FaBA Food and Beverage Accelerator

Precision Fermentation: A Future of Food in Australia

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The Food and Beverage Accelerator (FaBA) acknowledges the Traditional Owners and their custodianship of the lands where we live and work.

We pay our respects to their Ancestors and their descendants, who continue cultural and spiritual connections to Country.

We recognise their valuable contributions to Australian and global society.

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Megan Pope.

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Foreword

Australia's Food and Beverage Accelerator (FaBA) is investing to grow commercial outcomes from university research. We are working with companies across Australia's plant and animal industries and are investing in research to develop and deliver new ingredients, new food and beverage products, and new production and processing innovations. FaBA connects teams of talented researchers with companies that are start-ups, small- and medium-sized enterprises, and multinational companies that are all delivering benefits to Australia. Our fundamental role is to invest in great science that delivers great value!

As we look to the future where concerns around population growth and climate change are calling on us to innovate in our food system, approaches from synthetic biology and more specifically from precision fermentation offer considerable promise. FaBA is investing in lab-scale bioreactors, pilot-scale infrastructure and in commercial projects with start-ups and larger companies. Our investments include the use of precision fermentation to produce proteins, lipids and a range of other molecules for innovative ingredients. Our projects also include techno-economic analyses and studies underpinning the environmental credentials of precision fermentation.

This White Paper, *Precision Fermentation: A Future of Food in Australia*, provides a comprehensive overview of precision fermentation. As we consider a future food system that includes advanced production systems such as precision fermentation, it is vital that we consider all aspects supporting effective implementation of this approach – both the opportunities and challenges. I commend this report to you and welcome your participation as precision fermentation becomes part of our food system and compliments other approaches to food production.

Dr Chris Downs
Director, Food and Beverage Accelerator

Introduction

To sustainably feed the growing global population, we must significantly scale up food production while reducing its environmental impact. This includes increasing protein supply from traditional sources, including meat, dairy and plants, and innovative sources through precision fermentation.

What is precision fermentation?

Precision fermentation builds on well-established fermentation techniques that have safely diversified our food supply for centuries, adapting them for modern, large-scale applications. Traditional fermentation transforms ingredients through microbial processes, producing food staples like bread, cheese, yoghurt, beer and wine. Precision fermentation enhances this process, cultivating microbial strains specifically engineered to produce high-quality protein and other ingredients. This method has the potential to enhance and complement food production by creating efficient, scalable alternatives to conventional food production systems.

Future foods

Precision fermentation has the potential to create entirely new ingredients, flavours and tastes while protecting the environment. It is a complementary technology that can enhance and diversify our food. Consider how Italian cuisine would be without tomatoes, Thai food without chillies, or a world without chocolate. When Christopher Columbus arrived in the Americas in 1492, he introduced tomatoes, cocoa, and chillies to Europeans and chillies to Asians, transforming global cuisines.

Today, precision fermentation represents a similar innovation, enabling the creation of novel and improved food products through advanced biotechnological processes. This technology has the potential to reshape our food systems, offering sustainable solutions that align with modern demands.

Precision Fermentation: A Future of Food in Australia provides a comprehensive overview of precision fermentation's potential to revolutionise food systems and to contribute to economic growth, environmental sustainability and food security across the nation.

I trust you will find the practical and policy recommendations helpful in ensuring that Australia grabs the opportunity to become a global leader in this field.

Professor Esteban Marcellin
Program Lead, Innovative Ingredients,
Food and Beverage Accelerator

Recommendations for policymakers

Appoint a Minister for Food and develop a National Food Plan

- Develop a National Food Plan and appoint an Australian Minister for Food to coordinate the regulation, innovation, and promotion of precision fermentation. This aligns with the 2023 Australian Parliament's Agriculture Committee report and submissions to the 2024 Government Inquiry into the Future of Food and Beverage Manufacturing.

Develop enabling regulatory frameworks

- Establish comprehensive regulatory and ethical guidelines for precision fermentation that prioritise consumer health, safety and innovation. Ensure these guidelines meet standards that facilitate market entry and avoid unrealistic expectations about the technology's potential.

- Engage industry experts, academics and regulators like FSANZ and OGTR to ensure adaptable, robust guidelines that address technological advances and environmental risks.

- Encourage FSANZ to accept risk assessments from reputable international bodies to streamline approval processes.

- Promote international harmonisation of regulatory standards to ensure clear market access, consistent labelling and environmental impact assessments.

- Provide educational programs to assist industry, especially startups, in navigating local and global regulatory frameworks and sustainability initiatives.

- Ensure sufficient funding for regulators to support precision fermentation innovation.

Promote responsible production of precision fermentation-based foods

- Integrate precision fermentation with traditional agriculture to address global nutrition challenges while supporting sustainable food systems. Focus on:

    - o Diversifying and developing resilient, resource-efficient crops

    - o Creating products that meet diverse dietary and cultural needs

    - o Targeting niche markets like plant-based alternatives, allergen-free products, and specialised foods for the elderly

- Maintain transparency around the risks and benefits of precision fermentation while addressing food security issues.

Ensure economic viability

- Encourage repurposing of underutilised facilities for precision fermentation to accelerate scaling. Establish a database to catalogue potential facilities for reuse.

- Invest in pilot- and commercial-scale manufacturing facilities that prioritise sustainable practices.

- Support public-private partnerships (PPPs) to drive precision fermentation's commercialisation, pool resources between government, academia and industry to share risks.

- Provide financial support and training for traditional agriculture sectors to adopt precision fermentation technologies.

Foster innovation

- Increase investment in research and development, focusing on:
  - Technologies that improve efficiency and sustainability
  - Advanced bioprocessing
  - Screening technologies
  - AI and machine learning to optimise precision fermentation processes

- Promote diverse funding models such as venture capital, private equity and crowdfunding to help startups scale. Align funding with technology readiness levels to avoid delays in market entry.

- Ensure precision fermentation products are economically accessible to prevent food inequities.

Encourage continuous environmental improvement

- Develop standardised methods to assess the environmental impact of precision fermentation through comprehensive Life Cycle Analyses.

- Set measurable sustainability goals for companies and mandate transparent reporting on environmental performance.

Promote collaboration

- Foster collaboration between precision fermentation companies and traditional industries to accelerate technology adoption.

- Support international partnerships focused on joint research, regulatory harmonisation and shared market access.

- Establish forums and workshops to enhance communication between academia and industry, ensuring research aligns with market needs.

Enhance education and public awareness

- Implement public education programs that address consumer concerns and highlight the benefits of precision fermentation. Emphasise the environmental and health impacts using transparent data, including lifecycle assessments.

- Collaborate with academia and industry to develop flexible curricula on skills critical to precision fermentation.

- Engage with consumer advocacy groups to support education efforts and improve public understanding of precision fermentation.

Chapter 1

Innovations in precision fermentation

Theme lead:

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FaBA and The University of Queensland

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Blair Keating, CSIRO

Dr Laura Navone, Eden Brew

Professor Jason Stokes,
FaBA and The University of Queensland

Dr Chiurugwi Tinashe, Sugar Research Australia

Dr Jason Whitfield, Main Sequence

Sally Wilson, QUT

Image credit: Megan Pope.

Introduction

Microbial fermentation has traditionally been used to preserve and create foods and beverages, and improve the nutritional value and bioavailability of foods such as sauerkraut, yoghurt and kombucha.

Now, precision fermentation is transforming our food production systems.

Leveraging tools developed for cell engineering and large-scale fermentation to tailor cellular production systems, researchers and industry are enabling the synthesis of food ingredients that promise greater sustainability and healthier, tastier, more nutritious products.

Current interest in precision fermentation is driven by a demand for proteins to feed a growing global population, and sustainable and ethical food production. However, the concept originated with the advent of genetic engineering in the 1970s, which enabled the biotechnological production of enzymes, proteins and small molecules [1].

Though more widely adopted by pharmaceutical and chemical industries, which use genetically modified organisms to produce therapeutics, medicine, fuels and chemicals, the food industry has applied recombinantly produced enzymes in food processing since the late 1980s.

For example, invertase is an enzyme that hydrolyses sucrose into glucose and fructose, and is used to increase the sweetness of syrups and prevent crystallisation [2]. Another example is the development of microbially produced chymosin used for milk coagulation in cheese production. This ethical and sustainable alternative to traditionally used rennet, which is obtained from the lining of calves' stomachs, has completely replaced the animal-derived coagulant in most cheese-making processes [3].

These enzymes are used to produce food and are not actual food. Examples of food ingredients derived from fermentation are vitamins, which are sold as food supplements. These are predominately synthesised with non-engineered microorganisms [4], while amino acids – such as sodium glutamate which is used as a food additive – are to some extent produced by genetically modified organisms at an industrial scale [5].

What's new about the current push for precision fermentation is its application to large-scale production of structured proteins and the manufacturing of tailored ingredients to enhance food and beverage properties. This chapter explores the opportunities in precision fermentation to innovate food production, and the challenges of scaling and commercialisation.

Opportunities

Broadening the food landscape

By separating the production of target molecules from the natural source, precision fermentation creates a vast landscape of food ingredients with unique and valuable properties:

- Ingredients typically found in complex mixtures can be produced individually, and mixed and matched to create novel foods
- Molecules produced by their native hosts in minor amounts, or by species that are extremely rare or difficult to harvest, can be made more accessible by fermentation and produced more cost-efficiently and sustainably
- Precision fermentation can produce essential food ingredients without relying on animal farming, addressing ethical concerns related to animal welfare and unsustainable practices
- Novel variants can be created through directed evolution or rational design, yielding molecules outperforming natural compounds.

Innovative ingredient development

When discussing precision fermentation, the focus is often on the production of alternative proteins. These serve as substitute building blocks for meat and dairy products, and are projected to have the largest volumes. However, minor ingredients that improve taste, smell and appearance by adding flavour and colour or modulating texture are also important. Typically, innovations in this field are inspired by nature, leading to the development of ingredients that significantly enhance the sensory properties of food and thereby enhance the overall sensory experience of food products.

A prime example is Unilever's development of ice-structuring proteins, which revolutionised ice cream production in the mid-2000s. These proteins bind to ice crystals and protect organisms from damage in freezing conditions and are thus also referred to as anti-freeze proteins [6]. They alter ice crystal growth, morphology and stability when subjected to freeze-thaw cycles [7]. This enables the production of ice cream with less fat, sugar and calories while including more fruit [8] and radically reduces the melt time of ice lollies in hot climates. The commercial utilisation of ice structuring proteins was only made possible by precision fermentation because they were present in only minuscule amounts in plants. The success of this invention was due to transparent communication addressing concerns about safety and the use of genetically modified yeast for protein production, appealing to health-conscious customers.

> "The recombinant production of the ice structuring protein started from basic science by Unilever in understanding how it functions in nature. Yet it enabled a step-change in innovation and radically improved the product quality.
>
> — **Professor Jason Stokes**
> UQ School of Chemical Engineering and Lead, Premium Food and Beverage Program, FaBA

Another example is soy leghemoglobin, produced in tailored yeast fermentation by Impossible Foods. This heme protein adds a meat-like flavour and texture to plant-based burgers [9, 10], which improves consumer satisfaction and acceptance of this animal-free alternative to meat. The development of microbial production of animal-like fats by the Australian startup Nourish Ingredients is driven by the same motivation. The desire is to produce potent fats that enhance the taste, aroma and mouthfeel in animal-free products.

Currently, the most prominent precision fermented food ingredients being targeted for development are milk proteins, including whey proteins, caseins and beta-lactoglobulin. The goal is to enable the animal-origin-free production of a broad range of products that use dairy ingredients, including milk, cheese and ice cream or to add to plant-based products, such as plant-based protein bars to improve chewiness and reduce brittleness. However, the innovation in precision fermentation extends beyond merely replicating natural compounds. Its true potential lies in the creation of enzymes, proteins and compounds with enhanced properties. Given the availability of the modern tools of synthetic biology that enable the precision engineering of living cells, precision fermentation enables step-change improvements.

The production of steviol glycosides via precision fermentation is another notable advancement. DSM and Cargill successfully established yeast-based manufacturing to overcome the limited supply of plant-derived sweeteners, known as stevia. This yeast-based process replicates the dominant glycosides found in stevia and enables the precise synthesis of individual glycosides that naturally occur in minimal quantities and complex mixtures, hindering separation and taste testing. Notably, the microbial platform can be engineered to surpass natural limitations by producing novel glycosides with enhanced properties, such as reduced bitterness.

Precision fermentation also has the capability to revive ancient biology. The US company Geltor engineered yeast to produce collagen from extinct mastodons, currently for use in skin and hair products. While this may sound like science fiction and evoke images of *Jurassic Park*, resurrecting ancient proteins is an established practice in synthetic biology. Researchers have demonstrated that these ancient enzymes retain stability and activity at higher temperatures, reflecting the environmental conditions of their era [11]. Similarly, resurrected mastodon collagen can offer unique product features and applications and be further tuned to meet application-specific demands such as gelling viscosity or elasticity.

Health benefits

Innovative ingredients accessible through precision fermentation include allergen-free versions of traditionally allergenic ingredients. Startup companies like Eclipse Ingredients, All G Foods, Perfect Day, Eden Brew and Vivici use precision fermentation to produce synthetic dairy free ingredients from lactose, hormones and allergens typically found in traditional dairy products, whilst aiming to offer the same nutritional and sensory properties as conventional dairy.

> “There’s a whole group of consumers who are interested in sustainable food, but it’s not for them because of the allergenic components. Precision fermentation can fill this gap.
>
> — **Sally Wilson**
> Senior Manager, Industry Engagement (Agriculture), QUT

Beyond synthetic dairy, precision fermentation is used to develop other foods tailored for people with specific allergies. For instance, the production of egg proteins using precision fermentation can provide an alternative for those with egg allergies, one of the most common intolerances globally. The synthetic egg variant offers the same functionality in baking and cooking without the allergenic components. Similarly, precision fermentation could produce gluten-free wheat flour, in which hypoallergenic proteins enable people with coeliac disease or gluten sensitivity to enjoy baked goods with the same texture and elasticity as traditional products. Ultimately, precision fermentation has the potential to provide personalised dietary solutions that meet the specific requirements of consumers.

Enhancing sustainability

It's claimed that precision fermentation of proteins and fats reduces the environmental impact associated with traditional animal agriculture, by lowering greenhouse gas emissions, land use and water consumption (cf. Environmental Sustainability). While thorough life cycle analyses are needed to verify such claims, the potential for sustainable food ingredient production through precision fermentation is significant. Realising this potential requires designing innovative precision fermentation systems with sustainability as a core objective. This involves the development of closed-loop systems that maximise resource efficiency and minimise waste production. Such systems should be designed from the outset to support these goals.

One key approach is the engineering of 'opportunistic' microbial cell factories that can switch between different feedstocks in an agile manner. This would allow the use of complex feedstocks, typically from waste or side streams, such as residues from sugar cane farming [12]. By enabling the use of diverse and locally available feedstocks, precision fermentation can be more resilient and sustainable. Feedstock flexibility also enables the operation of the same fermentation process in regions with volatile feedstock availability, with minimal adaptation. This concept is in stark contrast to current technologies, which often optimise for yield at the expense of flexibility. This is explained by the complexity of engineering strains that maintain similar productivity on different feedstocks. Large research synthetic biology initiatives such as the US Defense Advanced Research Projects Agency's Switch program are necessary to realise such agile biomanufacturing processes.

