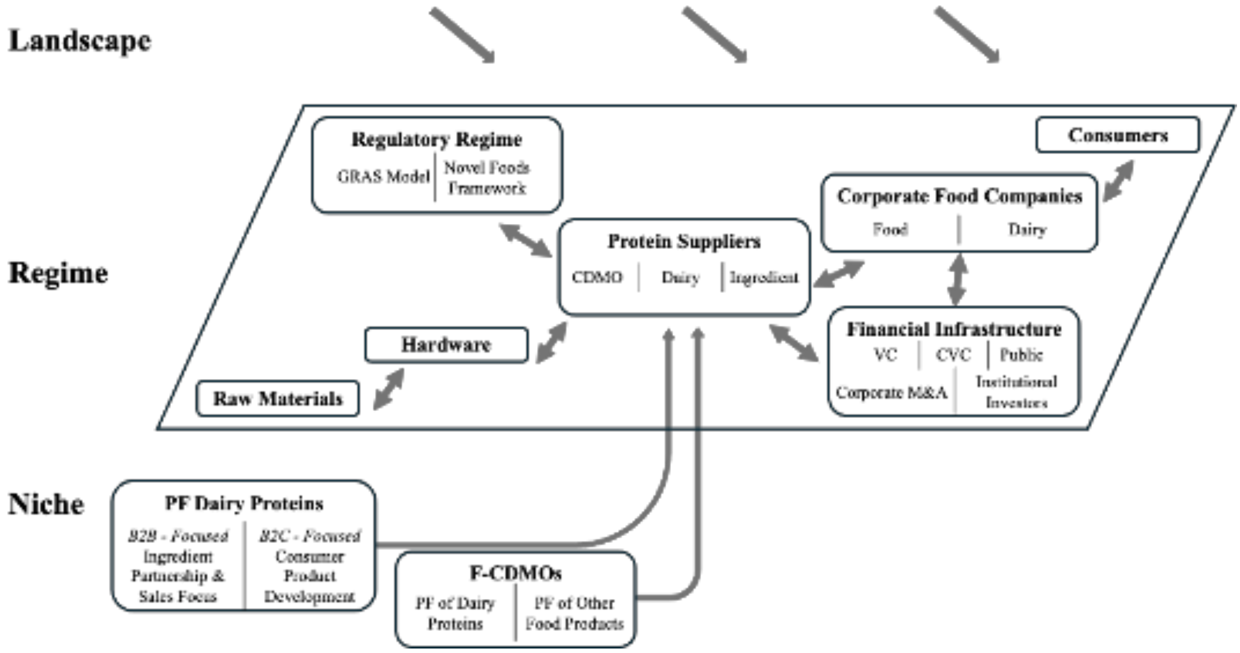
The sector of where this emergent niche fits overlaps the food, synthetic biology, and pharmaceutical industries, affected by a large range of exogenous trends, such as those mentioned in the previous paragraph. The most important path dependency to highlight is that the technology having been used is one stemming from the pharmaceutical industry (E12 and E14). Therefore talent has been drawn from said space, adopting a manufacturing strategy of using the network of pharmaceutical industry CDMOs as primary production partners (E12). With clear exogenous pressure on the regime and support for niches like precision fermentation of dairy protein, positive economic conditions, and proven technology from lab to pilot to even small commercial scale, startup actors were able to raise hundreds of millions of dollars to build out the global footprint of large scale precision fermentation manufacturing capabilities. This was mainly because of the considerable lack of available production capacity among the CDMOs. Co-investing with CDMOs or reserving production time over longer periods have been the main two strategic models even though the industry was and is aware of the suboptimality around utilizing pharmaceutical-grade manufacturing partners and equipment to produce food-grade product out of a purely economic perspective. At the very tailend of 2022, leading startups like Perfect Day and Remilk announced building large scale manufacturing sites in India and Denmark respectively, deviating from the general consensus production strategy (Watson, 2023a; Watson, 2023b). However, within only a few months Remilk halted their plans, refocusing on co-investing in an existing CDMO site, claiming they “de-risked sooner, at a fraction of the cost” (Watson, 2023a). This, all the while still claiming to be able to meet production capacity targets after recently having closed a financing round directed to this effort and underscored the importance of a dedicated facility for food grade products. In recent years, the global economic climate is in decline with rising interest rates and inflation. This has put pressure on the entire food industry and shifted the market demand from growth to profitability. The safe haven allowing for the niche to properly develop was lifted and the decreased access to capital created pressure on the startups to prove the business model of precision fermentation of dairy proteins. Concretely, path to profitability alongside showcasing volume production.

6.1.2 Mapping the Niche and Regime Clusters: Key Actors and Activities

In figure 3, key clusters of actors and activities within the regime and niche are highlighted and made explicit. The visual mapping below presents operationally or transactionally active clusters, approximately arranged along an imagined diagonal line from the bottom left corner to top right, and clusters with institutional influence and characteristics, approximately arranged from the top left corner to the bottom right. The niche, being precision fermentation of dairy proteins, consists of two main clusters of actors and activities; the development and optimization of strains, and the building and operating of food grade production infrastructure. The arrows between the boxes highlight the direct influence imposed by one cluster onto another. The purpose of this illustration is to support the reader with a visual representation of the interlinkages within the regime and niche for better understanding the dynamics within today's system and in the transition pathways going forward.

