EXTRACT

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SYNTHETIC BIOLOGY IN AUSTRALIA

AN OUTLOOK TO 2030

HORIZON SCANNING

ACOLA
AUSTRALIAN COUNCIL OF LEARNED ACADEMIES

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This project has been supported by CSIRO and the Australian Government Department of Health.

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Published 2018

CONTENTS

PROJECT AIMS

1. Examine the transformative role that synthetic biology might play in Australia across different sectors.
2. Consider the opportunities and challenges for advancing synthetic biology in Australia.
3. Analyse the future education, workforce and infrastructure requirements to support an Australian synthetic biology industry.
4. Examine the ethical, legal and social considerations and frameworks required to enable and support synthetic biology developments.

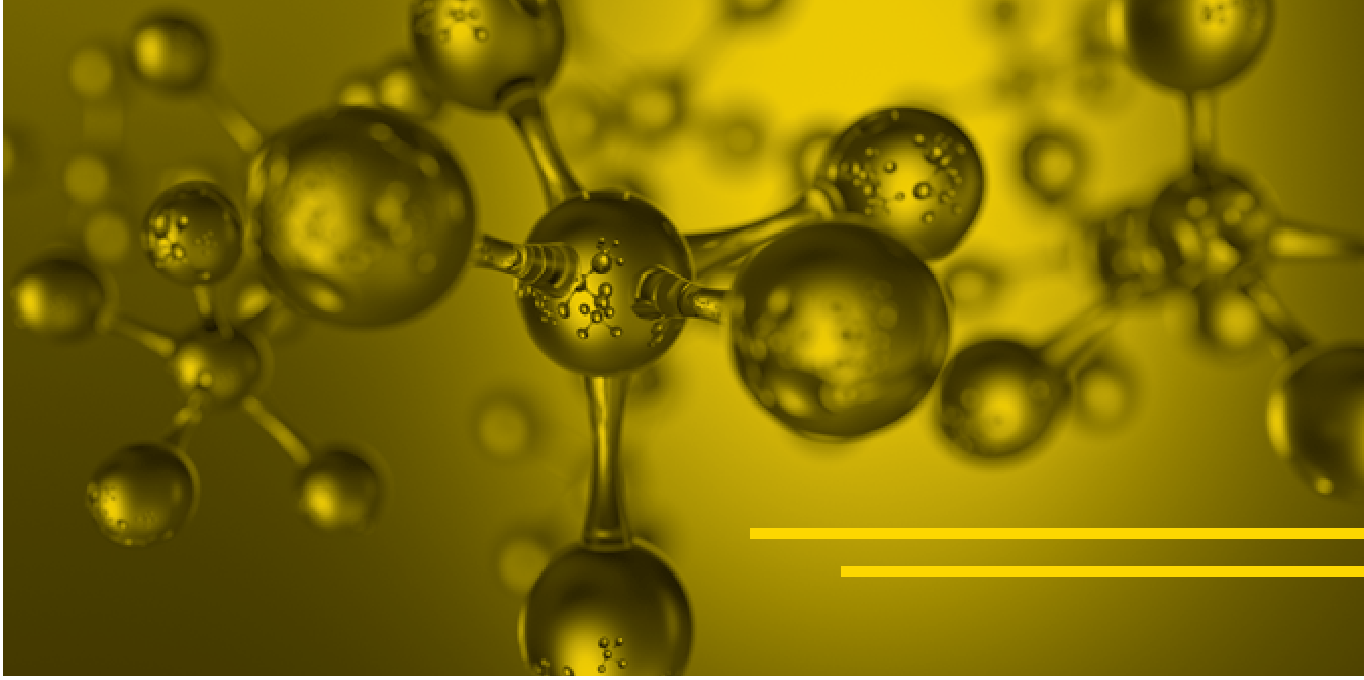
EXECUTIVE SUMMARY

The creation of novel and redesigned biological components, networks and systems is at the core of synthetic biology. Emerging from the established field of gene technology, synthetic biology applies engineering principles to biology to allow the rational design, construction and combination of nucleic acid sequences or proteins, using standardised genetic parts. This approach opens up new opportunities for us to design and create novel metabolic pathways, derive valuable biomolecules, and produce engineered organisms for use in a number of environmental, industrial, and medical applications.

Synthetic biology provides new ways to address major societal challenges in energy and food production, environmental protection and healthcare. The rapid advancement of synthetic biology as a field is being driven by major investments made by several leading research nations, including the US, the UK, China, Singapore and Korea.

Given the breadth of potential applications for synthetic biology, strategically building capabilities in areas of strength will be critical for Australia's future prosperity. The report identifies these areas as industry and energy, agriculture and food, environment and biocontrol, and health and medicine. Synthetic biology provides opportunities for the development of new industries that will produce new and improved products and services, ranging from specialty chemicals, pharmaceuticals and vaccines, to biosensors and bioremediation products, to biofuels. These industries will provide new jobs and exports and support the continued growth of the Australian economy. Our agriculture sector will be highly dependent on the adoption of synthetic biology to remain competitive and to control invasive pests and diseases. The health of Australians will be greatly enhanced by our uptake of synthetic biology applications to improve the diagnosis and treatment of disease, and to improve our diet.

Beyond the existing and developing applications discussed in this report, synthetic biology is also likely to have broad-reaching and unforeseen impacts. Diverse industries are likely to be expanded, while others will be transformed or replaced. There is substantial uncertainty surrounding the social, environmental and economic impacts that synthetic biology will have on Australia and we must be prepared for the transformative changes this field can and will have. Hence the report also considers the social, ethical and regulatory frameworks that will be needed to support its future governance and advancement.