The food industry has a long history of using co-cultures in traditional fermentation processes. Initially motivated by enhanced flavour profiles, synergism between microbial species has also been shown to improve process performance, robustness and resource utilisation. This concept has extended to industrial fermentation for products like ethanol and ascorbic acid (vitamin C), and likewise holds significant promise for precision fermentation. Developing synthetic co-culture systems where multiple microbial species work synergistically can expand the substrate range, improve stress tolerance and facilitate novel product synthesis. In these systems, one microorganism might produce a by-product that serves as a feedstock for another, creating a more efficient and integrated process. Co-cultures come with their own challenges – for example, optimising multi-species growth conditions to maintain population stability. Future research aims to deepen our understanding of microbial interactions and apply synthetic biology to engineer optimal consortia.

Challenges

Target molecule selection

While synthetic biology and automation have rapidly advanced the development of novel fermentation-based processes for food production, the ability to forward-design novel food ingredients is limited. As a result, novel ingredients are predominantly identified through bioprospecting, which involves exploring biodiversity to discover potential molecules, enzymes and microbes with desirable properties [13, 14].

Australia is well-positioned to leverage this approach, building on the millennia-old knowledge of its Indigenous populations and harnessing the country's broad biodiversity. By combining traditional ecological knowledge with modern bioprospecting techniques, Australia can accelerate the discovery of novel ingredients with interesting functional or sensory properties.

Innovative methods for untargeted screening of taste and flavour compounds – such as electronic tongues or cell-based assays – that link taste receptors to a measurable output, combined with advanced, mass spectrometry techniques [15], support such efforts. Once novel ingredients are identified through bioprospecting, synthetic biology and precision fermentation can be employed to identify biosynthetic production pathways and engineer microorganisms to produce these compounds at scale.

It can be expected that machine learning and artificial intelligence (AI) will significantly spur compound selection and enable flavour prediction based on molecular structures, physical and chemical properties [16]. A recent study highlighted the complexity of predicting food and beverage properties. The study, which developed a machine learning model for beer flavour, incorporated chemical and sensory analyses of 250 different beers covering 200 properties and data from more than 180,000 consumer reviews [17].

> "Only a few cell factories are commonly used in the food industry. Sticking to these 'tried and true' options might mean we miss out on discovering better strains that nature has to offer.
>
> — **Laura Navone**
> Eden Brew R&D Director

Many variants of a candidate target already exist in nature – for instance, nearly every living organism contains heme proteins. Yet, thorough testing is required to identify the proteins that best enhance flavour and provide the 'authentic colour' in the final product. Additional considerations in target selection include stability throughout production, downstream processing, product shelf life and which targets accumulate at the highest titres within host cells, to optimise economic viability.

Consumer Acceptance

Consumer acceptance is paramount. The benefits of the ingredients must be realisable beyond economic factors, such as enhanced functionality, sustainability or nutritional benefits. Educating consumers about the safety and benefits of these products is essential, which can be enhanced by understanding the historical introduction of precision fermented ingredients into commercial products (e.g. ice structuring protein) and the strategies used to highlight their safety and efficacy. Historical examples, such as the development of rennet for cheese production, demonstrate that overcoming initial scepticism through clear communication and regulatory support can lead to widespread acceptance (cf. Food Safety and Consumer Acceptance).

> "Using non-animal rennet is important to many consumers who prefer cheese made without it. This preference for non-animal rennet has become quite common and can significantly enhance the acceptance of precision fermentation-derived food products.
>
> — **Blair Keating**
> Business Development Manager, CSIRO

Feedstock availability

Precision fermentation has been proposed to stabilise supply chains by reducing dependence on volatile agricultural markets, offering a competitive advantage in the face of climate change and global disruptions. However, because precision fermentation relies on agriculturally sourced feedstocks, predominantly refined sugars, it is not entirely independent of agricultural markets. Serving an estimated US$200 billion market for precision fermentation products necessitates a 20-fold increase in current production capacity. Meeting the demand for the primary feedstock – sugar – would require approximately 100,000km^2 of land, which is roughly equivalent to the size of Tasmania [18]. This reliance may become a bottleneck as demand for fermentation grows and underscores the need for feedstock diversification, which can be facilitated by precision fermentation (as outlined above) and strategic localisation of fermentation facilities near abundant, low-cost feedstock sources, such as the Future Foods BioHub to be established in Mackay, Queensland.

The scale-cost paradox

To date, several recent precision fermentation-derived products have been commercialised, such as Impossible Food's soy leghemoglobin, and Perfect Day's animal-free dairy proteins and stevia, produced by DSM and Cargill's joint venture, Avansya. Essential for successful commercialisation, as demonstrated by these and other examples, is the need to establish the benefits of the ingredient in its intended application and then effectively translate those benefits into positive commercial outcomes. However, the 'scale-cost paradox' remains a critical challenge in scaling precision fermentation processes. This dilemma arises when companies have potentially viable unit economics, but only if they can operate at a significant scale. Achieving this scale presents a catch-22 situation: startups struggle to finance large-scale production facilities without demonstrating substantial market demand, yet they cannot effectively compete or prove market viability without the economies of scale that come with larger production capacities [19].

Early and frequent techno-economic analyses can be helpful in convincing investors that the technical risk is low, but the market potential is enormous. This can be further supported by bio-industrial manufacturing readiness levels (BioMRLs), a framework that guides the scaling process by providing a structured approach to assess and mitigate risks [20]. Venture capital is often reluctant to finance investment in infrastructure due to the significant opportunity costs involved, which can divert funds from crucial R&D, sales and marketing efforts necessary to launch new products and services. Therefore, start-ups should plan to work with contract manufacturing organisations (CMOs) to outsource processes that are too costly, time-consuming or complex to manage internally. Such collaboration allows companies to refine their processes and troubleshoot issues before investing heavily in their own facilities, ensuring more efficient use of time and financial resources.

This requires a greater availability of contract capacity because precision fermentation companies often struggle to secure line time at demonstration-scale and mid-scale commercial production facilities. In Australia, this need was recognised by Cauldron Ferm, a company that specialises in providing fermentation services to precision fermentation companies, including Eden Brew and Nourish Ingredients, and contributed to building the Future Foods BioHub in Mackay with larger scale-production capabilities [21].

Moving precision fermentation from pilot to demonstration and then to commercial scale faces additional limitations; it has been estimated that the fermentation capacity needs to increase 20-fold by 2040 to satisfy the projected increase in market demand for precision fermentation products [19]. One significant challenge in upscaling precision fermentation is the complexity of downstream processing, as different products often require specific purification methods. To address this, innovative ideas are needed to develop more generic or modular processes, enabling CMOs to provide facilities that cater to various precision fermentation processes.

> “Standardisation of equipment and processes as much as possible is key to reducing upscaling and product purification costs.
>
> — **Professor Jason Stokes**
> UQ School of Chemical Engineering and Lead, Premium Food and Beverage Program, FaBA

An alternative to the costly and time-consuming building of new facilities is to repurpose and retrofit existing, under-utilised facilities such as decommissioned ethanol plants or existing animal protein processing plants. For instance, plant-based milk can often be produced using equipment and processes used in fruit juice production. This could make scaling cheaper and faster. But not all existing infrastructure can be converted for precision fermentation because there is variation in fermentation processes, for example in aeration demand, and therefore equipment, and because some facilities might be just too old.

Developing a centralised database that catalogues under-utilised facilities, including their geographic locations, current state, capacity and infrastructure details could help precision fermentation companies to identify suitable infrastructure.

> There is already significant fermentation capacity available that can be adapted for precision fermentation. The scale-up speed will depend on our ability to develop innovative methods for repurposing existing infrastructure and utilising current talent.
>
> — **Dr Axa Gonzalez**
> Senior Bioprocess Engineer, FaBA

Building and retrofitting facilities for large-scale production requires significant investment and technical expertise. Collaboration with established industries, such as the dairy or pharmaceutical sectors, can provide valuable insights and resources. Such collaborative effort was recently initiated in France, where Danone, Michelin and other investors agreed to establish a Biotech Open Platform to accelerate precision fermentation processes from lab to industrial scale, with demonstration fermenter and purification equipment being built by 2025 [22]. This initiative demonstrates the traditional dairy and chemical industries' recognition of precision fermentation as a promising technology for producing food ingredients.

The development of precision fermentation is simultaneous with the development of a bio-based economy. This could increase competition for fermentation and process equipment but could also be an opportunity for integrated biorefineries, where equipment can be shared and waste streams such as heat and biomass valorised.

Regulatory hurdles

Start-ups should engage with regulatory bodies early to explain new processes and products, so that potential risks can be assessed, and the regulatory framework updated accordingly. Failing to do so can result in the regulatory framework trailing technological advances, causing uncertainty and delays in the authorisation of new food ingredients and production processes, ultimately postponing market entry.

> Regulatory bodies are not against innovation ... Start-ups must seek the dialogue as early possible to ensure their technologies are properly assessed, and regulations are adapted to support and not hinder innovation.
>
> — **Ben Baldwin**
> Director Agri-Food and Data Science, Queensland Department of Agriculture and Fisheries

Role of startups and venture capital

Start-ups drive innovation in precision fermentation as they often exhibit a higher level of agility compared to larger, established companies. They can quickly adapt to new technologies and market demands, enabling them to experiment with novel ideas and approaches. The willingness of start-ups to take risks and explore unproven technologies can lead to breakthrough innovations in precision fermentation, and their efforts in research and development (R&D) are crucial for advancing the field and bringing novel products to market.

Venture capitalists play a pivotal role in supporting these startups, providing the necessary funding to help advance technology, scale operations and navigate the regulatory landscape. The influx of venture capital also helps de-risk innovation which encourages larger companies to invest or start joint ventures. This is important because venture capital is suited to early-stage venture risk but not building production facilities at demonstration scale, particularly for commercial scale. Such an alliance was recently announced by the start-up Nourish Ingredients and Fonterra, a major dairy player, which promises to accelerate the commercialisation of innovative fat-based food ingredients derived through precision fermentation [23].

More government support is needed, either through direct grants for precision fermentation start-ups during the commercialisation phase or investments into pilot plant facilities that start-ups can access.

> “Involvement from major industrial players can play a really powerful role in helping build and integrate these new technologies into the supply chain.
>
> — **Jason Whitfield**
> Investment Associate, Main Sequence Ventures

Image credit: Megan Pope.

Chapter 2

Environmental sustainability in precision fermentation

Theme lead:

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Panel of experts:

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Dr Simon Eassom, Food Frontier

Dr Andrew Fletcher, CSIRO

Dr Carol Hartley, CSIRO

Dila Karinta, Mandalay Ventures Partners

Karen Rodriguez Martinez,
The University of Queensland

Mariko Terasaki Hart,
FaBA and The University of Queensland

Dr Jason Whitfield, Main Sequence

Introduction

Precision fermentation has the potential to be transformative, significantly enhancing environmental sustainability in food production. As global challenges related to climate change intensify, innovative solutions are urgently needed to address the significant burden that producing food has on the planet. Current food production methods are unsustainable, contributing significantly to greenhouse gas emissions, land degradation, water depletion, deforestation, biodiversity loss, soil erosion, and pollution of waterways and air. These impacts are particularly concerning as the global population approaches 10 billion.

Despite its ambitious commitments under the Paris Agreement, Australia faces considerable hurdles in reducing anthropogenic CO_2 emissions [24]. The current strategies for carbon management need to be revised to meet the national and global climate targets, particularly within the food production sector, which remains a major contributor to environmental degradation. To align with these targets, Australia must accelerate its decarbonisation efforts, requiring a reduction of 17 Mt CO_2-e annually—over 40 per cent faster than the rate achieved since 2009 [25].

Given the unsustainable nature of current global food production practices, as evidenced by increasing environmental pressures [26], there is a pressing need for a paradigm shift. Precision fermentation presents a unique opportunity to revolutionise food systems. This chapter critically examines the potential environmental risks and benefits associated with the widespread adoption of precision fermentation, focusing on the Australian context.

In this chapter, we aim to carefully consider the key risks and challenges associated with precision fermentation to enable a new industrial revolution characterised by environmentally friendly practices and a smaller ecological footprint. We explore how precision fermentation can contribute to sustainability by reducing greenhouse gas emissions, water usage and land use, influencing planetary boundaries [27, 28] within food production. This chapter also assesses precision fermentation adoption's environmental risks and benefits, particularly in Australia. Through this analysis, we provide a roadmap for integrating precision fermentation into food systems, promoting a sustainable and resilient future.

Opportunities

Pathway to adopting sustainable food production systems

Societal pressure to adopt sustainable production methods is increasing. Precision fermentation creates several pathways to achieving sustainable food production, offering social, economic and environmental benefits [29].

To achieve sustainability in food production, a comprehensive approach is essential. Precision fermentation can significantly reduce water usage, land use and greenhouse gas emissions. Realising its full potential requires political and governmental support and collaboration with researchers and industry stakeholders to ensure social and economic sustainability.

Building a robust ecosystem that supports technological breakthroughs in precision fermentation is crucial. Government policies and incentives are vital in encouraging investment and research in sustainable technologies. Industry participation is key to integrating these technologies into production processes and market strategies [29]. Social acceptance and consumer awareness drive demand for sustainable products and practices. Aligning efforts across these domains can promote sustainability at every stage of the product lifecycle, ensuring precision fermentation contributes effectively to a sustainable future.

Reduced resource consumption

1. **Water**: Precision fermentation offers an efficient solution to reducing water usage in food production. Conventional methods are highly water intensive – for example, conventional dairy farming requires between 1,000 and 2,000 litres of water per litre of milk, encompassing irrigation, animal drinking water and cleaning [30]. Actual water use varies greatly among farming systems, with irrigation-only farms using up to 505 litres per litre of milk, while dryland farms relying solely on rainfall use as little as eight litres per litre of milk. When accounting for water used to grow feed crops, the average water usage can rise substantially, with a global average of 1,833 litres per kilogram of energy-corrected milk [30]. There's no doubt that precision fermentation requires less water because it bypasses the need for livestock. Microorganisms are fed simple sugars and, through fermentation, they produce proteins and fats, which are harvested to create ingredients. This process requires significantly less water because it eliminates large-scale irrigation, feed crop cultivation and animal hydration. While a thorough quantitative analysis is needed, precision fermentation could cut water usage to a fraction of what traditional dairy farming requires, potentially conserving vast water resources.

2. **Land**: Precision fermentation reduces reliance on arable land and decreases the impact on freshwater resources. Traditional dairy farming contributes to water pollution through fertiliser runoff and animal waste. In contrast, precision fermentation conducted in controlled bioreactors minimises environmental contamination and allows for more efficient resource management.

3. **Raw materials:** Precision fermentation utilises microorganisms to produce specific ingredients, reducing reliance on traditional agricultural inputs such as fertilisers and pesticides. This method can utilise waste feedstocks and non-food biomass, lowering environmental impact. Using these alternative feedstocks, precision fermentation reduces the competition for arable land and minimises the depletion of soil nutrients, which are common issues associated with monocropping practices in traditional agriculture.