Figure 3

Mapping the Regime and Niche Clusters in an MLP Representation of the System (adapted from Elzen et al., 2011).



Note: Explanations for abbreviations, ordered from top left to bottom right:

GRAS: Generally Recognized as Safe. CDMO: Contract Development Manufacturing Organization. VC: Venture Capital. CVC: Corporate Venture Capital entity. Public: Public funding such as subsidies, sovereign fund investments, grants etc. M&A: Mergers and Acquisitions. Institutional Investors: Such as pension funds and large private equity firms that are characterized by having long-term investment strategies with comparatively lower expected returns on investments as a consequence of making lower risk investments compared to VCs and CVCs. PF: Precision Fermentation. B2B: Business to Business product sales. B2C: Business to Consumer product sales. F-CDMO: Food grade CDMOs, tailored for food protein (not necessarily dairy protein) production.

Today, as many interviewees concurred, the core state-of-the-art hardware technology has been around for at least three decades without much improvement. However it has been tailored for applications in the pharmaceutical industry where the business dynamics are characterized as low volume, high price which starkly contrasts many dairy proteins with the complete reverse price dynamic. Furthermore, the manufacturing infrastructure is completely dominated by pharmaceutical grade CDMOs. The findings from interviewing industry experts indicate that the true market production cost appears to be obscured for two primary reasons being: (a) absence of commercial food-grade tailored for precision fermentation capabilities, and (b) economies of scale have been misunderstood, they are in fact significant but improve alongside a discreet trend line (meaning stepwise) rather than a continuously along a linear or exponential trajectory.

As with any emerging niche, precision fermentation of dairy proteins is outside the traditional industry categorical structures or sectors and does not perfectly fit into incumbent regime rules and praxis. According to one industry expert, one of the main issues with today's precision fermentation startups is that they are "[..] synthetic biology research hubs posing as dairy food companies" (E9). Similarly, regulatory entities view and treat precision fermentation of dairy protein products differently. One of the more stark examples being that precision fermentation of dairy protein are considered and required to be labeled as GMO-products in the EU but not in the US.

The US compared to the EU and Singaporean markets are indicative of the two main categories of regulatory approach to approve or deny precision fermentation of dairy proteins. The EU is considered one of the most stringent regulatory markets when it comes to introducing new foods out of both the prospective health and safety approval, much covered by the Novel Foods Act, and limiting marketing through specific labeling laws and directives. For precision fermentation of dairy proteins the *EU GM Food Regulation* is applied as the microbes DNA is altered to produce the target protein, thus requiring it to be labeled as GMO even though the end products should in fact be a replica of the desired molecule.

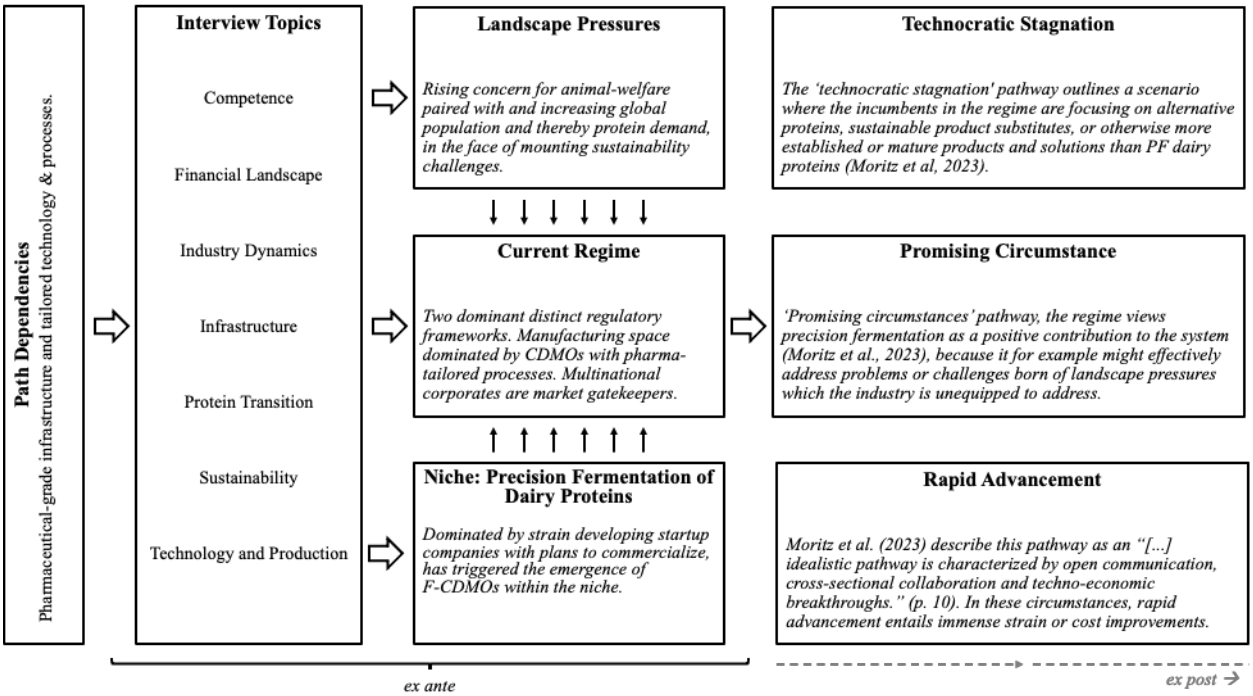
6.2 Part II: Potential Transition Pathways