Applications to transform the economy

Australia's strengths in several relevant fields of research and the availability of agricultural resources as feedstock for industrial biotechnology applications, give synthetic biology the potential to deliver significant benefits for Australia. These benefits can be expected across industry and transport, agriculture and food, sustainability and the environment, and health and medicine. In some cases, the use of synthetic biology will make entirely new products and services possible. In other cases, it will improve the efficiency and productivity of existing products, processes and systems. It will be important that Australia's regulatory environment anticipates the rapid advances occurring in synthetic biology.

Advanced biomanufacturing

Developments in synthetic biology at an industrial scale can be used for the production of fine and bulk chemicals, biologics and other valuable biomolecules using cell factories engineered through synthetic biology. An early success internationally which demonstrated feasibility was the commercial production of 1,4-butanediol (BDO), an intermediate chemical used in the manufacture of certain plastics, polyurethanes and elastic fibres. BDO is not a natural product and its synthesis in bacteria requires a combination of enzymes from several different organisms. Other examples include the development of microbial strains to make the high energy liquid fuels needed for aviation from renewable, low carbon, agricultural feedstocks and the production of high value biomolecules in crops, fragrances from yeast, and novel antimicrobial drugs and vaccines. As the field advances, the capture, extraction and integration of the vast amounts of data generated in the design and development of production processes will rely on artificial intelligence and machine learning to design suitable cell lines and microbial strains for use as superior cell factories.

Opportunities for agriculture

The introduction of desirable new traits to crop plants has the potential to transform Australian agriculture. Building upon earlier techniques for genetic modification, synthetic biology can provide higher levels of precision, predictability, control and sophistication than traditional gene technology approaches to help increase crop and livestock yields and sustainability. Possible improvements include more efficient use of water, increased photosynthetic performance, better nitrogen fixation and nutrient uptake, and resistance to pests and disease. Consumer benefits may include nutritional improvements, such as increased digestibility, dietary fibre, oil quality, and the removal of allergenic proteins from milk, eggs and nuts.

Protecting the environment

The release of toxic chemicals from industrial, agricultural and mining processes can threaten environmental health, the natural balance within ecosystems and the safety and use of water and other natural resources. Synthetic biology provides sensing systems which can inform us on the state of the environment, as well as sense-and-response systems that can be used to detect contaminants and respond by producing the enzymes required for remediation.

Synthetic biology can also provide alternatives to the use of chemicals to control invasive and pest species, such as mice and weeds, by introducing genetic changes that limit the capacity of the pest organisms to reproduce. Improved resilience to the effects of climate change in key ecosystem species is also a target. Strong capabilities in ecology and population modelling are required to predict the effects of releasing engineered organisms and will be critical to the effective use and safe implementation of such synthetic biology applications.

Health and quality of life

Australia is widely recognised for its excellence in health and medical research. This capability is enabled by modern research facilities and high-quality clinical trials infrastructure. Within this context, synthetic biology has the potential to revolutionise the way biological tools are developed and used to advance the wellbeing of humans, manage human and animal health and enhance commercial opportunity in biomedicine.

Cell engineering is an area of significant potential for Australia, with many different applications. One example is human cancer immunotherapy, with several Australian groups designing novel chimeric molecules to mediate aspects of immune function. Redesigned antibody molecules are being engineered into immune cells that can target tumours, bypass harmful immune responses and deliver therapeutics directly to the affected tissue.

Opportunities also exist to use synthetic biology to produce antibiotics and other molecules for which routine chemical synthesis is too complex or economically unfeasible. The ability to use genetic circuits in diagnostic devices or to synthesise vaccines and improved antimicrobial agents holds significant promise, both commercially and to benefit the health system.

A further example that demonstrates the powerful medical applications of synthetic biology is the study of brain function in people diagnosed with neuro-degenerative diseases such as Alzheimer’s, Parkinson’s or multiple sclerosis, where investigations are hampered by the inability to visualise the release and uptake of neurotransmitters. Biosensors with exquisite sensitivity and capable of differentiating between biochemicals would improve our understanding of the underlying pathology and greatly enhance pre-clinical models of these diseases.

Moral issues, ethics, legal and social aspects

Understanding the social context of technological innovation is important for both responsible development and technology uptake. Establishing active community engagement programs to share information with the public about synthetic biology, earn public confidence, and support appropriate governance and agile regulatory processes will be vital for innovation in synthetic biology to progress.

The emergence of synthetic biology presents an opportunity to develop community engagement approaches that are more effective than those deployed with the introduction of gene technology. Policy makers and researchers are aware of the shortcomings of previous approaches, which tended to focus on simply explaining the technology and its potential production benefits. New approaches are needed to integrate ethical, legal and social aspects (ELSA) of synthetic biology into the research and innovation process from its earliest stages. This includes acknowledgement that synthetic biology, in common with other technologies, can be used for both good and ill. The technologies and applications that are the end product of the research and innovation process need to reflect the values and concerns of the society they are to serve.

Quantitative and qualitative research in the US and the EU indicates that public awareness and understanding of synthetic biology is low. Equivalent studies undertaken in Australia show a similarly low awareness, but indicate generally positive sentiments towards how synthetic biology could improve our way of life in the future (Office of the Gene Technology Regulator, 2017).