Lower greenhouse gas emissions

Precision fermentation can significantly reduce greenhouse gas emissions by decreasing the need for livestock that is responsible for a considerable portion of global methane – a potent greenhouse gas – emissions. Precision fermentation bypasses the need for animals, eliminating methane emissions associated with livestock digestion and manure management. It can also reduce nitrous oxide emissions, another greenhouse gas, by minimising the use of synthetic fertilisers in feed crop production. This technology also lowers CO_2 emissions by reducing the need for large-scale irrigation and feed crop cultivation, contributing to overall emission reductions in the food production sector.

Agriculture contributes around 16 per cent of Australia's total greenhouse gas emissions, with dairy farms alone accounting for about 19 per cent of these emissions (or about 3 per cent of the national total) [31]. Emissions from dairy farms predominantly stem from several key sources, including:

- Methane produced by cows during rumination (60-70 per cent)
- Nitrous oxide from dung and urine (10 per cent)
- Energy and indirect losses from wet soils (10 per cent)
- Production of electricity used on-farm (10 per cent).

Each dairy farm's emissions profile varies based on specific practices, but this typical breakdown highlights the significant impact of methane and nitrous oxide emissions. A recent study suggests that phasing out livestock, combined with ecosystem restoration on land formerly used for grazing and feed crops, would provide half the emissions reductions needed to stay below a 2°C temperature rise [32] .

> "We have good metrics around sustainability improvements at small-scale fermentation, but at the larger scale, these are less clear and likely require the incorporation of complementary low-emission technologies, for example, to provide clean energy for fermentation processes.
>
> — **Dr Carol Hartley**
> Senior Research Scientist
> and Engineering Biology Team, CSIRO

Efficient waste management and by-product utilisation

Precision fermentation produces waste that needs to be managed effectively. However, it creates opportunities for efficient waste management and by-product utilisation. Utilising waste feedstocks that are currently going to waste can reduce environmental impact, and the by-products of precision fermentation can be repurposed or recycled, minimising waste and enhancing the sustainability of the production process. Developing comprehensive waste management strategies ensures the benefits of precision fermentation are maximised while minimising adverse effects. For example, spent microbial biomass can be used as animal feed or fertiliser, contributing to a circular economy and reducing the need for additional raw materials.

Genetically modified (GM) biomass from precision fermentation can be utilised in multiple ways to enhance sustainability in bioprocessing. It can be converted into high-quality fertiliser, enriching soil with essential nutrients and promoting plant growth. Alternatively, GM biomass can be a nutrient-rich animal feed, supporting livestock health and productivity. Additionally, recycling GM biomass back into bioreactors as a nutrient source for subsequent fermentation batches maximises resource efficiency, reduces waste and enhances the overall yield of the bioprocessing system. These applications highlight the versatility of GM biomass in circular bioeconomy strategies.

Complementing existing animal-based agricultural methods

While the onset of new technology has the potential to displace an existing industry, precision fermentation is likely to complement existing commercial food production methods for the foreseeable future. For example, producing high-quality protein supplements and essential nutrients through precision fermentation can enhance animal feed's nutritional content and efficiency. This can lead to better growth rates and health outcomes for livestock, allowing animals to achieve optimal growth with less feed. Consequently, the overall resource consumption of animal agriculture can be reduced, leading to a more sustainable system.

Moreover, precision fermentation can aid in utilising agricultural waste products, creating a circular economy within the food production sector. By using by-products and waste streams from animal agriculture as feedstocks for fermentation processes, valuable products – animal feeds and bio fertilisers – can be generated. This reduces waste and provides additional revenue streams for farmers. Integrating precision fermentation with traditional agriculture can also foster innovation and collaboration, driving the development of sustainable practices and technologies that benefit industry and the environment. This synergistic approach can enhance the resilience and sustainability of the overall food production system.

Addressing planetary boundaries

Precision fermentation has the potential to transform food production in Australia and globally, making it more environmentally sustainable. The concept of planetary boundaries, listed below, identifies nine critical Earth system processes that regulate the planet's stability and resilience [27, 33-35].

Addressing the transgression of these planetary boundaries is crucial and precision fermentation can significantly contribute to this effort. By evaluating its environmental benefits through the lens of these boundaries, we can better understand its impact on Earth's critical systems. This approach ensures precision fermentation helps maintain planetary stability and resilience, promoting sustainable and responsible food production.

1. **Climate change**: Precision fermentation can reduce greenhouse gas emissions by producing proteins and other food ingredients in controlled environments, eliminating the need for methane-emitting livestock. For Australians, this means mitigating the impacts of climate change, reducing the frequency and severity of droughts, bushfires and floods, and protecting communities and ecosystems.

2. **Biosphere integrity**: Traditional agriculture often leads to habitat destruction and biodiversity loss. Precision fermentation requires significantly less land, helping to preserve natural habitats and the unique biodiversity of Australia. Protecting biodiversity ensures the continued provision of essential ecosystem services such as pollination and water purification, which are critical for agriculture and human well-being.

3. **Land-system change**: Precision fermentation's minimal land requirements can alleviate pressure on land systems, allowing for reforestation and the restoration of natural habitats. For Australians, this translates to enhanced land productivity and the potential for land conservation efforts, promoting ecological balance and resilience.

4. **Biogeochemical flows**: Excessive use of fertilisers in traditional agriculture disrupts nitrogen and phosphorus cycles. Precision fermentation can reduce the need for these inputs by utilizing more efficient nutrient cycles within controlled environments. This reduces the risk of water pollution and eutrophication, benefitting Australia's waterways and aquatic ecosystems.

5. **Freshwater use**: Agriculture is a major consumer of freshwater resources. Precision fermentation can drastically cut water usage by eliminating the need for irrigation-intensive crops and livestock hydration. This is particularly important for Australia, where water scarcity is a critical issue. Reduced freshwater use helps preserve drinking water supplies and supports the health of freshwater ecosystems.

6. **Ocean acidification**: By reducing CO_2 emissions, precision fermentation indirectly helps mitigate ocean acidification. Healthier oceans support Australia's marine biodiversity and fisheries, which are vital for food security and the economy. This also protects the Great Barrier Reef, a critical natural asset and tourist attraction.

7. **Atmospheric aerosol loading**: Precision fermentation can be designed to emit fewer particulates and pollutants compared to conventional agricultural practices. Improved air quality benefits public health and reduces the environmental impact of food production, contributing to cleaner skies and healthier communities in Australia.

8. **Novel entities**: Precision fermentation minimises the release of novel entities such as pesticides and synthetic fertilisers, which can have harmful and long-lasting environmental impacts. By producing food ingredients in controlled settings, the technology reduces the introduction of potentially hazardous substances into the environment, protecting Australia's ecosystems and human health.

9. **Stratospheric ozone depletion**: While precision fermentation is less directly related to ozone depletion, promoting sustainable practices and reducing overall chemical emissions can contribute to global efforts to recover the ozone layer. By minimising the environmental footprint of food production, Australia can help maintain and improve atmospheric health.

By identifying which planetary boundaries precision fermentation can positively influence, efforts can be targeted where the technology has the most significant impact, aligning with global sustainability goals.

Considering planetary boundaries helps proactively address potential risks and unintended consequences, such as increased reliance on certain feedstocks leading to monoculture. This ensures a more sustainable implementation while providing a scientifically grounded basis for developing policies and regulations. Governments and regulatory bodies can create incentives and support systems that promote precision fermentation, ensuring it contributes to environmental sustainability.

Integrating precision fermentation into food and industrial production systems allows Australia to significantly contribute to global efforts to respect and restore planetary boundaries. This technology offers a scalable solution that aligns with the urgent need to transition to sustainable practices and mitigate the adverse impacts of human activities on the Earth's critical systems. By evaluating precision fermentation through the lens of planetary boundaries, countries like Australia can lead in global sustainability efforts, preserving the Earth's critical systems and inspiring other nations to adopt similar practices.

Challenges - Environmental

Achieving large-scale sustainability in food production requires a holistic approach, focusing on reductions in water usage, land use and greenhouse gas emissions. Precision fermentation offers significant benefits by producing ingredients more efficiently than conventional methods. However, precise data is needed to quantify these reductions accurately, especially on a larger scale. While precision fermentation holds promise, it also poses potential environmental risks.

Continuous evaluation and improvement of the environmental footprint of precision fermentation processes are necessary. This includes optimising energy use, sourcing renewable feedstocks and minimising waste. In addition, if additional infrastructure must be built, its environmental and ecological impacts (on local habitat, biodiversity, land and water management, etc.) must be considered.

Monocropping for feedstocks

Precision fermentation relies on feedstocks like sugar, corn, and potatoes, which could lead to monoculture practices. Monocropping can deplete soil nutrients, increase vulnerability to pests and diseases, and reduce biodiversity. To mitigate this risk, it is essential to ensure genetic diversity and a consistent supply of sustainable feedstocks. Using agricultural waste and non-food biomass as feedstocks can also help minimise environmental impacts.

Energy use and non-renewable electricity

The production process in precision fermentation facilities requires significant energy inputs. The overall environmental benefits could be diminished if these facilities rely on non-renewable electricity. Integrating green technologies, such as renewable electricity and hydrogen production, into new precision fermentation facilities is crucial to ensure sustainability [34]. A recent study demonstrated that beta-lactoglobulin produced via precision fermentation exhibits a comparable environmental impact to dairy-extracted milk protein, with carbon footprints ranging from 5.5 to 17.6 t CO_2e/t protein and water scarcity footprints ranging from 88 to 5030m^3 world eq./t protein [36]. The primary environmental contributors were sugar and electricity production, with significant variations influenced by location and feedstock proximity. Integrating renewable energy sources and sustainable carbon feedstocks is essential to enhance precision fermentation's sustainability.

Water and biomass usage

Improvements in water and biomass usage are necessary to minimise environmental impacts. Precision fermentation generally requires less water than traditional agriculture, but the production scale could still impose significant demands. Efficient water management systems and sustainable biomass sourcing are essential to maintain low environmental footprints.

Precision fermentation produces waste that needs to be managed effectively. Utilising waste feedstocks that are currently going to waste can reduce the overall environmental impact. Developing comprehensive waste management strategies will ensure that the benefits of precision fermentation are maximised while minimising adverse effects [37].

Challenges - Commercial

Comprehensive approach

Sustainability must encompass responsible resource use, financial and commercial viability, social sustainability, job opportunities and community involvement [31]. This holistic approach ensures benefits for all stakeholders and creates a foundation for long-term success in various industries.

Applying this comprehensive perspective to precision fermentation can significantly enhance its environmental sustainability in food production. To achieve its full potential, precision fermentation requires a strategy that considers social and economic sustainability, secures political and governmental support, and fosters collaborations with researchers and industry stakeholders. Building a robust ecosystem that supports technological breakthroughs is essential for driving sustainable practices.

This strategy involves the entire system, from ingredient manufacturing to consumer use, and requires collaboration across various sectors to foster innovation and implement sustainable technologies. Government policies and incentives are crucial in encouraging investments and research in sustainable technologies. Industry participation is vital for integrating these technologies into production processes and market strategies. Social acceptance and consumer awareness drive demand for sustainable products and practices.

Adopting biomanufacturing technologies like precision fermentation supports economic growth and aligns with domestic and global sustainability goals. Reducing emissions and remaining within planetary boundaries will mitigate the worst impacts of climate change while creating jobs and new industries [24] . The government's commitment to investing in a 'Future Made in Australia' will help establish a comprehensive, coordinated, and practical strategy to seize these opportunities [29]. This critical juncture in our climate narrative necessitates innovative carbon management and mitigation approaches. Biological solutions, utilising the natural capabilities of microbes and microbial communities, offer a scalable solution capable of effectively achieving gigaton reductions in the food and beverage sectors.

> "The next decade represents the initial phase of adopting precision fermentation. The industry must achieve technological breakthroughs to realise this potential. Precision fermentation has immense potential to produce complementary proteins and ingredients with significantly greater sustainability.
>
> — **Siobhan Coster**
> Chief Executive Officer/Co-founder, Eclipse Ingredients

Economic viability

Ensuring sustainable products are economically competitive is key. The industry must focus on commercial growth while embedding sustainability in its practices. This includes achieving economies of scale to lower production costs, creating market demand through consumer education and awareness, and developing value chains that support sustainable practices. Financial incentives and subsidies from the government can also help bridge the gap during the initial scaling phases.

Economic sustainability through normalisation and commercial viability is crucial, and regulations must promote industry accountability to address environmental impacts effectively.

Regulatory support

Obtaining robust regulatory support from state and national governments is vital for successfully adopting and expanding precision fermentation. Clear regulations and policies that support sustainable practices provide incentives for innovation and ensure food safety can help facilitate industry growth. This includes streamlining approval processes for new products and technologies, offering financial incentives, and fostering collaboration between regulatory bodies and industry stakeholders.

Connecting the theoretical benefits of precision fermentation with tangible outcomes underscores the importance of collective action, strategic planning and supportive ecosystems. This approach aligns with the holistic view of sustainability discussed earlier in the paper, integrating technological innovation with industry guidance. It provides a balanced view of the potential and challenges of precision fermentation, highlighting the need for collaboration between scientists, industry leaders and policymakers.

> "Investors require a comprehensive understanding of sustainability within the fermentation process itself. A detailed roadmap to market, outlining the benefits of each step, is currently lacking.
>
> — **Dila Karinta**
> Private Investment, Mandalay Ventures Partners

Transparency

Clear communication about the environmental and economic benefits of precision fermentation is essential. Investors and consumers need comprehensive information to understand the sustainability of the fermentation process itself [38].

Providing accurate and realistic information about sustainability practices helps maintain credibility and trust, especially when scaling up production. Aligning sustainability claims with actual practices ensures that stakeholders, including consumers and investors, can make informed decisions.

The food industry faces challenges in communicating sustainability due to consumers' focus on price, nutrition and health. Clear labelling and communication about sustainability practices can educate consumers and investors, fostering trust and demand for sustainable products. Ensuring that sustainability efforts are genuine, with accountability and transparency across regions and industries, is essential for the credibility and success of precision fermentation.

> Conversations about sustainability must adopt a holistic system view, especially since we primarily discuss ingredient manufacturing. This perspective should extend to the production of finished consumer products.
>
> — **Andrew Fletcher**
> Sustainable Food Systems, Fonterra

Infrastructure

Developing and maintaining the necessary infrastructure, including pilot-scale manufacturing facilities, is crucial for scaling up production and achieving commercial viability. This of course requires significant funding and investment from industry and the government.

The Commonwealth Scientific and Industrial Research Organisation (CSIRO) has emphasised the need for shared access to affordable and suitably accredited pilot-scale manufacturing facilities. This infrastructure is crucial for scaling innovations and achieving commercial feasibility. By streamlining and strengthening the translation of scientific advancements into practical applications, Australia could position itself as a leading supplier of sustainably manufactured products across various industries by expanding local precision fermentation capabilities.