In order to address what could trigger an industry transition of the current system, it is necessary to identify the most likely potential directions of movement from where the system stands today toward what it will become. Just as Geels and Schot (2007) point out, a system is never static (seen through an MLP lens), and therefore, even in a state of complete status quo, the system is constantly reproducing itself, dynamically rebooting into the same state as it currently is in. With this conceptual axiomatic foundation, it is trivial to theorize that any fundamental change, here being a landscape pressure, to the system can destabilize the reproduction process, i.e., current regime, but only through significant pressure from the landscape or niche, a transition occurs. Consider now that the previous sections, being *7.1 MLP Analysis* and *6 Results*, combined are effectively acting as proxies for what the actual system that is being analyzed is. Similarly, the prior sections outline the description of the niche's state of the art, i.e., maturity. Thus, what Geels and Schot (2007) conceptualize as nature is therefore described, and with the added consideration that the timing is now, the two conditions required for defining a transition pathway are fulfilled.

To anchor the following analysis to sound research principles, it is not the intention to in detail describe a potential future system but rather to outline potential pathways from today's system, based on categorizing the perceptions of industry experts into three distinct potential pathways and assess which of these three are most supported by said perceptions and recent literature. Figure 4 provides a visual summary of the current system, which represents the ex ante state, influenced by past path dependencies and described through the landscape, regime, and niche level perspectives. Potential transition pathways, stemming from todays system, will lead to an ex post system but only in the event that a transition occurs.

Figure 4

An MLP representation of the system illustrates path dependencies, the current landscape, regime, and niche (i.e., ex ante system), and three potential transition pathways into a future, potential ex post system (partly adapted from Moritz et al., 2023).



6.2.1 Rapid Advancement

For the rapid advancement pathway to be the most likely transition pathway, this would entail a system-wide alignment and embracement of the niche, leading to an immediate industry transition, enabling a complete breakthrough of the precision fermentation of dairy protein niche into the regime. Moritz et al. (2023) describe the rapid advancement as an "[...] idealistic pathway is characterized by open communication, cross-sectional collaboration and techno-economic breakthroughs." (p. 10). This pathway bears similarities with Geels and Schots (2007) P3 pathway 'technological substitution' which describes how a sudden landscape shock completely destabilizes the regime and given that the niche is sufficiently mature at this timing, a complete technological substitution occurs which in essence transforms the system fundamentally. P3 allows for creating a vivid image of what the ideal future would look like seen from the view of the niche given that the optimal landscape shock occurs creating a perfect gap in the regime for the niche to fill. However, for the purposes of this assessment it is more useful to consider the conceptualization that Moritz et al. (2023) puts forth, to focus more on the internal dynamics within the regime rather than merely the niche and landscape.

Assuming any shock-like landscape pressure will occur seen from today's vantage point has not been identified and is difficult to predict. From the perspective of the regime one could imagine two separate sets of underlying assumptions that if granted and are met by technological advancements could create a significant enough domino-effect to effectively transform the regime and industry. Assume first that the main or even only barrier of entry for precision fermentation dairy proteins is reaching price parity, which is indicated to be the case by multiple interviewees (E4, E6, and E12). Secondly, assume that regulatory approval is, as E6 and E15 underscores, more a question of timing than whether or not it will occur. Assuming these two are in essence facts of the industry, really the only requirement is to dramatically reduce cost of production to reach price parity.

Several interviewees underscore the reality of the effect that biochemical productivity has on the cost since every increment in titer or recovery has a direct cost reduction effect on the per-kg cost of target protein. Therefore, a rapid advancement scenario must be led by significant strain optimization gains. This can occur through two main ways: (a) regulatory approval of novel microbes strains with significantly higher potential biological productivity (maximum titer), or (b) parallel exponential improvements of titer and recovery rate of existing approved microbes, enabled by strain engineering breakthroughs and cost-effective high performance downstream processing.

Underlying these potential technological breakthroughs one must assume significant regime-wide alignment beyond just a much more favorable regulatory climate. Considering the established industry consensus that large corporate food and dairy companies are the gatekeepers to the market, they must act in accordance with the assumption that price parity is the main barrier for adoption. Since precision fermented dairy protein products in many ways most closely resemble an ingredient, seen through a product sales lens (E17), and that the few startups that previously created end consumer products have pivoted back to a focus on mere protein sales, these niche actors are dealing with B2B sales where large corporates make up the vast majority of the market. Even under rapid advancement conditions, the pathway is not disjunct from today's system. In contrary, today's niche, regime, and landscape in essence are path dependencies for the emerging transition pathway. Therefore, to speculate in the successful independent go-to-market strategy of D2C sales is less likely to conceive.

