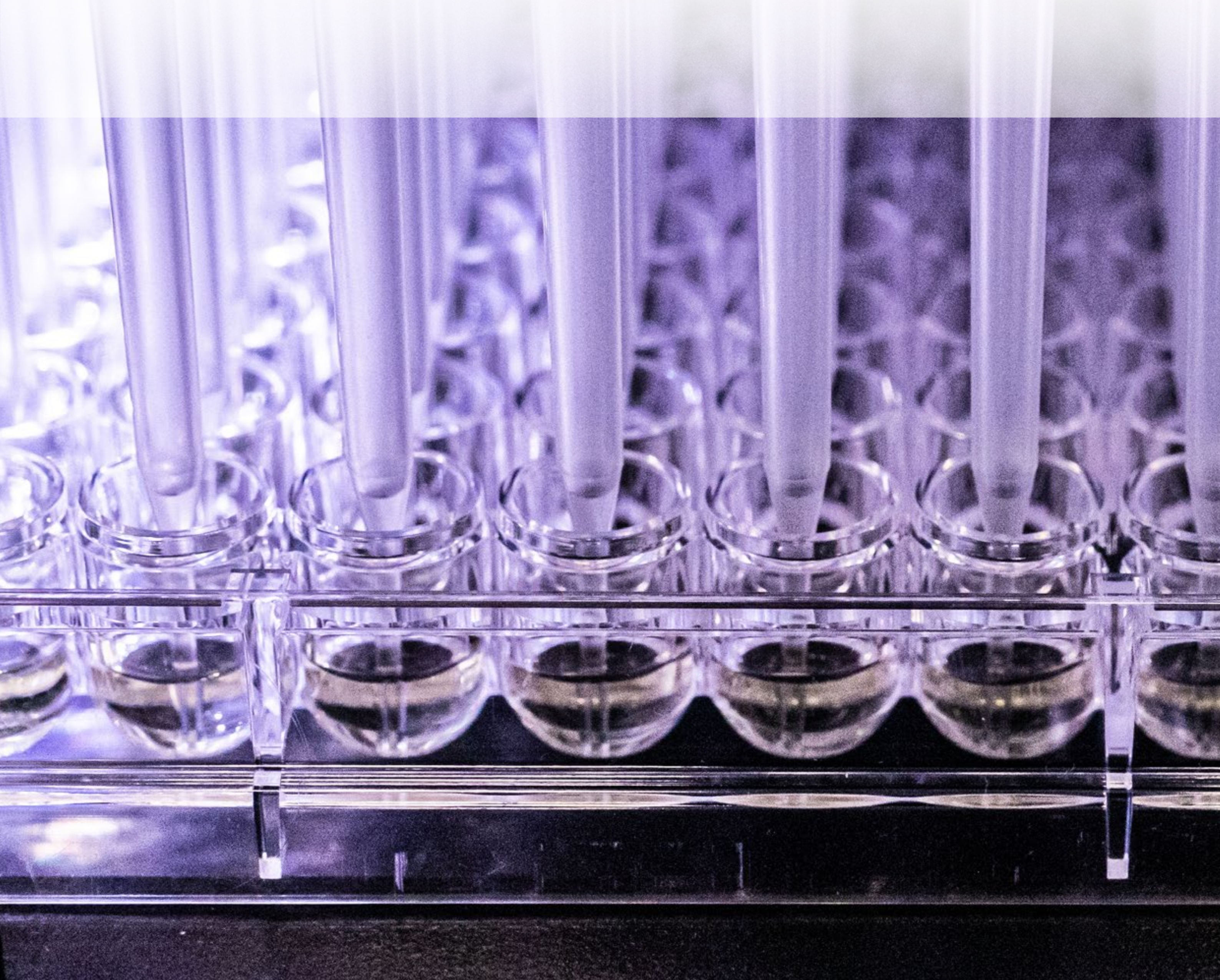
Australia's National Science Agency

A National Synthetic Biology Roadmap

Identifying commercial and economic opportunities for Australia



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Foreword

The era of synthetic biology is with us, accelerated by advances in biotechnology and computational power, and it represents a great opportunity for Australia. The promise of this field was demonstrated in a spectacular way with the development of the mRNA vaccines for COVID-19. This technology, which used synthetic RNA, was the first vaccine against a coronavirus, and is set to be the basis for many more in the future.

But we are just at the beginning. Synthetic biology has great potential in other fields of medicine, such as biosensors for diagnosis, personalised cancer vaccines and treatments, treatments for autoimmune diseases, and viruses that can be engineered to target antibiotic-resistant bacteria.

In agriculture, synthetic biology offers potential for everything from alternative forms of meat protein to biosensors for farm monitoring.

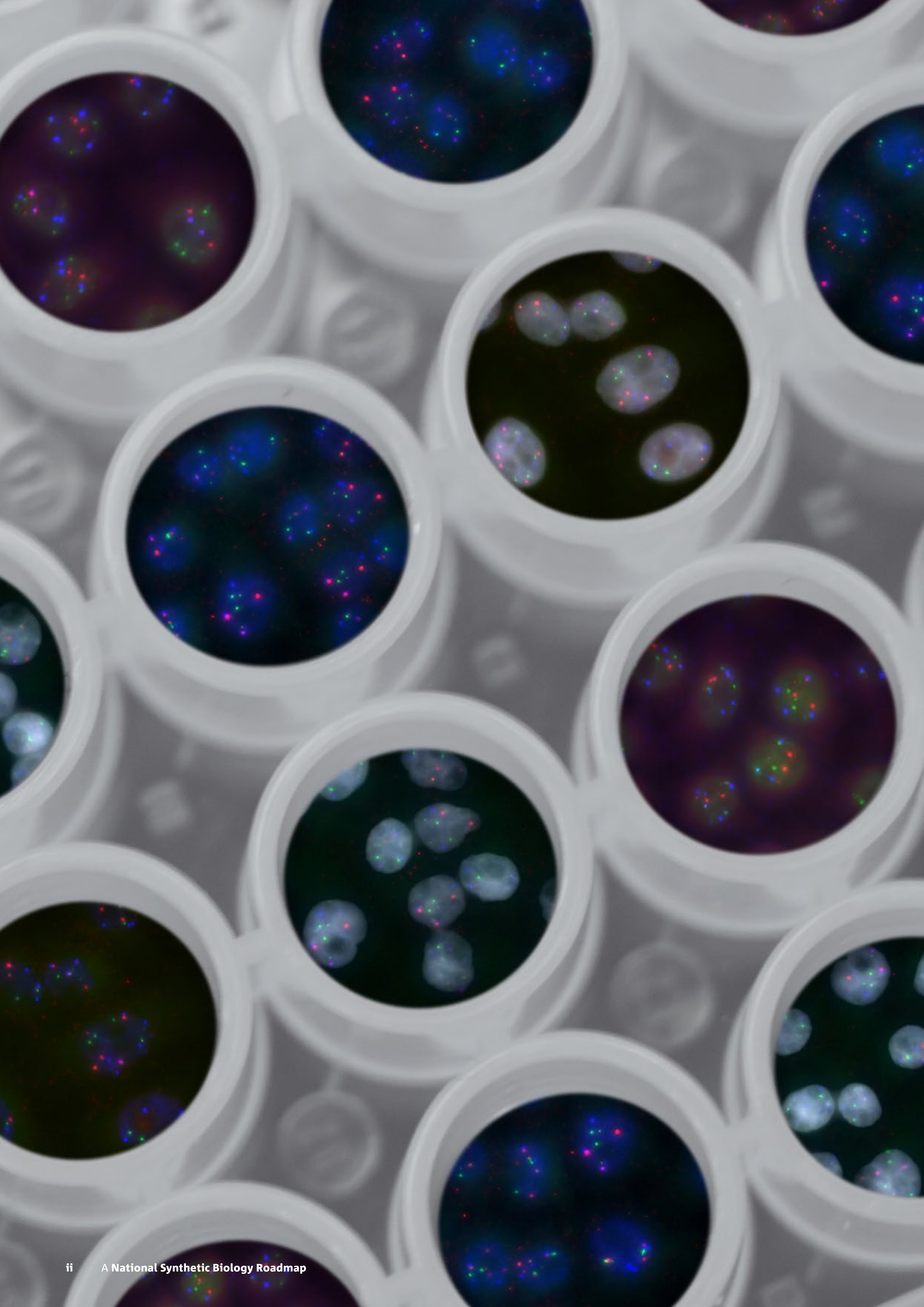
For our significant environmental challenges, bio-engineering could be the basis for new biofuels and for industrial chemicals.

Australia is well-placed to play a significant role in the field, but as this roadmap makes clear, good things don't simply land on your plate. We need to choose where to focus our efforts, by playing strategically to our strengths and our national priorities. This report indicates a $27 billion opportunity over two decades and provides a detailed steer of where effort is most likely to succeed, especially in applications relating to food and agriculture, and health and medicine.

It also draws attention to the critical issue of ensuring public trust and safety through strong regulation and a set of agreed ethical principles. Safety and public trust go hand in hand, but one doesn't presuppose the other. As the scientific community focuses on safety, it is important not to assume public trust will follow, but to actively engage the public throughout. Social licence is critical for success, and I am pleased to see the recognition it is accorded in this roadmap.

Australia has come a long way as a result of significant investment since 2016. That investment has accelerated our capability and this roadmap provides a detailed path forward. Now, a collaborative national approach is needed for Australia to build on the momentum and realise this great new opportunity.

Dr Cathy Foley
Australia's Chief Scientist



Executive summary

What is synthetic biology?

Synthetic biology is the rapid development of functional DNA-encoded biological components and systems through the application of engineering principles and genetic technologies.

Why synthetic biology?

Synthetic biology could create a $700 billion global opportunity by 2040.

The application of synthetic biology-enabled solutions to industrial, health and environmental challenges has the potential to be globally transformative. Synthetic biology can add value to a range of industries by enabling new products and biomanufacturing processes, and could underpin the growth of an economically and environmentally sustainable bioeconomy.

Why Australia?

Australia could position to be a leader in synthetic biology in the Asia-Pacific region and maintain the competitiveness of critical national industries.

With a growing synthetic biology research base and an attractive business environment for international partnerships, Australia could play a leading role in servicing the growing Asia-Pacific market for synthetic biology-enabled products which is expected to reach $3.1 billion by 2024. Developing a national synthetic biology ecosystem can also help to identify solutions to uniquely Australian agricultural and environmental challenges, establish cost-effective domestic manufacturing capabilities for supply chain resilience, and protect the nation from biological threats such as emerging infectious diseases or bioterrorism.

Why now?

Global synthetic biology capabilities are maturing rapidly with nations that invested early capturing greater market share.

Many countries (including the US, UK, China, Switzerland, France, Japan, Singapore, Denmark and Finland) have now identified synthetic biology as an important emerging capability. These nations have invested in research and commercialisation activities to support the growth of domestic synthetic biology capabilities, with some developing national strategies to guide investment.

Australia must act now if it is to secure a key role in this emerging global capability.

Australia has built a strong and growing synthetic biology research community however there is limited strategic alignment across jurisdictions, key government bodies and industry stakeholder groups. With national policies such as the Modern Manufacturing Strategy emphasising opportunities that could be unlocked by synthetic biology approaches, now is the time to coordinate government, industry and research thinking around Australia's synthetic biology strategy.

Building on detailed horizon scanning reports like *Synthetic Biology in Australia* – produced by the Australian Council of Learned Academies (ACOLA) in 2018 – this report seeks to be the next step towards this national coordination and discusses how Australia can approach accelerating the demonstration, scaling, and commercial success of applications. The report has been codeveloped with input from over 140 individuals representing more than 60 organisations from across government, industry and research.

Synthetic biology has the potential to unlock **$27 billion in annual revenue** and **44,000 jobs in Australia** by 2040

Given the significant uncertainty involved in estimating future market sizes for emerging technologies, a matrix framework was developed that considers two levels of global synthetic biology growth as well as two levels of market share that Australia could capture. Under the high global growth, high market share scenario, Australia's total economic opportunity by 2040 could be up to $27.2 billion in direct revenue.

Table 1: Industry breakdown for 2040 high growth, high market share scenario

	FOOD AND AGRICULTURE	HEALTH AND MEDICINE	OTHER
Australian annual revenue	$19.2 billion	$7.2 billion	$0.7 billion
Australian direct employment	31,200	11,700	1,100
Example applications	• Biomanufacturing sustainable alternatives to animal proteins and agricultural chemicals. • Engineered biosensors for biosecurity and surveillance of agricultural conditions. • Engineered crops and biological treatments for increased resilience and improved nutritional content.	• Biomanufacturing pharmaceutical ingredients and precursors that are traditionally plant-derived or chemically synthesised. • Engineered biosensors for diagnostic applications including rapid point-of-care tests. • Engineered cell-based therapies and vaccines.	• Biological solutions for waste management, recycling and minerals processing. • Biomanufacturing more sustainable industrial chemicals, materials, and fuels.

Microsilk technology designed for sustainable production of spider silk by Bolt Threads

Roadmap to 2040

Capturing the high market share scenario will require synthetic biology to be a critical national capability that underpins a thriving Australian bioeconomy. This will require Australia to sustain its investments in synthetic biology research while increasing support for the ecosystem's most critical challenges: industrial translation and scale-up. Demonstrating the commercial feasibility of synthetic biology by supporting research translation activities in Australia will help to raise broader industry awareness, build critical mass, and provide learnings that can be leveraged across other emerging applications. These efforts will need to be balanced with the need to invest in strategic research and development in longer-term opportunities.

The Roadmap's recommendations are designed to set the foundations for a strong synthetic biology ecosystem over the next 4 years and have been developed in collaboration with government, industry, and research stakeholders.

2040 Vision: Synthetic biology underpins a thriving Australian bioeconomy, creating new jobs and economic growth, enhancing competitiveness in key industries, and addressing critical environmental and health challenges.

2021–2025	2025–2030	2030–2040
Building capability and demonstrating commercial feasibility	**Early commercial successes and establishing critical mass**	**Growth through scaling market-determined application priorities**

THEME	ENABLING ACTIONS
Translation support	1. Prioritise translation support for applications that can most quickly demonstrate commercial feasibility.
	2. Establish bio-incubators to support the development of synthetic biology start-ups.
Shared infrastructure	3. Support national biofoundries to develop their scale and capability.
	4. Develop pilot and demonstration-scale biomanufacturing facilities certified to work with GMOs.
International partnerships	5. Attract international businesses to establish commercial operations in Australia.
	6. Attract leading international researchers and strengthen international research collaborations.
Foundational ecosystem enablers	7. Establish a national bioeconomy leadership council to advise government strategy.
	8. Maintain the safe governance of synthetic biology applications.
	9. Invest in growing foundational skills across social, economic and biophysical sciences.
	10. Develop and strengthen local industry-research collaborations to build capability, share knowledge, and increase employment pathways for graduates.

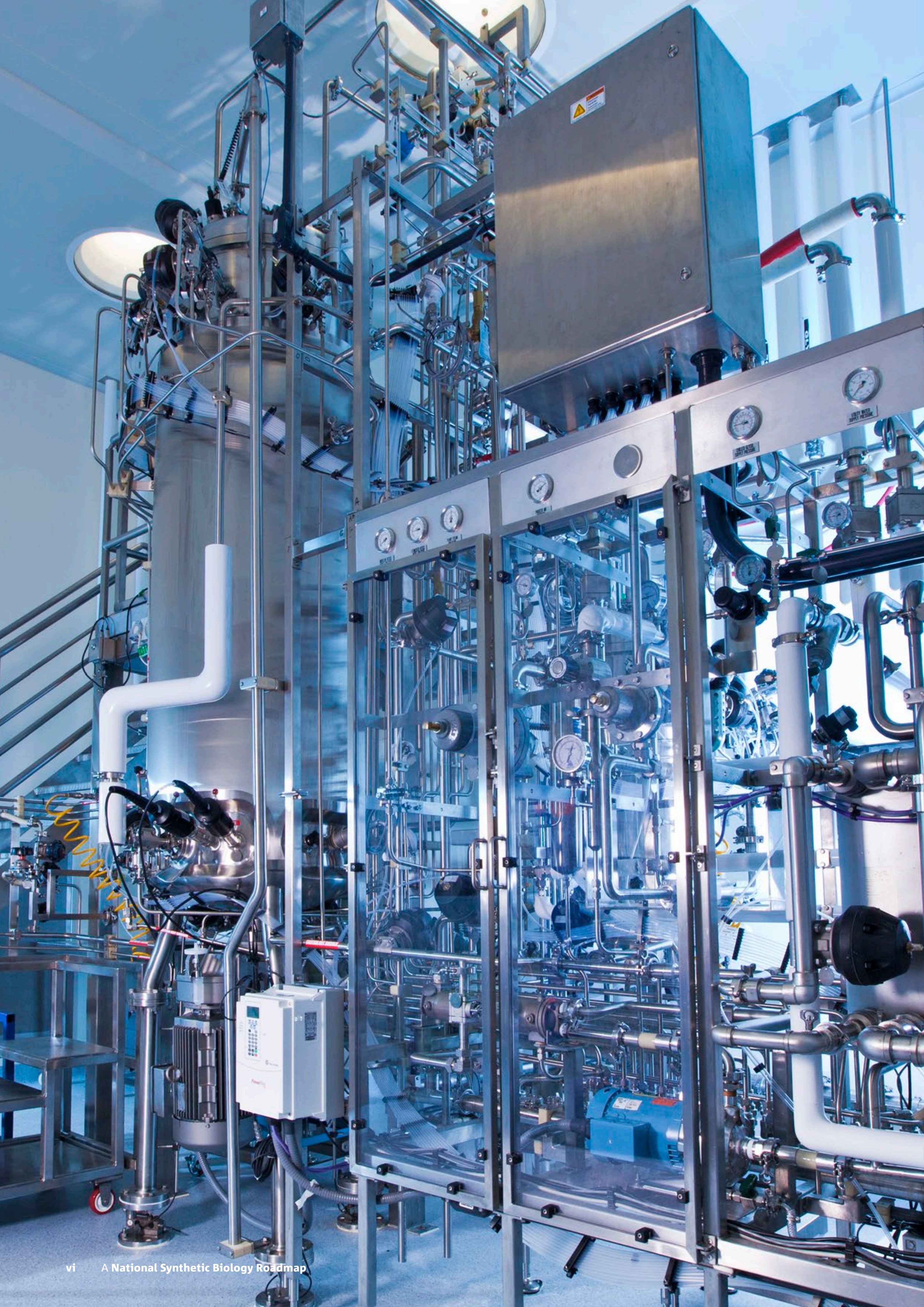


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Image: cGMP Manufacturing by BioCina

Glossary

TERM/ACRONYM	DEFINITION
Bioeconomy	The production of renewable biological resources and transformation of these resources and waste streams into value added products, such as bio-based products, bioenergy, feed and food.[1]
Biofoundry	A facility containing the resources, equipment and software required for high-throughput engineering of DNA-encoded biological components and systems. Biofoundries conduct the Design-Build-Test and Learn stages of advanced bioengineering and synthetic biology research and development (R&D).
Biomass	Organic material from plants, animals or microbes that can be used as an energy source.
Biosensor	A living organism or molecule (e.g. an enzyme) able to detect the presence of chemicals.[2]
CAR T-cells	Chimeric Antigen Receptor T- cells. Immune cells with a synthetic receptor designed to target a certain type of disease cell.[3]
GMP	Good Manufacturing Practice. GMP describes a set of principles and procedures that when followed help ensure that therapeutic goods, such as medicines, are of high quality.
GMO	Genetically Modified Organism. An organism that has been altered by gene technology or an organism that has inherited traits from an organism where the traits have resulted from gene technology.[4]
CRISPR	Clustered Regular Interspaced Short Palindromic Repeats. A technique which allows specific changes to be made to an organism's genome.[5]
PC1 – PC4	Physical Containment certification levels. A certification level for facilities suitable for working with different types of genetically modified organisms. PC facilities are classified according to levels of stringency of measures for containing GMOs. The classifications relate to the structural integrity of buildings and equipment used, as well as to the handling practices employed by those working in the facility. PC level 1 (PC1) facilities are used to contain organisms posing the lowest risk to human health and the environment. PC level 4 (PC4) facilities provide the most secure and stringent containment conditions.
PFAS	Per- and polyfluoroalkyl substances. Man-made chemicals with known health risks that have been used in industry and consumer products.
Synthetic Biology	Synthetic biology is the rational design and construction of nucleic acid sequences or proteins – and novel combinations thereof, using standardised genetic parts.[6] This enables the rapid development of functional DNA-encoded biological components and systems through the application of engineering principles and genetic technologies.
TRL	Technology Readiness Level. The TRL index is a globally accepted benchmarking tool for tracking progress of a specific technology from blue sky research (TRL1) to complete system demonstration (TRL9).

1 Europen Union (2012) Innovating for sustainable growth: A bioeconomy for Europe. Luxembourg.

2 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

3 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

4 Department of Health and Aging Office of the Gene Technology Regulator Record of GMO Dealings. Viewed 21 May 2021, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmorec-index-1#:~:text=Definition%3A The full definition of,Act 2000 (the Act).&text=An organism that has been,organism because of gene technology>.

5 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

6 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.


SARS-CoV-2
mRNA
Vaccine
COVID-19

1 Introduction

What is synthetic biology?