> Sustainability is a difficult message in terms of consumption. The path to go is through commercial growth. Sustainability is the objective, not the method. It will happen, we will produce more sustainable products, we are confident about what we're doing, but we don't sell it as sustainability, we sell the commercial viability and scale-up opportunity.
>
> — **Simon Eassom**
> Chief Executive Officer, Food Frontier

Chapter 3

Economic implications of precision fermentation

Theme lead:

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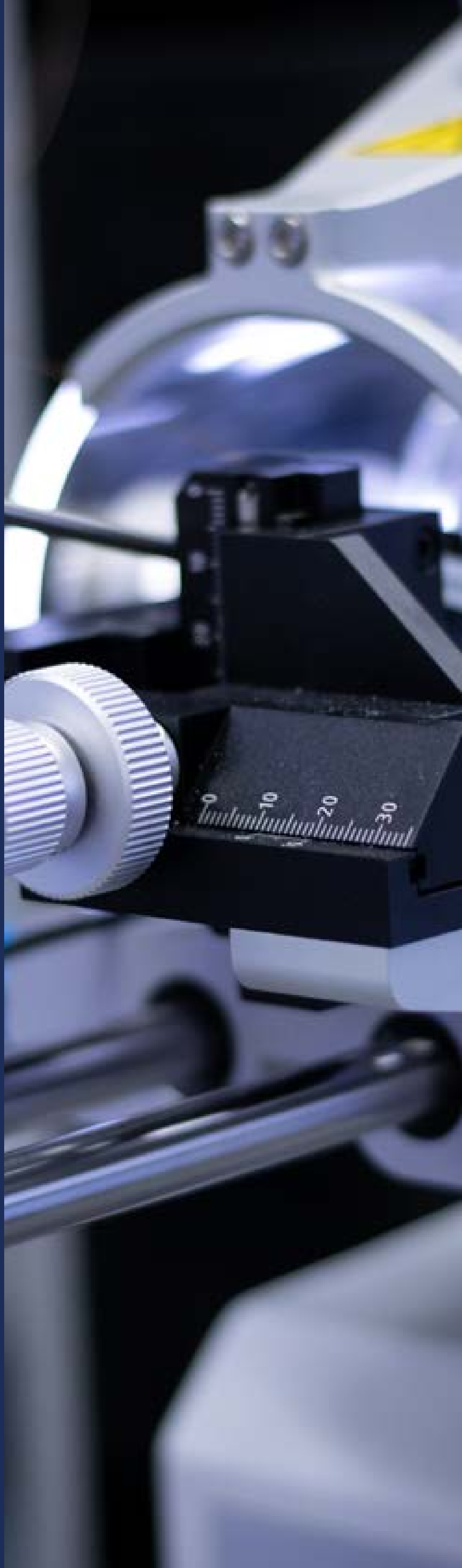

Introduction

Precision fermentation represents a transformative frontier in food production and is poised to revolutionise traditional agricultural practices. By integrating advances in engineering biology, molecular biology, genetics, systems biology and computational design, precision fermentation has the potential to manufacture innovative food products that are high quality and potentially more sustainable and nutritious [39-41]. Precision fermentation is at the forefront of innovation, offering potential solutions to some of the most urgent challenges faced by the global food industry, including resource depletion, environmental degradation and the ever-increasing demand for food due to population growth [40]. Its success, however, depends on building technical skills and the capacity to navigate complex and developing national and international regulatory systems, intellectual property rights and ethics.

The economic impact of integrating precision fermentation into food production is profound and diverse. It creates opportunities for cost reduction in the production process and the emergence of new markets for innovative food products. As well, precision fermentation holds the promise of improving the nutritional content of food while minimising the environmental impact of agricultural practices. According to a recent report by CSIRO and Main Sequence Ventures, precision fermentation advances could generate up to $30 billion in annual revenue across impacted sectors in Australia and create more than 50,000 new jobs by 2040 [42]. Like any disruptive technologies, the widespread adoption of precision fermentation in food production faces significant challenges – high initial costs, regulatory complexities, ethical considerations and the necessity for consumer acceptance [40, 43, 44].

In exploring these issues, this chapter aims to provide a comprehensive perspective on the economic impacts of precision fermentation in food production, highlighting both the vast opportunities and the potential challenges. We will delve into the complexity of integrating precision fermentation into the existing food supply chain, its effects on traditional farming communities and the broader economic benefits it could bring. Additionally, we will examine the regulatory framework necessary to foster innovation while ensuring safety and public confidence. Through this comprehensive examination, our goal is to equip policymakers, industry leaders and stakeholders with the knowledge needed to navigate the economic landscape shaped by precision fermentation in food production.

Opportunities

Enhancing food security

Precision fermentation offers significant opportunities to enhance global food security. By enabling food production in challenging agricultural conditions, precision fermentation can mitigate the impact of climate change – such as erratic rainfall and extreme temperatures – on food supplies. Engineered crops, designed to be resilient to these conditions, can ensure a stable food supply even where traditional agriculture might struggle [40, 45].

> "International collaborations, are crucial in making these technologies accessible and effective in regions where the environment and lack of arable land contribute to food insecurity, such as Singapore, Japan, the Maldives and the Middle East.
>
> — **Victoria Snelson**
> Head of Impact and Commercialisation, Bioplatforms Australia

Precision fermentation also contributes to food security by creating nutrient-dense foods, which addresses malnutrition and micronutrient deficiencies in developing countries. The ability to engineer microbes to produce higher levels of vitamins, proteins or essential fats has a profound effect on global health and nutrition. Beyond improving food quality, this aspect of precision fermentation enhances the quality of life for millions worldwide [46, 47].

Sustainability and environmental impact

The environmental sustainability of precision fermentation represents one of its most significant advantages [39, 43]. Precision fermentation has the potential to significantly reduce the ecological impact of food production. For instance, cultured meat (such as Eat Just, UPSIDE Foods, Aleph Farms and Vow) and dairy products (such as Nourish Ingredients, Eclipse Ingredients, All G Foods and Perfect Day) show potential to improve food safety, and require far less water and land compared to traditional livestock farming. This could decrease deforestation and carbon emissions associated with conventional farming, as well as animal cruelty.

Moreover, precision fermentation could contribute to a reduction in food waste by enhancing the shelf life and transportability of food products through bio-preservation techniques. These innovations promote sustainability and improve economic efficiency by reducing costs related to spoilage and logistics [39].

Economic diversification and innovation

Precision fermentation has the potential to play a crucial role in economic diversification and driving innovation. The creation of novel products, impossible through traditional methods, will open fresh market opportunities and stimulate economic growth. These products can offer unique flavours, textures and nutritional profiles, tailored to meet specific consumer needs [41, 47]. Food flavour via precision fermentation-based biomanufacturing could be cheaper and more efficient than large areas of planting. The innovations within precision fermentation also attract investments and generate high-value jobs, contributing to the overall economic well-being of regions that invest in this technology.

For example, one application for precision fermentation within the sugar industry, supported by government, was to produce ethanol, and other value added products, using sugar as feedstock. Based on previous practices and the existing sugar industry infrastructure in Queensland, it is necessary to carefully consider the location, feedstocks and government support from state and local community before driving commercial investment and tracking new precision fermentation food production technology [48].

Furthermore, precision fermentation could bolster economic resilience by reducing reliance on traditional agricultural inputs, which are vulnerable to price fluctuations and supply chain disruptions. Shifting toward more controlled and predictable production methods can lead to greater stability in food prices and supply.

Job creation and skill development

The adoption of precision fermentation in food production will create new job opportunities across various sectors, including research and development (R&D), biotechnology, manufacturing and regulatory affairs. This demand for skilled workers necessitates educational institutions to develop tailored curricula and training programs. The resulting growth in research, manufacturing and regulatory roles will stimulate innovation and economic growth [45] by enhancing R&D, increasing productivity, creating high-quality jobs, stimulating educational advancements, fostering entrepreneurship and improving global competitiveness. This expansion will require development of robust regulatory frameworks to ensure the safe and responsible implementation of precision fermentation in food production [45].

These emerging jobs are wide-ranging, from lab technicians and bioengineers to supply chain managers and regulatory specialists. This diversification in employment opportunities could help mitigate the impact on traditional farming jobs by providing alternative career paths. For example, a technician working in a traditional brewery who's responsible for monitoring fermentation could transition to a role as a bioprocess technician in a precision fermentation company producing fermented food products like dairy alternatives or meat substitutes.

Ongoing job creation and skill development relies upon:

- Governments providing incentives, clear regulations and public-private partnerships
- Education systems updating curricula, offering vocational training and promoting lifelong learning
- Industries offering internships, apprenticeships and collaborating with academia to ensure graduates are ready for the workforce
- Fostering essential support systems like career counselling, job placement services and mentorship programs
- Access to technology and infrastructure development.

Public awareness campaigns and community involvement would ensure widespread benefits, creating a robust ecosystem for skill transfer and alternative career paths, mitigating the impact on traditional farming jobs.

> Effective skill transfer to these new biotech jobs requires coordinated efforts in policy support, educational reform and industry collaboration ... But we need always to have in mind what the consumer needs are to shape and frame that collaborative effort to ensure a successful outcome.
>
> — **Dr Francisco Codoner**
> Chief Executive Officer, ScaleUp Bio

The growth of precision fermentation industries can simultaneously develop industry and talent. Transferrable skills from related fields, such as chemical engineering, can be leveraged to reduce training costs and accelerate workforce development. Collaborative efforts between governments and educational institutions are essential to ensure a steady supply of qualified professionals to meet the increasing demands of this sector.

> Precision fermentation enables the development of foods catering to specific dietary requirements.
>
> — **Anna Tao**
> Venture Builder, Beanstalk AgTech

Global health and nutritional improvements

Precision fermentation offers significant potential for improving global health outcomes through enhanced nutritional content [39]. By engineering foods to be richer in essential vitamins, minerals and other nutrients, precision fermentation can help combat malnutrition and address nutritional deficiencies that affect millions of people worldwide. For example, biofortified products with increased levels of vitamin A, iron or zinc can play a crucial role in regions where these deficiencies are prevalent, leading to better overall health and reduced incidence of related diseases [49].

Precision fermentation can also drive the development of functional foods with improved food flavour and colour that go beyond basic nutrition [50, 51]. It can enhance the sensory properties of foods, making them more appealing and enjoyable to consume. This can encourage healthier eating habits, as consumers may be more likely to choose nutritious options that taste better and look more appealing. Additionally, these functional foods can incorporate bioactive compounds that promote better health and potentially reduce the incidence of chronic conditions such as cardiovascular diseases, diabetes, obesity and cancer.

For instance, foods enriched with colourants such as betanin [50], antioxidants such as resveratrol, aromatics such as raspberry ketone [52] or omega-3 fatty acids [53] can contribute to improved health outcomes while also providing a pleasurable eating experience. The improvements in flavour and colour achieved through precision fermentation are not merely aesthetic but can also play a role in promoting healthier dietary choices and enhancing overall wellbeing.

The potential impact of precision fermentation on global health is immense [47]. By prioritising nutrient-dense and functional food production, this technology can significantly contribute to improving public health outcomes, particularly in regions where access to diverse and nutritious food is limited.

Challenges

High initial costs and economic viability

The implementation of precision fermentation in food production requires substantial initial investment [54]. Establishing the necessary infrastructure for bioprocessing facilities involves significant capital, which may discourage investment in this innovative technology. It is important to establish accessible pilot and scale-up facilities for the product development phase. These facilities play a pivotal role in enabling start-ups and spinouts to succeed in the global precision fermentation race. Also, the R&D phase is both lengthy and costly, requiring high-tech equipment and highly skilled personnel. To achieve economic viability, precision fermentation products must not only compete with but also surpass traditional products in terms of cost, yield and quality.

The scalability of production is critical for precision fermentation products to become mainstream and production must scale without a corresponding increase in unit costs. Addressing issues with batch consistency, quality control and supply chain logistics are more complex for biologically engineered products than their conventional counterparts. Achieving economies of scale in precision fermentation food is essential to ensure that these innovative products are both affordable and accessible [55].

In addition, the economic model underlying precision fermentation is not static, and it evolves alongside technological advancements and market dynamics. Factors such as government policies, regulatory frameworks and market acceptance significantly impact the long-term economic viability of precision fermentation products [40, 56]. Understanding and optimising these factors are key to fostering a competitive precision fermentation food industry.

Consumer acceptance and market penetration

Despite the potential benefits of precision fermentation, gaining consumer acceptance remains a challenge [40, 55]. The market penetration of foods derived from precision fermentation depends on shifting consumer perceptions, which currently favour natural and organically produced foods. There is widespread public debate regarding genetically modified organisms (GMOs) and products of precision fermentation often encounter similar concerns [46].

To tackle this challenge, significant efforts must be devoted to transparent communication and education. Consumers need to be informed about the processes involved in precision fermentation, the safety measures in place and the benefits of these products, such as enhanced nutritional content and reduced carbon footprint [56]. Furthermore, taste and aesthetic qualities must be comparable or superior to traditional products to win over consumers.

Labelling is another factor that influences consumer acceptance. Clear and informative labels, highlighting the benefits and safety of precision fermentation products, can enhance consumer trust. Engaging with consumers through educational campaigns and transparent communication is vital for fostering acceptance [56, 57].

Impact on traditional agriculture and local economies

Although precision fermentation could be a boost to future agriculture [58], sectors such as dairy and meat production may experience significant disruptions [58]. For foods that are becoming increasingly expensive or unsustainable to produce (e.g. coconut butter), alternative synthetic approaches should be considered. Smallholder farmers and communities whose livelihoods depend on traditional agriculture might struggle to compete with the efficiency and profitability of these synthetic alternatives. This transition could result in job losses within traditional farming sectors, necessitating strategies for economic transition and support. Policymakers must develop measures to mitigate adverse effects on these communities, including retraining programs, financial assistance and gradual integration of new technologies. There should be an opportunity to explore how precision fermentation can complement rather than completely replace traditional farming, such as creating hybrid models that leverage the strengths of both approaches.

The economic impact on traditional farming communities can be significant. The fishing industry, for example, is already affected by environmental changes and further challenges could arise due to the introduction of precision fermentation alternatives. For instance, lab-grown seafood from cell cultures can provide a sustainable alternative to traditional fishing, reducing overfishing and the depletion of wild fish populations. Precision fermentation omega-3 fatty acids through engineered microorganisms can reduce the need to harvest fish for these valuable nutrients, promoting ocean conservation [53]. Precision fermentation can benefit sustainable aquaculture through various advancements – developing more efficient and sustainable feed using engineered microbes, enhancing fish health by creating probiotics, and improving disease control and prevention with vaccines for common fish diseases.

To ensure affordable food and market stability, the scale of precision fermentation food production must be large enough to meet demand without causing significant disruptions to traditional farming practices. Companies like Impossible Foods and Beyond Meat have successfully scaled plant-based meat production, partnering with large food chains for wide distribution. Solar Foods and Air Protein are developing scalable technologies to produce protein from air and electricity. Governments can support these transitions through subsidies and tax incentives for sustainable practices (e.g. European Union's Common Agricultural Policy), public R&D funding (e.g. United States Department of Agriculture grants) and clear regulatory frameworks (e.g. US Food and Drug Administration, European Food Safety Authority). Education programs (e.g. US Sustainable Agriculture Research and Education) help farmers adopt sustainable methods, while public-private partnerships foster innovation (e.g. Protein Challenge 2040). These policies and practices ensure market stability and affordability in precision fermentation food production.