It is also the case that institutional investors must accelerate funding throughout the value chain of precision fermentation of dairy proteins to support the rapid advancement pathway trajectory. Regardless of the research and development efforts leading up to the dramatic cost reduction that is perceived, the commercialization of the product is still hindered by lacking infrastructure. As many interviewees underscore, the current infrastructure is both insufficient in terms of volume (E4) and having been built for commercial food scale production. This in turn puts pressure further down the supply chain, on hardware developers to not only develop the required technologies but also build and supply at sufficient rates, reducing the lead times that today can be up to two years for certain key equipment (E15).

Lastly, rapid advancement relies not only on regime alignment but also on niche alignment. As has been described before, the niche consists of two main clusters where the primary consists of strain developing startups. These actors have been assessed to at an industry level lack the competence, skill, and experience to own and operate production in the nearterm. Therefore CDMOs and more specifically the second niche cluster F-CDMOs are required to bridge the manufacturing gap. For this reason, rapid advancement also requires either rapid emergence of F-CDMOs or rapid adjustments of current CDMOs, which in both cases requires significant capital. As E16 highlights, geographical consolidation of manufacturing capabilities is a requirement for successful rapid scaling up of infrastructure and production footprint. Therefore, in a rapid advancement pathway scenario, funding alignment with regional focus will be required.

6.2.2 Promising circumstances

In the case of the ‘promising circumstances’ pathway, the regime views precision fermentation as a positive contribution to the system (Moritz et al., 2023), because it for example might effectively address problems or challenges born of landscape pressures which the industry is unequipped to address. In the case of precision fermentation of dairy protein, the definition of promising circumstances could be summarized in moderate actor and activity alignment. Seen through the lens of Geels and Schot’s (2007) transition pathways, promising circumstances could align somewhat with both P1, transformation pathway, and P4, reconfiguration pathway, depending on the response of regime actors to the nature of the niche. In both cases, the basic set of regime actors remains somewhat intact, but in the case of P4, the internal structure of actors and activities fundamentally changes gradually, which eventually leads to a completely altered regime architecture. P4 highlights the domino-effect that certain niche innovations, wherein the regime’s initial adoption of the niche to solve local problems leads to further related innovations which reconstructs the physical infrastructure and or regime dynamics.

It has already been concluded that there are already moderate landscape pressures on the system today which provides the regime’s need for adjustment. The problems faced by regime actors span from needing to globally produce more protein with less resources, preferably with lower CO_2e impact, while avoiding having to compromise on taste and nutritional value. precision fermentation of dairy proteins address these issues head on but have not been incorporated for reasons ranging from cost, lacking regulatory approval, and an incapability of producing commercial scale volumes. To create a favorable environment for the successful implementation of this niche, regime wide alignment is required but does not have to be unilateral. Meaning, that as long as there are enough actors in each regime cluster to enable and accept precision fermentation of dairy proteins, the circumstances are favorable for incremental development and adoption over time. As a starting point it should be pointed out that regime actors, like incumbent food and dairy companies, have surprisingly been shown to respond to precision fermentation of dairy proteins in a much more positive manner than what was to be expected (Grebow, 2023; Haslam, 2023). Thus, this niche appears not to face the same level of hostility as plant-based dairy did (E6) nor cultivated meat (Bulah et al., 2023) which argues for there already being a foundational degree of promising circumstances already.

Considering that precision fermented food products and proteins are not a complete regulatory novelty and that even under the Novel Foods Framework, there are guidelines in place and proofs of concept it can be argued that there is a clear regulatory path to approval for this niche. Furthermore, although the consumer perception of precision fermented dairy protein products still remain unknown to an extent, recent literature point to positive attitudes (Banovic & Grunert, 2023) and since the nature of the product is comparable to that of food ingredients and flavoring products, it is conceivable to assume there is already sufficient consumer acceptance to achieve market adoption, albeit a smaller share of the total.

Recent emerging F-CDMOs are also enabling the infrastructure scale up required for commercialization. The system has been made aware of the inefficiencies with traditional pharmaceutical grade CDMOs and responded with recent development in the niche of emerging F-CDMO startups in parallel with CDMO-learnings adjustments. This is an indicator of the industry following a P4 trajectory wherein there is a combined effort of both incumbent and emerging CDMOs to build new infrastructure, thus gradually altering the regime architecture over time.

Lastly, the promising circumstances would require reaching a market acceptable price point, which the industry experts indicate that current precision fermentation startups are not reaching. The increasing access to commercial scale production capabilities both increases supply, creating more favorable negotiation conditions for current strain developers, and since new capacity is built for food-grade applications, sometimes even specifically tailored for dairy proteins, OPEX and CAPEX are decreasing. However, as many point out, although the cost savings due to the emerging economies of scale and food tailored production sites, the cost of production still surpasses the price points of dairy proteins derived from traditional sources. This requires that the market must be willing to pay a premium for the product which there are indications already that the market is willing to do. Whether it is alternative proteins or alternative dairy, a 30-100% premium appears to be accepted by the consumer which logically should trickle back to the gatekeeping food companies as well. This is a sign of price parity not necessarily having to match the dairy-derived counterpart, but instead compete and compare with other alternative protein or dairy products. In this case, the route to price parity is shorter and more conceivable, and assuming this viewpoint is adopted by a sufficient number of large corporate actors, a market segment will be available in the nearterm. This is perhaps the ultimate determining indicator of whether the system is in fact moving into a promising circumstances pathway.