Looking to the horizon

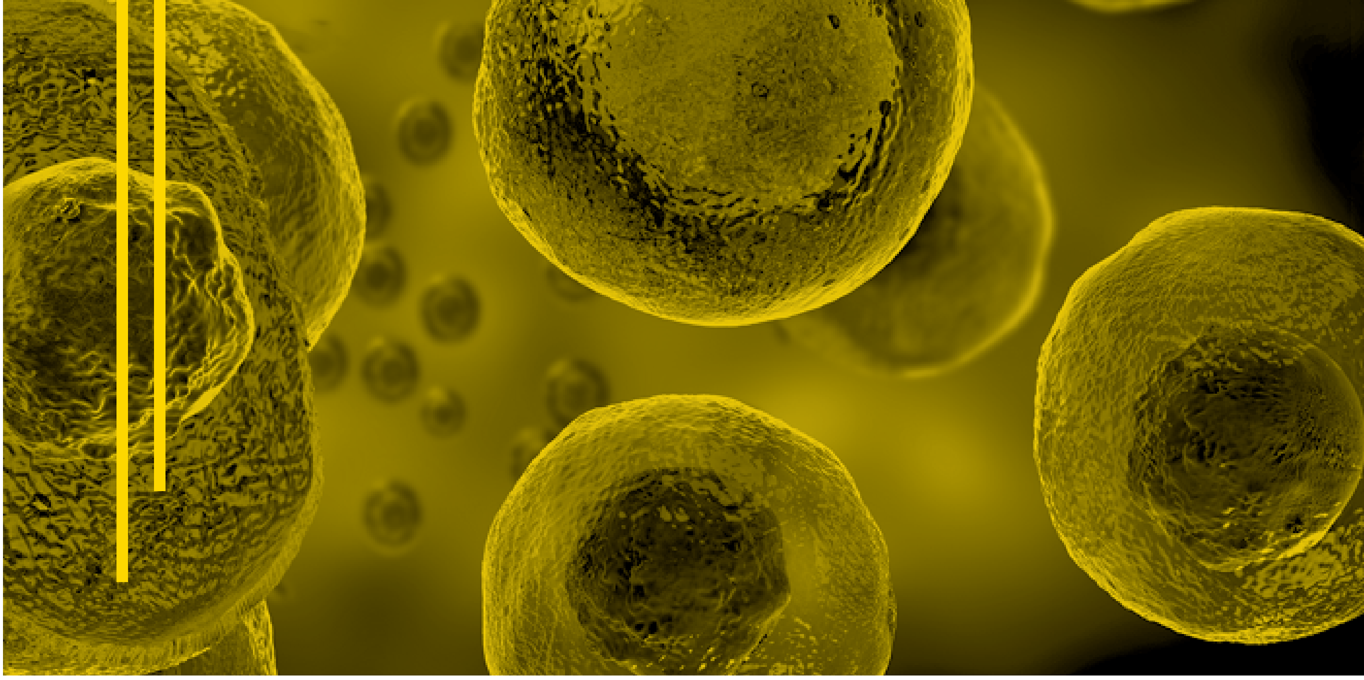
Maximising the future economic and societal benefits of synthetic biology will involve several complementary activities that must be delivered in parallel. These include the development of a shared vision by key stakeholders working cooperatively towards a national road mapping strategy, strategic investments in education and infrastructure, understanding both benefits and risks of synthetic biology, and earning public trust through active consideration of ethical, legal and social aspects of the field in ways that engage the wider community.

Developments in synthetic biology are poised to underpin innovations in a wide range of applications, including in areas in which Australia has been traditionally strong: food and agriculture; manufacturing; environmental monitoring and remediation; and, health and medical technologies. To remain globally competitive in these areas, Australia will need to strengthen its culture of technology development and commercialisation, including key infrastructure, effective regulation and a well-protected intellectual property base. To sustain this culture, the tertiary education of the next generation of practitioners must integrate interdisciplinary teaching and research training across science, technology, engineering and mathematics (STEM) with the humanities, arts and social sciences (HASS) disciplines.

KEY FINDINGS

1. **Synthetic biology presents a unique opportunity to address many global challenges: to meet increasing demands for energy and food; to mitigate the effects of environmental degradation; to enhance human and veterinary health and well-being. Australia is well-placed to become a leader in this emerging field with its strong science base in many essential disciplines and high-level expertise in agro-industries.**
   - Major economies including the US, UK, China, Singapore and Korea are investing heavily to advance their capabilities in synthetic biology. This interest is driven by the advantages of precision, predictability, control and sophistication that synthetic biology offers compared with previous approaches for genetic manipulation.
   - Australia has world-leading expertise in contributing fields including protein engineering, metabolic engineering and genetic circuit design. By extending capabilities in genome design and artificial gene construction, Australia has the potential to become globally competitive in synthetic biology as the field advances.
   - Without strategic national investment in synthetic biology, Australia will fall behind other leading nations, to its societal and economic disadvantage.

2. **Synthetic biology is poised to transform existing industries and create new business opportunities for Australia in health, industrial biotechnology and agriculture. Focused and coordinated efforts will allow Australia to build new globally competitive industries, and to protect the export base for existing agro-industries.**
   - Australia's capabilities in synthetic biology, allied to our expertise in health and medical sciences, agriculture and environmental management, present opportunities to develop specific applications for these industries. For example: by linking Australia's strengths in agro-industries with expertise in industrial biotechnology, synthetic biology will lead to new industries producing higher value products from agricultural feedstocks; synthetic biology will be essential to maintain and improve Australia's agricultural competitiveness in crops such as wheat and sugar cane; and scientific leadership in immunotherapy will lead to the development of new treatments and novel health products in this and related fields of research excellence.
   - Improved translation and commercialisation of synthetic biology research is essential for Australia to establish global competitiveness in



these areas of strength. Encouraging and strengthening linkages between synthetic biology research and industry must be a priority to foster this transition. Targeted support for collaborative research programs between researchers and our biotechnology industry would help forge such linkages.

- Australia's system for intellectual property protection is well regarded internationally and provides confidence for business investment. Due to the key role played by standardised, reusable components in synthetic biology inventions, the protection of intellectual property in the field differs from biotechnology more broadly, and Australia should actively engage with the organisations that will determine the international standards that will be applied.