Regulatory and ethical considerations

The regulatory landscape presents a critical challenge for precision fermentation food production [45]. Global regulatory bodies are grappling with how to classify and manage products derived from precision fermentation, given their novel nature. Society requires clear, scientific data-based regulatory frameworks that ensure safety and efficacy while also promoting innovation [59].

For precision fermentation to live up to its perceived potential, an enabling policy and regulatory environment is needed. International governance and regulation associated with precision fermentation is complex and would benefit from a coordinated and cooperative approach including Good Manufacturing Process and International Standards developed through the International Organization for Standardization (ISO) system.

Further, social license and equity need to be addressed. Social license is essential and must be designed from the outset in conjunction with strong, clearly communicated and unbiased scientific evidence-based advice. How ethics, values, risks and benefits are considered, and what role they play in the public perception of these technologies, vary worldwide so different regulations exist in different countries.

Ethical concerns often arise regarding genetic modification and biodiversity. The potential for monopolisation of food products through patents on genetically engineered organisms could limit access to these technologies and worsen global inequalities. Global inequalities arise as high costs of patented GM crops burden farmers in developing countries, exemplified by Bt cotton in India leading to farmer debt, and limited access to agricultural innovation due to concentrated corporate control of patents [49].

To address these challenges, fostering an ongoing dialogue among regulators, industry stakeholders, researchers and consumers is important. Developing ethical guidelines and adaptive regulatory standards will be crucial. These regulations should protect consumers and the environment, and support the development and commercialisation of precision fermentation applications in food [45].

Regulatory frameworks must be flexible yet robust, ensuring safety without stifling innovation. The variability in food regulation across different countries adds complexity, as products may require different labels or approvals in various markets. Harmonising international regulations could facilitate smoother market entry and broader acceptance of precision fermentation products.

Technological challenges and scalability

The complexity of precision fermentation processes poses significant challenges in terms of scalability and integration into existing food production systems. While laboratory successes show promise, translating these achievements into commercial-scale operations is not straight forward. These challenges include maintaining genetic stability in organisms, achieving consistent yields and ensuring that the sensory and nutritional qualities of precision fermentation products meet consumer expectations [54, 58].

Advancements in precision fermentation, automation and process engineering are critical to address these obstacles. The industry must invest in R&D to refine and optimise production processes. Collaboration with academic and research institutions can accelerate technological improvements and lower barriers to scale. Developing robust, scalable technologies will be key to the widespread adoption of precision fermentation in food production [45].

Technological innovations must also consider feedstock costs and waste management. Utilising waste or low-cost feedstocks can reduce production costs and improve economic viability. Optimising these processes can lead to more efficient and sustainable production methods, enhancing the overall appeal of precision fermentation.

Image credit: Megan Pope.

Chapter 4

Workforce and partnerships for precision fermentation

Theme lead:

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Pakornwit Sarnpitak, MSF Sugar

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Adjunct Professor Claudia Vickers, QUT

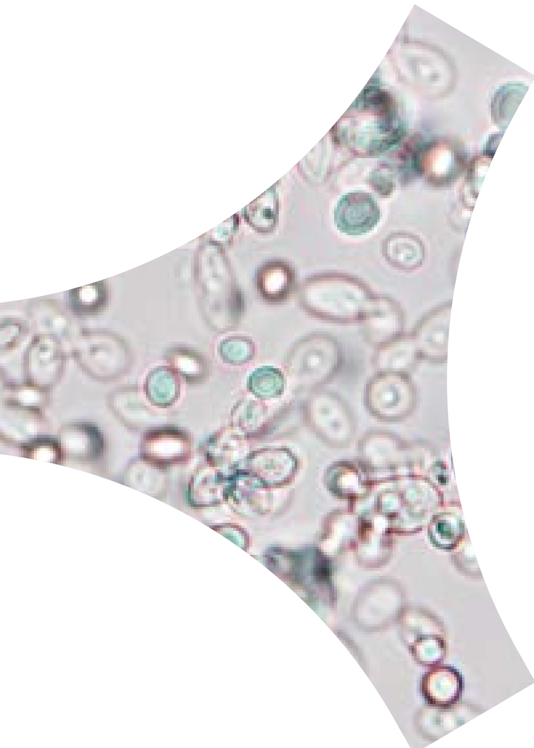
Farzan Zare, The University of Queensland

Introduction

The intersection of precision fermentation and food science presents a transformative opportunity in food production, driven by advancements in biotechnology and the need for a more sustainable and resilient foundation to our food systems. To date, few precision fermentation-based products have reached the market. If acceptance and adoption increase over time, the development of a skilled workforce and the establishment of robust partnerships between academia, industry, government agencies and communities will be critical to its success. As a nascent industry, workforce development and strategic partnerships will determine the pace of investment and development, which in turn will influence the amount and success of innovation in precision fermentation-driven food production.

To realise the full potential of precision fermentation, a robust and agile workforce, coupled with strong industry-academic partnerships, is essential. A workforce supporting precision fermentation for non-animal based dairy products, for example, will have a profile more akin to industrial production than agricultural. However, not all stages of the supply chain will look different. As products approach the retail end of the chain, the skills and roles will look little different to those in traditional industries.

As a burgeoning industry, precision fermentation in food is yet to benefit from the successes that have already occurred in more advanced industries like chip production, social media, pharmaceuticals, agriculture and traditional food production. For many of these industries, the science and technologies that underpin them have been validated and widely adopted which reduces the risk for investors, increasing the flow of capital. Precision fermentation is yet to overcome its risks and remains dominated by small startups, many of



which are yet to release products to market. Most would be regarded as R&D companies rather than manufacturing companies. The skills required for R&D are vastly different to those needed for manufacturing. In fact, the entire business model looks different. However, the industry will evolve, as will the skills needed.

The importance of partnerships in this context cannot be overstated. Effective collaboration between academia and industry is essential for fostering innovation, derisking and translating research into commercial applications, and ensuring that education and training programs remain responsive to the needs of the market. These partnerships facilitate mobility of capital, labour, experience and knowledge, and associated human, intellectual, financial and physical resources, enabling the rapid development and scaling of innovative technologies.

Moreover, industry partnerships help ensure that academic research has the right mix of science and technology push, and market pull, to increase the likelihood of successful commercialisation. Significant barriers to collaboration, including communication gaps between academic institutions and industry, mismatched timelines, differing priorities and, in some areas, an underinvestment in infrastructure exist. Overcoming these challenges requires deliberate efforts to build long-term partnerships that are mutually beneficial. This could involve creating more opportunities for industry placements, internships and joint research initiatives that embed students and researchers within industrial settings, and more fluid exchanges between industry and academic personnel, enhancing their practical experience and understanding of the commercial landscape [60].

Opportunities

As the precision fermentation sector continues to evolve, numerous opportunities arise to address current challenges and drive innovation forward. Solutions to the current challenges can be leveraged by the sector to accelerate its impact on sustainable food production, ensuring that it remains at the forefront of technological advancements and market readiness.

Opportunities in workforce development

There are numerous opportunities to enhance workforce development in the precision fermentation sector, ensuring that curricula remain aligned with industry needs.

Collaborative curriculum design and development: Academic institutions should work closely with industry stakeholders to co-design and co-develop curricula that reflect the latest trends and technologies, the needs of industry (now and in the future), the complexities of working in interdisciplinary teams and the intricacies of navigating regulatory pathways. This can be achieved by incorporating case studies and inviting industry professionals as guest lecturers to provide practical insights and align academic learning with industry expectations.

Modular and flexible learning pathways: Creating modular courses that allow students to specialise in areas such as precision fermentation, bioprocessing or regulatory compliance can help students acquire specific skills that are in high demand, making them more attractive to employers.

Enhancing practical and hands-on training: Theoretical knowledge alone is not enough to prepare students for the precision fermentation industry. Practical experience is critical. Industry placements and internships embed students in industry providing them with direct experience, deepening their understanding of precision fermentation manufacturing processes. Simulation and laboratory-based learning can also prepare students for the complexities of industrial precision fermentation systems [64]. Some universities offer honours pathways where students split their time between academic research and industry work.

Developing interdisciplinary programs: Programs that integrate knowledge from biology, engineering, chemistry and data science are essential [65]. Cross-disciplinary courses and collaborative research projects can enhance students' ability to collaborate across fields, a crucial skill in the precision fermentation industry. Creating learning experiences that are truly interdisciplinary – including cost accounting and production economics, market analytics, regulatory science, and contract and intellectual property law – and feed directly into the work integrated learning experience rather than the disintegrated way it is typically taught will be highly beneficial.

Incorporating regulatory and ethical training: As precision fermentation develops, the industry will face increased scrutiny. Education programs must therefore emphasise regulatory and ethical considerations. Courses on local and international regulatory frameworks should be integral to precision fermentation education. Understanding regulations, particularly those concerning genetically modified organisms, is essential for navigating the approval processes required for new precision fermentation products. Ethical training should address the societal and environmental implications of precision fermentation technologies, covering topics like bioethics, sustainability and public engagement to prepare students for their responsibilities as professionals. It's important to understand the drivers and implications of environmental initiatives such as the Nagoya Protocol, Paris Agreement, reporting on Scope 60-62 emissions, definitions of genetically modified and the decision making of bodies such as Office of the Gene Technology Regulator.

Opportunities in strengthening industry-academia partnerships

Formal partnerships and Memoranda of Understanding (MOUs): Following initial non-disclosure agreements, formal partnerships and memoranda of understanding (MOUs) as precursors to more detailed contractual agreements can be effective in overcoming barriers to collaboration. These agreements can outline the scope of collaboration, define shared goals and set expectations for both parties. For example, MSF Sugar has successfully utilised MOUs to formalise partnerships with universities, thereby integrating students into their sustainability-focused projects.

> "MSF Sugar has a big sustainability focus and work on partnerships by establishing MOUs with universities that help to formalise bringing in students.
>
> — **Dr Pakornwit Sarnpitak**
> Business Improvement Officer, MSF Sugar

Such formal arrangements not only clarify the terms of collaboration but also ensure that both parties are committed to shared goals.

Industry-academia forums and workshops: Frequency of communication is important to further bridge divides. Regular forums and workshops can serve as platforms for knowledge exchange and awareness of each other's capabilities and development status [66]. These events allow academics to present their research to industry stakeholders and vice versa, so each can provide feedback and potentially produce outputs that are backed by rigorous science and commercial reality. Such forums also provide industry stakeholders with the opportunity to share their challenges, which can inspire new research directions in academia. This bi-directional flow of information helps align academic research with industry requirements, particularly in the precision fermentation sector, where technological advancements need to be closely tied to practical applications, outputs and products that can successfully navigate Food Standards Australia New Zealand's (FSANZ's) regulatory pathways.

Building trust through joint projects: One way to build trust and foster a collaborative culture is through joint projects that require both parties to contribute their unique strengths. For example, industry partners can provide practical experience, a deep understanding of the economics of production and a view of investment horizons, while academic researchers can offer deep scientific knowledge and the quest for the novel. Successful joint projects can demonstrate the value of collaboration and encourage a more integrated approach to problem-solving. In precision fermentation for food, the dominance of startups and SMEs with links back to universities can be a collaborative boon. The cultural and communication barriers are less pronounced, exchanges are valued and the prospect of co-developed intellectual property and products highly appealing for both parties.

Sector-specific training programs: Sector-specific training programs can help bridge the cultural divide by educating participants about the priorities and challenges of the other sector. For instance, training programs that focus on the commercialisation of precision fermentation technologies can help researchers understand the practical realities and constraints of bringing a product to market, while industry professionals can gain insight into the scientific rigor and extensive research infrastructure required for developing robust and innovative solutions. Further, sector-specific training has the potential to assist employees in the conventional agriculture workforce to transition to jobs in the precision fermentation sector as their former roles are disrupted.

Strengthening collaboration with technical and further education institutions: Given many roles in the precision fermentation food manufacturing sector may not require university degrees, collaboration with Technical and Further Education (TAFE) institutions is vital. Joint efforts between universities and TAFE institutions can ensure that the entire workforce, from process workers to engineers, receives appropriate training, creating a clear progression from vocational training to advanced education.

Leveraging effective funding models

While government and institutional grants remain a cornerstone of funding for early-stage precision fermentation research, particularly for projects that may be too risky for private investors, there are several effective funding models and collaborative frameworks that are essential for advancing precision fermentation initiatives. In the fast-paced precision fermentation sector, where speed to market is a decisive factor in success, timely and sufficient investment is often the difference between leading the market and lagging competitors.

Public-Private Partnerships (PPPs): These collaborations between government entities and private companies leverage the strengths of both sectors, combining public funding and oversight with private sector efficiency and innovation. In PPPs, government grants often provide the initial capital needed for early-stage research, while industry partners contribute additional funding and resources to scale up the project. For example, the Australian Government's funding of the Food and Beverage Accelerator (FaBA) initiative, in collaboration with industry stakeholders, has been pivotal in advancing precision fermentation technologies in the food sector. Both the European Union and United States have made significant strategic investments in precision fermentation [67, 68]. This model allows for risk-sharing between public and private entities, reducing the financial burden on individual companies while accelerating the commercialisation of new technologies. Establishing collaborative research centres, where academia and industry work together under a PPP framework, allow pooling resources and expertise to achieve breakthroughs more efficiently than isolated research efforts.

Venture capital and private equity: These are essential funding sources for precision fermentation startups, particularly as they transition from early development to commercialisation. Venture capital firms not only provide crucial financial backing but also offer strategic guidance. As companies progress through Technology

Readiness Levels (TRLs) and move closer to commercialisation, their Investment Readiness Level (IRL) increases, making them more attractive to investors. At higher TRLs, securing growth equity or late-stage investments becomes critical to accelerate their go-to-market strategies, expand into new markets and increase production capacity. Private equity firms often step in at this stage.

Corporate partnerships and strategic alliances: Joint ventures and co-development agreements between precision fermentation companies and established food manufacturers can enable precision fermentation startups to leverage the manufacturing capabilities, distribution networks and market knowledge of larger companies. Another model involves licensing precision fermentation technologies to established companies, allowing startups to generate revenue while leveraging the larger company's market presence and regulatory expertise. Technology transfer agreements can also be a valuable funding mechanism.

Crowdfunding: This has emerged as a novel funding model for precision fermentation initiatives, particularly for projects that have strong public appeal or aim to solve pressing environmental or social challenges. Crowdfunding ranges from donation-based financial support to crowd-based investment that is very close to traditional equity financial instruments and vehicles, for which an Australian Financial Services (AFS) licence is required by the Australian Securities and Investments Commission (ASIC).

Non-profit and philanthropic funding: Foundations such as the Bill & Melinda Gates Foundation have provided substantial grants to support precision fermentation projects aimed at addressing global food security and health challenges. These grants often target high-risk, high-reward research that might not attract traditional venture capital. Impact investors, who seek to generate both financial returns and positive social or environmental impact, are another important source of funding for precision fermentation initiatives that address global challenges such as climate change, food security and sustainable agriculture.