Another lever to consider in the space of reaching price parity would be to consider the point made by investor and industry expert E8, who suggests that the amount of subsidies and governmental financial support that the traditional dairy industry is receiving, particularly in Europe, creates an imbalanced market favoring the incumbent regime structurally in a significant way. If the price playing field between traditional and precision fermented dairy proteins would be leveled, price parity would be reached at a much sooner point. But evidence for such a change is non-existent today and therefore should be considered unfeasible and unrealistic to expect. However, the role of financial support both from public and private sources play a vital role in the promising circumstances pathway. Again, unilateral support is not required for enabling a successful transition. Here, the P1 transformation pathway by Geels and Schot (2007) requires an added component of consideration. The maturity of the niche in its current state is still not reached, as has been underscored by previous paragraphs. For this reason, to bridge the gap, a financial life-line must be provided by financial actors along the entire value chain from supporting strain developers in cashflow management to F-CDMOs through mixed financing of loans, equity, subsidies, grants, or other guarantees to alleviate the burden of high CAPEX. Only through improving these conditions, the maturity of the niche can occur in parallel with its adoption. Here, again Geels and Schots (2007) underscoring timing is an important factor to consider. Assuming the nature of the regime and landscape are in accordance with the P1 and P4 pathways, the niche must in both cases be sufficiently mature to be adopted. As it currently is not, bridging this gap in the very near term is critical. Thus, to summarize the state and trajectory of the promising circumstances one can conclude that many aspects of the system are in fact pointing to unfolding of a promising circumstances pathway. Geels and Schots (2007) conceptualizations of P1 and P4 provide useful guidance as to which possible concrete trajectorial directions the niche could evolve into, provided the very nearterm gap of lacking niche maturity is bridged. The sum of these considerations serve as the final definition of both what the promising circumstances pathway is defined as in this study, and what it would entail.

6.2.3 Technocratic stagnation

The ‘technocratic stagnation' pathway outlines a scenario where the incumbents in the regime are focusing on alternative proteins, sustainable product substitutes, or otherwise more established or mature products and solutions than precision fermented dairy proteins (Moritz et al, 2023). Although the industry, through a technocratic stagnation pathway, will in fact evolve and transition, it will happen through investments into only somewhat novel alternatives to the majority incumbent products and solutions. The system as a whole under this pathway progression will therefore favor more established innovations, like plant-based proteins, over emerging ones, like precision fermented dairy proteins in this case.

Seen through the lens of Geels and Schots (2007) the P2 de-alignment and realignment comes to mind since P2 highlights that in absence of a mature niche during the impact of a severe landscape shock, the regime will turn to multiple niches to help address the solution. However, there is a major distinction being that this system is currently not experiencing a severe or shock-like landscape pressure event. Thus, conceptually it is better to consider technocratic stagnation as distinct from P2, yet bearing some similar characteristic which could assist in mapping out the future pathway trajectory. Instead, consider how Moritz et al. (2023) further details their definition of technocratic stagnation:

> On a more general level, the “technocratic stagnation” pathway represents a failure to recognise increasing landscape-level pressures, is geared to maintain the status quo and to support activities of the current livestock-based food regime. The regime concentrates on incremental development activities and on fine-tuning the current food system. (p.8)

In the context of precision fermented dairy proteins, the closest incumbent rival could be considered to be dairy companies. The attitude within dairy is varying, where one industry expert highlights how European dairy companies are more attuned and responsive to emerging climate pressures, in part as a consequence of increasing European regulations around CO2e measuring and reduction, than the US-based counterparts (E6). However, the main driver in favor of precision fermented dairy proteins even for these more open-minded companies is not defined by the prospect of precision fermented dairy proteins offering a more sustainable substitute to the livestock-derived, but rather the niche has caught there interest as it offers a mode of increasing the current product portfolio. This distinction is important since the same expert expressed that in fact there are a lot of investments and efforts going into traditional dairy to for example address the issue of CO2e. One concrete example is that of the Swedish startup company Volta Greentech who are introducing a supplement for cows to consume which reduces the methane output from the farts and burps, thus significantly reducing the life cycle CO2e impact (Lindeberg, 2022). Emerging innovations such as this might be something that fulfills the problem gap within the regime.

Other incumbents are of course ingredient suppliers and collectively large multinational food corporations (CPGs). These companies are also experiencing the landscape pressures and are curious for emerging solutions. However, significant investments are being made in other alternative proteins with already proven profitability and demand such as plant-based dairy and other alternative protein products. There is a risk that as long as precision fermentation of dairy proteins has not reached a critical commercial volume at a commercially attractive price point, these actors will hesitate to adopt this niche and instead favor the status quo or potentially other alternative proteins. This is in part supported by one industry expert from a corporate such as this who also underscores that the barrier of entry of precision fermentation of dairy proteins is also not only defined by its cost but also its novelty. Although corporates are the gatekeepers and most likely customers in the current regime, the end consumer must accept or even advocate the emergence of this product. So even if the hesitancy for precision fermented dairy proteins is lower than at the time of entry for plant-based products, a core difference is that many plant-based products emerged thanks to consumer driven pull. The mere fact that precision fermentation is unknown to most consumers makes communication, marketing and choice of end product both more challenging and increases the perceived uncertainty among corporates.