3. **Developing effective mechanisms to proactively communicate the potential benefits and risks of synthetic biology will be critical to earning and maintaining public trust. Without effective community engagement and strong societal oversight, it may be difficult to apply synthetic biology and realise its potential benefits.**

- Social science and cultural research on community attitudes to synthetic biology in Australia is limited. Some uses of synthetic biology will be considered more acceptable than others. Social science research will be essential to the design of effective community engagement processes to identify issues early.
- Engagement processes must facilitate communication between researchers, industry, government and the community about new technologies and their benefits and risks.
- Australia will need to adopt international best practice in Responsible Research and Innovation (RRI) and ensure that ethical, legal and social considerations are integrated into the research and innovation process from its earliest stages.
- Scientists, regulators and policy makers must ensure that regulatory policies and processes have incorporated the legitimate concerns of the community.

4. **Australia's gene technology regulatory system is considered to be among the most effective and progressive in the world. The proactive approach taken to ensuring the regulatory system stays up-to-date with new genetic technologies, industry trends and international developments will be essential for the development of a thriving synthetic biology industry in Australia.**
   - To encourage innovation and responsible advancement of synthetic biology in Australia, review mechanisms must continue to ensure that new and emerging technologies are identified and regulated in a manner that is commensurate with the safety risks they pose.
   - Regulators must maintain effective communication with other countries' regulatory systems regarding applications of synthetic biology that may impact across international boundaries and harmonise systems to the greatest extent possible to ensure that Australia both protects human and environmental health and remains internationally competitive.

5. **Development and improvement of Australia's synthetic biology capability will require a skilled workforce with advanced capabilities spanning both the STEM (Science, Technology, Engineering and Mathematics) and HASS (Humanities, Arts and Social Sciences) disciplines.**
   - The advancement of synthetic biology research and development must be underpinned by strong STEM teaching at all levels of education, from primary through to tertiary.
   - The tertiary sector must recognise and meet demands for training in areas such as molecular biology, biochemistry, computational modelling and simulation, bioengineering, systems biology, bioinformatics and analytical chemistry.
   - Engineering of biology requires skills and knowledge currently derived separately through Engineering and Science faculties. A greater integration between these faculty training programs is required to gain sufficient expertise to effectively use synthetic biology to engineer biology.

- Implementation of synthetic biology solutions in society requires the integration of social and life sciences to deliver ethically and socially responsible outcomes. Integration of HASS specialties will therefore be required to provide a well-balanced interdisciplinary workforce that has competences in science communication, social science, law and ethics.
- The co-delivery of HASS and STEM subjects in synthetic biology research training would facilitate cross-disciplinary learning and promote sharing of creative, social and technical knowledge to broaden and advance the field. Graduates with these broad skills are required to service the research sector and market opportunity that synthetic biology represents.
- The successful development and implementation of synthetic biology will require multi-disciplinary teams comprised of discipline-specific experts in the fields of molecular biology, social sciences, bioengineering, programming, data analysts and analytics, as well as experts in ethics, and cultural and communication studies, who are good team players.

6. **There is a need for an integrated, national infrastructure platform for synthetic biology that supports efforts to achieve international competitiveness.**
    - To bring Australia to the level of capability of other countries, there is a need for a nationally accessible facility with capabilities in high-throughput synthetic biology component assembly, analysis and testing (a Synthetic Biology Foundry). It is essential that the opportunity is taken to learn from other countries' experiences in providing such capabilities.
    - A database of Australian synthetic biology componentry with both public and private sections will provide an enabling platform for Australian synthetic biology applications and protection for Australian genetic resources.
    - Recent announcements by the Australian Government in the National Research Infrastructure Investment Plan to support Australia's national omics and high-performance computing research infrastructure and a synthetic biology scoping study is welcomed and is considered critical to achieving future advances.
    - Establishing commercial-scale production facilities for synthetic biology products would significantly assist in realising commercial impact from industrial biotechnology applications.