Challenges

Many of the startups that currently dominate precision fermentation have links to academia, having been generated by formal university research programs or well educated, entrepreneurial students who translated products from the lab. This is the lifeblood of any new and emerging technology focused industry. Collaboration between academia and industry enables the translation of innovative research into commercially viable products, ensuring that technological advancements meet real-world needs. However, fostering such collaborations requires strategic efforts, as academia and industry often operate with different priorities, timelines and cultures. Breakthrough science often operates on a different timeline to commercial realities. However, academia needs industry collaboration, investment and capabilities to take many breakthroughs from early technology readiness levels (TRL 1-4) to be investable propositions (TRL 6) through to products on market (TRL 9 and beyond). This section explores gaps that exist between academia and industry, drawing on insights from the precision fermentation and food manufacturing industries.

Workforce development in precision fermentation

Workforce development in precision fermentation is particularly challenging due to the rapid pace of innovation and technological trajectories, and the complexities of the interdisciplinary nature of the field. Precision fermentation sits at the cross-roads of biochemistry, molecular biology and chemical engineering, which are themselves underpinned by the core disciplines of chemistry, biology, physics and mathematics. Few individuals have the polymath capabilities to design, develop and manufacture precision fermentation-based food solutions on their own. As such, precision fermentation is a team sport and as with any team sport, requires highly effective management to perform.

The food production sector, especially within precision fermentation, requires a workforce equipped with not only technical expertise in areas like genomics, microbiology and bioengineering [61], but also an understanding of industrial processes including chemical engineering, process engineering, the navigation of new and rapidly evolving regulatory frameworks, policy, competition and market dynamics.

Integrating industry-relevant curriculum

There is a pressing need for education and training programs that are agile, industry-aligned and capable of producing graduates who can thrive in the fast-paced environment of precision fermentation startups. This need extends beyond traditional university education, as much of the practical knowledge required for precision fermentation applications is industry-specific and rapidly evolving [62]. Embedded training programs and internships that provide direct experience and foster a systems-level understanding of manufacturing processes can bridge the gaps between R&D and commercial scale production. This approach not only enhances the skill set of emerging professionals but also aligns educational outcomes with industry needs. However, striking the balance between breadth and depth of skills and practical experience will remain a challenge in this rapidly evolving environment. Investment in work integrated learning to rapidly upskill entire industries, in an environment where many of the products and the technologies have yet to be validated, points to a substantial role for government as an investor and the design of large-scale education and training solutions. Countries whose governments accept this challenge sooner will reap the rewards as precision fermentation-based food sectors begin to mature and scale to generate revenue.

Establishing clear communication and understanding gaps

One of the primary challenges in fostering collaboration between academia and industry is the communication gap that often exists between these sectors. Industry stakeholders may not be fully aware of the innovative research conducted in academic institutions, while academics may not fully understand the practical needs and constraints of industry. On technology readiness levels, academics often believe their science and technology is more advanced in its development than it is – they may see precision fermented flavours and ingredients as being at a very palatable TRL 6, whereas a potential industry partner will want to see a working prototype of the ingredient in a final product such as a cheese, bread, dip, oil or health drink. This creates its own 'valley of death', which has the researcher waiting by the phone for a call that never comes because their sustainable ingredient hasn't been sufficiently derisked through sensory, nutritional and consumer tests. To address this, it is essential to establish clear communication channels that facilitate regular dialogue between both parties and foster a mutual understanding of each sector's priorities.

Overcoming cultural barriers

A significant barrier to effective collaboration is the cultural divide between academia and industry [63]. Academics are often driven by the pursuit of knowledge and may prioritise perfection and thoroughness, while industry partners are typically more focused on speed, efficiency and meeting market demands. Bridging this cultural divide requires a mutual understanding of each sector's priorities and constraints, and achieving an effective balance between novelty, relevance to market, and speed through the research and development cycle. Along the way, especially for academics and students, a clearer understanding of the practicalities and importance of scaling to commercial production can break down a fundamental barrier – the experience of scale.

Navigating regulatory challenges

Partnerships with government agencies are crucial for navigating the regulatory challenges associated with precision fermentation. These partnerships also extend to funding agencies and consumers. The lag that has traditionally occurred between technological development and the regulation of the products of that development remain difficult to bridge. However, the developments in artificial intelligence (AI) that have enhanced the development of precision fermentation are just as relevant and valuable to regulatory science. AI driven 'Reg Tech' has the potential to reduce the regulatory lag. AI supported anticipatory regulation can even shift regulation from its perceived sea anchor role to an industry enabling one.

For this to occur, regulatory frameworks must evolve in tandem with technological advancements to ensure the safety and efficacy of new food products. Funding models that incentivise collaborative research and development, including with the regulatory agencies as exemplified by the US Food and Drug Administration (FDA) and European Medicine Agency (EMA), can accelerate innovation and reduce the financial risks associated with bringing novel precision fermentation products to market. Additionally, engaging consumers and relevant community stakeholders early in the development process can help address concerns about the safety and ethical implications of precision fermentation foods, fostering greater acceptance and market adoption. Streamlining these processes through coordinated efforts can help accelerate the deployment of new technologies while ensuring that safety and ethical considerations are adequately addressed.

Developing effective funding models and partnerships

The precision fermentation sector, particularly within food manufacturing, is at the forefront of innovation. However, bringing these innovations to market requires significant financial investment and strategic partnerships.

> "The cost of scaleup is ridiculous!
>
> — **Dr Leon Scott**
> Director, Research Infrastructure Operations, QUT

The complexity and interdisciplinary nature of precision fermentation projects necessitate robust funding models and collaborative frameworks that can support research, development and commercialisation.

Image credit: Megan Pope.

Chapter 5

Regulation of precision fermentation

Theme lead:
Professor Jolieke van der Pols, QUT

Panel of experts:

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The University of Queensland

Fiona Fleming,
Australian Institute of Food Science and Technology

Nhat Huynh, The University of Queensland

Xianxian Jiang, The University of Queensland

Adjunct Associate Professor Brenda Mossel,
The University of Queensland

Dr Lisa Ronquest-Ross, v2food

Robin Sherlock, Safe Food Production Queensland

Mathias Talbo

Kim Tonnet, Kim Tonnet Consulting

Introduction

A robust regulatory framework will play an important role in the successful growth of the emerging precision fermentation industry. This chapter explores:

- The barriers in current regulation frameworks – Food Standards Australia New Zealand (FSANZ), Office of the Gene Technology Regulator (OGTR) and other jurisdictions – that limit successful growth of this industry
- The best and preferred ways to improve Australia's regulatory framework such that collective benefits are achieved for this industry now and into the future
- How our capacity to achieve regulatory change could be increased so that industry-wide benefits are realised.

> “Current regulatory challenges in Australia need to be addressed so that we can all fully benefit from this promising new way of producing foods and ingredients.
>
> — **Kim Tonnet**
> Regulatory Scientist, Kim Tonnet Consulting (formerly All G Foods)

Opportunities

Appointment of a Minister for Food

In 2023, the Australian Parliament's Agriculture Committee delivered its recommendations following the release of the report *Australian Food Story: Feeding the Nation and Beyond* [77], the outcome of an inquiry into food security in Australia. One of the recommendations was to appoint a Minster for Food. This recommendation is fully supported by the authors, with the view that better coordination of food regulation reform by a well-informed Minster for Food would be a great outcome for the precision fermentation industry and broader food manufacturing sector.

Modernisation of the regulatory setting

With the review of the FSANZ Act, proposals were released in February 2024 for different pathways towards the modernisation of the food regulatory setting in Australia [75]. Several suggestions were highlighted in the report commissioned by the Department of Health and Aged Care, including the option that FSANZ could accept risk assessments from overseas jurisdictions and that selected international standards could be automatically recognised. Currently, the FSANZ framework is processed-based – all applications need to provide data on a standard set of domains that are the same for all food products, irrespective of the anticipated risks associated with that product. It's recommended that FSANZ move to a more risk focused regulatory framework for the precision fermentation industry, like those in the US and Canada. This regulatory framework reform option is also one of the pathways discussed by the Department of Health and Aged Care.

Improved collaboration between jurisdictions

Given the complexity of the current regulatory landscape across the federated states in Australia, improved collaboration between agencies would be beneficial, particularly if it resulted in streamlining processes. It was suggested a system of Memoranda of Understanding (MOU) could be a suitable pathway to achieve this. As an example, the Great Barrier Reef Marine Park Authority has MOUs in place with several government agencies, such as the Department of Defence. MOUs between food regulation and enforcement agencies are regarded as a possible way forward to support precision fermentation-based food production in Australia.

Increased collaboration between industry and regulators

While there may be a level of distrust by current regulators of the industry's ability to self-regulate, much of the knowledge and know-how of food innovation lies within the industry itself. In an ideal world, regulatory frameworks need to be agile to respond to future novel technologies and applications. Increased collaboration between industry and regulators – for example, pre-collaborative knowledge sharing in the industry when something new is going to be regulated – would be beneficial. The regulator could gain insights into whether a new regulation is fit-for-purpose, while industry could design and adapt business processes based on a new regulation they informed and co-designed.

Challenges

Complex application processes

The Australian Government requires foods produced by precision fermentation be subject to pre-market assessment as a novel food under the current Food Standards Code (Standard 1.5.1 Novel foods and Standard 1.5.2 Foods produced using gene technology) [69]. Precision fermented foods are also subject to existing labelling requirements in the Code and Australian Consumer Law. Currently, companies need to apply for amendment of the FSANZ Food Standards code to obtain approval for selling a precision fermented ingredient or food formulated with such an ingredient in Australia and New Zealand.

To date, few precision fermented foods or ingredients have been the subject of FSANZ applications. In 2022, FSANZ approved the sale of soy leghaemoglobin in meat analogue products marketed by Impossible Foods, with leghaemoglobin being a protein produced from genetically modified Komagataella phaffii (Pichia pastoris) yeast [70]. Other food additives and processing agents produced using precision fermentation have been approved, including an invertase produced from a genetically modified strain of Trichoderma reesei. This product, which can be used to reduce sugar levels in treated fruit and vegetable products or to produce a prebiotic, was approved in 2024 [71].

Long timeframes

Two of the main challenges with the current FSANZ regulatory processes are the timeframes involved and the fact that an application needs to be made for each new food product or ingredient, unless that new variant was already specified and reviewed in a previous application.

Impossible Food's application for approval of its soy leghaemoglobin in 2019 took 18 months from the initial application to approval. A full application process was completed and followed international risk analysis frameworks, including two calls for public submissions, and evidence of the safe use of the product in other countries, including the US and Singapore, for three years prior to the application being submitted to FSANZ.

No applications for precision fermented novel whole foods or main food ingredients have been made to FSANZ (as at October 2024). However, in 2023, under the broader umbrella of cellular agriculture for food production, cultured meat company Vow applied for variation of the FSANZ Food Standards Code to permit marketing and sale in Australia and New Zealand of cultured quail made from the isolated embryonic fibroblasts of Japanese quail as a component in food products (FSANZ application A1269). Under standard 1.5.1 of the Food Standards Code, cellular agriculture techniques including cell culture and precision fermentation will be considered 'novel foods' due to the processes involved in production and the sources from which they are derived. The application by Vow was estimated to take at least 18 months for the FSANZ review process – this timeframe has already been exceeded.

Under the current FSANZ Act and Food Standard Code, a substantial amount of time is required to obtain market approval for novel precision fermented food products. Applications for precision fermented processing agents have been quicker – for example, approval for the invertase product subject of application A1278 was obtained within nine months of submission.

The time it takes to gain FSANZ regulatory approval is a major hurdle and a barrier for successful development and establishment of the precision fermented food and beverage manufacturing sector in Australia. At this stage, it's unclear if precedent will be set should Vow's cultured meat product be admitted to the Australian market.

Australia's current state of nil FSANZ applications for mainstream precision fermented ingredients (besides Impossible Food's leg haemoglobin) and approvals, and where possible any precedents, for this sector appear to be still a long way off. It is hoped that discussions and submissions such as the 2024 FSANZ Stakeholder Engagement Forum and the 2024 Commonwealth Government's inquiry into the food and beverage manufacturing sector [72], plus the review of the FSANZ Act [75], will help improve regulatory processes towards market approval for precision fermented foods and ingredients (note, Australia's Food and Beverage Accelerator made submissions to both).

Complexity of the regulatory framework

The current complexity of food standards regulation and enforcements in Australia exist due to the federation of states which results in several layers of regulation and enforcement. This is less of an issue in the sovereign state of New Zealand. It's hoped FSANZ proposals [73] to amend the definitions in the Australia New Zealand Food Standards Code for 'food produced using gene technology' and 'gene technology' will be made in time to allow for the marketing and sale of a wide range of precision fermentation products in Australia. Subsequent enforcement will be dealt with by each state individually, due to differences in organisation and [74] interpretation of food law. For example, in New South Wales there is a central state level authority that deals with food safety regulation and enforcement (NSW Safe Food Authority). In Queensland, food safety and regulation are shared among different government departments including Queensland Health, Safe Food Production Queensland and local councils which are responsible for licensing.

Precision fermented foods and ingredients offer an opportunity for the Australian food industry to become global leaders in this field.

> "We need to work collaboratively with regulators and other stakeholders to ensure the appropriate risk assessment processes are implemented to support innovation.
>
> — **Fiona Fleming**
> Chief Executive Officer, Australian Institute of Food Science and Technology (AIFST)

Siloing between regulatory bodies

Siloing can occur between different regulatory bodies within the same jurisdiction, such as in situations where different government departments are involved in regulation and enforcement of one product group. The collective experience was that regulatory bodies appear to be quite set in their well-established ways of dealing with issues and applications, with each application needing to be reviewed by many actors. The current system was deemed to be limited by a level of inertia and bureaucracy that is discouraging, particularly for small start-up companies that aren't as well-resourced to deal with regulation as large established food and beverage manufacturers. As well, different agencies expect different information in their risk assessments.

The complexity of the current regulatory framework in Australia is another limiting factor for growth of the precision fermentation for food sector, due to the different levels of regulatory obstacles in place in each jurisdiction.

Sufficient resourcing of regulatory bodies

With the current long pathways towards FSANZ approvals and the intensive consultation processes involved, regulatory approvals currently demand a lot of resources both on the regulatory side as well as the applicant side (who also pay a substantial fee). Increased resourcing of FSANZ – and, where needed, regulators and enforcement agencies in state and council jurisdictions – is required for precision fermentation, and indeed all cellular agriculture and novel food businesses, to be successful in Australia and New Zealand. It's hoped the current review of the FSANZ Act may create opportunities for an appropriately resourced central regulator that can support the food and beverage industry across traditional and novel food production systems.

Ambiguous pathway for new innovations

While the pathway towards FSANZ market approval is currently long, it's relatively clear. Most businesses in the precision fermentation sector, however, also need to deal with the Office of the Gene Technology Regulator (OGTR) as their work typically involves genetically modified microorganisms that produce the target food substance – such as casein or beta-lactoglobulin – and require OGTR approval to operate. Licensing with local councils may also be needed, and there are additional regulatory requirements for exportation of product and importation of GM organisms (including World Trade Organization agreements). Some products may be regulated by the Therapeutics Goods Association of Australia instead of FSANZ, creating an additional layer of complexity for business to navigate when establishing a precision fermentation business in Australia.