7 Discussion

As shown in tables 2 and 3, the data collection consisted of 20 interviews conducted with industry experts and academics ranging from representatives from foodtech, manufacturing, large corporates in dairy, food processing and real estate development, investors, NGOs, university and strategy consulting. The analysis of these 20 different interviews regarding the challenges with scaling up precision fermentation of dairy proteins, resulted in five different themes, all of which are displayed in table 3. These themes were used to present and analyze the different perceptions in the *5 Results* section. The MLP framework was applied to analyze the different perceptions, in section *6 MLP Analysis*, in order to: (a) map the current system wherein the niche, precision fermentation of dairy proteins, is situated, and (b) identify potential transition pathways from which the current ex ante system can potentially transition. In order to evaluate the potential for transition, three transition pathways were constructed, influenced by Geels and Schot (2007) and Moritz et al. (2023), and analyzed.

7.1 What are the perceived major challenges with scaling up precision fermentation of dairy proteins to commercial scale?

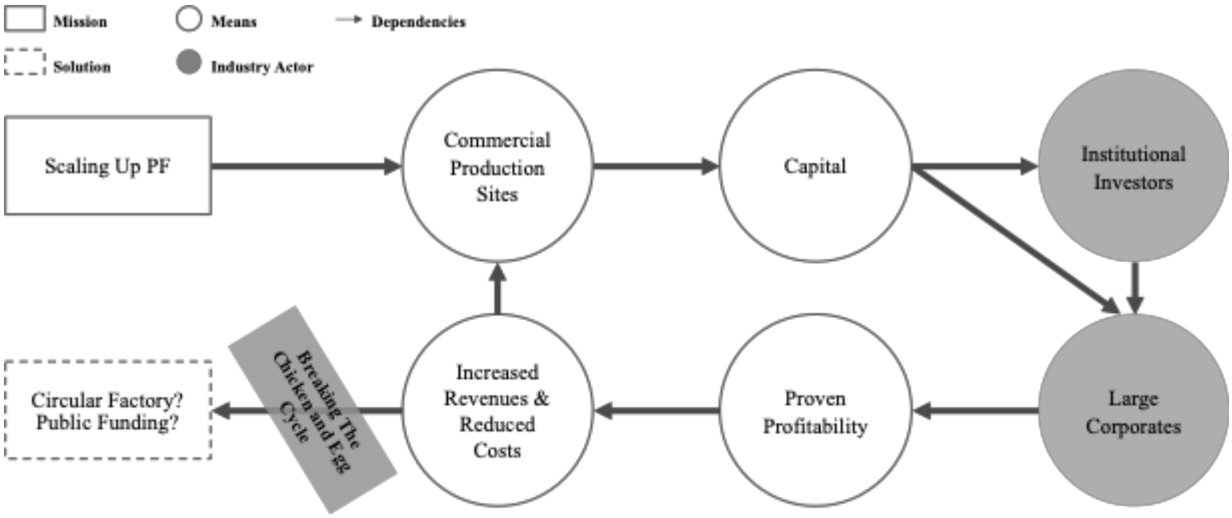
At first glance, it appears rather attractive to get involved in the industry of biomanufactured foods (of which precision fermentation of dairy proteins are part of), as estimates suggest that the market size has the potential to reach USD 100 billion in the year 2040, from today's close to non-existent market size. However, the estimated market size is calculated based on the assumption that price parity with incumbent animal-derived products will be reached, which has been pointed out by some of the interviewees as one of the major challenges with scaling up. For many precision fermented dairy proteins in particular, it has been said to be utterly unattainable to reach price parity. While this paints a somewhat bleak picture of the future of precision fermented dairy proteins, it is important to note that this does not apply to all dairy proteins, as high-value dairy proteins seem to have a perceived greater potential according to several interviewees. It has also been emphasized that reaching price parity, compared to traditional animal derived dairy proteins, is potentially not necessary in order to scale up, as consumers would be willing to pay a premium for certain precision fermented dairy proteins considering their vegan nature and potential sustainability benefits.

Although some technological innovations are estimated to drastically reduce both OPEX and CAPEX and that current technology has not been innovated and enhanced in over three decades, scaling up precision fermentation of dairy proteins does not seem to be an issue from a purely technological standpoint, as many industry experts are determined that today's technology is sufficient if tailored for food grade production and as long as entire infrastructure is made for this purpose. But the current technology itself should not be confused with the possibility to produce precision fermented dairy proteins at commercial scale. As has been established by now, the current and only viable option to produce dairy proteins using precision fermentation at commercial scale is to go through CDMOs. Current CDMOs are optimized for pharmaceutical purposes, and the pharmaceutical market operates on low volumes and high margins, whereas most dairy proteins follow a high-volume, low-margin model, creating a mismatch with current CDMOs optimized for pharmaceuticals. Considering that today's CDMOs might be overqualified for the production of dairy proteins, in combination with unbalanced supply and demand, one could argue that there are incentives to consider new alternatives. In the analysis, except for CDMOs, two other alternatives have been covered, brownfield and greenfield. While brownfield could be a possible solution, it appears based on the interviews that greenfield is the least complicated and best way forward. Since the feasibility and potential of precision fermentation lies within extreme economies of scale, it is suggested to build new, large precision fermentation production facilities, optimized for the production of dairy proteins.