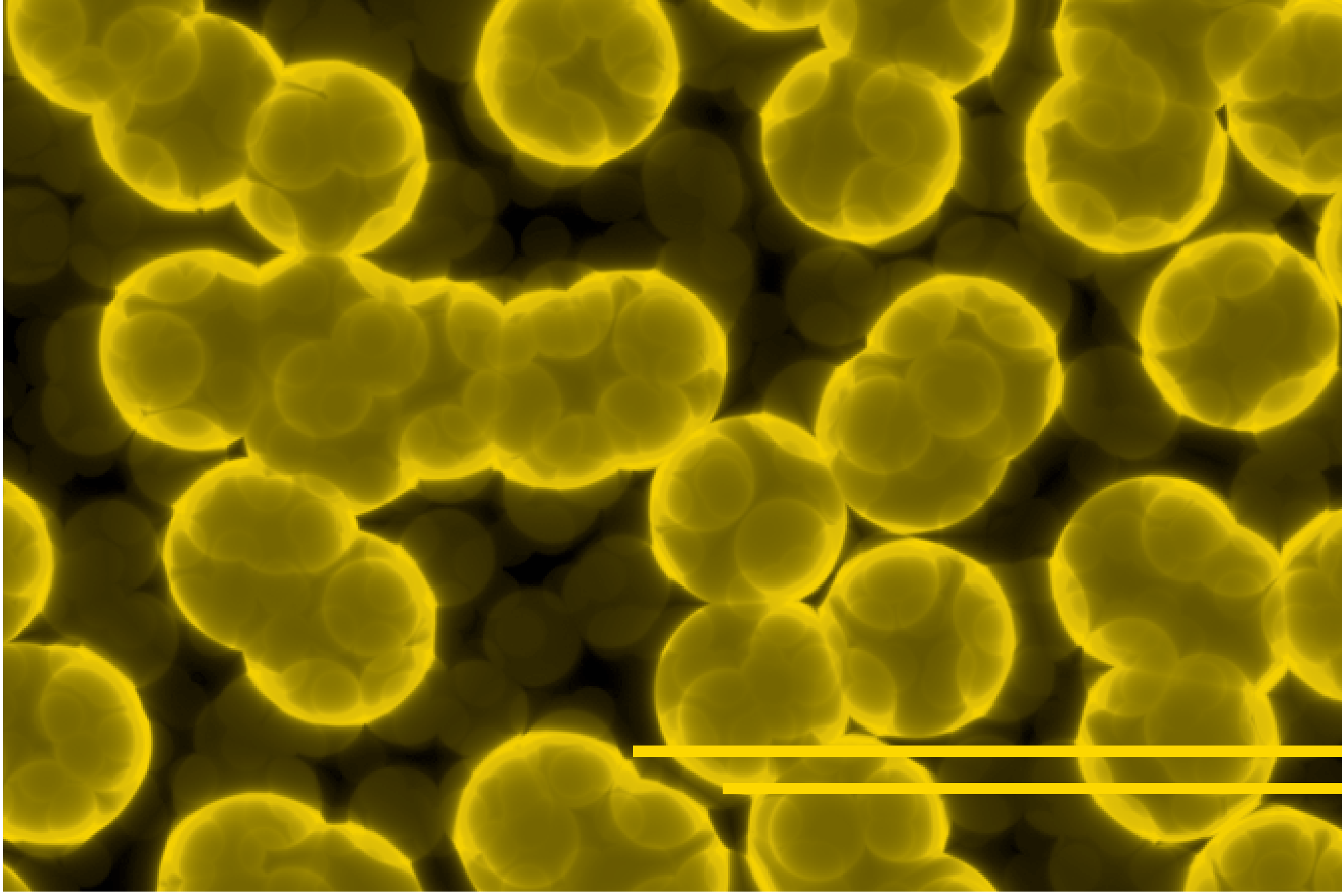
INTRODUCTION

Why synthetic biology?

Synthetic biology involves the application of engineering principles to biology, making it possible for biological systems (or components thereof) to be built to design. By customising biological systems, synthetic biology aims to provide sustainable solutions to many grand challenges of modern society, with applications in energy, manufacturing, agriculture, the environment and health amongst many others (Si and Zhao, 2016). While the term synthetic biology has no single common definition (Appendix A), defining characteristics include rational design, nucleic acid-encoded parts, standardisation and modularisation of parts, abstraction of information, high through-put construction, and improvement on entities that have naturally evolved. For the purposes of this report, synthetic biology has been defined as **'the rational design and construction of nucleic acid sequences or proteins – and novel combinations thereof, using standardised genetic parts'**. Synthetic biology is an extension of earlier genetic engineering approaches based on recombinant DNA technology.

As defined by Australia's Gene Technology Act 2000, organisms altered or developed by synthetic biology are considered to be genetically modified. Our ability to engineer biology to do useful things underpins the Fourth Industrial Revolution – the intersection of biotechnology, information technology, manufacturing, and automation. Synthetic biology builds upon earlier techniques for genetic modification to generate toolboxes with which we can advance this revolution, and as such is driving the bioeconomy (Flores Bueso and Tangney, 2018).

Synthetic biology presents new opportunities to develop industrial chemicals and fuels, cure diseases, monitor and remediate our bodies and our environment, and control invasive and pest species – the applications are limited only by our imagination. As such, synthetic biology could be considered as one of the most transformative technologies to have developed since the advancement of information technology. The two primary enabling tools for synthetic biology are reading and writing DNA. Both are



progressing more rapidly than the advances in computing power that defined the information technology revolution. This has been exemplified by the dramatic decrease in the cost to read DNA sequences, which has fallen 100,000-fold in the past 15 years.

There has been increasing global investment in development and support of synthetic biology technologies. In 2014, the UK identified synthetic biology as one of eight great technologies of the future and established three new synthetic biology research centres, training centres, provided seed funding for innovative companies and established a Synthetic Biology Leadership Council to manage the continued development of the field. The US has several education and research initiatives (ranging from high school to postgraduate level) to encourage and support a synthetic biology industry. US public agencies have conducted several roadmap studies that provide visions and recommendations to address the key challenges and deliver important applications of synthetic biology (Si and Zhao, 2016).

China recognises synthetic biology as a priority research area and the country's Ministry of Sciences and Technology has invested heavily in synthetic biology projects through its basic research funding scheme (Chen, 2014). Synthetic biology was listed as one of 22 science and technology initiatives of strategic importance to China's modernisation in a 2010 roadmap (Cao et al., 2010), and as a strategic emerging industry for development in China's 2016 Five-Year Plan (Central Compilation & Translation Press, 2016). In Singapore, the National Research Foundation recently announced that it will launch a Synthetic Biology Research and Development Programme to advance the nation's research agenda and expertise (National Research Foundation, 2018). These are just some of the initiatives underway internationally and represent international prioritisation of technology development in this field.

Private investment into synthetic biology companies is also increasing rapidly. In 2017, fifty of the top synthetic biology companies raised US$1.7 billion in capital for technology development (compared to approximately US$175 million in 2009), with the number of synthetic biology companies and overall venture funding increasing (Synbiobeta, 2018).