Synthetic biology[7] is the application of engineering principles and genetic technologies to biological engineering. Common characteristics of synthetic biology platforms include laboratory automation, computational design, biological parts standardisation, and high-throughput prototyping and screening.

This enables the rapid development of functional DNA-encoded biological components and systems with increased predictability and precision when compared to other forms of genetic modification.

Synthetic biology can add value to a range of industries by enabling both new manufacturing processes and new products (See Figure 1).

Figure 1: Synthetic biology can enable new manufacturing processes and products

Synthetic biology

Rapid development of engineered biological components and systems (e.g. yeast, bacteria, algae or mammalian cell lines) with new or optimised functionality.

Synthetic biology enabled biomanufacturing

Using synthetic biology outputs to manufacture products from agricultural and waste feedstocks.

Current commercial examples include:

- **Food ingredients**: Impossible Foods (US) use an engineered yeast to manufacture the heme that gives their plant-based meat its meaty flavour and colour.
- **Materials:** Bolt Threads (US) use an engineered yeast to produce a spider silk protein used in textiles and cosmetics.

Engineered biological products

Using synthetic biology outputs in products.

Current commercial examples include:

- **Pharmaceuticals:** COVID-19 vaccines developed by Pfizer/BioNTech (US/DEU) and Moderna (US) use synthetic mRNA strands to stimulate the production of antibodies to defend against COVID-19.
- **Agriculture:** Pivot Bio (US) has developed nitrogen fixing bacteria that can be applied to corn as a sustainable alternative to ammonia-based fertiliser.

7 Synthetic biology, also known as engineering biology, is defined by ACOLA as “the rational design and construction of nucleic acid sequences or proteins – and novel combinations thereof, using standardised genetic parts”. Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

Why synthetic biology?

The application of engineered biological solutions to industrial, health and environmental challenges has the potential to be globally transformative. Synthetic biology techniques can underpin the economic and environmentally sustainable growth of a global bioeconomy.

Economic and productivity growth

The global synthetic biology-enabled market is estimated at $6.8 billion (2019) and could plausibly grow to $700 billion by 2040.[8] Synthetic biology has the potential to:

- **Increase cost competitiveness** across existing and nationally significant supply chains like health, agriculture, and manufacturing. Examples include accelerating vaccine development,[9] increasing agricultural yields through crop engineering, and enabling more efficient manufacturing processes by harnessing engineered biology to replace complex chemical reactions.[10]
- **Develop novel high-value products and technologies** such as biosensors, engineered biotherapeutics, and biomanufacturing platforms for high value food and medical products. Value could also be captured by licensing technologies and intellectual property.

Environmental sustainability

Environmental policies and consumer preferences are increasing the demand for more environmentally sustainable industry practices and solutions. Synthetic biology has the potential to:

- **Improve waste management** and support the transition to a more circular economy by optimising biological processes to efficiently break down waste and degrade environmental pollutants. Synthetic biology could also enable production of more sustainable alternatives to petroleum-based products.[11]
- **Reduce land and water use** by engineering crops with increased yield and water use efficiency,[12] and developing more sustainable alternatives to (or production methods for) land and water intensive products.
- **Reduce carbon emissions** by developing low emission-intensive products and processes (e.g. alternatives to livestock agriculture) and using carbon dioxide (CO_2) as a manufacturing feedstock.
- **Address biodiversity loss** by using genetic methods for invasive species and pest population control.

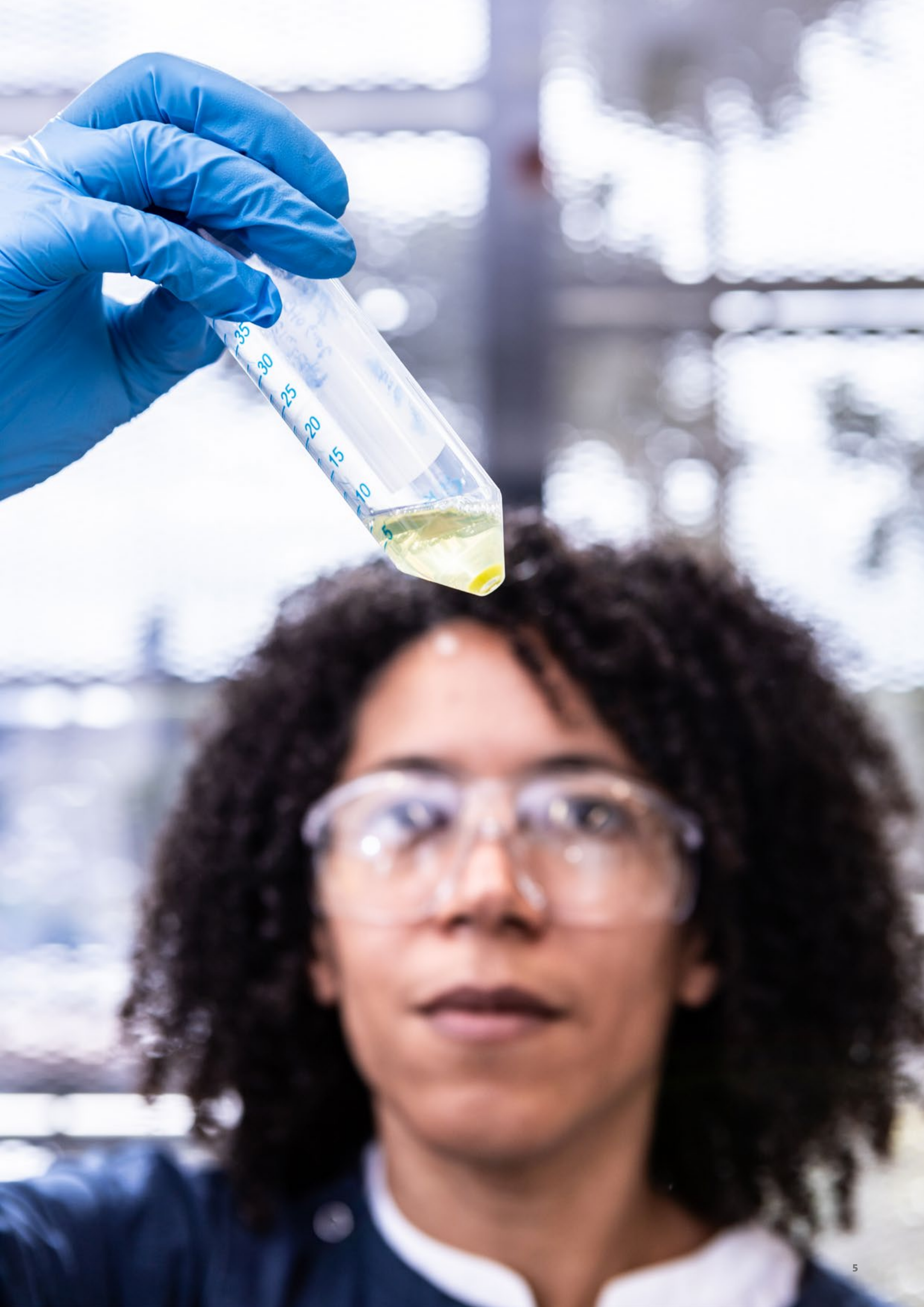
8 CSIRO analysis. See Appendix B.

9 Perkel JM (2015) Revolutionizing Vaccine Development with Synthetic Biology. <https://www.biocompare.com/Editorial-Articles/174945-Revolutionizing-Vaccine-Development-with-Synthetic-Biology/>.

10 For example, Royal DSM NV was able to cut 11 steps out of the original chemical process to produce an antibiotic using fermentation. Bergin J (2020) Synthetic Biology: Global Markets. <https://www.bccresearch.com/market-research/biotechnology/synthetic-biology-global-markets.html>.

11 French KE (2019) Harnessing synthetic biology for sustainable development. Nature Sustainability 2(4), 250–252. DOI: 10.1038/s41893-019-0270-x.

12 Batista-Silva W, da Fonseca-Pereira P, Martins AO, Zsögön A, Nunes-Nesi A and Araújo WL (2020) Engineering Improved Photosynthesis in the Era of Synthetic Biology. Plant Communications 1(2). DOI: 10.1016/J.XPLC.2020.100032.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Why Australia?

Building upon Australia's competitive strengths could position Australia as a leader in synthetic biology within the Asia-Pacific region.

Research strengths

Australia is ranked 10th globally (from 2015–2020, see Research Landscape) for synthetic biology publication volume and has a breadth of relevant research strengths which may support development of synthetic biology innovations. These include protein engineering, recombinant protein production, plant engineering, biological circuit design, metabolic engineering, immunology, fermentation and stem cells.[13] Australia is also a world leader in integrating biophysical and social science programs in the field of synthetic biology, and is one of the first nations to have conducted a baseline survey of public attitudes towards synthetic biology.[14]

Australia has significantly increased its focus on synthetic biology research in recent years through initiatives including Synthetic Biology Australasia and the CSIRO Synthetic Biology Future Science Platform. Recent public investments including the establishment of the ARC Centre of Excellence in Synthetic Biology (CoESB), and National Collaborative Research Infrastructure Strategy (NCRIS) funding for shared biofoundry infrastructure will also help to further develop Australia's synthetic biology research capabilities.

Trusted regulatory environment

Australia's robust regulatory environment for gene technology enhances the nation's reputation for safe and high quality genetically modified (GM) products and supports investor confidence in synthetic biology developments in Australia.[15] Australia's National Gene Technology Scheme is highly regarded by consulted stakeholders; with reviews to existing regulations occurring approximately every five years. The third review of Australia's Gene Technology Scheme found that the existing risk assessment framework and regulatory system is appropriate to cover current synthetic biology applications and recommended that the Office of the Gene Technology Regulator (OGTR) maintain a watching brief to ensure that emerging applications are appropriately regulated under the Scheme.[16]

Feedstock availability

Carbon-based feedstocks are the primary raw material and often the largest single input cost for biomanufacturing processes.[17] As such, the availability of competitively priced feedstocks is critical for the economic performance of biomanufacturing. Australia grows and exports significant volumes of sugar,[18] which is one of the most cost-effective and efficient feedstocks for biomanufacturing.[19] Australia also produces large amounts lignocellulosic biomass (in the form of agricultural waste) which could be used as a more sustainable feedstock for biomanufacturing if satisfactory fermentation efficiencies can be achieved.[20]

13 Based on a combination of stakeholder interviews and Web of Science publication count analysis.

14 CSIRO (2021) Public attitudes towards synthetic biology. Viewed 4 March 2021, <https://research.csiro.au/synthetic-biology-fsp/public-attitudes/>.

15 Office of the Chief Scientist (2020) Synthetic Biology in Australia. Canberra.

16 Department of Health (2018) The Third Review of the National Gene Technology Scheme October 2018 Final Report. <https://www1.health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review>.

17 National Research Council (2015) Industrialization of biology: A roadmap to accelerate the advanced manufacturing of chemicals. National Academies Press.

18 Australia produces around 4.2 million tonnes of raw sugar a year approximately 80% of which is exported. Department of Agriculture Water and the Environment (2021) Agricultural commodities: March quarter 2021. <https://www.agriculture.gov.au/abares/research-topics/agricultural-outlook/data#agricultural-commodities>; Department of Agriculture Water and the Environment (2020) Crops: Sugar. Viewed 29 October 2020, <https://www.agriculture.gov.au/ag-farm-food/crops/sugar#senate-inquiry-into-sugar-marketing-arrangements>.

19 Key biomanufacturing organisms including *E.coli* bacteria and *saccharomyces* yeast use fermentable sugars as a carbon and energy source.

20 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

Gateway to Asia

Australia's location and existing trade agreements within the Asia-Pacific region position the nation well to become a key provider of synthetic biology-enabled products and processes. This proximity is an advantage for food and medical exports which can require cold chain distribution. Synthetic biology is expected to have significant growth in the Asia-Pacific market at a compound annual growth rate (CAGR) of 24.3% from $1 billion in 2019 to $3.1 billion in 2024.[21]

Attractive business environment

Australia's intellectual property arrangements (ranked 11th in the world for security)[22] provide businesses with confidence that the value of their innovations can be protected. Businesses looking to operate in Australia may also benefit from a range of federal innovation support programs including the R&D Tax Incentive, the Business Research and Innovation Initiative (BRII), the Modern Manufacturing Strategy,[23] and the Patent Box for medical and biotech innovations announced in the 2021–22 Federal Budget.[24] State based strategies such as the Queensland Biofutures 10-Year Roadmap and Action Plan[25] can also support the growth of synthetic biology businesses in Australia.

Further, internationally based industry stakeholders noted Australia's highly skilled workforce with similar cultural norms and an English-speaking business environment is an attractive feature when considering collaboration partners and locations for establishing additional manufacturing bases in the Asia-Pacific region.

21 Table 112: Global Synthetic Biology Market, by Region, Through 2024 ($ Millions). Conversion rate from RBA Historical Data – Exchange Rates, Series ID: FXRUSD, USD$1=AUD$1.29 from Jan 2000 – Dec 2020. Bergin J (2020) Synthetic Biology: Global Markets. <https://www.bccresearch.com/market-research/biotechnology/synthetic-biology-global-markets.html>.

22 World Economic Forum (2019) The Global Competitiveness Report 2019. Geneva.

Why now?

Advances in synthetic biology tools and knowledge have increased the speed, precision, and affordability of their applications

Synthetic biology tools and workflows have experienced significant cost reductions, capability improvements, and increased availability over the past two decades. This includes DNA sequencing,[26] computer aided design,[27] DNA synthesis, genome editing,[28] and microfluidics technologies. The application of automation and machine learning capabilities is also helping to accelerate synthetic biology's design, build, test, and learn workflows. These advances have enabled the development of high throughput organism development capabilities in commercial and research biofoundries.

The global synthetic biology market is predicted to grow rapidly and is attracting substantial private investment

The global synthetic biology market, including synthetic biology-enabled products, could plausibly grow from $6.8 billion in 2019 to $700 billion in 2040, with a CAGR of 24.6% (see chapter 3 and Appendix B). In 2020, synthetic biology companies received almost $11 billion in private and public investment and non-dilutive government grants.[29] A further $6.4 billion was invested in the sector in Q1 2021 alone.[30]

Synthetic biology tools and approaches are strongly aligned to recent national policies for industry development

The Critical Technologies Policy Coordination Office has identified synthetic biology as a potentially critical technology capability for Australia's health and agriculture sectors that is likely to have a major impact on Australia's national interest within the next decade.[31] Synthetic biology techniques can also underpin opportunities relevant to a range of Federal Government policies, including the $1.5 billion Modern Manufacturing Strategy[32] and the commitment to develop an onshore mRNA vaccine manufacturing capability in the 2021–22 Budget.[33]

Australia lags leading nations and will require sustained strategic investments to pursue the opportunities offered by synthetic biology

Synthetic biology investment is growing as the world continues to take global challenges like climate change, food sustainability, and infectious disease resilience more seriously. The US and UK have made substantial investments in synthetic biology since the early 2000s and as a result have captured greater market share and attracted higher levels of private investment compared to other nations. Many other countries (including China, Switzerland, France, Japan, Singapore, Denmark and Finland) have now identified synthetic biology as an important emerging capability. These nations have invested in research and commercialisation activities to support the growth of their domestic synthetic biology capabilities, with some developing national strategies.

23 Department of Industry Science Energy and Resources (2020) Make it Happen: The Australian Government's Modern Manufacturing Strategy. <https://www.industry.gov.au/data-and-publications/make-it-happen-the-australian-governments-modern-manufacturing-strategy>.

24 Treasury (2021) Tax incentives to support the recovery. <https://budget.gov.au/2021-22/content/factsheets/download/factsheet_tax.pdf>.

25 Department of State Development Manufacturing Infrastructure and Planning (2016) Biofutures 10-Year Roadmap and Action Plan. <https://www.statedevelopment.qld.gov.au/industry/priority-industries/biofutures>.

26 For example, the cost of sequencing a human genome fell from around US$100 million to US$1000 since 2000. National Human Genome Research Insitute DNA Sequencing Costs: Data. Viewed 15 March 2021, <https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Costs-Data>.

27 For example, a computer aided design system has been developed to automate genetic circuit construction in E. coli bacteria.

28 The development of CRISPR-Cas9 has enabled incredibly precise modification of genomes.

29 Wisner S (2021) Synthetic Biology Investment Reached a New Record of Nearly $8 Billion in 2020 – What Does This Mean For 2021? Viewed 5 February 2021, <https://synbiobeta.com/synthetic-biology-investment-set-a-nearly-8-billion-record-in-2020-what-does-this-mean-for-2021/>.

30 SynBioBeta (2021) 2021 Q1 SynBioBeta market report. <https://synbiobeta.com/q1-shatters-previous-synthetic-biology-investment-record-signals-projected-2021-investment-of-up-to-36-billion/>.

31 Critical Technologies Policy Coordination Office (2021) Critical Technologies Discussion Paper: Health. <https://www.pmc.gov.au/resource-centre/domestic-policy/critical-technologies-discussion-paper-health>.

32 Synthetic biology has potential applications within all six National Manufacturing Priorities (resources technology and critical minerals processing, food and beverage, medical products, recycling and clean energy, defence, and space).

33 Australian Government (2021) Budget Paper No. 2: Budget Measures. <https://budget.gov.au/2021-22/content/bp2/index.htm>.

Since 2016, Australia has made strategic investments in synthetic biology research capabilities and infrastructure. In absolute terms, Australia's early investments are at least an order of magnitude smaller than the investments in the US and UK (see Table 2). However, when adjusted for economy size – as measured by Gross Domestic Product (GDP) – the scale of public investment in Australia is comparable to the US but less than a third of that in the UK.

Australia must act now if it is to secure a leading role in this emerging global capability

Stakeholders suggested that Australia must accelerate research translation and commercialisation while sustaining its investments in synthetic biology research if the nation intends to pursue synthetic biology-enabled opportunities in global markets. Without sustained investment in research, demonstration and commercialisation, Australia will be a purchaser of disruptive synthetic biology-enabled tools and end-products; being more heavily reliant on international supply chains to ensure key industries remain competitive and missing out on the majority of the economic opportunity estimated in this report.

Table 2: Early strategic public investments in the US and UK have helped to enable growth in terms of start-ups, private investment, and market share.

COUNTRY	SCALE OF EARLY PUBLIC INVESTMENT	SYNTHETIC BIOLOGY START-UPS	SCALE OF PRIVATE INVESTMENT	ESTIMATED MARKET SHARE[34]
US	**$1.4B**[35] (2005–2015)	**336**[36]	**$5.3B**[37]	**33–39%**
UK	**$550M**[38] (2009–2016)	**150**[39]	**$910M**[40]	**8–12%**
AUS	**$80.7M**[41] (2016–2021)	**10**	**$20M**[42]	**Negligible**

Note: China, France, Germany, and Japan also have notable synthetic biology market shares (estimated 6–9%).

34 Estimated market share for 2019. Technavio (2020) Global Synthetic Biology Market 2020–2024. <https://www.technavio.com/report/synthetic-biology-market-industry-analysis>.

35 Published figures for this period range from between US$140-220M annually during this time period. See Gronvall GK (2015) US Competitiveness in Synthetic Biology. Health Security 13(6), 378–389. DOI: 10.1089/hs.2015.0046; Si T and Zhao H (2016) A brief overview of synthetic biology research programs and roadmap studies in the United States. Synthetic and Systems Biotechnology 1(4), 258–264. DOI: 10.1016/j.synbio.2016.08.003.

36 Analysis of data from Golden (n.d.) List of synthetic biology companies. Viewed 21 May 2021, <https://golden.com/list-of-synthetic-biology-companies/>.

37 2018 private investment total. Converted from USD. The SynBioBeta data set is US-centric, but may include investment in some start-ups outside the US. Schmidt C, Costa KA, Limas M and Cumbers J (2019) Synthetic Biology Investment Report 2019 Q1. <https://go.synbiobeta.com/l/408192/2019-04-10/h3scx8>.

38 Synthetic Biology Leadership Council (2016) Biodesign for the Bioeconomy: UK Strategic Plan for Synthetic Biology. <https://ktn-uk.org/perspectives/biodesign-for-the-bioeconomy-uk-strategic-plan-for-synthetic-biology/>.

39 Synthetic Biology Leadership Council (2019) Synthetic Biology UK: A Decade of Rapid Progress 2009–2019. <https://ktn-uk.org/programme/synthetic-biology-leadership-council/>.

40 2018 private investment total of £500M provided by SynbiCITE.

41 Sum of public funding committed to the ARC CoESB ($37M from the ARC and NSW Government), CSIRO Synbio Future Science Platform and BioFoundry ($27.7M), NCRIS Biofoundry Capability ($8.3M), Macquarie Biofoundry ($2.5M), and the QUT Mackay Renewable Biocommodities Pilot Plant ($5.2M). A significant portion of this funding is yet to be spent. This figure does not include funding for specific research projects.

42 2020–2021 financial year. Includes seed investments in Provectus Algae (US$3.25 million in October 2020) and Nourish Ingredients (US$11 million in March 2021)

2 Australia’s synthetic biology landscape

Research landscape

Australia is well regarded internationally for its research capability in synthetic biology and ranks 10th globally for synthetic biology publication output between 2015 and 2020. Over this time, Australia’s yearly share of publication output grew slightly from 3.54% to 3.93%.[43] The US (38%), China (16%) and UK (13%) were the top publishing countries during this period.