Although regulatory approval and demand are raised as other major challenges related to scaling up precision fermentation, the interests from foodtech companies and large corporates remain. Based on the perception of the interviewees, large corporates seem determined that precision fermentation is the future of food, hence are keen to get involved in precision fermentation of dairy proteins. So why is nothing happening, and why are not billions of dollars continuing to be invested in new production facilities around the world that are optimized for dairy proteins? Again, based on the perception of the interviewees, it is rather simple, there is clearly a chicken and egg problem wherein none of the major parties is willing to assume the financial responsibility.

Figure 5

Mapping of the Chicken and Egg Problem.



This chicken and egg problem is visualized in Figure 5 above. The chicken and egg problem involves three main actors: large dairy and food processing corporates, foodtech companies, and infrastructure investors. Foodtech companies have the competence and technology for R&D, including the necessary and optimized strains. Infrastructure investors that are solely interested due to financial returns, can provide the capital required to build production facilities at commercial scale. Large corporates, that are interested due to both synergy effects and financial returns, have in addition to the necessary capital, the competence and knowledge required too. On one hand, infrastructure investors hesitate to allocate funds to precision fermentation facilities due to its status as an emerging industry lacking a proven track record at commercial scale (for dairy protein production). On the other hand, large corporates are not willing to engage until the profitability of precision fermentation for dairy protein production is proven. Yet, reaching profitability is not possible without the capital needed to build production facilities optimized for commercial scale and dairy protein production. Hence, scaling up precision fermentation for dairy protein production is a complex problem, where at least two key stakeholders (large corporates and investors), must dare to take the first step, either together or alone, to enable the acceleration of scaling up precision fermentation of dairy proteins. According to the perceptions of the interviewees, large corporates alone have the means and power to break the chicken and egg problem but are awaiting proven profitability or strengthened business model, that potentially could be achieved by demonstrating the adoption of a circular business model on factory-level, which again is emphasized by some interviewees to be an impossible task. Another potential solution to break the chicken and egg problem is public funding, which according to the literature aligns with the risky nature of innovations, the long-term agreements and lead-times this specific case is characterized by.

7.2 What could potentially trigger an industry transition and can it be achieved with today's technology?

The answer to the first research question paired with MLP analysis serves as the foundation from which this research question is to be answered. As has been concluded in the previous section, there is a financial gap that needs to be bridged for the niche to succeed. Solving the chicken and egg dilemma and reaching price parity are the likely triggers of a potential industry transition. From the standpoint of the current system it appears that if a transition were to occur, it would do so following the promising circumstances trajectory. This conclusion is based on the fact that the moderate landscape pressure that is being put on the current regime has resulted in a heterogeneous regime actor responses with varying degrees of acceptance or rejections of the niche. For a successful industry transition to occur, it is evident that multiple factors and actors must align in favor of the integration of precision fermented dairy proteins considering the early stage of maturity of this niche alongside perceived lack of ability to completely substitute large parts of the regime. The most realistic pathway for alignment will not be system-wide and unilateral as is suggested by the rapid advancement pathway, but will rather be more local within the regime. Successful cases of precision fermented dairy proteins will occur through the alignment of specific regulatory approvals in certain regions, with specific corporates integrating the product in an existing distribution channel, and food grade manufacturing plants supporting the financial feasibility of the niche. What potentially could unfold thereafter is difficult to predict, but Geels and Schots (2007) P1 and P4 transition pathways could help to make predictions about this future.

7.3 Limitations of the Study

The results of this study are primarily based on the collected interview data from the US, EU and Singapore which allowed for the comprehensive analysis of the challenges related to scaling up precision fermentation of dairy proteins and the potential transition pathways. While the intention was to interview representatives from main stakeholders of the industry, the definition of main stakeholders is subjective, hence it is possible that the findings and conclusions could have been different if others were interviewed. The bottom line is that the results are not statistically significant and do only represent a small group of industry experts- and academics' perceptions described by themselves. However, the interviewees were carefully selected to give a picture as broad and close to reality as possible. Although the interviewees originate from different regions, their perceptions on the topic vary insignificantly, which argues for the global character of precision fermentation of dairy proteins.

This study focuses on a transition that has not yet occurred and is ongoing, which is a rather unusual situation for applying the MLP framework which is widely used for already occurred transitions. The application of the MLP framework in this study, is substantially guided by how Moritz et al. (2023) applied it in their paper to study cultivated meat, which at the time of their study was, and still is, an ongoing transition. Due to the extraordinary similarities between the nature of this study and the topic or theirs, it appeared wise and appropriate to use the same three transition pathways as constructed by Moritz et al. (2023). Although these three transition pathways are notably suitable in the case of this study, it should not be neglected that there may be additional or even better transition pathways to use in the case of precision fermentation of dairy proteins.