Developments in synthetic biology are poised to underpin innovations in a wide range of applications, including in areas in which Australia has been traditionally strong: manufacturing, food and agriculture, environmental monitoring and remediation, and health and medical technologies. Health and medical science are traditionally disciplines where advanced technologies have a very high uptake rate. This is therefore likely to be one of the important areas where synthetic biology delivers early impact. However, Australia will need to strengthen its culture of technology development and commercialisation, including key infrastructure, effective regulation and a well-protected intellectual property base, to remain competitive in these areas. Further, there will be risks associated with not sufficiently attending to social and ethical concerns related to synthetic biology. Policy makers, regulators, scientists and social scientists will need to proactively engage the community and different interest groups to develop dialogue and build consensus on both benefits and risks and on the regulation of the field.

Structure of the report

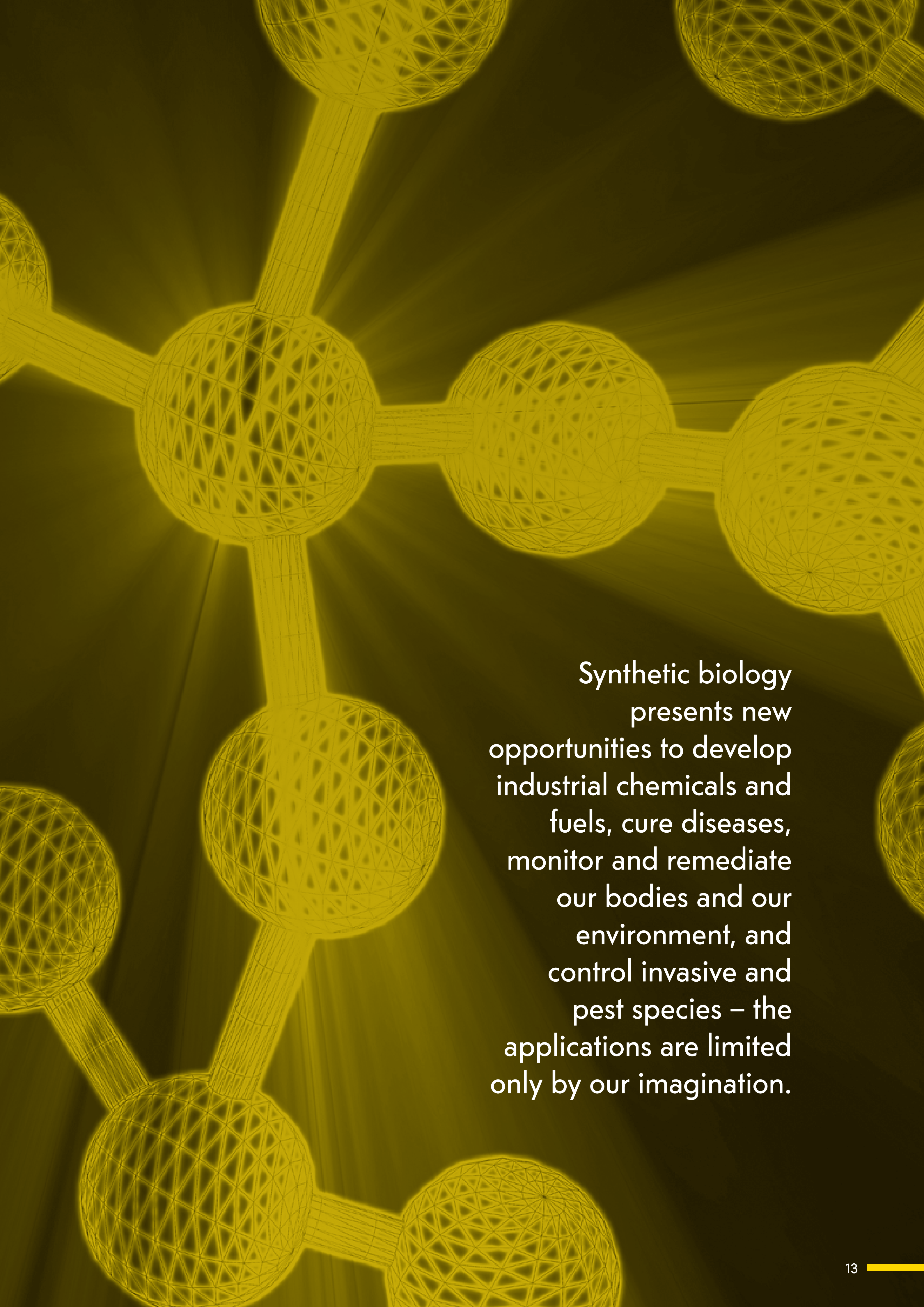
Chapter one provides an overview of the core features of synthetic biology. The chapter introduces examples of what we consider as synthetic biology and provides an overview of the complexity of the field.

Chapter two examines the emergence of synthetic biology in Australia, involvement in international synthetic biology initiatives and activities and our national research outputs. Drawing on information collected through a survey conducted for this ACOLA study, chapter two also reviews the requirements to strengthen Australia's synthetic biology sector.

Chapter three analyses synthetic biology opportunities and challenges, technological advances, and economic prospects across four broad areas in which synthetic biology is most likely to deliver opportunities in the Australian context. The areas examined are industry and energy, agriculture and food, environment and biocontrol, and health and medical applications.

Chapter four reviews social scientific, ethical and legal research on synthetic biology. It gauges the degree of public understanding and examines the importance of adequate public engagement, current regulatory regimes and the international regulatory landscape. The chapter also considers intellectual property issues that arise from the advancement of synthetic biology.

The final chapter summarises the key messages developed throughout the report and closes with scenarios of how synthetic biology may address future global challenges.