Image credit: Megan Pope.

Chapter 6

Safety and consumer perception of precision fermentation

Theme lead:

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Panel of experts:

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Ning Chen

Tao Dai, The University of Queensland

Wenkang Huang, The University of Queensland

Hayley Laraghy, Trade and Investment Queensland

Professor Janet McColl-Kennedy,
FaBA and The University of Queensland

Sanaz Sanayei

Joanne Tunna, Cellular Agriculture Australia

Felicitas Vernen, Eden Brew

Introduction

Precision fermentation involves the use of genetically modified (GM) microbes to produce a variety of food processing aids, such as proteases (chymosin), amylases, lipases, pectinases and ice structuring protein. More recently, it's been used to create specific food ingredients such as human milk oligosaccharide, soy leghemoglobin, milk casein, milk whey and egg white protein. These technologies hold significant potential for enhancing food sustainability, reducing reliance on traditional agriculture and addressing food security issues [69]. Despite these benefits, however, the acceptance and safety of foods produced through precision fermentation remains the subject of significant debate and research.

> "Just because a product can be produced, doesn't necessarily mean it should be produced. How consumers perceive the product is critical for market success.
>
> — **Professor Janet McColl-Kennedy**
> UQ Business School and Lead,
> Innovation Pathways Program, FaBA

Consumer perception is a critical determinant of the success of precision fermentation technologies. Factors influencing these perceptions include the role of retailers, the origin of ingredients, labelling practices, global sustainability trends, taste and cost considerations. Understanding these factors is essential for addressing consumer concerns and fostering acceptance [70]. Additionally, the safety of precision fermentation-derived food ingredients is paramount. This involves rigorous regulatory assessments, managing environmental risks and ensuring the purity and safety of starting materials and final products.

Improving people's understanding and acceptance of novel foods produced through precision fermentation requires strategic communication, effective education and involvement of primary production sectors. The historical context of genetically modified foods, the role of trusted regulatory bodies, and the benefits of precision fermentation in terms of sustainability and health must be clearly communicated to consumers. This chapter explores the opportunities and challenges associated with the safety of foods produced through precision fermentation, and consumer perception of those foods, and provides recommendations for policy and practice to enhance acceptance and ensure safety.

Opportunities

To enhance consumer perception and acceptance of precision fermentation foods, it is essential to focus on the perceived benefits to consumers [71, 38]. Beyond taste, health and price rank the next highest in importance. Emphasising the sustainability and health benefits of these foods can help shift consumer perceptions [70]. Highlighting environmental advantages, such as reduced greenhouse gas emissions and lower resource use, can appeal to environmentally conscious consumers. As well, highlighting the benefits of novel food ingredients to animal welfare may further lower any barriers to consumer adoption [72].

Building trust through transparent and accurate messaging [71], including labelling, is another critical opportunity. Ensuring consumers have access to clear, accurate information about the origin and production processes of precision fermentation foods can help build trust [69]. Consumer education campaigns, leveraging lessons learned from previous introductions of novel foods, can help improve understanding and acceptance. Engaging with consumer advocacy groups and industry associations is essential.

Advancements in safety and regulatory approvals

Innovations in regulatory processes offer significant opportunities to streamline the approval of precision fermentation foods while maintaining safety standards. Collaborative efforts between regulatory bodies, industry and academia can help develop more efficient regulatory pathways. The use of advanced risk assessment tools – including protein structure predictions (e.g. Alphafold) and highly sensitive analytical methods – can enhance the safety evaluation of precision fermentation products. Additionally, international harmonisation of regulatory standards can facilitate the global commercialisation of these foods [69].

Ensuring the safety of precision fermentation foods through rigorous testing and long-term exposure studies remains a priority through:

- The development of improved bioinformatics methods (e.g. machine learning) can assist allergenicity prediction
- Comprehensive testing protocols (e.g. production host stability, growth media contaminants, final product purity) [73]

Engaging with the scientific community and leveraging existing knowledge from related fields, such as biotechnology and food science.

Sustainable production practices

Sustainable production practices offer significant opportunities for the precision fermentation industry. Innovations in feedstock utilisation, such as using crop waste or food waste, can enhance the sustainability of production processes. Developing closed-loop systems, in which by-products are reused or recycled, can reduce environmental impacts and improve resource efficiency. Also, advancements in bioprocessing technologies, such as continuous fermentation and bioengineering, can enhance the scalability and efficiency of precision fermentation processes.

The investment in infrastructure required for scale-up is significant [74]. Dedicated contract development and manufacturing organisations (CDMOs) housing bioreactors of varying sizes may provide opportunities for precision fermentation start-ups to save costs and improve sustainability.

Collaborative efforts between industry and academia can drive innovation in sustainable production practices. Research and development initiatives focused on improving feedstock utilisation, enhancing bioprocessing technologies and reducing environmental impacts can support the growth of the precision fermentation industry. Engaging with policymakers to develop supportive regulations and incentives for sustainable production practices can further promote the adoption of these technologies.

Public engagement and education

Effective public engagement and education strategies are essential for improving the understanding and acceptance of precision fermentation foods. Developing science communication skills within the industry and engaging with media can help convey accurate and positive messages about these foods. Media articles with headline grabbing titles such as 'Sugar cane milk' can be misleading, as they oversimplify or distort the scientific and technological aspects of precision fermentation. Educational initiatives can help improve consumer understanding and acceptance of products. Cellular Agriculture Australia has developed media guides to assist in communication. Highlighting the long history of fermented foods and the similarities between traditional and precision fermentation processes can also help normalise these foods.

> "A language guide designed specifically for journalists and media outlets can encourage those reporting on cellular agriculture to use consistent and appropriate language and imagery.
>
> — **Joanne Tunna**
> Chief Operating Officer,
> Cellular Agriculture Australia

Engaging with primary production sectors and involving them in the development of precision fermentation food applications can support acceptance. Collaborative efforts between traditional agriculture and the precision fermentation industry can help align interests and promote the complementary benefits of these technologies. Additionally, involving trusted industry names and emphasising the environmental and health benefits of precision fermentation can enhance public trust and acceptance.

Challenges

Consumer perceptions and acceptance

The acceptance of precision fermentation foods is influenced by multiple factors, including labelling, nomenclature and consumer understanding [69]. Labelling plays a critical role in shaping consumer perceptions. Accurate and clear labelling, distinguishing between GM organisms and products derived from GM processes, is essential for building trust. The terminology used, such as 'precision fermentation' or 'cellular agriculture', must be carefully selected to avoid confusion and negative sentiment. Studies have shown that consumers can have a limited understanding of food processing technologies, leading to scepticism and resistance to novel foods [76].

Global trends towards improved animal welfare, sustainability and health also influence consumer choices [77]. While precision fermentation may offer significant sustainability benefits, scare campaigns and misconceptions about the artificiality of these foods can hinder acceptance. Historical examples, such as the introduction of GM plants, where the benefits did not directly reach consumers, highlight the importance of perceived benefits in driving acceptance [78].

Australia is a net exporter of food, and most Australians currently enjoy access to a wide variety of fresh and healthy foods. However, future challenges related to food production and sustainability – such as climate change, water scarcity and soil degradation – require innovative solutions to maintain this level of food security. Taste and cost are also critical factors that can influence consumer preferences. Ensuring that precision fermentation products are tasty and affordable is essential for broad adoption.

Regulatory and safety challenges

Ensuring the safety of precision fermentation-derived food ingredients involves navigating complex regulatory landscapes. In Australia, the Office of the Gene Technology Regulator (OGTR) and Food Standards Australia and New Zealand (FSANZ) play crucial roles in the production and assessment of new precision fermentation food ingredients. The regulatory approval process is often time consuming and costly, posing a significant barrier to the commercialisation of novel foods. Streamlining these processes while maintaining rigorous safety assessments is a key challenge for the industry. FSANZ currently uses a risk-based public health and safety assessment process for novel food ingredient applications (FSANZ, 2022). This approach may require adjustments to address the novel types and applications of food ingredients arising from precision fermentation in the future, with a shift from food processing aids to major food ingredients.

Ensuring the safety of starting materials and by-products is another critical challenge [73]. The use of inexpensive by-products as starting materials can introduce toxins, heavy metals and allergens which must be rigorously controlled to ensure they do not contaminate the final products. Standard risk analysis approaches, such as Hazard Analysis and Critical Control Points (HACCP), can be adapted to address these challenges.

Production and environmental risks

The potential release of GM organisms into the environment and the associated risks must be carefully managed. Precision fermentation processes often involve the use of genetically modified microbes, which must be contained to prevent environmental contamination. Scaling up precision fermentation processes from laboratory to commercial production presents significant challenges. Maintaining safety and environmental standards during commercial scale-up requires careful management of production processes, including the handling of wastewater and spent GM yeast cells. The purity of the final products must be ensured, and any potential environmental impacts must be mitigated. Innovations in feedstocks, such as using crop or food waste or side-streams, offer opportunities to improve sustainability but also introduce potential safety risks that must be addressed.

Consumer understanding and communication

Improving consumer understanding and acceptance of precision fermentation foods requires effective communication and education strategies. Misconceptions about GM foods and the perceived unnaturalness of precision fermentation can be significant barriers to acceptance [79]. Aligning nomenclature and key messaging, based on consumer research, can help prevent confusion and negative sentiment. Lessons learned from consumer responses to GM foods and cell-cultivated meat can inform communication strategies for precision fermentation foods [78].

Engaging with primary producers to bring them on the journey can help gain broader acceptance. In Australia, investments in precision fermentation start-up companies have come from large, well-established animal-based food companies. Investments from known industry names and emphasising the environmental and health benefits of precision fermentation can enhance trust. Highlighting the essential role of food processing in underpinning food security [80] and ensuring transparent communication through trusted regulatory bodies like FSANZ are crucial. Effective engagement with media and developing science communication skills are also essential for improving public understanding and acceptance.

Chapter 7

Nutritional impact of precision fermentation

Theme lead:

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Introduction

In the evolving landscape of the food industry, precision fermentation presents an opportunity to transform how we produce, process and enhance the quality or shelf-life of foods. Precision fermentation introduces new, sustainably produced products to the market, with nutritional profiles often tailored to specific dietary needs.

Through precise genetic alterations, precision fermentation enables the enhancement of existing nutrients, the addition of novel nutrients and the reduction of undesirable nutrients in foods.

Cutting edge approaches

Precision agriculture and precision fermentation are two innovative approaches to creating foods and food ingredients. Precision agriculture involves using advanced genetic engineering to develop crops that are nutritionally enhanced and more resilient to environmental stresses [88], for example biofortified crops that address specific nutritional deficiencies, such as Golden Rice enriched with vitamin A [89]. Through smart crop management, resource optimisation and sustainable farming practices, precision agriculture provides a way to meet the growing demand for food sustainably. While promising, precision agriculture faces environmental challenges such as greenhouse gas emissions and intensive use of water and land.

Precision fermentation [77] uses microbial hosts (bacteria, yeast or fungi) to produce high-value nutrients, proteins, enzymes or other beneficial compounds, reducing the carbon footprint of agricultural practices. These microbes can be engineered to efficiently produce nutrients that are typically derived from animal sources, providing a sustainable alternative.

Precision fermentation can produce modified carbohydrates with enhanced digestibility or health benefits, including prebiotic properties that support gut health. Similarly, microbial fermentation can be used to develop proteins with increased amino acid diversity or hypoallergenic properties. Precision fermentation processes can also be used to synthesise high-value nutritional supplements such as vitamins, antioxidants and omega-3 fatty acids, which are otherwise expensive or challenging to extract from natural sources. Engineered microbes can also be used to produce nutrients typically sourced from environmentally sensitive areas (e.g. flavour or pigments from rare plants) more sustainably.

Precision fermentation processes enable the production of a broad array of nutrients such as modified carbohydrates, proteins, fatty acids, vitamins, minerals and antioxidants [90], which are vital for developing functional foods and nutraceuticals.

Opportunities

Problem solving innovation

The digital era has transformed how industries harness data to drive innovation. Precision fermentation is uniquely positioned to integrate insights from genomic data with consumer health information and behaviour metrics to provide nutritionally enhanced food products that precisely align with what consumers need and want. In doing this, industries can significantly increase trust which is important in a world where consumers are more informed and demand transparency about the products they consume.

Addressing hidden hunger

Precision fermentation, like conventional biotechnology, can be used to combat 'hidden hunger' [41], a form of malnutrition prevalent in developing countries where individuals consume sufficient calories but lack essential micronutrients. Using engineered microbes or yeasts, precision fermentation can produce vitamins and minerals that are deficient in certain populations. These nutrients can then be added to staple foods, enhancing their nutritional value without requiring changes to dietary habits. This biofortification strategy allows for seamless integration of essential nutrients into existing diets across different cultures and regions.

> "Precision fermentation can leverage data-driven approaches to develop predictive models that identify nutritional deficiencies.
>
> — **Dr Giorgio La Fata**
> Senior Project Manager,
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By combining data on lifestyle factors with environmental inputs such as soil nutrient levels, pollution and climate conditions, these models can pinpoint populations at high risk of specific deficiencies. This capability enables targeted interventions, allowing for deployment of nutritionally enhanced precision fermentation crops and foods tailored to the needs of these populations. Additionally, precision fermentation technologies can be used to engineer soil microbes that enhance nutrient availability in the soil, or to engineer food products fortified with essential nutrients that might be lacking in conventional crops due to soil depletion.

Niche product development

In areas where food is abundant, different nutritional challenges emerge. In developed countries, opportunities for precision fermentation to innovate often lie in creating niche products aligned with shifting dietary preferences toward healthier foods. For instance, with growing health concerns linked to animal-based diets, more consumers are turning to plant-based alternatives. Precision fermentation can provide a more balanced amino acid profile in plant-based alternatives, ensuring they can effectively replace animal-derived proteins in diets. Single-cell proteins from yeasts and algae also represent promising alternative protein sources. The rise of coeliac disease and gluten intolerance also creates opportunities for precision fermentation innovations, such as developing gluten-free grain strains or engineering enzymes to break down gluten into non-reactive forms. Hydrocolloids like xanthan gum can improve the texture of gluten-free products, making them more like gluten-containing ones.

The growing ageing population opens further possibilities for precision fermentation in food. Older adults need foods with modified textures and enhanced flavours due to changes in their physical and sensory capabilities. Hydrocolloids can soften food textures without compromising the taste, addressing difficulties with chewing and swallowing. Precision fermentation can also intensify flavours, making food more appealing to those with a diminished sense of taste and smell. By focusing on these aspects, food producers can not only enhance people's quality of life but also tap into a growing market segment with specific needs and preferences.

Precision fermentation can be used to remove or modify proteins known to cause allergic reactions, making staple foods like wheat, dairy and peanuts safe for broader consumption. It can also reduce or eliminate anti-nutritional factors in foods, improving their overall nutritional value. This level of personalisation can increase consumer trust by directly addressing their health concerns. Using precision fermentation to improve nutrient bioavailability can ensure quicker and more efficient absorption of nutrients. This can involve modifying the molecular structure of nutrients to increase their solubility or designing novel delivery systems that ensure nutrients survive the acidic environment of the stomach.