Australia is developing research biofoundry capabilities at CSIRO and Macquarie University (see Figure 2), and researchers have access to cutting edge infrastructure through NCRIS-funded programs including Bioplatforms Australia, the National Biologics Facility, Phenomics Australia and the Australian Plant Phenomics Facility. Recent national and state-level investments exceeding \$80 million[44] will further enhance Australia’s synthetic biology research capabilities and performance.

Major public investments include:

- \$35 million over seven years for the ARC CoESB.[45]
- \$27.7 million in CSIRO’s Synthetic Biology Future Science Platform and BioFoundry.[46]
- \$8.3 million to establish a national shared biofoundry capability through NCRIS.[47]
- \$5.5 million invested in Macquarie University’s Biofoundry and synthetic biology research.[48]
- \$5.2 million to upgrade the Queensland University of Technology Mackay Renewable Biocommodities Pilot Plant.[49]

Sustained research investment will be essential for advancing the technical maturity of synthetic biology approaches and positioning Australia for targeting long-term success in this field. However, the real-world impact of this research will likely stall if additional investment is not directed towards translational support.

43 Based on Web of Science search results for publications under topic "synthetic biology” between 2015 and 2020.

44 Excludes ARC and NHMRC investment other than that listed for the ARC Centre of Excellence in Synthetic Biology.

45 Funding period between 2020–2026. Australian Research Council 2020 ARC Centre of Excellence in Synthetic Biology. Viewed 21 May 2021, <https://www.arc.gov.au/grants/linkage-program/arc-centres-excellence/2020-arc-centre-excellence-synthetic-biology>.

46 CSIRO has directly invested \$25.4 M in the SynBio FSP from 2016–2022. A total of \$4.1 M has been spent by CSIRO to establish the CSIRO BioFoundry but only \$2.3 M of this investment is additional to the FSP’s funding.

47 Announced in the 2020 federal budget. Department of Education Skills and Employment 2020–21 Budget Research Package. Viewed 21 May 2021, <https://www.dese.gov.au/2020-21-budget-research-package>.

48 Includes NSW Government (Office of the Chief Scientist and Engineer and Department of Primary Industry) investments in the Macquarie Biofoundry, ARC CoESB, and Yeast 2.0 project.

49 Queensland University of Technology (2021) QUT Mackay pilot plant to get capability upgrade. Viewed 26 May 2021, <https://www.qut.edu.au/news?id=176208>.

Figure 2: Australia's synthetic biology research organisations[50]

26 Synthetic biology research organisations around Australia

11 Academic partners in the ARC Synthetic Biology CoE

2 Members of the Global Biofoundries Alliance

National
CSIRO

WA
University of Western Australia
Curtin University
Murdoch University

SA
University of Adelaide
SA Health and Medical Research Institute

VIC
Deakin University
La Trobe University
Monash University
University of Melbourne
Peter MacCallum Cancer Centre

NSW
Macquarie University
University of Newcastle
University of New South Wales
Western Sydney University
University of Sydney
University of Technology Sydney
NSW Department of Primary Industries

ACT
ANU
University of Canberra

QLD
University of Queensland
Queensland University of Technology
University of the Sunshine Coast
Griffith University
James Cook University
QIMR Berghofer Medical Research Institute

- ARC Synthetic Biology CoE Member
- Biofoundry Alliance Member

50 Identified Australia's synthetic biology research organisations include ARC Centre of Excellence in Synthetic Biology academic partners, organisations with a synthetic biology research program on their website or those with >1% of Web of Science search results for topic "synthetic biology" between 2015–2020. See Appendix C for full list of Australian universities and corresponding Web of Science search results.

Industry landscape

Australia has a small but growing number of synthetic biology engaged businesses. At least ten synthetic biology start-ups have been established in Australia in recent years (see Figure 3). Some of these synthetic biology start-ups have begun to attract interest from local and international investors with a total of $20 million invested in Nourish Ingredients and Provectus Algae.[51]

There are at least 20 other Australian businesses engaged in broader synthetic biology-related activities including research collaborations and the provision of enabling technologies or services.[52] For example, Nuseed is commercialising omega-3 producing canola crops developed in Australia.

Broad industry awareness of synthetic biology is low, but some businesses are beginning to take notice of synthetic biology's potential. For example, BHP has taken a strategic stake in the Cemvita Factory (US) developing bio-engineered pathways for carbon utilisation, enhanced oil recovery and biomining applications.[53] The ARC CoESB also collaborates with a range of industry partners.

This early level of industry activity is promising but Australia will need to accelerate the translation and commercialisation of synthetic biology applications if it is to build a critical mass of synthetic biology industry activity.

Figure 3: Synthetic biology start-ups founded in Australia

BONDI	Bondi Bio is engineering cyanobacteria to sustainably produce high-value compounds from light, water and CO_2 – for a broad range of markets such as flavours and fragrances, health and medicine, agriculture, and specialty chemicals.	nourish INGREDIENTS	Nourish Ingredients is engineering new, specialty food lipids comparable to those found in animal products. These products are currently in prototype stage of development.
change FOODS	Change Foods is developing animal-free cheese and other dairy products using microbial biotechnology. The company was founded in Australia however is now based in the US.	ppb technology	PPB Technology is developing biosensor technology with synthetic biology that allows food companies to check that their products meet the safety and quality needs of consumers.
EDEN BREW ANIMAL-FREE DAIRY	Eden Brew is developing animal-free dairy products using proteins produced by synthetic biology.	PROVECTUS ALGAE	Provectus Algae is optimising a synthetic biology algal platform to produce high-value compounds for use in a range of industries including chemicals, food, and agriculture.
HydGENE renewables	HydGENE Renewables is engineering bacteria with synthetic biology to produce hydrogen on-site from renewable plant material.	PYC Therapeutics	PYC Therapeutics is using synthetic biology to develop RNA therapeutics to treat diseases which existing drugs cannot target effectively.
MICROBIOGEN	MicroBioGen is developing optimised industrial strains of *Saccharomyces cerevisiae* (baker's) yeast for production of biofuels and high protein feed.	SAMSARA	Samsara is using synthetic biology to engineer enzymes that can degrade polymers or chemicals safely and efficiently.

51 Provectus Algae (US$3.25 Million in October 2020) and Nourish Ingredients (US$11 Million Seed round, March 2021)

52 Appendix D provides further details on the synthetic biology engaged businesses operating in Australia that were identified during this project.

53 Cemvita Factory (2019) BHP Takes a Stake in Cemvita Factory due to Bioengineered pathway for Mine Rehabilitation. Viewed 21 May 2021, <https://www.cemvitafactory.com/post/bhp-takes-a-stake-in-cemvita-factory-due-to-bioengineered-pathway-for-mine-rehabilitation>.

Omega-3 canola seeds by Nuseed

3 Synthetic biology opportunities for Australia

Australia's potential 2040 market sizes

Economic analysis was undertaken to assess the commercial opportunity in synthetic biology for Australia by 2040. Given the significant uncertainty involved in estimating future market sizes for emerging technologies, a matrix framework was chosen that considers two levels of global synthetic biology growth as well as two levels of market share that Australia could capture.

Under the high global growth, high market share scenario, Australia's total economic opportunity by 2040 could be up to $27 billion in direct annual revenue and the creation of 44,000 new jobs (see Figure 4). This revenue figure includes $19 billion for the food and agriculture industry and $7 billion for the health and medicine industry (see Table 3).[54]

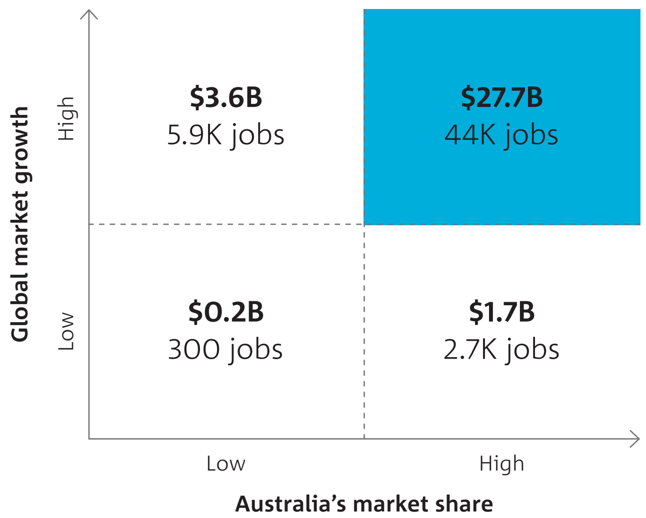


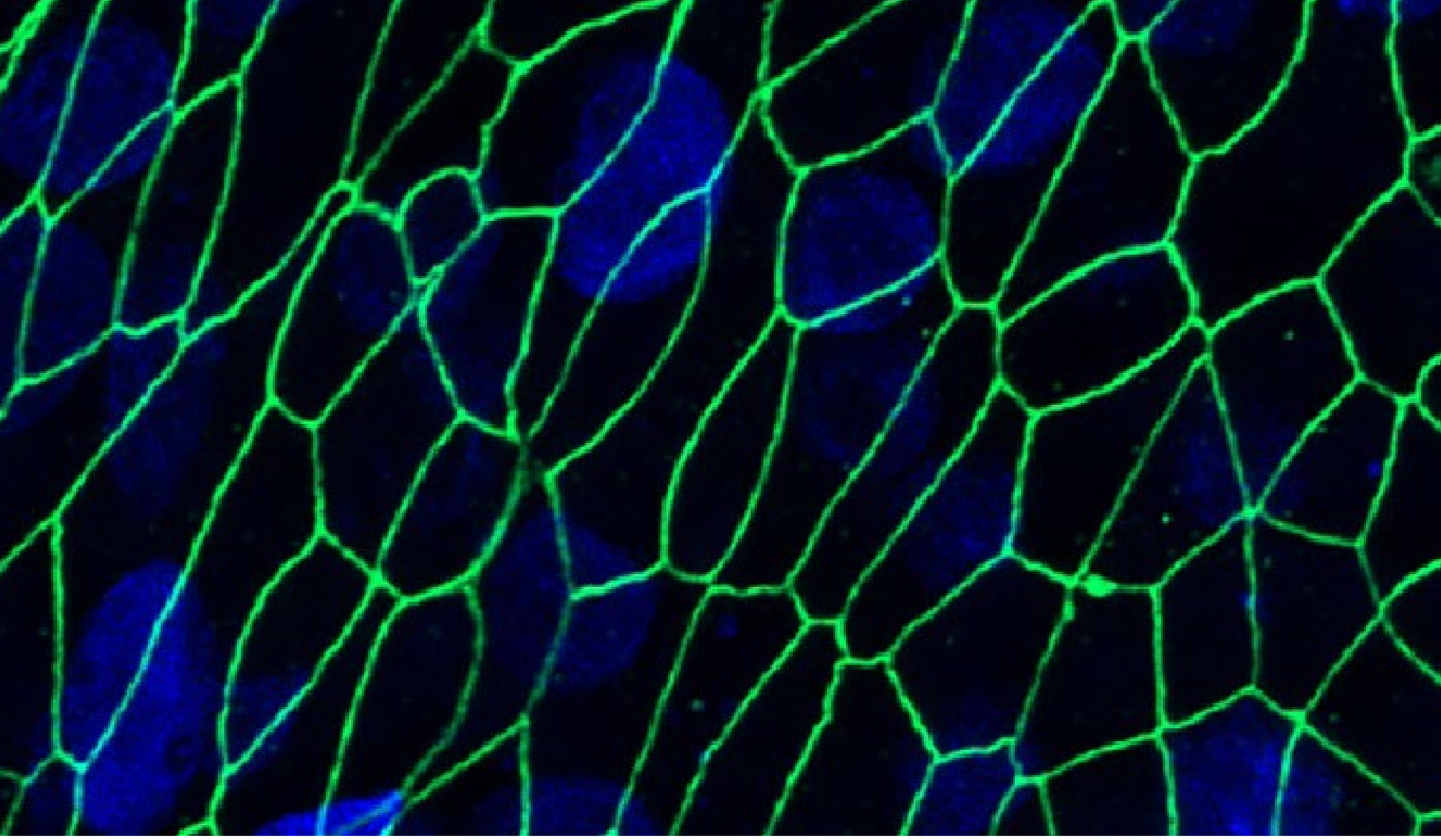
Figure 4: Matrix framework results for Australia's potential 2040 revenue (AUD) and employment

Table 3: Market breakdown for the 2040 high growth, high market share scenario

	FOOD AND AGRICULTURE	HEALTH AND MEDICINE	OTHER	TOTAL
Potential global revenue by 2040 (AUD)	$428.2B	$241.1B	$28.2B	**$697.4B**
Potential Australian annual revenue by 2040 (AUD)	$19.3B	$7.2B	$0.7B	**$27.2B**
Potential Australian headcount employment by 2040	31,200 jobs	11,700 jobs	1,100 jobs	**44,100 jobs**

Discrepancies in summations are attributed to differences in rounding.

54 Full results and the associated methodology, assumptions, and sensitivity analysis are included in Appendix B.

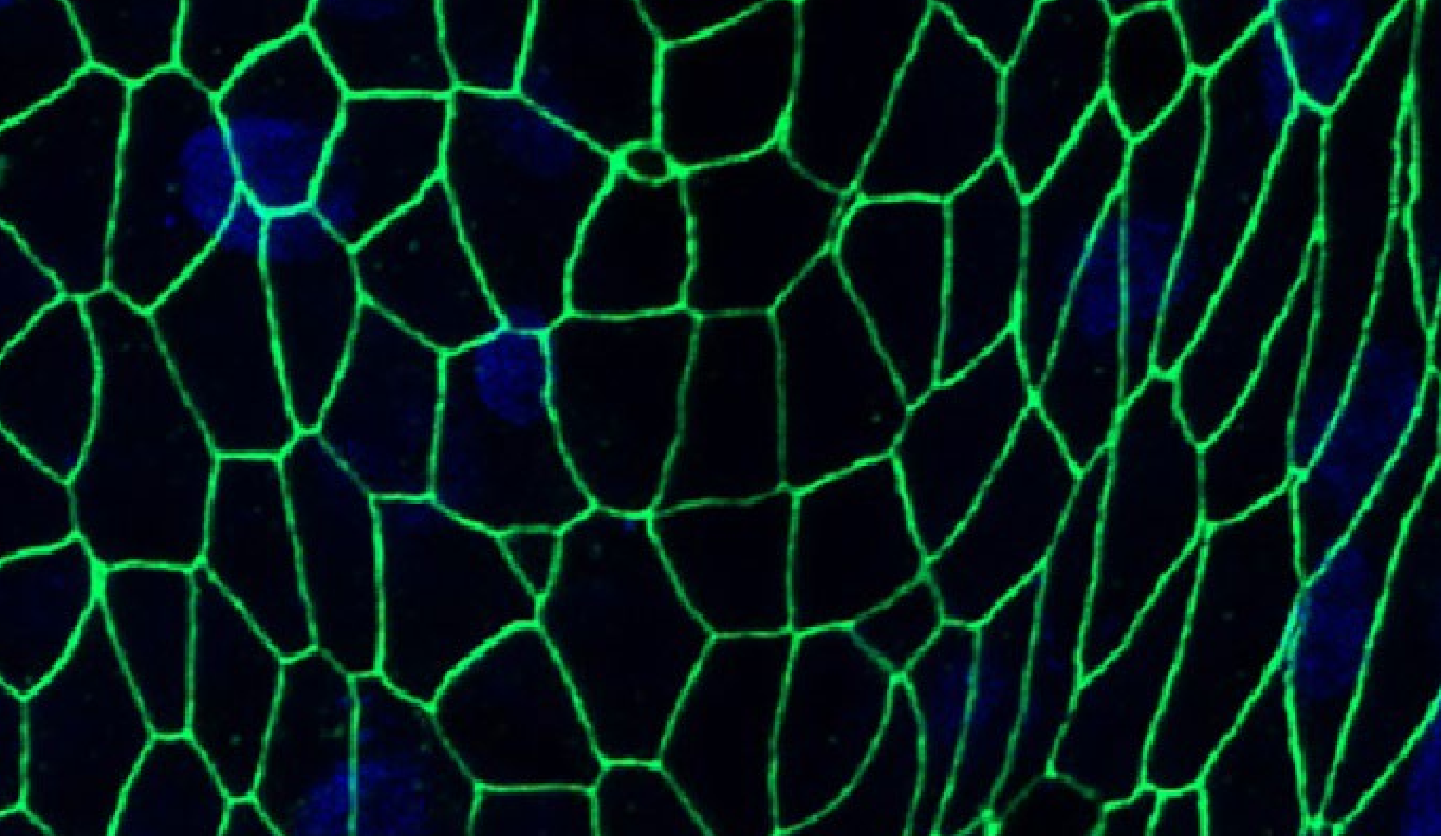


Application assessment framework

If Australia is to pursue the high market share scenario outlined in the economic analysis, it must consider which markets and applications are most viable for development and commercialisation within the national context. However, comparing between synthetic biology applications is challenging due to the diversity of potential benefits and low maturity of most applications. To assist with this challenge, an application assessment framework (Table 4) was developed. It assesses 19 potential applications of synthetic biology across a range of criteria.

The selection of applications was informed by the economic analysis, consultations, and literature review and is not intended to be exhaustive. The framework considers the following criteria:

- **2030 readiness in Australia**: How likely is it that this application will be commercially feasible by 2030 in Australia? This assessment considers social acceptance, regulation, technology readiness level and whether synthetic biology is expected to enable an economically feasible solution.
- **Addressable parent market growth**: What is the level of current yearly growth in the most relevant addressable parent market for which data could be identified? 'High' yearly growth is considered greater than $10 billion annually, whilst 'low' indicates growth less than $1 billion annually. While related, this should not be interpreted as a proxy for the application's market size or growth rate as synthetic biology will have differing impacts in each parent market.



- **Value to volume ratio**: What level of profit can be captured per unit? 'High' describes high value, low volume (niche) applications and 'low' describes low value, high volume (commodity) applications.
- **National research strength**: To what degree is Australia comparatively well placed to come up with synthetic biology-enabled solutions? This assessment considers Australia's share of synthetic biology and synthetic biology-related research publications for each application area,[55] as well as qualitative stakeholder insights.
- **Domestic end-user industry**: To what degree does Australia have a strong end-user industry and associated supply chain networks to ensure solutions are fit-for-purpose and benefiting local industry?
- **Primary sovereign value**: What is the primary form of value that this application would bring to Australia across economic, environmental, and social dimensions (noting that all applications can provide multiple types of value)?

Specific research programs and business cases should be considered on their individual merits as variation exists within application areas. The remainder of the chapter provides further detail on the assessed applications, with additional discussion for those larger markets identified in CSIRO's economic analysis.

55 Australia's share of research publications was calculated using Web of Science results for simple relevant search terms determined by CSIRO. The data sets were not manually reviewed for false positives.

Table 4: Application assessment framework

MARKET	APPLICATION	TYPE OF SYNTHETIC BIOLOGY	2030 READINESS IN AUSTRALIA
Food and Agriculture	**Food products** (e.g. animal-free proteins and fats)	Biomanufacturing	High – some applications are already available internationally and an Australian start-up exists in this space.
	Animal feed products (e.g. enzyme additives to improve nutrient uptake)	Biomanufacturing	High – some applications in development within Australia are likely to be commercialised.
	Agricultural chemicals (e.g. fertilisers, pesticides, herbicides)	Biomanufacturing	Medium – some applications show technical feasibility however commercial scale challenges remain.
	Agricultural and food biosensors (e.g. detection of contaminants in air and liquids)	Synthetic biology product	High – some applications are already being commercialised in Australia.
	Biological agricultural treatments (e.g. topical RNA-based sprays and biological alternatives to fertiliser)	Synthetic biology product	Medium – transient expression likely to be more socially accepted than permanent genetic changes however some technical challenges remain.
	Engineered crops (e.g. nutritionally enhanced crops)	Synthetic biology product	Medium – existing successes can expect to see scaled implementation, but new applications may take longer due to long regulatory and development timelines and high development costs.
Health and Medicine	**Pharmaceuticals** (e.g. artemisinic acid – a precursor to antimalarial medication)	Biomanufacturing	Medium – technical feasibility has been demonstrated but sustainable commercial business models have not, and new products will face long times to market.
	Biosensor based diagnostic tools (e.g. rapid point of care tests)	Synthetic biology product	High – cell-free and in-vitro diagnostic tools are high TRL with some applications likely to be commercially available by 2030.
	Engineered biotherapeutics (e.g. CAR-T cell therapies and mRNA vaccines)	Synthetic biology product	High – some CAR-T cell therapies exist already and recent government investments in building mRNA manufacturing capabilities will accelerate the maturing of this application area.