8 Conclusion

While precision fermentation is a well established technology used for pharmaceutical purposes, it is emerging for the purposes of producing dairy proteins. As climate change is becoming a reality, continual animal cruelty, and increasing global population, the combined escalation enables the emergence of technologies such as precision fermentation to produce food ingredients and create hope for the future. This paper aimed to first identify the perceived major challenges of scaling up precision fermentation of dairy proteins, and secondly to find the answer to what will trigger an industry transition and if it can be achieved with today's technology. In the attempt to seek these answers, data was collected through semi-structured interviews with academics and industry experts. After analyzing the insights from the interviews and applying the MLP framework to detect potential transition pathways, it is believed that the sought answers have been found.

While many challenges related to scaling up precision fermentation of dairy proteins have been found, two of these are perceived to be of the main ones. The first issue is related to the current viable production capabilities which are dominated by CDMOs. Not only are current CDMOs optimized for pharmaceutical purposes and ill-suited for the production of dairy proteins, but the demand far exceeds the capacity which indicates multiple factors contributing to higher than necessary production costs. The obvious solution to this is to build and construct new precision fermentation facilities of large scale that are optimized for dairy protein purposes. Although today's technology in terms of manufacturing hardware has not been innovated and enhanced in over three decades, the current solutions with slight tailoring toward dairy protein and food-grade production can, if correctly executed by current regime and niche actors, achieve an industry transition according to the consensus perceptions of the interviewees (E4, E5, E7, and E9). But building and operating new precision fermentation facilities entails substantial capital investment, which leads to the second major challenge, the chicken and egg problem where no party seems willing to assume the financial responsibility.

In terms of the transition pathways, the 'promising circumstances' appear most realistic given the current stage at which precision fermentation of dairy proteins finds itself. Although price parity with incumbent animal-derived dairy protein is far from reached, it has through the analysis become clear that this is the single most important factor that would create promising circumstances. A reconsideration for what price parity is by large corporate actors, comparing the proteins not to its dairy derived counterpart but rather to alternative dairy and proteins immediately provides a 30-100% increase in what is considered to be price parity today. Furthermore, considering the substantial subsidies received by traditional dairy, many experts indicate that 'fair market price' of dairy is in fact not 'fair'. A public-actor driven leveling of the playing field through financial vehicles such as grants, subsidies, tax cuts, or loan guarantees could further reduce the distance from the cost of precision fermented dairy proteins today and the sought after market price point. Regardless of the route to it, achieving price parity is believed to be what would ultimately trigger an industry transition and as has been underscored previously, the role of incumbent large corporates taking action is critical for a conceivable near-term pathway to enable lead to an industry transition.

8.1 Future Research

The research field of precision fermentation of dairy proteins is rather limited, thus it is suggested that more research should be allocated to this area, especially since the world is facing challenges related to climate change, overpopulation, and animal welfare, among additional concerns. Although it is not proven that precision fermentation is the solution to all of these challenges, it is a promising emerging technology within food ingredients that many of the interviewees, of which many have no financial interests in regards to its success, believe is the future of food. While this paper contributes to existing literature by mapping the perceived major challenges of scaling up precision fermentation of dairy proteins, and by analyzing potential transition pathways, there are many challenges that require further research to help initiate progress. For instance, in terms of financial feasibility, it appears crucial to achieve circular production. Not only is existing literature lacking in this area, but it seems to be a knowledge gap among industry experts too. It has, however, been emphasized by the interviewees that it is extremely important as well as being impossible to achieve due to the uncertainty regarding the use cases of the biomass. Another potential solution for breaking the chicken and egg dilemma is public funding, hence it would be necessary to conduct further research on how this can be done in practice. While Singapore and Israel appear to be frontrunners in terms of public funding of new technologies and innovations, there should be ample opportunities for learning and constructing frameworks that could be applied universally.

Lastly, one domain that has been mentioned but not investigated in depth in this paper are the challenges related to the regulatory environment. Regulatory approval is for obvious reasons of utterly importance to reach commercial scale, and the need for further research to provide legal frameworks about the regulatory approval process has been pointed out in previous literature (Deng et al., 2023).

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Appendix A. Transition Pathway Operationalization Strategy

	Past	Future Oriented
MLP literature on transition pathways	Four transition pathways (4Ps) that are have typically been used in literature to analyze past, already ocurred, industry transitions. P1 Transformation pathway P2 De-alignment and re-alignment pathway P3 Technological substitution pathway P4 Reconfiguration pathway Geels & Schot, 2007	Three transition pathways developed to provide an analytical framework for analysis of a current system and make assessment of the msot likely tranistion pathway going forward. Technocratic Stagnation Promising circumstances Rapid Advancement Moritz et al., 2023
Theoretical framework operationalization		Operationalized adaptations of the pathways devloped by Moritz et al., with consideration for Geels and Schot's (2007) four pathways in the analysis. Technocratic Stagnation Promising circumstances Rapid Advancement Moritz et al., 2023