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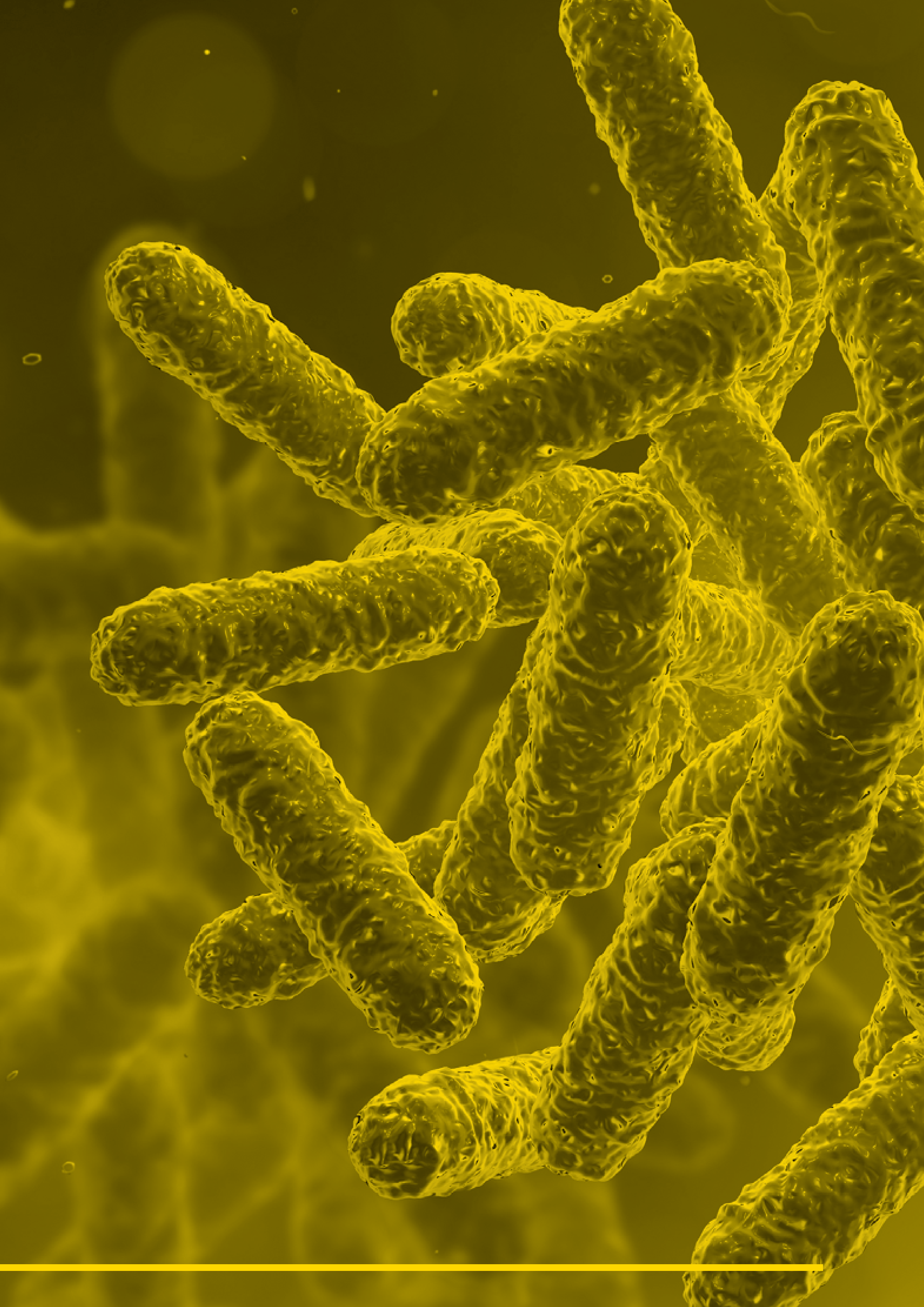