Crop diversification

Charles Darwin's insight into natural evolution underscored the importance of diversity for the resilience and survival of biological systems. Genetic diversity enables species to adapt to changing environments. Without it, a population can become exceedingly vulnerable to collapse, potentially leading to extinction if environmental conditions change unfavourably. In agriculture, monocultures – the extensive cultivation of a single crop over a large area – can lead to decreased biodiversity and increased vulnerability to pests and diseases. Precision fermentation offers a solution by facilitating the genetic diversification of crops. This helps crops better withstand pests and diseases, and enhances their ability to adapt to climate change or degrading soil conditions. By reducing dependency on single crops, precision fermentation can contribute to more resilient agricultural systems. Precision fermentation also allows for intricate genetic manipulations, often involving entire metabolic pathways or networks, enabling the synthesis of complex molecules. This capability expands the range of nutrients that can be produced, offering a wider variety of food products. Further, precision fermentation can be used to preserve the nutritional content of food for longer periods, reducing waste and improving food security.

Challenges

Limitations in scale

While the overarching goal of precision fermentation food products is often described as 'feeding the world', these products initially target high-value niches rather than the mass population. This strategic focus arises because yields from precision fermentation processes tend to be low, making it more financially viable to develop high-value products or functional substitutes in high-value markets. By targeting these niches, companies can achieve higher margins, enabling them to recover costs and attract further investment. Additionally, high-value niches allow companies to build strong brands around unique selling points, such as enhanced nutrition. This strategic differentiation can create loyal customer bases and establish a strong market presence.

Consumer behaviour

Consumers play a central role in the food ecosystem, serving as the primary drivers of demand and ultimate determinants of success for the acceptance of nutritionally enhanced foods developed through precision fermentation. Their preferences, needs and values shape the market and determine which innovations thrive. In 2022, the health food market was valued at US$945.9 billion and is projected to grow to US$1,405.69 billion by 2032 [91]. While the market is growing rapidly, consumers are showing a preference for healthier options that do not require drastic alterations to their existing eating patterns or lifestyles.

> "Consumer habits or preferences often dictate food choices more than nutritional needs, presenting a challenge for the promotion of nutritionally enhanced foods.
>
> — **Sailesh Patel**
> Technical consultant, Majans

To capitalise on this trend, it's important for industries to develop products that incorporate nutritional enhancements in a way that does not compromise taste and convenience, ensuring consumer acceptance and continued use. However, many precision fermentation products are nutrients or ingredients used as intermediary products, requiring further processing or formulation before reaching the consumer market. Consequently, much precision fermentation activity occurs predominantly in a business-to-business (B2B) context, rather than directly reaching consumers (B2C).

Safety and education

The safety of nutritionally enhanced precision fermentation foods plays a crucial role in their acceptance. Existing scepticism and resistance towards genetically modified organisms (GMOs) can extend to precision fermentation due to its reliance on advanced genetic engineering techniques. Overcoming this requires transparent, data-driven communication about the benefits and risks associated with consuming foods made or processed using precision fermentation. Rigorous testing is essential to identify potential allergenicity, toxicity or unintended effects arising from genetic modifications.

The importance of implementing Good Manufacturing Practices (GMP) for nutritionally enhanced precision fermentation-based foods should be emphasised, as a comprehensive set of guidelines and procedures is needed to ensure the safety and quality of these innovative products. Further, the impact of precision fermentation foods on the human microbiome should be considered.

Like conventional biotechnology, there is also a risk of horizontal gene transfer of antibiotic resistance markers from GMOs to native microbial populations. To mitigate these risks, rigorous measures are necessary such as using selection markers that don't confer antibiotic resistance or using kill switches that can trigger cell death, preventing the escape of GMOs into the environment. Consumer education is also pivotal in fostering the adoption of precision fermentation foods. Through rigorous process design, product testing and proactive public education about how these foods are made, their safety and their effects on human health, public acceptance of precision fermentation-based foods can be significantly increased.

Perception of CRISPR technology

Precision fermentation, using CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) technology [92], has significantly advanced the precision of genetic modifications beyond traditional methods. CRISPR enables highly accurate genome editing, allowing specific genes to be removed or enhanced without introducing foreign DNA. This targeted approach reduces the risks associated with unintended genetic consequences and minimises the potential for horizontal gene transfer, which could unintentionally spread antibiotic resistance genes to native crops or microbes.

Since some CRISPR-modified organisms do not contain foreign DNA, they may not fall under some regulatory definitions of GMOs. This distinction can significantly affect both regulatory oversight and public perception, potentially leading to greater acceptance of nutritionally enhanced, CRISPR-modified products compared to traditional GMOs. By offering a more controlled method of genetic alteration, CRISPR provides a path toward more socially and environmentally responsible genetic engineering.

Global acceptance

> "Integrating nutritionally enhanced precision fermentation foods into global food systems is essential for improving global nutrition, fostering sustainable practices and supporting economic and social wellbeing.
>
> — **Professor Jeremy Hill**
> Chief Science and Technology Officer, Fonterra

Precision fermentation crops can be engineered to contain higher levels of essential vitamins and minerals, helping to combat nutrient deficiencies prevalent in many parts of the world. They should be affordable and accessible, particularly in low-income regions, to ensure equitable access to enhanced nutrition. Precision fermentation crops can also be engineered to require fewer resources (e.g. less water and land use, fewer pesticides), contributing to more sustainable agricultural practices. They can also be made more resilient to climate change, contributing to global food security by providing reliable sources of nutrition. For precision fermentation foods to be widely adopted, however, they need to be developed with an understanding of cultural dietary habits and preferences to ensure acceptance and possible integration into traditional cuisine. Both precision fermentation foods and crops must comply with international safety and regulatory frameworks to ensure they are safe for consumption and can be traded across borders.

Economic viability

Making nutritionally enhanced precision fermentation foods economically viable is key to broad market adoption. Cost-effective production methods and scalability are essential to ensure these foods are not just innovative but also accessible and affordable for diverse consumer groups. A major bottleneck for the industry is the high cost of bioreactors necessary for scaling up precision fermentation processes, limiting market access primarily to large enterprises. Small companies can overcome this barrier by partnering with larger firms or joining industry consortia to share the costs. Alternatively, leasing equipment or using contract manufacturing organisations (CMOs) would enable production of products without large initial investments. Smaller enterprises can also benefit from partnerships with government bodies and academic institutions, which often have access to funding and facilities that can alleviate the financial burden of scaling-up. Taking a multi-stakeholder approach including government agencies, private sectors, non-governmental organisations and consumer groups can help in aligning goals, pooling resources and creating a unified front to effectively tackle regulatory, economic and social hurdles.

Regulatory approvals

Meeting the complex regulatory requirements for GMOs can be costly and time-consuming, potentially delaying the introduction of beneficial innovations to the market. However, a careful approach – whereby precision fermentation products are not put in market until all risk assessments and regulatory compliance are completed – draws on lessons from conventional biotechnology, where overpromising resulted in discrepancies between consumer expectations and actual industry performance. Setting realistic expectations for precision fermentation-based foods is vital not only for maintaining credibility but also for building long-term public trust and acceptance. This strategy could be crucial to ensuring precision fermentation innovations are not prematurely dismissed and can evolve into sustainable solutions to effectively address global nutritional challenges.

Chapter 8

Ethics in precision fermentation

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Introduction

The ethical landscape for precision fermentation is complex, encompassing issues related to biosafety and biosecurity, ecological impact, intellectual property and social justice. Precision fermentation has the potential to contribute to improving health and sustainability, but these possibilities must be balanced against the risks of unintended consequences and reinforcing current issues. To maximise the benefits of precision fermentation, understanding the relevant ethical principles and issues to guide decision-making and building robust ethical frameworks into research, application and regulation is essential. This chapter outlines key ethical principles and ethical challenges, and the importance of new approaches to risk management and assessment.

The overlying key principles for ethical decision-making for the precision fermentation sector – with the caveat that, depending on the context, additional or different principles may be applicable – are outlined below.

Intellectual autonomy: Scientific advancement relies on the freedom to test new ideas and methods, exchange ideas and knowledge, and to critique established norms and engage in scientific debate. The regulation of synthetic biology by governments, universities and corporations should protect the space required to practice academic freedom while protecting against social and ecological harms.

Precautionary principle: The precautionary principle states 'where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation' (Rio Declaration, Principle 15). At the Tenth meeting of the Conference of Parties to the Convention on Biological Diversity, governments were urged to 'apply the precautionary approach… to the introduction and use of living modified organisms'. Enacting this principle relies on incorporating comprehensive risk assessment processes that are future-focused, early and effective risk prevention, and stopping or postponing research and development that cannot be adequately managed.

Act/omission distinction: This ethical principle focuses on, in part, whether a specific harm was caused by a deliberate act or by a failure to act. In some circumstances, people and institutions should be more responsible for actively causing harm as opposed to failing to act. However, the moral implications of omitting to do something are far more pronounced when people and institutions have the expertise and authority to avoid a significant harm. In these instances, failing to act is, potentially, equally as morally wrong as deliberately causing harm. This principle is in some ways interconnected with the precautionary principle.

Justice: Various dimensions of justice are relevant to precision fermentation including in scenarios where precision fermentation has the potential to disrupt livelihoods or access is required to certain genetic resources. Relevant justice principles include:

- Intergenerational equity – relates to the interests of future generations and is especially relevant in the context of environmental risks and maximising public benefits.

- Access and benefit-sharing – concerns the ways in which genetic resources are accessed and who benefits from the access. This concept is especially important where genetic material has been developed and preserved by Indigenous and traditional groups.

- Distributive justice – relates to the ways in which benefits from precision fermentation and the burdens from it are allocated across society. Fundamentally, these benefits and burdens should be shared.

Public good: Public good refers to general benefits for society. Ultimately, the purpose of precision fermentation should be to advance public interest outcomes including health and sustainability as opposed to private, market-focused outcomes. This end goal should inform the development and application of synthetic biology, as well as how precision fermentation is regulated.

Public participation: Public participation in the development, application and regulation of precision fermentation ensures that technologies and decisions reflect the values and priorities of society. It also allows for the broad range of perspectives and concerns to be accounted for in risk assessment and management. Public participation is connected to maintaining the legitimacy of institutions, enabling ideological debate, developing common ground, and ensuring procedural fairness.

Opportunities

Moving beyond narrow risk assessment

Conventional risk assessments tend to be purely quantitative and narrowly focused on human safety, rather than a broader set of ecological and societal issues and perspectives. Even within a risk assessment focused on human safety, a broad range of decisions are made about what evidence is included, what factors are considered and what parts of the process are analysed. Yet sometimes these decisions are not clearly delineated or publicly provided. Investment pressures on scientists, and the related pressure to get to market, restrict the time available to conduct comprehensive assessments. Generally, risk assessments for technology or application are not collated in the same database, making it more difficult to track and analyse how they are conducted and what management responses are implemented [96].

Despite the complexity and the commercial pressures, ethical decision-making requires an approach to risk assessment that can better identify and deal with uncertainties and lack of knowledge associated with a broader range of risks.

Implementing new approaches to risk assessments [97], developing ways to collate risk assessments across jurisdictions and actors, and regulating the factors that put pressure on risk assessments to be done quickly, are important starting points for advancing precision fermentation and other areas of technological development. As part of this, there is a need for more (and publicly provided) environmental impact assessments of the effects of a proposed precision fermentation application on animals, plants, biodiversity, soil, water, ambient air, the climate, the landscape and cultural goods. Moreover, local governments and related authorities intending to host precision fermentation facilities should receive more support to undertake additional, strategic environmental assessments.

Managing expectations

Positive expectations, or hype, about a new technology is important for attracting talent and investors, and overcoming setbacks and challenges [98]. Like other technologies, precision fermentation has been the subject of highly positive expectations related to its role in addressing global challenges. However, overly positive or simplistic expectations about what a technology can achieve risks harming long-term investment and public acceptance if the benefits are not delivered [99]. In the case of precision fermentation, the final outcomes are unresolved. Hype can make it difficult to assess the risks of a technology appropriately where the purported benefits are especially grand. Hype also draws resources and attention from other important ways of addressing a particular problem, which tend to be less technologically reliant. For instance, claims that precision fermentation will solve, or significantly improve, food insecurity make it seem as if food insecurity has one technological solution when in fact a range of political and economic interventions, especially those that reduce poverty, are required [100]. Cultural and regulatory change could help address hype including, for instance, changes to grant schemes to require more nuanced claims about the benefits of a particular technology.

Meaningful engagement

The application, regulation and discourse regarding precision fermentation tends to be dominated by scientific perspectives. Current regulatory approval processes, for instance, do not engage with intrinsic concerns from oppositional groups, which often centre on the unnaturalness of precision fermentation and related technological areas.

Yet research shows that underlying these perspectives are proportionate and legitimate concerns, including how:

- The fundamental causes of global issues need to be addressed in conjunction with technological advancement
- Previous governments and industry actors have undermined trust and concerns about unintended consequences
- Risk management is conducted [103].

Allowing these perspectives to be validated and effectively responded to would ultimately improve the outcomes of precision fermentation applications and build more public acceptance and support.

Regulatory and technological processes generally don't engage with public perspectives in a way that meaningfully incorporates feedback into relevant regulatory approvals or technological and scientific work [94]. Seeking and engaging with these perspectives in a meaningful way aligns with ethical principles, helps avoid future public controversies and opposition, builds public trust and increases the chance that the end outcomes will serve public interest [95].

Challenges

Responding to environmental risks

The environmental risks associated with precision fermentation relate to the intentional release of, or failure to contain, a synthetic organism that then causes harm to human, animal and/or environmental health. Specific environmental risks include ecological disruption, gene contamination, ecosystem services disruption and negative impacts on non-target organisms [94]. These risks are sometimes difficult to account for due to uncertainty in terms of how a particular organism will interact with the wider environment. But uncertainty and ignorance of risks are not an ethical basis for inaction, especially where the risk relates to irreversible and catastrophic harms. Responding to these risks requires comprehensive risk assessments, investment in technologies to better detect and address unknown risks and the creation of responsibilities on actors where unanticipated risks still eventuate.

Diversifying power

Industry support is essential for advancing synthetic biology. However, the influence of the private sector can impact how precision fermentation achieves high-quality scientific results (such as by pressuring scientists to work faster rather than more meticulously). It can also impact the extent to which precision fermentation develops in a way that is socially beneficial as what is commercially lucrative may not necessarily have wider benefits for humans, environments or animals. Industry support, and reliance of innovation systems on private support, may result in some of the benefits from precision fermentation being disproportionately held by corporate actors, while the harms from disruption by precision fermentation are experienced by wider society.

Corporate consolidation and anti-competitive practices have long been an issue in spaces where precision fermentation is being developed and applied [101]. Addressing these issues requires university-level and regulatory responses. This includes careful consideration of the terms and conditions in contracts between universities and other actors, as well as the potential introduction of statutory guarantees to address issues. While intellectual property has an important role to play in enabling innovation, it can also foster corporate power and consolidation [94]. Regulators and universities should explore ways to increase open access to information regarding precision fermentation to foster innovation amongst diverse actors.

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