ADDRESSABLE PARENT MARKET GROWTH	VALUE TO VOLUME RATIO	NATIONAL RESEARCH STRENGTH (Australian % of web of science publications)	DOMESTIC END-USER INDUSTRY	PRIMARY SOVEREIGN VALUE
Medium (Specialty Food Ingredients Market)	High	High – 4%	Medium – strong agriculture industry but limited food manufacturing industry.	Providing environmentally sustainable manufacturing processes or energy sources
High (Global Animal Feed Market)	Medium	High – 4%	High – strong agriculture industry and animal feed capability.	Providing environmentally sustainable manufacturing processes or energy sources
High (Global Agricultural Chemicals Market)	Low	High – 4%	Low – strong agriculture industry but limited chemical manufacturing industry.	Providing environmentally sustainable manufacturing processes or energy sources
Low (Global Market for Biosensor Applications, Process Industries)	High	Medium – 3%	High – strong agriculture industry.	Supporting competitiveness of existing key national industry
Medium (Global Market for Agricultural Biotechnology, Biologicals)	High	High – 5%	High – strong agriculture industry.	Supporting competitiveness of existing key national industry
Medium (Global Market for Agricultural Biotechnology, Biotech Seeds)	Low	High – 4%	High – strong agriculture industry.	Supporting competitiveness of existing key national industry
High (Active Pharmaceutical Ingredients Market)	High	High – 4%	Low – limited pharmaceutical manufacturing industry.	Supporting the health of Australians
Medium (Global Market for Biosensor Applications, Point-of-Care + Home Diagnostics)	High	Medium – 3%	Low – few medical technology biosensor companies.	Supporting the health of Australians
High (Biologic Therapeutic Drugs Global Market)	High	Low – 2%	Low – few biotherapeutic companies and CSL only vaccine company.	Supporting the health of Australians

High Medium Low

Table 4: Application assessment framework (continued)

MARKET	APPLICATION	TYPE OF SYNTHETIC BIOLOGY	2030 READINESS IN AUSTRALIA
Environment	**Waste management solutions** (e.g. engineered enzymes or insects for waste processing)	Synthetic biology product	Medium – may lack required commercial drivers but plausible with government support given high TRL, high social acceptance and low regulatory barriers.
	Environmental biosensors (e.g. detection of per- and polyfluoroalkyl substance (PFAS), heavy metals, antibiotics)	Synthetic biology product	Medium – may lack required commercial drivers but plausible with government support given high TRL and high social acceptance
	Environmental bioremediation (e.g. engineered enzymes or organisms for PFAS removal)	Synthetic biology product	Low – High social acceptance and some high TRL examples but many solutions face regulatory barriers and weak commercial drivers.
	Genetic pest control (e.g. Sterile Insect Technology for fruit-flies and mosquitos population control)	Synthetic biology product	Low – low technology readiness, high regulatory and social acceptance barriers.
Chemicals	**Fine chemicals** (e.g. production of squalene for use in high margin products like skincare and vaccines)	Biomanufacturing	Medium – high TRL but significant commercialisation challenges to compete with established chemical production.
	Commodity chemicals (e.g. production of chemical intermediates such as ethylene and ethanol)	Biomanufacturing	Low – scaled production faces significant technical and commercial challenges.
Materials	**Biomanufactured materials** (e.g. bioplastics and textiles)	Biomanufacturing	Medium – production at commodity scale will be challenging by 2030 however high value, low volume simple biomaterials may see commercial success.
	Functional biomaterials (e.g. regenerative composite materials for Defence)	Synthetic biology product	Low – low TRL and priority target applications yet to be identified.
Energy	**Biofuels** (e.g. hydrogen produced by fermentation of biomass)	Biomanufacturing	Low – likely to only be off-grid, niche applications by 2030.
Mining	**Biomining** (e.g. bioleaching or metallurgy for sustainable mining practices)	Synthetic biology product	Low – slow pace of change in mining and high regulatory barriers.

ADDRESSABLE PARENT MARKET GROWTH	VALUE TO VOLUME RATIO	NATIONAL RESEARCH STRENGTH (Australian % of web of science publications)	DOMESTIC END-USER INDUSTRY	PRIMARY SOVEREIGN VALUE
Low (Global Waste Management Equipment Market)	Medium	High – 5%	Medium – few commercial companies offering technology solutions but there is a significant waste management industry.	Protecting Australia's unique environment
Low (Global Market for Biosensor Applications, Environmental)	Medium	Medium – 3%	Medium – potentially relevant to many industries however limited commercial demand.	Protecting Australia's unique environment
High (Global Bioremediation Market)	Medium	High – 4%	Medium – potentially relevant to many industries however limited commercial demand.	Protecting Australia's unique environment
Low (Global Biological Pest Control Market)	High	High – 8%	High – significant demand for pest control solutions in the biosecurity, agriculture, and environment sectors.	Protecting Australia's unique environment
High (Fine Chemicals Global Market)	Medium	High – 4%	Low – limited chemical manufacturing.	Providing environmentally sustainable manufacturing processes or energy sources
High (Global Commodity Chemicals Market)	Low	High – 4%	Low – limited chemical manufacturing.	Providing environmentally sustainable manufacturing processes or energy sources
High (Global Biomaterials Market)	Low	High – 4%	Low – limited material manufacturing.	Providing environmentally sustainable manufacturing processes or energy sources
High (Global Biomaterials Market)	High	High – 4%	Low – limited material manufacturing.	Providing environmentally sustainable manufacturing processes or energy sources
High (Bioenergy Global Market)	Low	Medium – 3%	High – large exporter of energy inputs (e.g. LNG, coal).	Providing environmentally sustainable manufacturing processes or energy sources
Low (Global Biomining Market)	Medium	High – 5%	High – large mining industry.	Providing environmentally sustainable manufacturing processes or energy sources

High Medium Low

Food and agriculture

Australia’s opportunity: Up to $19 billion in annual revenue and 31,200 jobs by 2040

Applications

Synthetic biology can help feed the world in more sustainable ways as climate change, declining arable lands, and increasing demand for more environmentally friendly products challenge traditional agricultural production.[56]

Synthetic biology could enable sustainable biomanufacturing of food and agricultural products, and create biological solutions to productivity and environmental challenges in the agricultural sector.

Table 5: Food and agriculture applications

APPLICATION	DESCRIPTION	EXAMPLES
Food products	Biomanufacturing of diverse food products and ingredients including high-value specialty flavours, sweeteners, colours, vitamins, food processing enzymes, lipids and nutraceuticals.[57] This could help improve cost[58] and sustainability of food production through reductions in land use, water use or ruminant emissions.	• Nourish Ingredients (AUS) are using fermentation to produce specialty fats and oils that mimic the molecular structure of animal fats to improve the flavour of plant-based proteins.[59] • Eden Brew (NSW) is developing fermentation processes able to produce dairy products[60] in an animal-free and more sustainable manner.
Animal feed products	Biomanufacturing of ingredients and additives for livestock and aquaculture feed. Synthetic biology-enabled manufacturing could reduce costs and improve the sustainability of aquaculture[61] by reducing its dependence on an ecologically limited supply of wild-captured forage fish as feed inputs.[62]	• Deep Branch Biotechnology (UK) are engineering microbes that transform the CO_2 and hydrogen in flue gases into protein to replace soy and fishmeal in aquaculture and agriculture feeds.[63] • Bioproton (AUS) is working with QUT to engineer fermentation of astaxanthin, a nutritional antioxidant used in animal feed and aquaculture industries, to replace petrochemical-based production methods.[64]
Agricultural chemicals	Biomanufacturing of agricultural chemicals including fertilisers, pesticides and herbicides. This could help improve the sustainability of production systems or reduce the negative environmental impacts from agricultural chemical residues on soil and water quality.	• Provectus Algae (AUS) is designing algal-based biomanufacturing platforms to produce inputs for agricultural chemical (e.g. biopesticide) production.[65]

56 OECD (2020) Towards Sustainable Land Use: Aligning Biodiversity, Climate and Food Policies. Paris. Viewed 12 July 2021, <https://www.oecd.org/environment/towards-sustainable-land-use-3809b6a1-en.htm>.

57 LBergin J (2020) Synthetic Biology: Global Markets. <https://www.bccresearch.com/market-research/biotechnology/synthetic-biology-global-markets.html>.

58 United Nations Conference on Trade and Development (2019) Synthetic biology and its potential implications for biotrade and access and benefit-sharing and its potential implications for biotrade and access and benefit-sharing. <https://unctad.org/webflyer/synthetic-biology-and-its-potential-implications-biotrade-and-access-and-benefit-sharing>.

59 Nourish (n.d.) Nourish Ingredients: Home. Viewed 21 May 2021, <https://nourishing.io/>.

60 Main Sequence Ventures (n..d.) Eden Brew. Viewed 1 June 2021, <https://www.mseq.vc/msv-portfolio/eden-brew>.

61 McCarty N (2020) How Aquaculture Innovation Can Save Seafood. Viewed 21 May 2021, <https://synbiobeta.com/how-aquaculture-innovation-can-save-seafood/>.

62 Froehlich HE, Jacobsen NS, Essington TE, Clavelle T and Halpern BS (2018) Avoiding the ecological limits of forage fish for fed aquaculture. Nature Sustainability 1(6), 298–303. DOI: 10.1038/s41893-018-0077-1.

63 Drax (2019) New carbon capture technology could help industry and agricultural sector decarbonise. Viewed 21 May 2021, <https://www.drax.com/press_release/new-carbon-capture-technology-help-industry-agricultural-sector-decarbonise/>.

64 QUT Institute for Future Environments (2019) Funding awarded for sustainable antioxidant in animal feed and aquaculture industries. Viewed 21 May 2021, <https://www.qut.edu.au/institute-for-future-environments/about/news?id=140356>.

65 Advanced Manufacturing Growth Centre Ltd (2020) AMGC backs Provectus Algae’s blooming great idea. Viewed 27 May 2021, <https://www.amgc.org.au/news/amgc-backs-provectus-algaes-blooming-great-idea/>.

Table 5: Food and agriculture applications (continued)

APPLICATION	DESCRIPTION	EXAMPLES
Agricultural and food biosensors	Engineering protein- or cell-based sensors[66] used for food safety, biosecurity, quality control, provenance tracing, and surveillance of agricultural conditions such as water needs and exposure to contaminants. Synthetic biology-enabled biosensors can detect novel targets, enable more complex functionality and greater efficiency than existing offerings.[67]	• Australian Wine Research Institute, QUT and CSIRO (AUS) have collaborated to explore the use of biosensors to rapidly detect levels of smoke contamination in wine grapes, to enable more efficient wine production. • PPB Technology (AUS) is commercialising biosensor technology for real-time testing of food safety, nutritional value and quality to reduce costs of current testing methods and processing delays.[68]
Biological agricultural treatments	Biological treatments for crops including alternatives to fertilisers and pesticides. Engineered biological treatments may offer more environmentally sustainable alternatives to traditional agricultural chemicals.	• Sustainable Crop Protection Hub (AUS) are developing an RNA-based bio-pesticide spray to reduce chemical use, increase productivity and improve the sustainability of crop farming.[69] • Pivot Bio (US) has engineered naturally occurring soil microbes to improve their ability to fix atmospheric nitrogen, increasing nutrient uptake by the crop and reducing traditional ammonia fertiliser use.[70]
Engineered crops	Engineering of novel crop characteristics which could include disease, insect and drought resilience, improved nitrogen fixation, greater yields, and improved nutritional content. These traits help to reduce waste and inputs required from agricultural production of food and other products.	• Nuseed (AUS) CSIRO and the GRDC are developing a canola crop engineered to produce omega-3 fatty acids typically sourced from fish. [71] • Tropic Biosciences (UK) are using CRISPR gene-editing technologies to design banana crops with resistance against Panama disease, which is causing crop damage in the Asia-Pacific region including Australia.[72]

Why Australia?

- **Industry strength:** Agriculture is a key industry for Australia that makes up 11% of Australia's goods and services exports.[73] Australia's agriculture industry is known for its large scale, highly automated and efficient operations, and high technology adoption rate.[74] This positions Australia well for the commercialisation and deployment of agricultural applications of synthetic biology, whereby the global synthetic biology market for agriculture and food could be worth up to $430 billion by 2040.
- **Disruption risk:** If the global animal-free food market continues its potentially disruptive growth trajectory it could impact Australia's agricultural export revenues. Synthetic biology could provide an opportunity for Australia to diversify its exports by developing new, competitive food products. Non-dairy products already make up 15% of the US dairy market[75] and some estimates predict that proteins produced by fermentation could be ten times cheaper than animal-based proteins by 2035.[76]

66 Hicks M, Bachmann TT and Wang B (2020) Synthetic Biology Enables Programmable Cell-Based Biosensors. ChemPhysChem 21(2), 132–144. DOI: 10.1002/cphc.201900739.

67 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

68 PPB Technology (n.d.) Rapid dairy diagnostics – Home of the CYBERTONGUE technology. Viewed 21 May 2021, <https://ppbtechnology.com.au/>.

69 Sustainable Crop Protection Hub (n.d.) About Us. Viewed 21 May 2021, <https://crophub.com.au/about>.

70 Bergin J (2020) Synthetic Biology: Global Markets. <https://www.bccresearch.com/market-research/biotechnology/synthetic-biology-global-markets.html>.

71 Nuseed Australia (n.d.) Omega-3 Canola. Viewed 21 May 2021, <https://nuseed.com/au/omega-3/>.

72 Technavio (2020) Global Synthetic Biology Market 2020–2024. <https://www.technavio.com/report/synthetic-biology-market-industry-analysis>.

73 2019–20 financial year data. Department of Agriculture Water and the Environment (n.d.) Snapshot of Australian Agriculture 2021. Viewed 21 May 2021, <https://www.agriculture.gov.au/abares/products/insights/snapshot-of-australian-agriculture-2021>.

74 Australian Trade and Investment Comission (2019) Australia: Shaping the future of food security and agriculture. <https://www.austrade.gov.au/agriculture40/why-australia>.

75 Cumbers J (2020) Preventing Another Pandemic Might Be As Simple As Trying Alternative Meat. Viewed 21 May 2021, <https://www.forbes.com/sites/johncumbers/2020/05/09/preventing-another-pandemic-might-be-as-simple-as-trying-alternative-meat/>.

76 RethinkX (2019) Food and Agriculture Executive Summary. Viewed 21 May 2021, <https://www.rethinkx.com/food-and-agriculture-executive-summary>.

- **Research translation strengths:** Australia has a long history of commercialising GM crops and has successfully demonstrated the application of synthetic biology approaches to crop development. GM cotton was first commercially grown in Australia in 1996 and more than 99% of cotton grown in Australia now contains GM traits.[77] More recently, Nuseed, CSIRO and the GRDC used synthetic biology principles to develop omega-3 producing canola in Australia.[78]
- **Protecting natural assets and export value:** Agricultural biosensors can help detect invasive pests and diseases; reducing losses to the value of exports as well as Australia's unique flora and fauna. Australia has environmental assets valued at over $6 trillion and a reputation globally for high quality food and agriculture exports, both of which require protection from more frequent and severe biosecurity events.[79]

Considerations

- **Scale up of biomanufacturing:** Commodity food products require large capital expenditure to establish the scaled infrastructure needed to achieve economic feasibility. For example, Clara Foods (US) is investing in the expansion of their fermentation technology capacity to around 500,000–1 million litres with the goal of reducing costs and increasing the supply of their animal-free egg product to compete with the existing egg market.[80]
- **Time to market:** Engineering of crops for enhanced productivity and functionality can face significant timeframes and costs for product development compared to other non-permanent genetic changes performed through RNA interference or contained biomanufacturing of food and agricultural products. For example, at least $50 million has been invested in the development of Nuseed Omega-3 Canola[81] and it took over 10 years to obtain approval to grow the engineered crop in Australia and the United States. While synthetic biology may help accelerate development and reduce costs, consultations suggested that only some high-value opportunities (e.g. engineered nitrogen fixation pathways and enhanced photosynthesis capabilities) can justify this level of investment.
- **Waste biomass:** Spent biomass in synthetic biology-enabled manufacturing waste streams will need to be managed to ensure that no active GMOs are released into the environment without regulatory approvals. To help address this challenge the US Engineering Biology Research Consortium (EBRC) has set research goals to develop microbes able to efficiently produce multiple products simultaneously, ultimately reducing biomanufacturing waste.[82] However, spent biomass may have the potential to be used for other value adding opportunities such as animal feed if regulatory requirements can be met.
- **Social acceptance:** CSIRO's research into public attitudes towards synthetic biology found that public support may be driven by factors including advantages of the product compared to current solutions and perceived benefits (such as environmental benefits or improved animal welfare).[83] Given some food and agricultural products have greater perceived benefits over others, public acceptance and associated consumption will vary depending on the application.

77 Cotton Australia (n.d.) Biotechnology and cotton. Viewed 21 May 2021, <https://cottonaustralia.com.au/fact-sheet>.

78 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

79 CSIRO (2020) Australia's Biosecurity Future: Unlocking the next decade of resilience. <https://www.csiro.au/en/work-with-us/industries/health/health/biosecurity-futures>.

80 Poinski M (n.d.) Brewing eggs: AB InBev venture arm to help Clara Foods scale up animal-free protein. Viewed 21 May 2021, <https://www.fooddive.com/news/brewing-eggs-ab-inbev-venture-arm-to-help-clara-foods-scale-up-animal-free/598740/>.

81 Thompson B (2018) Nufarm hails milestone for genetically modified canola. Viewed 31 May 2021, <https://www.afr.com/companies/nufarm-hails-milestone-for-genetically-modified-canola-20180828-h14mn1>.

82 Engineering Biology Research Consortium (2019) Engineering Biology: A Research Roadmap for the Next-Generation Bioeconomy. <https://ebrc.org/focus-areas/roadmapping/engineering-biology-2019/>.

83 CSIRO (2021) Public attitudes towards synthetic biology. Viewed 4 March 2021, <https://research.csiro.au/synthetic-biology-fsp/public-attitudes/>.

Health and medicine

Australia's opportunity: Up to $7 billion in annual revenue and 11,700 jobs by 2040

Applications

Australia's health expenditure as a share of GDP is projected to increase to 11.7% of GDP by 2030.[84] Developing cost-effective solutions to current and emerging health challenges will be critical to maintain Australia's ranking as one of the healthiest countries in the world.

Australia has an opportunity to apply its emerging synthetic biology capabilities to develop new high-value health and medical products for humans and animals, enable cheaper and more reliable pharmaceutical production, and accelerate product development times.

Table 6: Health and medicine applications

APPLICATION	DESCRIPTION	EXAMPLES
Biomanufacturing pharmaceuticals	Biomanufacturing may enable efficient production of small molecule pharmaceutical ingredients or precursors that are currently plant-derived or chemically synthesised. This could help to lower production costs and stabilise the supply of certain drugs. Biomanufacturing is already widely used to produce insulin and therapeutic protein biologics. The application of synthetic biology tools and workflows may also accelerate biologics discovery or enable development of improved production hosts.	• Yeast strains developed by Amyris (US) have been used for commercial scale production of semi-synthetic artemisinin (SSA) for antimalarial therapies.[85] Other companies are exploring SSA production routes using bacteria and plant cells.[86] • Bondi Bio (AUS) is engineering photosynthetic cyanobacteria to produce the vaccine adjuvant squalene, as well as a large range of terpenes with anti-cancer and anti-inflammatory therapeutic value.[87] • Patheon by ThermoFisher Scientific (NLD/US) contract manufactures over 40 different clinical and commercial protein biotherapeutics in Brisbane.
Biosensor-based diagnostic tools	Synthetic biology can be used to program DNA-, protein-, enzyme-, and cell-based biosensors for diverse diagnostic applications including rapid point-of-care tests and continuous monitoring systems. This could support rapid responses to infectious disease, expand the medical countermeasures toolkit, and enable detection of medical conditions including infection, gut inflammation, sepsis, and antimicrobial resistance.[88]	• PPB Technology (AUS) is expanding biosensor technology originally developed at CSIRO to be able to detect biomarkers of animal and human diseases.[89] • Caspr Biotech (US) is developing CRISPR-based diagnostic tools for diverse applications including pathogen detection and genetic analysis.[90]
Engineered biotherapeutics	Synthetic biology has the potential to accelerate the design, scale-up and production of engineered biological therapeutics (including cell-based therapies and vaccines) that target emerging pathogens and existing diseases. Live biological systems (e.g. bacteria) could be engineered to deliver targeted therapeutic effects but these new treatments are at an early stage of development.[91] [92]	• Pfizer/BioNTech (US/DEU) and Moderna (US) have deployed synthetic mRNA-based vaccines to combat the COVID-19 pandemic. • Cell Therapies (AUS) is licensed to manufacture autologous chimeric antigen receptor (CAR) T-cell therapy developed by Novartis (US) for the treatment of B-cell acute lymphoblastic leukemia. • Cartherics (AUS) is developing allogeneic CAR immune therapy products for cancer treatment that could have greater impact than current autologous CAR-T cell therapies which require the use of a patient's own stem cells.

See following page (p26) for footnotes.

84 Organisation for Economic Cooperation and Development (2019) Health at a Glance 2019. Paris. <https://www.oecd-ilibrary.org//sites/3d1e710c-en/index.html?itemId=/content/component/3d1e710c-en#figure-d1e1099>.

Why Australia?