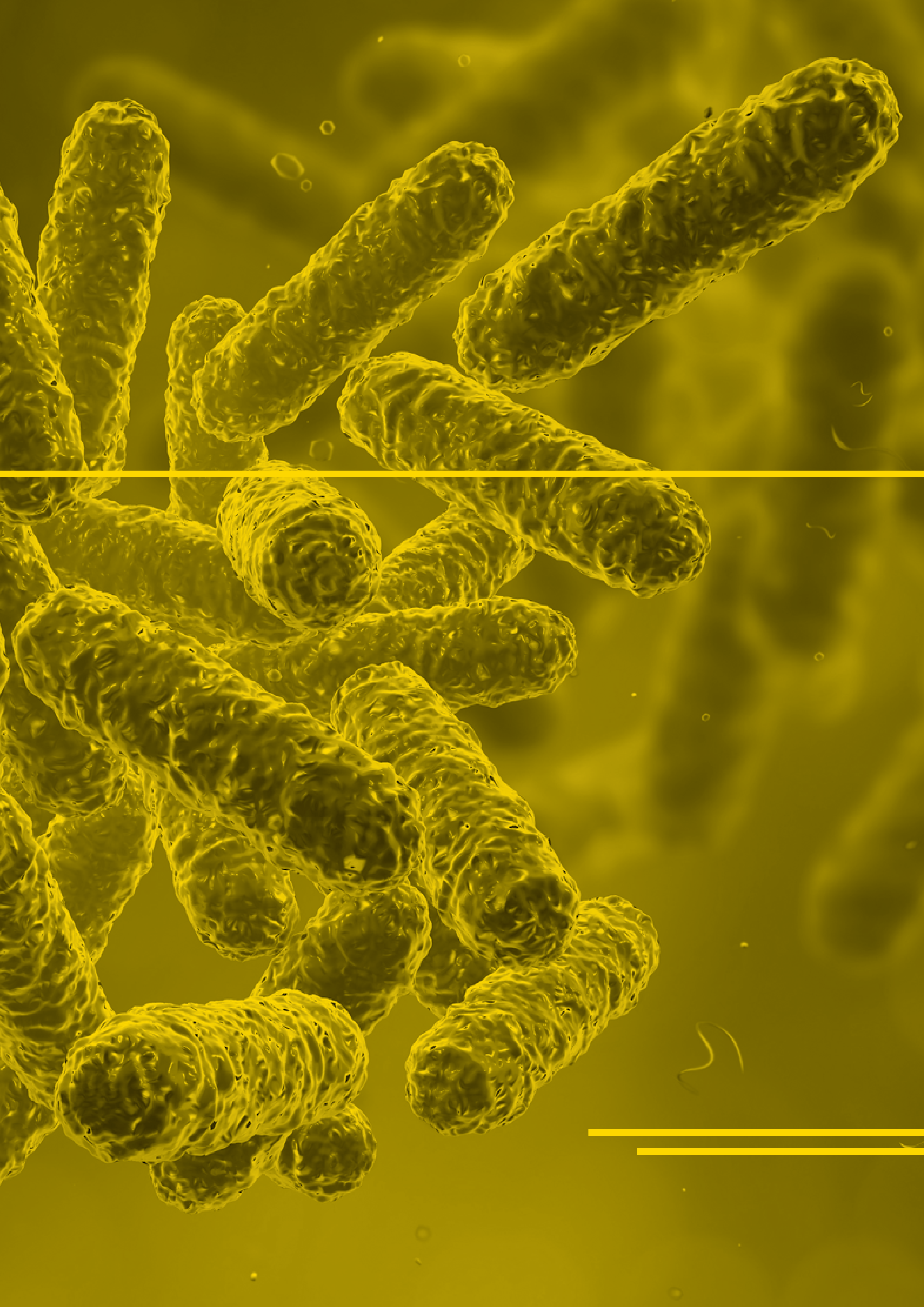

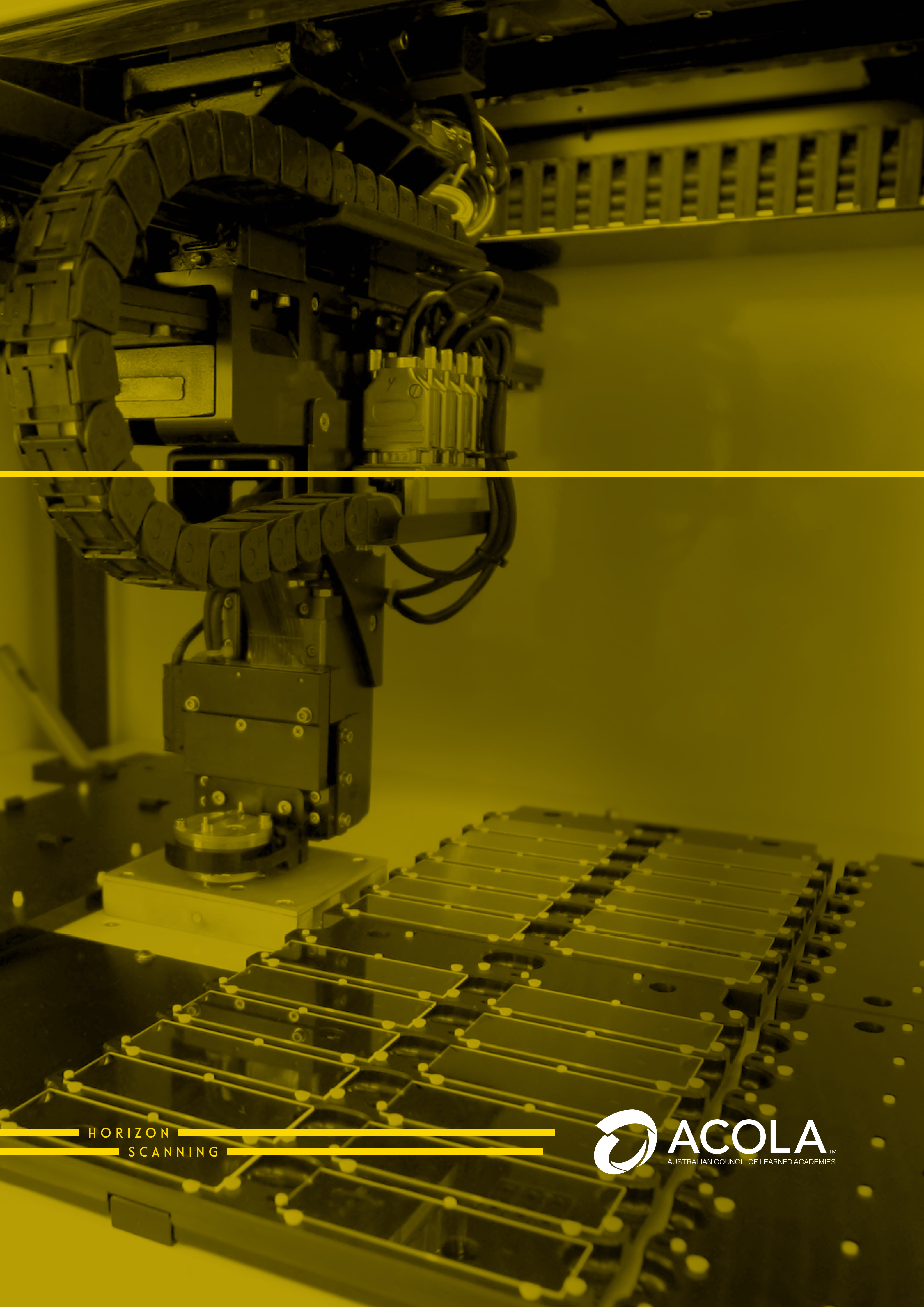

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