- **Industry strength:** Medical technologies and pharmaceuticals is a growth sector for Australia and the nation's 8th largest export by value ($8.2 billion) in 2019.[93] Australia is also recognised for its high-quality early phase clinical trials which contributed $1.4 billion of value to the Australian economy in 2019.[94] Based on comparative advantage and strategic needs, medical products has been identified as a National Manufacturing Priority as part of the Australian Government's Modern Manufacturing Strategy.[95]
- **Research strengths:** Australia has a relatively small but world class medical technology research ecosystem. Australia spent $1.6 billion on medical technology, biotechnology and pharmaceutical R&D in 2019.[96] Key strengths of this sector include strong public investment and world-class medical research infrastructure, including the National Biologics Facility[97] and the Centre of Excellence in Cellular Immunotherapy at Peter MacCallum Cancer Centre.[98]
- **Sovereign need:** The COVID-19 pandemic has demonstrated the importance of strong domestic health and medicine supply chains. Synthetic biology could underpin a range of platform medical countermeasure capabilities to improve Australia's resilience to future infectious disease outbreaks.

85 Amyris (n.d.) Malaria Treatment. Viewed 24 May 2021, <https://amyris.com/products/malaria-treatment/>.

86 Peplow M (2018) Looking for cheaper routes to malaria medicines. Viewed 7 June 2021, <https://cen.acs.org/articles/96/i11/Looking-cheaper-routes-malaria-medicines.html>.

87 Bondi Bio (n.d.) Pharmaceuticals. Viewed 31 May 2021, <https://www.bondi.bio/pharmaceuticals.html>.

88 Hicks M, Bachmann TT and Wang B (2020) Synthetic Biology Enables Programmable Cell-Based Biosensors. ChemPhysChem 21(2), 132–144. DOI: 10.1002/cphc.201900739.

89 PPB Technology (n.d.) Rapid dairy diagnostics – Home of the CYBERTONGUE technology. Viewed 21 May 2021, <https://ppbtechnology.com.au/>.

90 Caspr Biotech (2020) Accelerating CRISPR Diagnostics. Viewed 24 May 2021, <https://caspr.bio/>.

91 Charbonneau MR, Isabella VM, Li N and Kurtz CB (2020) Developing a new class of engineered live bacterial therapeutics to treat human diseases. Nature Communications 11(1), 1–11. DOI: 10.1038/s41467-020-15508-1.

92 Tew D (2019) Synthetic biology and healthcare. Emerging Topics in Life Sciences 3(5), 659–667. DOI: 10.1042/etls20190086.

93 MTPConnect (2020) Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan 2020. <https://www.mtpconnect.org.au/reports/SCP>.

94 MTPConnect (2021) Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth. Viewed 25 May 2021, <https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021>.

95 Department of Industry Science Energy and Resources (2021) Medical Products National Manufacturing Priority Road Map. Viewed 17 March 2021, <https://www.industry.gov.au/data-and-publications/medical-products-national-manufacturing-priority-road-map>.

96 MTPConnect (2020) Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan 2020. <https://www.mtpconnect.org.au/reports/SCP>.

97 The National Biologics Facility is a contract research organisation established with NCRIS funding which offers manufacturing solutions for the development and production of biological therapeutics. National Biologics Facility (n.d.) Home. Viewed 24 May 2021, <http://www.nationalbiologicsfacility.com/>.

98 The Commonwealth Government committed $80 million to establish this facility in 2019. Peter MacCallum Cancer Centre (2020) On-shore commercial manufacture and wider subsidy for CAR T Cell therapy. Viewed 24 May 2021, <https://www.petermac.org/news/shore-commercial-manufacture-and-wider-subsidy-car-t-cell-therapy>.

Considerations

- **Manufacturing capabilities:** Australia has biomanufacturing facilities capable of producing recombinant proteins and biologics for clinical trials and small commercial production (see Appendix E) but has limited large scale therapeutics manufacturing capabilities. During consultations stakeholders noted capability gaps including the absence of GMP viral vector and mRNA production facilities, and the relative scarcity of large scale GMP cell production facilities in Australia. Recent investments in the development of mRNA vaccine and therapeutic manufacturing[99] capabilities recognise the strategic importance of domestic therapeutic manufacturing. However, significantly expanded capabilities across the full value chain (from active pharmaceutical ingredient manufacturing to fill and finish) would be needed if Australia sought to establish itself as a global leader in pharmaceutical production.
- **Market maturity:** With large multi-national pharmaceutical and vaccine manufacturers dominating global supply chains, Australia may be more competitively placed to focus on applying synthetic biology tools and workflows to develop next-generation medical products and solutions. New medical innovations could be commercialised in Australia or licensed to global companies. Consultations noted the development of novel therapeutic applications of mRNA, novel cellular immunotherapies, improved encapsulation solutions for vaccines, and new mammalian cell lines for biologics production as examples of possible innovations.
- **Time to market:** Human health applications require rigorous validation of their safety and efficacy through clinical trials which slows time to market and contributes to their high development costs. Medical technology applications (such as diagnostic tools) typically face a shorter time to market and cost less to develop than drugs or biologics. As a result, biosensor-based diagnostic tools are expected to be a more promising opportunity for early commercialisation in Australia than novel therapeutics.
- **Permitted home-use tests:** Most home-use tests for serious diseases are prohibited from supply in Australia under the *Therapeutic Goods Excluded Purposes Specification 2010*. Following public consultations by the Therapeutic Goods Administration (TGA), the Australian Government changed the regulations to make home-tests for targeted serious diseases and conditions eligible to be approved for inclusion in the Australian Register of Therapeutic Goods (ARTG).[100] Developers of synthetic biology-enabled diagnostic tools could consider targeting home-testing applications for diseases where clearer regulatory pathways exist.
- **Social acceptance:** CSIRO research has found that the Australian public's support for synthetic biology is highest when it is addressing a public health or environmental need.[101] However, misinformation related to COVID-19 vaccines highlights the need for ongoing public engagement and social research regarding the risk and regulation of synthetic biology-enabled health solutions.

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99 The Victorian Government has committed $50 million towards establishing mRNA vaccine and therapeutic manufacturing capabilities in Melbourne, and the Federal Government committed an unspecified amount of funding in the 2021 Federal Budget to develop an onshore mRNA vaccine manufacturing capability. Premier of Victoria (2021) Victoria Ready To Lead On New Vaccine Manufacturing. Viewed 24 May 2021, <https://www.premier.vic.gov.au/victoria-ready-lead-new-vaccine-manufacturing>. and Australian Government (2021) Budget Paper No. 2: Budget Measures. <https://budget.gov.au/2021-22/content/bp2/index.htm>.

100 Therapeutic Goods Administration (2020) Summary and outcomes: review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia. <https://www.tga.gov.au/resource/summary-and-outcomes-review-regulation-certain-self-testing-vitro-diagnostic-medical-devices-ivds-australia>.

101 Public support for the example synthetic biology technologies assessed was moderate to high overall. CSIRO (2021) Public attitudes towards synthetic biology. Viewed 4 March 2021, <https://research.csiro.au/synthetic-biology-fsp/public-attitudes/>.

Other opportunities

Australia's opportunity: Up to $700 million in annual revenue and 1,100 jobs by 2040

As early synthetic biology applications become commercially successful and the underlying capabilities become commodified, it is likely that engineered biology applications will impact a broad range of industries. This report focuses primarily on food and agriculture, and health and medicine applications of synthetic biology because economic analysis suggests that these markets will be the most commercially significant for Australia over the next 20 years. This section provides an overview of other emerging applications from the chemicals, fuels, materials, environment and resources sectors.

Chemicals, fuels and materials

Synthetic biology-enabled biomanufacturing could help to replace petrochemically-derived chemicals, fuels and materials. This has the potential to improve sustainability by reducing reliance on petrochemicals, thus reducing greenhouse gas emissions associated with production. Biomanufacturing solutions are also being developed that aim to utilise CO_2 as a feedstock (e.g. engineered algae and cyanobacteria), which could enable carbon-negative manufacturing.

Overcoming barriers to cost competitive biomanufacturing at scale will be essential to unlocking many of these opportunities. As an example, the application of synthetic biology to enable cost-effective biofuel production at commodity scale has so far failed. Synthetic biology may have success targeting higher margin applications where there are limited low carbon alternatives, such as the production of energy dense fuels for aviation.

Table 7: Chemicals, fuels and materials applications

APPLICATION	DESCRIPTION	EXAMPLES
Fine and commodity chemicals	Biomanufacturing can be used to produce chemicals from renewable feedstocks. This has the potential to improve the sustainability or efficiency of chemical production processes.	• Novamont's (ITA) Mater-Biotech plant produces industrial scale butanediol using biomanufacturing (fermentation) for use in bioplastics.[102] • Provectus Algae (AUS) and Bondi Bio (AUS) are engineering algae to produce a variety of target chemicals and other molecules using CO_2 as feedstock.
Biofuels	Biomanufacturing can be used to produce biofuels. First-generation biofuels have significant socioeconomic impacts due to competition with agriculture, but synthetic biology may enable efficient conversion of more sustainable feedstocks like agricultural waste and CO_2.	• Lanzatech (US) is using synthetic biology to develop ethanol and other higher value fuels from waste gas and syngas streams. • HydGENE Renewables (AUS) are engineering bacteria to efficiently produce hydrogen on-site from renewable plant material.

102 Novamont (2021) Mater-Biotech. Viewed 24 May 2021, <https://www.novamont.it/eng/materbiotech/>.

Table 7: Chemicals, fuels and materials applications (continued)

APPLICATION	DESCRIPTION	EXAMPLES
Biomanufactured materials	Biomanufacturing can be used to produce polymers, proteins and other materials more sustainably or with novel characteristics for use in diverse markets.	• Bolt Threads (US) has demonstrated commercial production of spider silk proteins using engineered yeast.[103] • Zymergen (US) use biomanufacturing to produce novel transparent polyimide films for electronic device screens.[104]
Functional biomaterials	Synthetic biology could enable manufacturing of advanced functional biomaterials containing engineered biological systems or components. This application is at a very early stage of development.	• No applied research projects were identified in this area, however stakeholders noted that early applications could include advanced functional biomaterials for defence applications.

Environment and resources

Synthetic biology tools and approaches can improve waste management, improve the sustainability of mining, address environmental contamination, protect Australia's biodiversity, and manage pests, weeds and diseases. Australian federal and state governments will be the primary customer for many of these environmental applications. This creates an opportunity to support the growth of Australia's synthetic biology capabilities through challenge-oriented research and procurement. Recycling and clean energy, and resources technology and critical minerals processing have been identified as National Manufacturing Priorities as part of the Australian Government's Modern Manufacturing Strategy.[105]

Developing public trust and meeting high regulatory standards may be challenging for environmental applications that require environmental release of GMOs. As such, contained (e.g. waste management) and cell-free applications (e.g. biosensors) are likely to be feasible sooner than applications like invasive species control. However, CSIRO research has found that public support for synthetic biology applications is highest when it is creating an environmental (or health) benefit.[106]

103 Bolt Threads (n.d.) Microsilk. Viewed 24 May 2021, <https://boltthreads.com/technology/microsilk/>.

104 Zymergen (n.d.) Hyaline Z2. Viewed 24 May 2021, <https://www.zymergen.com/products/electronics/hyaline/hyaline-z2/>.

105 Department of Industry Science Energy and Resources (2020) Make it Happen: The Australian Government's Modern Manufacturing Strategy. <https://www.industry.gov.au/data-and-publications/make-it-happen-the-australian-governments-modern-manufacturing-strategy>.

106 CSIRO (2021) Public attitudes towards synthetic biology. Viewed 4 March 2021, <https://research.csiro.au/synthetic-biology-fsp/public-attitudes/>.

Table 8: Environment and resources applications

APPLICATION	DESCRIPTION	EXAMPLES
Waste management	Biological solutions that can break down waste can help to enable the transition to a more circular economy and enable value recovery from waste streams.	• Samsara (AUS) is developing engineered enzymes to degrade polymers or chemicals safely and efficiently.
Biomining and biohydrometallurgy	Engineered microorganisms have shown potential to be applied to extract metals from mineral ores. Synthetic biology could be used to engineer new biocatalysts to extract metals from ores, concentrates and waste materials in aqueous solutions (biohydrometallurgy).[107]	• BHP (AUS) has taken a stake in Cemvita Factory (US) to explore synthetic biology applications including biomining and bioremediation of acid mine drainage. • CSIRO has explored engineering of acidophilic biomining microorganisms to be more resilient to inhibitory compounds that may be present in ores or process waters.[108]
Environmental biosensors	Cell-free (e.g. CAS-enzyme) and cell-based environmental biosensors can provide rapid and cost-effective solutions for detecting contamination and pollutants.	• Bio Nano Consulting (UK), in collaboration with researchers at Imperial College, is developing an enzyme-based, portable biosensor for rapid detection of arsenic contamination in drinking water.[109] • Cell-free paper-based biosensors have potential for detection of environmental contaminants including heavy metals and antibiotics.[110]
Environmental bioremediation	Bioremediation uses microorganisms to degrade organic contaminants by using them as an energy source for growth, or to convert inorganic contaminants to less harmful forms. Synthetic biology can be used to engineer enzymes and microbes that are more efficient in remediating environmental contaminants[111]	• Despite early technical successes[112] there appears to be a limited market for new environmental bioremediation technologies and no current commercial examples were identified. However, consultations suggested that remediation of per- and polyfluoroalkyl substances (PFAS) could be a valuable opportunity due to the absence of effective alternatives.
Invasive species control	Genetic control of invasive species populations can help to protect Australia's biodiversity and improve agricultural productivity. Synthetic biology is being used to help identify targeted modifications to a pest species' genes so that offspring are infertile, limited to a single sex, or other population suppressing options. Genetic control approaches are being explored for diverse pests including mosquitoes, weeds, mice, cane toads, carp, and feral cats.	• University of Adelaide and CSIRO are partners in the global Genetic Biocontrol of Invasive Rodents program which targets invasive rodents on islands.[113] • Macquarie University and CSIRO are collaborating to develop proof of concept genetic biocontrol approaches for vertebrates as part of Australia's Centre for Invasive Species Solutions.[114]

107 Kaksonen AH, Deng X, Bohu T, Zea L, Khaleque HN, Gumulya Y, Boxall NJ, Morris C and Cheng KY (2020) Prospective directions for biohydrometallurgy. Hydrometallurgy 195(March), 105376. DOI: 10.1016/j.hydromet.2020.105376.

108 Gumulya Y, Boxall NJ, Khaleque HN, Santala V, Carlson RP and Kaksonen AH (2018) In a quest for engineering acidophiles for biomining applications: Challenges and opportunities. Genes 9(2). DOI: 10.3390/genes9020116.

109 Bio Nano Consulting AquAffirm™: portable arsenic sensor. Viewed 10 June 2021, <https://www.bio-nano-consulting.com/product-development/drinksafe>.

110 Zhang L, Guo W and Lu Y (2020) Advances in Cell-Free Biosensors: Principle, Mechanism, and Applications. Biotechnology Journal 15(9), 2000187. DOI: 10.1002/biot.202000187.

111 Rylott EL and Bruce NC (2020) How synthetic biology can help bioremediation. Current Opinion in Chemical Biology 58, 86–95. DOI: 10.1016/j.cbpa.2020.07.004.

112 For example, Orica Watercare and CSIRO commercialised Landcare (an enzyme-based bioremediation solution for organophosphate pesticide residues in water) in 2006 but the business was closed in 2008 due to limited market uptake.

113 GBIRd – Genetic Biocontrol of Invasive Rodents. Viewed 24 May 2021, <https://www.geneticbiocontrol.org/>.

114 Centre for Invasive Species Solutions (n.d.) Proof of concept for genetic biocontrol in vertebrates. Viewed 24 May 2021, <https://invasives.com.au/research/proof-of-concept-for-genetic-biocontrol-in-vertebrates/>.

4 Roadmap to 2040

Capturing the high market share scenario described in Chapter 3 will require synthetic biology to be a critical national capability that underpins a thriving Australian bioeconomy. This chapter presents a pathway for Australia to realise this vision by 2040, which will require sustaining investments in synthetic biology research while increasing support for the ecosystem's most critical challenge: industrial translation and scale-up. It will also be important to balance the need for short-term commercial validation of synthetic biology applications with the need to invest in strategic research and development of longer-term opportunities.

The recommendations in this chapter are designed to set the foundations for a strong synthetic biology ecosystem over the next 4 years. Recommendations have been developed in collaboration with government, industry, and research stakeholders. Actions for beyond 2025 should be informed by a review of the effectiveness of activities over this initial period.

2040 Vision: Synthetic biology underpins a thriving Australian bioeconomy, creating new jobs and economic growth, enhancing competitiveness in key industries, and addressing critical environmental and health challenges.

2021–2025	2025–2030	2030–2040
Building capability and demonstrating commercial feasibility	**Early commercial successes and establishing critical mass**	**Growth through scaling market-determined application priorities**

Priority actions for the next 4 years include:

- **Support research translation** and seed new businesses through targeted investments and bioincubator programs.
- **Develop shared infrastructure** to enable development and demonstration of synthetic biology applications.
- **Attract international businesses and talent** to build critical mass and enhance international collaboration.
- **Strengthen foundational ecosystem enablers** including leadership, governance, skills, and collaboration.

2021–2025: Building capability and demonstrating commercial feasibility

Support research translation

ACOLA identified Australia's limited capacity to transform research into commercial products as one of the largest barriers for synthetic biology impact.[115] There are many complex and intertwined factors underpinning this challenge including low levels of industry-research collaboration, cultures of risk aversion, below OECD median venture capital investments, and restrictive IP agreements.[116 117]

Demonstrating synthetic biology's commercial feasibility by supporting research translation activities within the Australian landscape will help to raise broader industry awareness, build critical mass, and provide learnings that can be leveraged across other emerging applications. However, this support should not be to the detriment of developing broad capabilities in this emerging field which will be essential to unlocking longer term opportunities.

Recommendation 1: Prioritise translation support for applications that can most quickly demonstrate commercial feasibility

As a comparatively small nation with the goal of establishing a leading role in an emerging global market, it is critical that Australia demonstrates commercial feasibility of synthetic-biology applications in the near term. Focusing translational investments towards high value, low volume applications that could be commercially feasible before 2030 could help to attract additional private co-investment and accelerate the commercial validation of synthetic biology approaches within the Australian context.

Prioritising these two criteria from the framework presented in Chapter 3 suggests that biomanufactured food products, agricultural and food biosensors, engineered biotherapeutics, and biosensors for medical diagnostics could be promising opportunities for initial investments seeking to demonstrate short-term commercial viability in Australia.

Recommendation 2: Establish bio-incubators to support the development of synthetic biology start-ups

The development of commercially oriented bio-incubators can support researchers and entrepreneurs to translate their ideas into commercial outcomes. Bio-incubators provide start-ups with access to shared office and laboratory facilities, and the business mentoring and research services required to establish proof of concept and attract private investment.

Bio-incubators could be set up adjacent to existing or planned capability hubs and research infrastructure (including the shared infrastructure facilities described in recommendations 3 and 4) to kickstart the development of knowledge-rich communities that are focussed on a common underpinning technical capability or pursuit of solving a shared industry challenge. This critical mass may reduce the temptation of industry participants to move developed products offshore.

Bio-incubator programs often offer competitive grants to enable affordable access for start-ups. Funding should consider the start-up's ability to demonstrate commercial, social or environmental impact in the near term. Incorporating an accelerator program could also add value by helping more mature start-ups prepare their products or services for global markets.

115 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

116 Department of Industry Science Energy and Resources (2015) National Innovation and Science Agenda. <https://www.industry.gov.au/policies-and-initiatives/boosting-innovation-and-science>.

117 Department of Industry Science Energy and Resources (2016) Australian Innovation System Report 2016. <https://www.industry.gov.au/data-and-publications/australian-innovation-system-report/australian-innovation-system-report-2016>.

Case study: SynbiCITE

SynbiCITE is one of seven Innovation and Knowledge Centres set up by the UK in 2007 with the goal of building critical mass in areas of disruptive technology. SynbiCITE is home to the London Biofoundry and has functioned as a synthetic biology accelerator since 2013.[118] The centre provides funding for proof of concept and demonstration projects that meet clear selection criteria and can demonstrate significant commercial potential. Over £4 of private investment is associated with every £1 of public money invested in synthetic biology start-ups through the SynbiCITE program.[119] [120]

Case study: Industrial Biotechnology Innovation and Synthetic Biology Accelerator (IBISBA 1.0)

The EU's IBISBA 1.0 is a transnational access research facility that provides access to research and development services and infrastructure to accelerate the development of biomanufacturing solutions. IBISBA offers opportunities to researchers, small and medium-sized enterprises (SMEs), and large companies to obtain subsidised access to its research facilities.[121] As of January 2021, the facility has completed four calls for projects and received 38 applications from 21 countries in Europe and Latin America. Of these, 21 projects were selected to receive access to IBISBA's services.[122]

Develop shared infrastructure

To develop a commercialisation pipeline of synthetic biology-enabled opportunities, Australia will need to strengthen its emerging research biofoundry capabilities and develop new shared access infrastructure to support demonstration and scale-up. Addressing these infrastructure gaps related to translation and commercial activities will support the retention and development of Australian start-ups while also helping to attract more established international partners and private sector funding.

Recommendation 3: Support national biofoundries to develop their scale and capability

Research biofoundries provide access to automated, high throughput organism design services to support academic and industrial R&D. Further developing these capabilities will support the creation of a pipeline of commercial opportunities beyond the initial near-term focus of commercial validation.

Australia currently has two organisations that are developing biofoundry capabilities: CSIRO in Queensland and Macquarie University in New South Wales. In 2020, the Federal Government also committed NCRIS funding of $8.3m to further enhance Australia's national synthetic biology infrastructure.[123]

The further development and financial sustainability of these biofoundries requires robust project pipelines however, anecdotally, demand for at-cost large-scale biological data generating projects is minimal in Australia. As seen with international research biofoundries,[124] the maturing of this national capability will require government subsidisation. Providing project-based grants that support businesses to access biofoundry services is one option that could help to develop a sustainable pipeline of collaborative projects in Australia.

118 This was enabled by £28 million ($51 million) funding provided by the UK's Engineering and Physical Sciences Research Council (EPSRC), Biotechnology and Biological Sciences Research Council (BBSRC), Innovate UK, and its industrial and academic partners. SynbiCITE (n.d.) About us. Viewed 26 May 2021, <http://www.synbicite.com/about-us/>.

119 SynBioBeta (2018) Investment fuels cutting-edge synthetic biology in UK. Viewed 24 May 2021, <https://synbiobeta.com/investment-fuels-cutting-edge-synthetic-biology-in-uk/>.

120 SynbiCITE (2017) UK Synthetic Biology Start-up Survey. <http://www.synbicite.com/news-events/materials/uk-Synthetic-biology-start-up-survey-2017/>.

121 IBISBA (2020) Subsidised Access. Viewed 24 May 2021, <https://www.ibisba.eu/Services/Subsidised-Access>.

122 European Commission's Community Research and Development Information Service (2021) Periodic Reporting for period 2 – IBISBA 1.0 (Industrial Biotechnology Innovation and Synthetic Biology Accelerator). Viewed 24 May 2021, <https://cordis.europa.eu/project/id/730976/reporting>.

123 Department of Education Skills and Employment (2020) 2020–21 Budget Research Package. Viewed 21 May 2021, <https://www.dese.gov.au/2020-21-budget-research-package>.

124 Hillson N, Caddick M, Cai Y, Carrasco JA, Chang MW, Curach NC, Bell DJ, Le Feuvre R, Friedman DC, Fu X et al. (2019) Building a global alliance of biofoundries. Nature Communications 10(1). DOI: 10.1038/s41467-019-10079-2.

Recommendation 4: Develop pilot and demonstration-scale biomanufacturing facilities certified to work with GMOs

Consultations with local and international synthetic biology start-ups identified a strong demand for access to affordable biomanufacturing facilities to enable demonstration and scale-up of synthetic biology applications. Level 2 physical containment (PC2) certification is typically required for facilities that work with GMOs. Except for biomedical recombinant protein production capabilities, Australia has very limited PC2-certified biomanufacturing infrastructure (see Appendix E). Consultations found that the limited ability to scale synthetic biology-enabled manufacturing applications beyond laboratory scale has deterred some international companies from undertaking industrial research and development activities in Australia.

The regulatory requirements associated with PC2 certification create significant additional upfront costs for start-ups seeking to build their own facility. Some applications, including biomanufacturing food or medicine products, introduce additional regulatory requirements for infrastructure which can further increase the cost burden.[125] Subsidised access to regulatorily compliant infrastructure can support the demonstration and scale-up of emerging biomanufacturing applications.

Australia already has some existing facilities for pilot scale fermentation and upgrading these to achieve PC2 certification could be a cost-effective option for developing these capabilities. For example, the Federal Government committed $5.2 million in May 2021 to upgrade the biomass processing, fermentation, separation and purification equipment at the QUT Mackay Renewable Biocommodities Pilot Plant to enhance its ability to demonstrate synthetic biology applications.[126]

CSIRO's economic analysis and application assessment (see Chapter 3) identified synthetic biology-enabled biomanufacturing of food and feed products as a promising short-term opportunity. To enable this opportunity, Australia could consider supporting the establishment of accessible food grade biomanufacturing infrastructure (with PC2-certified precision fermentation and downstream processing capabilities) to support emerging companies to demonstrate food-related synthetic biology applications. Demonstration scale will vary between applications and organisms but is typically at least 1000 litres based industrial fermentation systems (see Table 9).

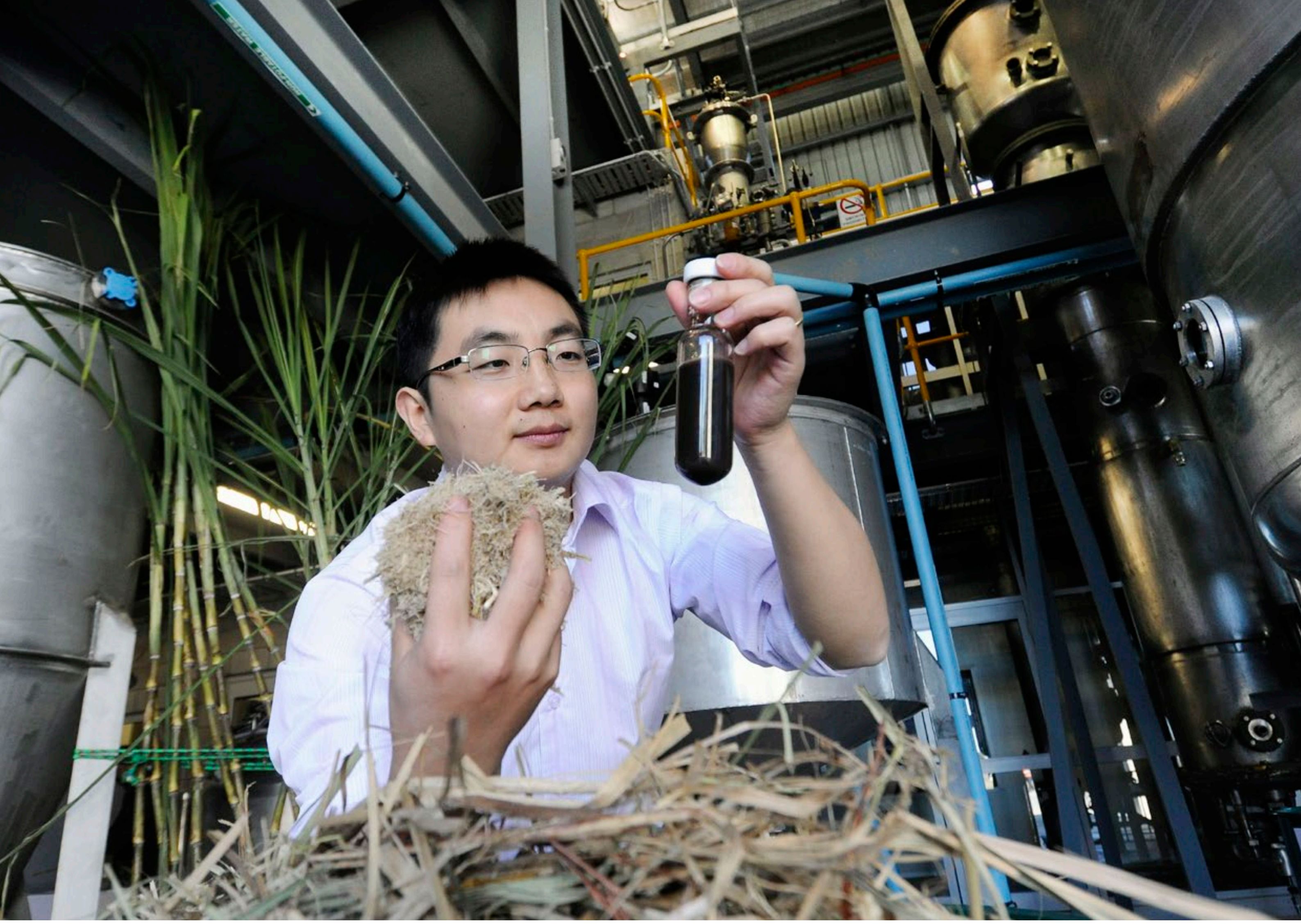
Table 9: Typical scale of biomanufacturing systems

BIOMANUFACTURING SYSTEM	EXAMPLE PRODUCTS	LABORATORY SCALE	PILOT SCALE	DEMONSTRATION SCALE	COMMERCIAL SCALE
			PROCESS DEVELOPMENT →	MARKET EVALUATION →	SCALED PRODUCTION
Industrial fermentation (yeast or bacteria)	Proteins, chemicals	mL to L	10 L to 1000+ L	1000 L to 10 000+ L	10,000 to 100 000+ L
Biotherapeutics (mammalian cell)	Biologicals, vaccines	mL to L	500 mL to 10 L	10L to 2000 L	500L to 15,000 L

Note: The scales provided are indicative orders of magnitude for biomanufacturing systems. Actual system sizes are highly organism and product dependent.

125 For example, the TGA requires that manufacturers of medicines and biologicals are required to hold a licence demonstrating compliance with the relevant code of Good Manufacturing Practices which cover many aspects of production including premises and equipment. Food manufacturing also adds additional regulatory complexity involving local council, state governments and the Commonwealth.

126 Queensland University of Technology (2021) QUT Mackay pilot plant to get capability upgrade. Viewed 26 May 2021, <https://www.qut.edu.au/news?id=176208>.



Mackay Renewable Biocommodities Pilot Plant (QUT)

Case study: The UK have invested significantly in initiatives to accelerate the scale-up and translation of biomanufacturing applications

In February 2021, the UK's Network's Centre for Process Innovation (CPI)[127] announced plans to develop a novel food, feed and nutraceuticals innovation centre of excellence at its £24 million ($43.6 million) National Industrial Biotechnology Facility.[128] The facility is investing a further £4 million ($7.3 million) in food-grade precision fermentation and pilot plant capabilities in order to support industrial process development and scale-up.

127 Part of the UK's Catapult Network a £1.3 billion ($2.4 billion) network of R&D facilities focused on research translation.

128 CPI (2021) CPI unveils plans for its Novel Food, Feed and Nutraceuticals Innovation Centre of Excellence. Viewed 24 May 2021, <https://www.uk-cpi.com/news/cpi-unveils-plans-for-its-novel-food-feed-and-nutraceuticals-innovation-centre-of-excellence>.

Attract international businesses and talent

Attracting international companies and researchers to work in Australia will assist in accelerating the growth of a strong synthetic biology ecosystem through transfer of critical knowledge, the creation of job and training opportunities, and accelerating the development of a critical mass of synthetic biology-enabled businesses in Australia. This is a complementary strategy to supporting the development and growth of Australian-owned businesses and start-ups.

Recommendation 5: Attract international businesses to establish commercial operations in Australia

To accelerate the development of a critical mass of synthetic biology-enabled industry activity, Australia could consider supporting or incentivising more mature international synthetic biology businesses to establish operations in Australia. This could help demonstrate synthetic biology's potential for job creation and commercial impact, and enable knowledge and skills transfer. Federal and state governments, industry bodies and research organisations can all play a role in identifying suitable international partners and promoting Australia's advantages and capabilities.

Consultations identified several relatively mature businesses that have expressed interest in establishing operations in Australia to access Asia-Pacific markets for biomanufactured goods. If current market growth rates are maintained, an emerging global shortage of both commercial scale precision fermentation infrastructure and expertise can be expected.[129] Australian governments could consider public-private partnerships to accelerate the development of scaled biomanufacturing operations in Australia, either with individual companies or through the development of a contract manufacturing facility.

Recommendation 6: Attract leading international researchers and strengthen international research collaborations

To accelerate the growth of Australia's synthetic biology ecosystem, research organisations and companies could endeavour to attract the best international talent. Existing government programs, such as the Federal Government's Global Talent programs[130] and Victoria's veski Innovation Fellowships program,[131] could be leveraged to support the attraction and relocation of these individuals.

Developing new research collaborations with international businesses and researchers will also help. This would provide local researchers with access to world-leading capabilities and demonstrate the strength of Australia's synthetic biology research capabilities to help attract international researchers and businesses.

129 Market analysis by Warner Advisors LLC (2020) estimates that the available precision food fermentation capacity could be consumed within the next 12–24 months.

130 Department of Home Affairs (2021) Visas for innovation. Viewed 24 May 2021, <https://immi.homeaffairs.gov.au/visas/working-in-australia/visas-for-innovation>.

131 veski (n.d.) About veski. Viewed 24 May 2021, <https://www.veski.org.au/about-veski/>.

Strengthen foundational ecosystem enablers

As Australia's synthetic biology capability matures beyond the research sector, it is important that a range of broader ecosystem enablers mature with it, including leadership and governance, industry-research collaboration, and skills development.

Recommendation 7: Establish a national bioeconomy leadership council to advise government strategy

As consumer demands and government policies continue to shift national attention towards the growth of a bioeconomy, investments in enabling platform tools like synthetic biology need to be made in consideration of other tools that target similar markets and global challenges. Establishing a bioeconomy leadership council would signal that the bioeconomy – and by association synthetic biology capabilities – are an important part of Australia's future.

The council could contribute to the development and ongoing refinement of a national bioeconomy strategy that improves alignment, communication and differentiation across jurisdictions and organisations to prevent duplication of efforts and ensure national investments align to a long-term strategy. Other responsibilities could include contributing to national and international policies relating to responsible innovation in biological engineering and promoting Australia's synthetic biology and biomanufacturing capabilities to industry. This will help to build broader awareness of these capabilities and may increase commercial interest and private investment in synthetic biology.

The council could be established as a sub-council that reports to the National Science and Technology Council chaired by Australia's Chief Scientist and should consist of members from across government, industry and research but be primarily focused on enabling industry growth.

Case study: UK Engineering Biology Leadership Council

Following the development of a Strategic Roadmap for Synthetic Biology in the UK in 2012,[132] the UK Government established the Engineering Biology Leadership Council (EBLC) – formerly known as the Synthetic Biology Leadership Council (SBLC). This Council is co-chaired by a relevant government minister and provides a governance body to assess progress against the roadmap, to update recommendations and advise on future priorities for the UK. Due in part to the UK government's leadership and investment, there are now more than 150 UK-based synthetic biology start-ups attracting private investment.[133]

Case study: US Engineering Biology Research Consortium

The US EBRC is a non-profit organisation comprising of members from industry, research and government dedicated to advancing engineering biology.
The EBRC relies on membership based working groups supported by a full-time secretariat to run programs and activities targeting four focus areas: Research Roadmapping, Education, Security, and Policy & International Engagement. The EBRC is a public-private partnership that is funded by institutional membership fees and government grants.[134]

132 UK Synthetic Biology Roadmap Coordination Group (2012) A synthetic biology roadmap for the UK. <https://www.gov.uk/government/groups/synthetic-biology-leadership-council>.

133 Synthetic Biology Leadership Council (2019) Synthetic Biology UK: A Decade of Rapid Progress 2009–2019. <https://ktn-uk.org/programme/synthetic-biology-leadership-council/>.

134 EBRC activities are supported by grants and cooperative agreements with various government agencies including the National Science Foundation, the US Department of Homeland Security, the US Department of Defence and the National Institute of Standards and Technology.

Recommendation 8: Maintain the safe and equitable governance of synthetic biology applications

To maintain public trust in the safe and responsible development of synthetic biology technologies, it is critical that Australia maintains a fit-for-purpose regulatory framework and contributes to the development of international standards and ethical principles for synthetic biology.

Synthetic biology applications are likely to be regulated by multiple agencies. All applications and products involving genetically modified organisms are regulated by the Gene Technology Regulator (assisted by the OGTR). However, many products including food,[135] agricultural chemicals,[136] and therapeutic products[137] need to comply with additional industry-specific standards and regulation. Australia's regulators must be adequately resourced to ensure current and future regulation and legislation reviews can keep pace with the growing number, diversity and complexity of synthetic biology-enabled products. Maintaining effective communication channels and a clear differentiation of responsibilities between the OGTR and end-product regulators will also be increasingly important, both for the efficient operation of entities as well as maintaining a regulatory approval framework that is as simple as possible for local and international industry to navigate.

Ensuring that Australia contributes to developing and upholding international standards, protocols[138] and ethical principles[139] associated with synthetic biology would also support the safe and effective governance of synthetic biology technologies and applications in Australia and abroad. This international engagement could be coordinated by a national bioeconomy leadership council but would require engagement from stakeholders including the National Measurement Institute, and relevant government departments and regulators.

Recommendation 9: Invest in growing foundational skills across economic, digital, and social sciences alongside biophysical sciences

As discussed in Chapter 2, Australia has strengths in a selection of relevant biophysical science areas (e.g. biological engineering). While it is important that these capabilities continue to mature, positioning Australia's synthetic biology ecosystem for sustained growth over the coming decades will also require the integration of other science domains, specifically:

- Economic sciences: Economic assessment tools (including techno-economic modelling and life cycle analysis) provide a critical decision-making tool to help guide applied research investments by assessing the potential impact (triple bottom line benefits) of emerging applications. Providing opportunities for students to develop broader entrepreneurial and business skills is also critical.
- Digital and data sciences: Artificial intelligence, machine learning and automation can be applied to enable faster design and development of synthetic biology solutions. Other related skills to be developed include bioinformatics, computational modelling and simulation, automation and process engineering, robotics, and software engineering.
- Social sciences: The continued consideration of the social sciences supports the responsible and ethical development of synthetic biology and will support public trust in synthetic biology innovations.

135 Food Safety Australia and New Zealand (FSANZ) is responsible for the Australia and New Zealand Food Standards Code, which prohibits the use of foods produced using gene technology unless a safety assessment and specific approval has been obtained.

136 The Australian Pesticides and Veterinary Medicines Authority (APVMA) assesses and registers chemicals for agricultural and veterinary purposes. Some bio-based products fall under the agricultural and veterinary code and therefore must be registered with the APVMA.

137 The TGA administers the Therapeutic Goods Act 1989, a framework for regulating medicines, medical devices, tissues and blood in Australia, also assessing the efficacy and safety of GM and GM-derived therapeutic goods.

138 For example, the Convention on Biological Diversity's Nagoya Protocol on Access and Benefit establishes a framework that helps researchers access genetic resources for biotechnology R&D in return for a fair share of any benefits from their use. The Protocol means that indigenous and local communities may receive benefits through a legal framework that respects the value of traditional knowledge associated with genetic resources. Australia is not currently a party to the Nagoya Protocol, but Australia's existing domestic measures are consistent with the Protocol. See Department of Agriculture Water and the Environment (n.d.) The Nagoya Protocol – Convention on Biological Diversity. Viewed 8 June 2021, <https://www.environment.gov.au/science-and-research/australias-biological-resources/nagoya-protocol-convention-biological>.

139 For example, refer to Mackelprang R, Aurand ER, Bovenberg RAL, Brink KR, Charo RA, Delborne JA, Diggans J, Ellington AD, Fortman JL "Clem", Isaacs FJ et al. (2021) Guiding Ethical Principles in Engineering Biology Research. ACS Synthetic Biology 10(5), 907–910. DOI: 10.1021/acssynbio.1c00129.

As a highly interdisciplinary field, the next generation of researchers, industry professionals and public servants working in synthetic biology will need to be able to effectively communicate and work as part of multi-disciplinary teams.[140] In the short term, as awareness of synthetic biology as a career path is still growing, it may be most reasonable to incorporate relevant modules into existing University and TAFE application-aligned courses such as food science and technology, and pharmaceutical manufacturing.

Recommendation 10: Develop and strengthen local industry-research collaborations to build capability, share knowledge, and increase employment pathways for graduates

CSIRO surveys suggest that 85% of Australians have little or no knowledge of synthetic biology and its applications.[141] Targeted consultations with relevant government and potential end user industries also showed a high degree of variance in synthetic biology awareness.

Broader industry awareness of synthetic biology will develop naturally as commercial activity grows. However, developing programs that facilitate improved industry-research networking and collaboration can accelerate this. The ARC CoESB has a variety of industry partners and will undertake collaborative research. However, establishing targeted networks that undertake mission-driven collaborative R&D could accelerate the application of synthetic biology to address critical national challenges (see Case Study on the UK Networks in Industrial Biotechnology and Bioenergy).

With limited industry awareness and therefore uptake of synthetic biology platforms, graduates are often applying relevant skills in other sectors or are moving abroad for employment opportunities. Industry placements for early career researchers and industry PhDs are useful tools for enhancing the employability of synthetic biology researchers and allowing industry to develop their understanding of synthetic biology.

Case study: UK Networks in Industrial Biotechnology and Bioenergy

The UK has committed £11 million to fund six collaborative and multidisciplinary Networks in Industrial Biotechnology and Bioenergy in the second phase of this program.[142] Each network targets a different research challenge in the bioeconomy such as exploiting algae or converting waste carbon to chemicals, fuels, and animal feed. The networks organise events and provide proof of concept funding to encourage networking and academic-industry collaborations. Phase 1 of the program involved over 2600 UK based researchers and around 750 companies.[143] The management board of each network is required to have at least 50% industry participation to reinforce the focus on commercialisation pathways. US-based initiatives including the EBRC and BioMADE[144] also have a strong focus on enabling industry-research collaboration to achieve their objectives.

140 Gray P, Meek S, Griffiths P, Trapani J, Small I, Vickers C, Waldby C and Wood R (2018) Synthetic Biology in Australia: An Outlook To 2030. <https://acola.org/hs3-synthetic-biology-australia/>.

141 CSIRO (2021) Public attitudes towards synthetic biology. Viewed 4 March 2021, <https://research.csiro.au/synthetic-biology-fsp/public-attitudes/>.

142 Phase II of the program runs from 2019–2024. Biotechnology and Biological Sciences Research Council (n.d.) Networks in Industrial Biotechnology and Bioenergy (BBSRC NIBB). Viewed 24 May 2021, <https://bbsrc.ukri.org/research/programmes-networks/research-networks/nibb/>.

143 Biotechnology and Biological Sciences Research Council (2017) Networks in Industrial Biotechnology and Bioenergy – Activities update, March 2017. <www.bbsrc.ac.uk/bbsrcnibb>.

144 Established in 2021 with US$87.5M funding from the US Department of Defense, BioMADE is a Bioindustrial Manufacturing Innovation Institute. BioMADE uses a membership model to facilitate collaborations designed to accelerate deployment and address barriers to scale-up and commercialization of biomanufacturing technologies.

2025–2030: Early commercial successes and establishing critical mass

Building a critical mass of industry activity

Hubs or bio-precincts may naturally evolve around Australia's bio-incubators, biofoundries and shared infrastructure facilities as additional businesses set up to draw on these services. Successful precincts are likely to be ones that focus on a specific capability (e.g. biomanufacturing) or end-market (e.g. food and agriculture) to reduce competition for government funds.

An effective form of government support during this time could be co-investment in industry projects rather than investing in further shared infrastructure. However, if demand for additional affordable demonstration scale facilities continues to grow towards 2030 then these could be considered on a case by case basis. Continuing to provide subsidised access schemes to shared infrastructure through bioincubator programs may still be a valuable way to enable continued growth and develop a critical mass of commercial activity in the Australian synthetic biology ecosystem.

By 2030, early successful Australian start-ups, and Australian businesses who are prepared to be early adopters of synthetic biology outputs, should aim to be deeply integrated with supply chains in the Asia-Pacific region. Further, established research biofoundries should aim to be financially sustainable, achieving full cost recovery for services offered to mature industry clients.

Unlocking longer term opportunities

As a growing number of synthetic biology applications and businesses demonstrate commercial feasibility in Australia (i.e. sustainable revenue models), broader industry awareness and interest in synthetic biology can be expected to grow. This increasing level of demand should result in greater private investment in translation activities; allowing public investments to place additional focus on supporting longer-term applications of national strategic importance. This could include applications that unlock benefits for critical industries (e.g. agriculture, resources) or applications that have a stronger public good dimension (and so may require continued public subsidisation), such as those targeting health security and environmental protection.

While the pursuit of high volume (commodity) products is unlikely to be commercially successful over this time period due to the required large-scale infrastructure and demand required for it to be profitable, technical advances or government policies (e.g. around environmental impact accountability) may drive stronger business cases for mid-value, mid-volume targets, especially where an expanded market size (e.g. Asia) is considered.

2030–2040: Growth through scaling market-determined application priorities

In this decade, it is possible that novel engineered organisms designed using synthetic biology become widely commercially available. As it becomes clearer which markets and applications can gain most from synthetic biology approaches, Australia should continue to assess which of these applications are best suited to national strengths and needs. Focusing on these priority areas, Australia could position itself as an established biomanufacturing destination and provider of quality synthetic biology products and componentry for multinationals, SMEs and start-ups in the Asia-Pacific region.

As private demand drives the maturing of Australia's synthetic biology ecosystem, public sector funding can focus on early-stage and applied research, demonstrating applications with public good benefits (e.g. achieving Australia's environmental sustainability goals), and ongoing improvements to the foundational ecosystem enablers discussed earlier in this chapter.

5 Conclusion

Public attitude surveys conducted by CSIRO found that despite poor awareness of synthetic biology, many Australians are "curious", "hopeful" and "excited" about how the emerging field of synthetic biology could address some of Australia's environmental, health and agricultural challenges.[145] To realise the potential benefits of synthetic biology, Australia must sustain its investments in synthetic biology research and build stronger support for translating research into commercially successful ventures.

This report was designed to inform and encourage the development of national strategy. As synthetic biology is an early stage capability that is maturing rapidly at the global level, Australia's strategy will require frequent updating. Deeper analysis of specific markets, including techno-economic assessments and life cycle analysis for individual application areas would add significant value. Ongoing assessment of national security risks, ethical considerations, and technical challenges related to synthetic biology's development will also be valuable.

Through a nationally coordinated strategy with sufficient public and private investment, synthetic biology could underpin a thriving Australian bioeconomy, creating new jobs and economic growth, enhancing competitiveness in key industries, and addressing critical environmental and health challenges for the nation.

145 CSIRO (2021) Public attitudes towards synthetic biology. Viewed 4 March 2021, <https://research.csiro.au/synthetic-biology-fsp/public-attitudes/>.

Appendix A: Consulted stakeholders

CSIRO would like to thank the following organisations for their contributions to the project through interviews, survey responses and reviews. The insights expressed throughout this report were developed by considering the collective views obtained alongside independent economic and qualitative research and may not always align with the specific views of one of the consulted individuals or organisations.

ARC Centre of Excellence in Synthetic Biology

AusBiotech Ltd

AusIndustry

Australian Academy of Health and Medical Sciences

Australian Council of Learned Academies

Australian Institute for Bioengineering and Nanotechnology

Australian Institute of Marine Science

Australian National University

Australian Space Agency

Australian Sugar Milling Council

Bolt Threads

Bondi Bio

Cartherics

Cell Therapies

Cemvita Factory

Centre for Invasive Species Solutions

Critical Technologies Policy Coordination Office, Federal Department of the Prime Minister and Cabinet

CSL

Defence Science and Technology Group

Earlham Institute

Engineering Biology Leadership Council

Engineering Biology Research Consortium

Federal Department of Education, Skills and Employment

Federal Department of Industry, Science, Energy and Resources

Food Innovation Australia Limited

Food Standards Australia New Zealand

Full Circle Fibres

Ginkgo Bioworks

HydGENE Renewables

Life Sciences Queensland Limited

Macquarie University

Main Sequence Ventures

MTP Connect

North Carolina State University

Northern Territory Government

Nourish Ingredients

Novum Lifesciences

NSW Department of Planning, Industry and Environment

NSW Department of Primary Industries

Office of the Chief Scientist

Office of the Gene Technology Regulator

Office of the NSW Chief Scientist & Engineer

Patheon by Thermo Fisher Scientific

Provectus Algae

QLD Department of Environment and Science

Queensland University of Technology

River Stone Biotech

SA Department for Trade, Tourism and Investment

Seqirus

Sugar Research Australia

SynbiCITE

Synthetic Biology Australasia

The University of Adelaide

The University of Queensland

The University of Western Australia

The Westmead Institute for Medical Research

Trade and Investment Queensland

Twist Bioscience

University of Adelaide

University of Florida

VIC Department of Jobs, Precincts and Regions

Vow

WA Department of Jobs, Tourism, Science and Innovation

Walter and Eliza Hall Institute

Appendix B: Economic analysis

Economic analysis was undertaken by CSIRO Futures to assess the commercial opportunity in synthetic biology for Australia by 2040. This section summarises the results, methodology and parameters, developed in consultation and used to produce the estimates presented in this Roadmap.

Methodology

Scenario analysis matrix framework

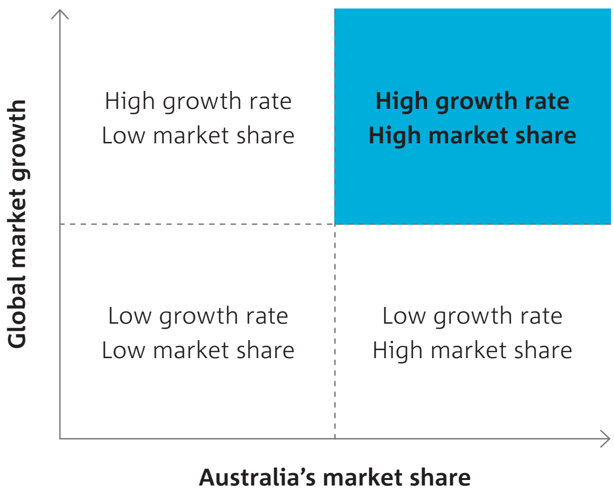


Figure 5: Scenario analysis matrix framework

Given the significant uncertainty involved in estimating future market sizes for emerging technologies, a matrix framework was chosen that considers low and high disruptive growth scenarios as well as Australia having low and high shares of the global market:

- The **low disruptive growth scenario** describes a state where the synthetic biology market continues to grow but synthetic biology does not become a major disruptive capability and instead its growth rate remains at a lower level, on par with broader and more mature parent markets by 2040.
- The **high disruptive growth scenario** describes a state where the synthetic biology market continues to grow at the high rates seen in recent years and synthetic biology becomes a major disruptive capability, replacing significant sections of traditional supply chains (e.g. dairy and livestock) by 2040. This scenario does not consider indirect or secondary effects of the disruptive growth such as productivity effects which are also likely to be significant.
- The **low market share scenario** describes a state where Australia continues to make relatively small investments in synthetic biology research and continues to translate its research into commercial outputs in only a few cases. This scenario does not consider the plausible situation where other countries increase their relative investments in synthetic biology and take greater market shares, leaving Australia with an even smaller market share than it currently holds.
- The **high market share scenario** describes a state where Australia decides it will make synthetic biology a strategic priority both in terms of research funding and commercial translation. Under this scenario, Australia significantly increases its investment and commercialisation activity and captures a larger market share than it currently holds.

Calculations

A top-down approach to market sizing was employed. First the **global opportunity for synthetic biology by 2040 (1)** was modelled based on existing market research. From this figure, **Australia's potential share of the global market (2)** was calculated.[146] The **potential headcount employment for Australia (3)** was then calculated using an assumed ratio between wages and revenue in synthetic biology-enabled industries. The calculations used are as follows:

(1) Global opportunity for synthetic biology by 2040 = $A \times (1+B)^{21}$

(2) Australia's share of the synthetic biology market by 2040 = $A \times (1+B)^{21} \times C$

(3) Potential headcount employment for Australia by 2040 = $(A \times (1+B)^{21} \times C \times D) / E$

Assumptions

A. Current estimate of global synthetic biology market

Current estimates are based on averages of 2019 synthetic biology revenue reported by BCC Research, Frost & Sullivan, and Technavio.

- **Food and agriculture:** The global synthetic biology food and agriculture market in 2019 is estimated at $0.57 billion USD,[147] or $0.74 billion AUD at an exchange rate of 1.29 AUD per USD.[148]
- **Health:** The global synthetic biology health market in 2019 is estimated at $2.43 billion USD,[149] or $3.13 billion AUD.
- **Other:** The global synthetic biology other market in 2019 is estimated at $2.30 billion USD, or $2.97 billion AUD, as the difference between the overall synthetic biology market and the two industries of focus (food and agriculture, and health and medicine)
- **Total:** The global total synthetic biology market in 2019 is estimated at $5.31 billion USD,[150] or $6.84 billion AUD.

Table 10: Economic analysis assumptions

PARAMETERS			(I) FOOD AND AGRICULTURE	(II) HEALTH AND MEDICINE	(III) OTHER	(IV) TOTAL
A	**Current estimate of global synthetic biology market (AUD 2019)**		$0.74B	$3.13B	$2.97B	$6.84B
B	**Forecast annual growth in global synthetic biology opportunity**	**Low**	9.3%	10.8%	10.7%	10.6%
		High	35.4%	23.0%	11.3%	24.6%
C	**Market share of synthetic biology captured by Australia by 2040**	**Low**	0.6%	0.4%	0.3%	0.4% (low CAGR)
						0.5% (high CAGR)
		High	4.5%	3.0%	2.5%	2.9% (low CAGR)
						3.9% (high CAGR)
D	**Wages as a % of revenue for biotechnology in Australia by 2040**		26.3%	26.3%	26.3%	26.3%
E	**Average wage for workers in biotechnology in Australia by 2040 (AUD)**		$162,420	$162,420	$162,420	$162,420

146 The top-down approach used here does not include an initial estimate of the total addressable market (that is, the total market size theoretically possible for synthetic biology products) because market reports for the global synthetic biology are directly available.

147 BCC Research 2020, Synthetic Biology: Global Markets, sum of separate food and beverage category and agriculture category; Frost & Sullivan 2018, Global Synthetic Biology Industry Outlook; Technavio 2020, Global Synthetic Biology Market 2020–2024.

148 RBA Historical Data – Exchange Rates, Series ID: FXRUSD, USD$1=AUD$1.29 from Jan 2000 – Dec 2020.

149 BCC Research 2020, Synthetic Biology: Global Markets; Frost & Sullivan 2018, Global Synthetic Biology Industry Outlook; Technavio 2020, Global Synthetic Biology Market 2020–2024.

150 BCC Research 2020, Synthetic Biology: Global Markets; Frost & Sullivan 2018, Global Synthetic Biology Industry Outlook; Technavio 2020, Global Synthetic Biology Market 2020–2024.

B. Forecast annual growth in global synthetic biology market

Global demand for synthetic biology applications in food and agriculture markets, health markets, and other markets are expected to increase. This is due to expected widening of industry adoption, incremental technical improvements, and spending on new innovations over the next two decades.

Synthetic biology market report sources estimate revenue for synthetic biology sub-markets to grow from between 16.8% to 64.4% per annum over the next 5 years from different revenue bases.[151] The comparable but more mature global biotechnology industry is growing at an average of 1.5% per annum from 2007 to 2025.[152] The scenarios for 2019–2040 synthetic biology market growth were selected by taking weighted averages of these estimates for each sub-market and projecting forwards. The low growth rate scenario considers addressable parent markets, such as biotechnology, whilst the high growth rate scenario assumes high short-term forecasts for synthetic biology are maintained to 2040.

C. Market share of synthetic biology captured by Australia by 2040

The analysis considers scenarios where Australia can capture between 0% to 5% of the global synthetic biology market by 2040. Australia currently accounts for up to 8.6% of published non-classified synthetic biology research,[153] about 2.1% of global synthetic biology start-up companies,[154] and less than 1% of global synthetic biology public and private investment.[155] As a proxy industry of what synthetic biology could grow into, Australia accounted for 2.7% of global revenue and 1.9% of global employment in the biotechnology industry from 2015 to 2020.[156] The scenarios for 2019–2040 synthetic biology market growth were selected by applying approximate proportions across markets (I) to (IV) between low and high market share realisations.

To realise (or even exceed) these estimated high market shares, Australia must accelerate research translation and commercialisation through effective planning and targeted investment (see Chapter 4). Without this, Australia is likely to end up with a low market share realisation by 2040. For the purpose of our economic analysis, the low market share scenario is deemed our base case and the high market share scenario is our preferred scenario (hence the findings from this preferred scenario are the ones that are emphasised in the Roadmap).

D. Wages as a % of revenue for biotechnology in Australia by 2040

The ratio of wages to revenue for Australian biotechnology was used as a proxy from a comparable industry to estimate the relationship between wages and revenue in synthetic biology, and then when combined with the average wage per worker (below), ultimately estimate the potential headcount employment in synthetic biology. It is currently estimated that wages account for 26.3% of biotechnology revenue in Australia.[157] Moreover, this ratio of wages to revenue for the industry appears to be relatively constant, both in the historic data and in short-term forecasts to 2027. To reflect both the relative historic and forecasted constancy of this ratio, a ten-year average of wages as a proportion of revenue from 2018 to 2027 was taken from the most recently available source estimates for the sector.

E. Average wage for workers in biotechnology in Australia by 2040

The average wage per workers in Australian biotechnology was used as a proxy for the average wages in synthetic biology. Average wages in domestic biotechnology are currently over $125,000, with annual wage growth calculated to range between -1% to 1% in the past three years, and 1% to 2% in short-term forecasts to 2027.[158] Similar to how the ratio of wages to revenue was calculated, a ten-year average growth rate for wages was calculated from 2018 to 2027 from source estimates. This average growth rate (of around 1.2%) was then used to grow the forecasted 2027 average wage further out to 2040.

151 BCC Research 2020, Synthetic Biology: Global Markets; Frost & Sullivan 2018, Global Synthetic Biology Industry Outlook; Technavio 2020, Global Synthetic Biology Market 2020–2024.

152 IBISWorld 2020, X0001 Biotechnology in Australia Industry Report.

153 Based on Web of Science search results for publications under topic "synthetic biology"

154 BCC Research 2020, Synthetic Biology: Global Markets; Golden.com 2021, List of Synthetic Biology Companies.

155 See Table 2: Early strategic public investments in the US and UK have helped to enable growth in terms of start-ups, private investment, and market share.

156 IBISWorld 2020, L6724-GL Global Biotechnology Industry Report; IBISWorld 2020, X0001 Biotechnology in Australia Industry Report.

157 IBISWorld 2020, L6724-GL Global Biotechnology Industry Report; IBISWorld 2020, X0001 Biotechnology in Australia Industry Report.

158 IBISWorld 2020, L6724-GL Global Biotechnology Industry Report; IBISWorld 2020, X0001 Biotechnology in Australia Industry Report.

Summary of reported results

The highest plausible market sizing estimates (from our preferred high growth rate, high market share scenario) used throughout the report are summarised here. Any discrepancies in summations are due to differences in rounding. All figures are reported unadjusted for inflation in current dollars.

To put these results into context, the figures below are 2019 data and provide useful whole-of-economy and sectoral comparisons:

- Global GDP was approximately $113 trillion and Australian GDP was approximately $2 trillion.[159]
- Australian biotechnology employment was approximately 17,000 people.[160]
- Australian agriculture revenue was approximately $78 billion, and the gross value of Australian milk and cattle commodities was approximately $17 billion.[161]
- Australian agricultural employment was approximately 377,000 people.[162]
- Australian pharmaceutical product manufacturing revenue was approximately $12 billion and pharmaceutical product manufacturing employment was approximately 16,000 people.[163]

Table 11: Summary of economic analysis results by market

	(I) FOOD AND AGRICULTURE	(II) HEALTH AND MEDICINE	(III) OTHER	(IV) TOTAL
Potential global revenue by 2040 (AUD)	$428.2B	$241.1B	$28.2B	$697.4B
Potential Australian revenue by 2040 (AUD)	$19.3B	$7.2B	$0.7B	$27.2B
Potential Australian headcount employment by 2040	31,200 jobs	11,700 jobs	1,100 jobs	44,100 jobs

159 United Nations Statistics Division, 2019 National Accounts; RBA Historical Data – Exchange Rates, Series ID: FXRUSD, USD$1=AUD$1.29 from Jan 2000 – Dec 2020; Australian System of National Accounts 2019–20, ABS cat. no. 5204.0.

160 IBISWorld 2020, X0001 Biotechnology in Australia Industry Report.

161 Australia Industries, 2018–19, ABS, 2020 (measured from sales and service income of Agriculture industry subdivision); Value of Agricultural Commodities Produced, Australia, 2018–19, ABS, 2020.

162 Australia Industries, 2018–19, ABS, 2020.

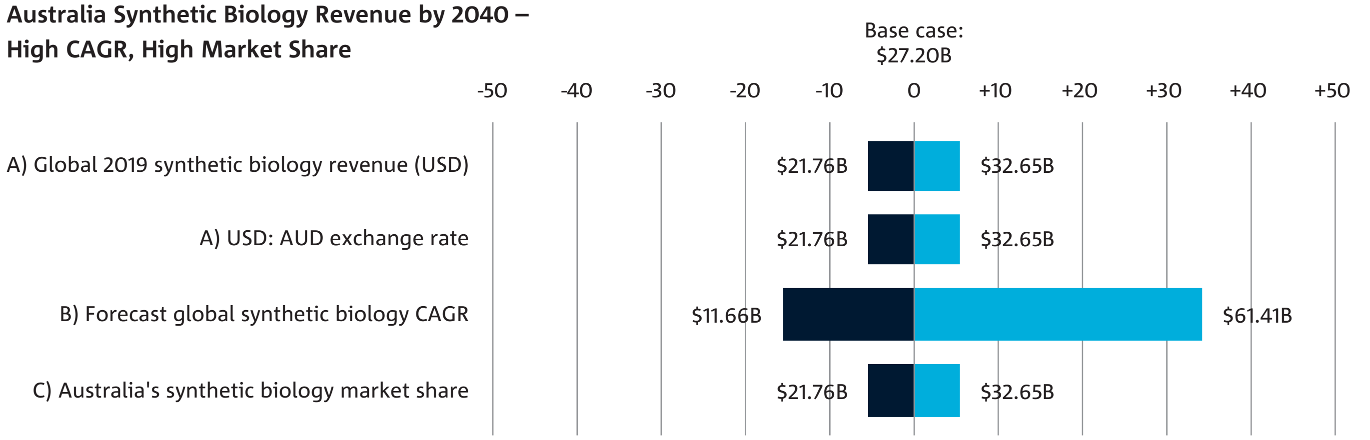
163 IBISWorld 2021, C1841 Pharmaceutical Product Manufacturing in Australia Industry Report

Scenario analysis results

Table 12: Detailed scenario analysis results

SCENARIO		(I) FOOD AND AGRICULTURE	(II) HEALTH AND MEDICINE	(III) OTHER	(IV) TOTAL
Low growth rate, low market share	Potential global revenue by 2040 (AUD)	$4.78B	$27.10B	$25.05B	$56.93B
	Potential Australian revenue by 2040 (AUD)	$0.03B	$0.11B	$0.08B	$0.21B
	Potential Australian headcount employment by 2040	50 jobs	180 jobs	120 jobs	340 jobs
Low growth rate, high market share	Potential global revenue by 2040 (AUD)	$4.78B	$27.10B	$25.05B	$56.93B
	Potential Australian revenue by 2040 (AUD)	$0.22B	$0.81B	$0.63B	$1.65B
	Potential Australian headcount employment by 2040	350 jobs	1,320 jobs	1,010 jobs	2,680 jobs
High growth rate, low market share	Potential global revenue by 2040 (AUD)	$428.16B	$241.05B	$28.23B	$697.44B
	Potential Australian revenue by 2040 (AUD)	$2.57B	$0.96B	$0.08B	$3.62B
	Potential Australian headcount employment by 2040	4,160 jobs	1,560 jobs	140 jobs	5,860 jobs
High growth rate, high market share	Potential global revenue by 2040 (AUD)	$428.16B	$241.05B	$28.23B	$697.44B
	Potential Australian revenue by 2040 (AUD)	$19.27B	$7.23B	$0.71B	$27.20B
	Potential Australian headcount employment by 2040	31,210 jobs	11,720 jobs	1,140 jobs	44,070 jobs

Sensitivity analysis results



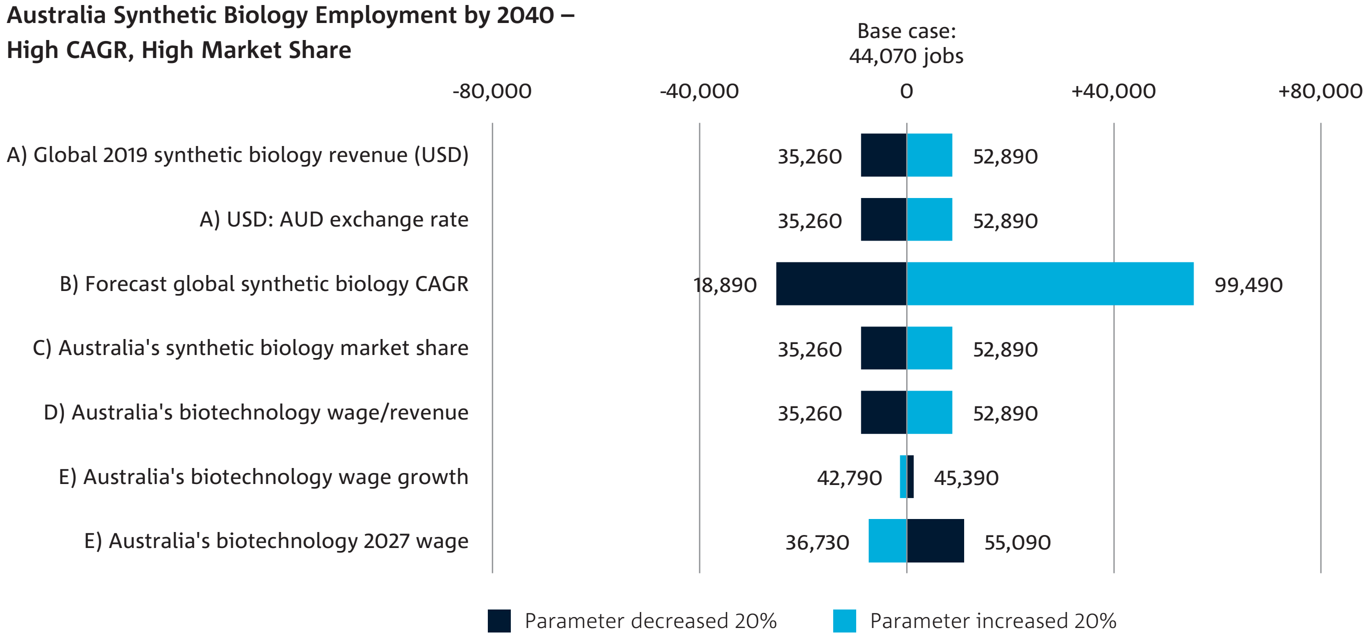


Figure 6: Sensitivity analysis results

Sensitivity analysis was conducted to assess model variability to parameter changes for the synthetic biology economic analysis. As seen in the above figures, compound annual growth rate is the model parameter with the highest variability for both revenue and employment outputs.

- Decreasing compound annual growth rate by 20% from 24.6% in the base case to 19.7% decreases estimated revenue by $15.54B and decreases estimated headcount employment by 25,180 jobs.
- Increasing compound annual growth rate by 20% from 24.6% to 29.6% increases estimated revenue by $34.21 billion and increases estimated headcount employment by 55,420 jobs.

Altering the following parameters changes model outputs in equal symmetric proportions: global 2019 synthetic biology revenue (USD), the US to Australian Dollar exchange rate, Australia's synthetic biology market share, and Australia's biotechnology wage/revenue.[164]

164 The global 2019 synbio revenue (USD) and US to Australian Dollar exchange rate are used to calculate parameter A. Australia's biotechnology wage growth and Australia's biotechnology 2027 wage are used to calculate parameter E.

Appendix C: Australian synthetic biology research capabilities

Table 13: Universities and Institutes in Australia with Synthetic Biology research programs

UNIVERSITY/INSTITUTE	SYNTHETIC BIOLOGY RESEARCH PROGRAMS[165]	% OF AUSTRALIAN SYNTHETIC BIOLOGY RESEARCH[166]	% OF AUSTRALIAN SYNTHETIC BIOLOGY-ASSOCIATED RESEARCH[167]
Australian Catholic University		N/A	N/A
Australian National University	●	4.96%	6.83%
Bond University		N/A	N/A
Central Queensland University		N/A	N/A
Charles Darwin University		N/A	N/A
Charles Sturt University		0.90%	0.51%
Children's Cancer Institute	●	N/A	N/A
CSIRO	●	13.06%	10.75%
Curtin University	●	2.70%	6.49%
Deakin University	●	0.45%	1.70%
Edith Cowan University		N/A	N/A
Federation University Australia		N/A	0.51%
Flinders University		N/A	0.17%
Griffith University	●	2.70%	1.88%
James Cook University	●	0.90%	0.51%
La Trobe University	●	3.15%	3.07%
Macquarie University	●	17.57%	8.87%
Monash University	●	7.21%	10.24%
Murdoch University	●	0.90%	0.34%
NSW DPI	●	N/A	0.51%
Peter MacCallum Cancer Centre	●	N/A	1.02%
QIMR Berghofer Medical Research Institute	●	N/A	0.51%
Queensland University of Technology	●	3.60%	3.41%
Royal Melbourne Institute of Technology		0.45%	2.56%
SA Health and Medical Research Institute	●	N/A	N/A

165 Identified from consultations, information on institution websites, and occasionally follow up phone conversations.
166 Based on Web of Science search results for publications in Australia under topic "synthetic biology" between 2015 and 2020.
167 Based on Web of Science search results for publications in Australia under synthetic biology associated terms between 2015 and 2020.

UNIVERSITY/INSTITUTE	SYNTHETIC BIOLOGY RESEARCH PROGRAMS[165]	% OF AUSTRALIAN SYNTHETIC BIOLOGY RESEARCH[166]	% OF AUSTRALIAN SYNTHETIC BIOLOGY-ASSOCIATED RESEARCH[167]
Southern Cross University		0.90%	0.68%
Swinburne University of Technology		0.45%	0.17%
University of Adelaide	●	2.70%	4.10%
University of Canberra	●	4.96%	2.05%
University of Melbourne	●	4.51%	12.29%
University of New England		N/A	0.17%
University of New South Wales	●	10.81%	6.66%
University of Notre Dam		N/A	N/A
University of Newcastle	●	4.51%	2.22%
University of Queensland	●	19.37%	20.14%
University of South Australia		N/A	1.54%
University of Southern Queensland		N/A	0.17%
University of the Sunshine Coast	●	0.90%	0.51%
University of Sydney	●	2.25%	4.27%
University of Tasmania		0.45%	1.02%
University of Technology Sydney	●	3.60%	3.07%
University of Western Australia	●	6.76%	6.31%
University of Wollongong		0.90%	1.02%
Victoria University		N/A	N/A
Western Sydney University		N/A	N/A
Walter & Eliza Hall Institute of Medical Research	●	0.45%	2.05%

Appendix D: Australian industry stakeholders

The companies listed below are involved in synthetic biology through core business activities, partnerships, or through the provision of products and services to synthetic biology-related businesses. These companies were identified through consultations and online research, and as such, this may not be an exhaustive list.

Table 14: Australian industry stakeholders

COMPANY (LOCATION)	ABOUT (MATURITY, BUSINESS MODEL ETC.)	PARTNERSHIPS AND INVESTMENT
ENABLING TECHNOLOGY		
Agritechnology Pty Ltd (NSW)	• Agritechnology has experience in fermentation, contract R&D, scale up and industrial translation. The company is focusing on product and process development. • See Appendix E for more information on biomanufacturing capabilities.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.
BMG Labtech (VIC)	• BMG Labtech manufactures and supplies microplate readers used in synthetic biology laboratories.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.
Bondi Bio (NSW)	• Bondi Bio is engineering cyanobacteria to sustainably produce high-value compounds from light, water and CO_2 – for a broad range of markets such as flavours and fragrances, health and medicine, agriculture, and specialty chemicals.	• Industry Partner at the Centre of Excellence in Synthetic Biology. • Awarded $463,000 for a Linkage Project with University of Queensland and Macquarie university to biosynthesise flavours and fragrances using cyanobacteria.
Decode Science (VIC)	• Decode Science is distributing synthetic biology and genomic research tools. • Products and services enabled by synthetic biology include synthetic DNA, cloning, and oligo pools.	• Industry Partner at the ARC Centre of Excellence in Synthetic Biology.
MicroBioGen (NSW)	• MicroBioGen is using synthetic biology to develop and optimise industrial strains of the yeast, *Saccharomyces cerevisiae* for production of first- and second-generation biofuels as well as high protein feed.	• MicroBioGen has developed yeast for first-generation biofuels under the Innova brand, which is marketed and sold by major partner and investor, Novozymes.
Proteowa (WA)	• Proteowa is developing recombinant protein products as well as offering consulting, contract R&D and manufacturing services for synthetic biology product development. • See Appendix E for more information on biomanufacturing capabilities.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.
FOOD AND AGRICULTURE		
AB Biotek (NSW)	• AB Biotek is developing yeast for fermentation-based production of beverages, animal feed, bioethanol and nutritional products.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.
Bioproton (QLD)	• Bioproton is producing high quality, nutrient rich animal feed supplements.	• Undertaking collaborative research with QUT to develop yeast-based production method for the antioxidant feed additive *astaxanthin*.
Change Foods (US/VIC)	• Change Foods is developing animal-free cheese and other dairy products using microbial biotechnology.	• Raised $4 million ($3.1 million USD) in funding from a range of venture capitalists, private funders and angel investors across the US, Singapore, New Zealand and Australia.

COMPANY (LOCATION)	ABOUT (MATURITY, BUSINESS MODEL ETC.)	PARTNERSHIPS AND INVESTMENT
Eden Brew (NSW)	• Eden Brew is developing animal-free dairy products using proteins produced by synthetic biology.	• Farmer owned Norco Co-Operative Ltd is a co-funder and partner. • Spin-out from CSIRO with support from Main Sequence Ventures.
Ex Planta Pty Ltd (WA)	• Ex Planta is a synthetic biology start-up working to scale biomanufacturing of natural isoflavonoids for nutraceutical and pharmaceutical applications.	• Ex Planta is a spin out commercialising UWA research through an investment of $400,000 in October 2020 supported by Alto Capital.[168]
Nourish Ingredients (ACT)	• Nourish Ingredients is engineering new, specialty food lipids comparable to those found in animal products. These products are currently in prototype stage of development.	• Spin-out from CSIRO with support from Main Sequence Ventures. • Nourish Ingredients raised $14.2 million ($11 million USD) of seed funding, as announced in March 2021.
Novum Lifesciences (QLD)	• Novum Lifesciences, originally BioFilm Crop Protection, is a microbial biotechnology company developing products and services for the horticulture and beef industries.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.
Nuseed (VIC)	• Nuseed, a wholly owned subsidiary of Nufarm is developing omega-3 producing canola approved for production, human consumption and use in animal feed in Australia. This unique strain provides a reliable land-based source of omega-3 fatty acids.	• Nuseed, CSIRO and the GRDC are working in collaboration to develop the Omega-3 Canola strain.
PPB Technology (ACT)	• PPB Technology is developing biosensor technology that allows food companies to check if products meet safety and quality needs of consumers.	• Technology developed at CSIRO by Founder and Managing Director, Dr Stephen Trowell. • Member of the Centre for Entrepreneurial Agri-Technology Innovation hub.
Vow (NSW)	• Vow is a synthetic biology-adjacent business developing cell-based meat products.	• Investors include the Australian Government and Blackbird. • Raised $7.7 million ($6 million USD) as announced in January 2021.
HEALTH AND MEDICINE		
BioCina (SA)	• BioCina is a biologics CDMO offering microbial process development and PC2 certified GMP manufacturing solutions. The company has a US-FDA and TGA approved facility for commercial manufacturing.	• mRNA vaccine development with the South Australian Health and Medical Research Institute (SAHMRI) and collaborating with the University of Adelaide to develop plasmid DNA and RNA manufacturing technologies.
Cartherics (VIC)	• Cartherics is developing allogeneic therapies based on immune killer cells with CAR for cancer treatment.	• Internationally, Cartherics partners with ToolGen Pharma Korea. • Australian partners include ARMI, Monash University as well as Peter Mac and Cell Therapies for CAR-T, CAR-NK clinical trials.
Cell Therapies (VIC)	• Cell Therapies is focused on GMP-manufacturing of cell-based products.	• Situated at Peter MacCallum Cancer Centre • Australia's TGA approved manufacturer of Novartis' CAR T-Cell therapies.
CSL (VIC)	• CSL is developing and producing blood plasma, vaccines, antivenom as well as other laboratory and medical products. • See Appendix E for more information on biomanufacturing capabilities.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.

168 The University of Western Australia (2021) Why investor funding could be the best option for your research. Viewed 25 May 2021, <https://www.uwa.edu.au/news/article/2021/march/why-investor-funding-could-be-the-best-option-for-your-research>.

COMPANY (LOCATION)	ABOUT (MATURITY, BUSINESS MODEL ETC.)	PARTNERSHIPS AND INVESTMENT
Microbial Screening Technologies (NSW)	• Microbial Screening Technologies has established BioAustralis Fine Chemicals for supplying rare, high purity metabolites to the research sector using synthetic biology. • Microbial Screening Technologies is using bioengineered actinomycetes and fungi from collaborators for enhancing and diversifying their metabolite production.	• Industry Partner at the ARC Centre of Excellence in Synthetic Biology. • Partners include Macquarie University and University of Western Australia. • Received $6.9 million in funding from the CRC-P Grant Program which supported expansion of their BioAustralis business for metabolite production.
Microba (QLD)	• Microba provides gut microbiome testing services with a key focus on irritable bowel disease and cancer. The company is using synthetic biology to investigate new treatments.	• No publicly disclosed, synthetic biology-relevant partnerships and investments identified.
Patheon by Thermo Fisher Scientific (QLD)	• Patheon offers manufacturing of GMP-grade clinical and commercial pharmaceutical active ingredients focusing on mammalian cell-culture biologics. • See Appendix E for more information on biomanufacturing capabilities.	• Originated as public-private partnership between Bioplatforms Australia and DSM Biologics in 2012, now fully private.
PYC Therapeutics (WA/US)	• PYC Therapeutics is using synthetic biology to develop RNA therapeutics to treat diseases which existing drugs cannot target effectively. Company is currently in preclinical stages of development.	• ASX-listed biotechnology company raised $41 million in 2020 for development of multiple drug candidates. • Formed Vision Pharma Ltd subsidiary with the Lions Eye Institute for the development of drugs for eye diseases.
River Stone Biotech Australia (Denmark/VIC)	• River Stone Biotech is a synthetic biology venture with a focus on small molecule pharmaceutical applications and expertise in improving the efficacy and safety of drug candidates.	• Collaborative R&D with University of Melbourne (Gras Lab) on fermentation downstream processing. • Industry Partner at the ARC Centre of Excellence in Synthetic Biology.
OTHER		
Cemvita Factory (US/WA)	• Cemvita Factory is developing synthetic biology technology for CO_2 utilisation, biomining and bioremediation purposes.	• BHP has taken a strategic stake in Cemvita. • Industry Partner at the Centre of Excellence in Synthetic Biology.
Gratuk Technologies (NSW)	• Gratuk is developing products that designed to modify the intestinal microbiome for health improvements. • Gratuk is interested in using synthetic biology technology for fermentation-based production of small molecules such as polyphenols for medicinal purposes.	• Industry Partner at the ARC Centre of Excellence in Synthetic Biology for understanding modifications needed to improve intestinal microbiomes. • In pharmaceuticals, Gratuk is working with a company developing novel anti-microbial strategies through modified microorganisms.
HydGENE Renewables (NSW)	• HydGENE Renewables is engineering bacteria to produce hydrogen on-site from renewable plant material.	• Technology developed at Macquarie University with $2.8 million in ARENA R&D funding. • $100,000 BRII funding. • CSIRO OnAccelerate participant.
Provectus Algae (QLD)	• Provectus Algae is optimising a synthetic biology algal platform to produce high-value compounds for use in a range of industries and applications such as chemicals, food and agriculture.	• In October 2020, Provectus Algae announced a US $3.25 Million investment from a seed round led by Hong Kong's Vectr Ventures. • Advanced Manufacturing Growth Centre (AMGC) co-funded a project with Provectus Algae.
Samsara (NSW)	• Samsara is using synthetic biology to engineering enzymes able safely and efficiently degrade polymers or chemicals.	• Research partnership with ANU. • Supported by Main Sequence Ventures.

Appendix E: Australian biomanufacturing capabilities

The organisations and capabilities listed below were identified through online searches and consultations. As such, this may not be an exhaustive list of relevant infrastructure capabilities.

Table 15: Australian biomanufacturing infrastructure capabilities

ORGANISATION	AVAILABLE BIOLOGICAL SYSTEMS AND SERVICES	SCALE
Agritechnology Pty Ltd (NSW)	Systems: Yeast, bacteria, algae Services: Provides commercial services to laboratories and staff typically focused on synthetic biology projects. HACCP approved for food production.	Up to 10,000L (25 — 150L pending PC2 certification)
BioCina (SA)	Systems: Bacteria (*E.coli*) Services: GMP manufacturing and testing of microbial-based products. PC2-LS (large scale) certified facility	Up to 500L
CSIRO – Recombinant Protein Production and Purification Facility (VIC node of the NBF)	Systems: Bacteria, yeast Services: Molecular engineering, optimisation, scale up, protein purification and characterisation	Up to 500L mg – g scale
LuinaBio (QLD)	Systems: Bacteria, yeast Services: Scale up, GMP manufacture, protein purification and characterisation, anaerobic systems	Up to 500L
Novum Lifesciences (QLD)	Systems: Bacteria, fungi Services: Metabolite production services	5,000L reactors
Olivia Newton-John Cancer Research Institute, Mammalian Protein Expression Facility (VIC)	Systems: Mammalian Services: Transient expression, stable expression, and isolation/enrichment of high producing clones, protein purification, protein characterisation	10 – 300 mg scale
Patheon by Thermo Fisher Scientific (QLD)	Systems: Mammalian Services: Contract GMP manufacturing	250L – 2x2,000L (4000L)
Proteowa (WA)	Systems: Bacteria (*E.coli*) Services: Recombinant protein production with protein purification on columns. Consulting, contract R&D and manufacturing services for synthetic biology product development	Up to 1L mg-g scale
Queensland University of Technology – Mackay Renewable Biocommodities Pilot Plant (QLD)	Systems: Yeast, fungal and bacterial fermentation Services: Biomass processing, industrial fermentation, scale-up, research, biopolymers, biochemicals, proof of concept.	Up to 10,000L (upgrade planned for up to 1000 L PC2)
University of New South Wales – Recombinant Products Facility (NSW)	Systems: Bacteria, yeast Services: Expression optimisation, scale up, protein purification, protein characterisation	Up to 20L mg – g scale
University of Queensland – BASE (QLD) (Joint facility between UQ's National Biologics Facility and Protein Expression Facility)	Systems: Microbial, enzymatic and chemical synthesis Services: Research to pilot scale production of nucleic acids (plasmids, single stranded DNA and mRNA)	mL to L µg – mg
University of Queensland – National Biologics Facility (QLD) (QLD Node of the NBF)	Systems: Mammalian Services: Antibody discovery, protein engineering, cell line development, upstream and downstream process development, pilot scale PC2 production , manufacturability assessment, transient production, analytical development	Up to 50L mg – g scale
University of Queensland – Protein Expression Facility (QLD)	Systems: Bacteria, yeast, insect, mammalian Services: Molecular engineering, optimisation, scale up, protein purification and characterisation	Up to 20L mg – g scale
University of Technology Sydney – Biologics Innovation Facility (NSW node of the NBF)	Systems: Mammalian Services: GMP bioprocessing and training, production of monoclonal antibodies and other recombinant products	Up to 200L

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