Australia's National
Science Agency

The future of biological management in Australia

Discussion paper

2025

Citation and authorship

CSIRO (2025) The future of biological management in Australia – Discussion paper. CSIRO, Canberra.

This report was authored by CSIRO Futures, with support from CSIRO's Ag2050 and Biosecurity teams.

CSIRO Futures

At CSIRO Futures we bring together science, technology, and economics to help governments and businesses develop transformative strategies that tackle their biggest challenges. As the strategic and economic advisory arm of Australia's national science agency, we are uniquely positioned to transform complexity into clarity, uncertainty into opportunity, and insights into action.

Accessibility

CSIRO is committed to providing web accessible content wherever possible. If you are having difficulties with accessing this document, please contact csiro.au/contact

Acknowledgement

CSIRO acknowledges the Traditional Owners of the land, sea, and waters, of the area that we live and work on across Australia. We acknowledge their continuing connection to their culture, and we pay our respects to their Elders past and present.

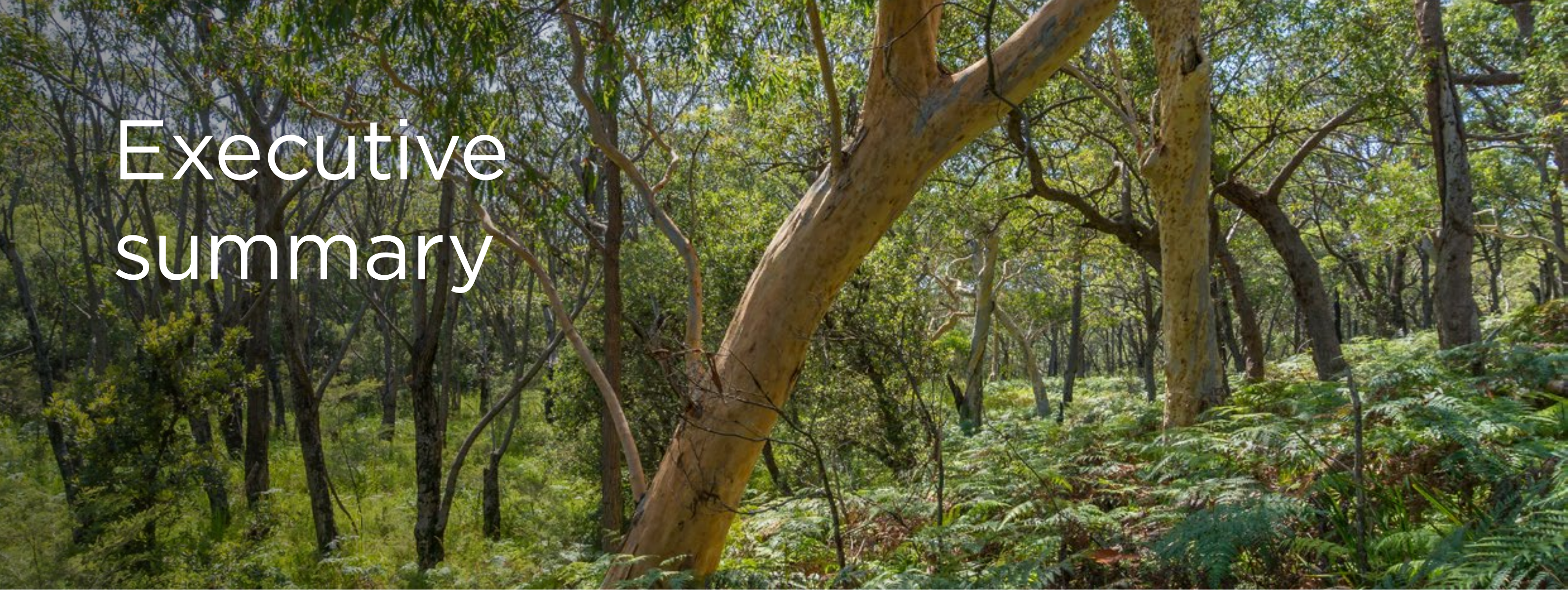
The authors are grateful to experts who generously gave their time to provide input to this project through consultations, reviews and feedback. We thank the scientists from CSIRO's Agriculture and Food Research Unit, Environment Research Unit, Health and Biosecurity Research Unit, Responsible Innovation Future Science Platform, and the Australian Centre for Disease Preparedness.

Copyright notice

Disclaimer

Contents

Executive summary



This discussion paper articulates the need for more sophisticated approaches to manage biological threats to Australia's agricultural industries and environment. It provides an overview of next generation approaches to biological management, cross-cutting challenges, and the national planning required to support the development and deployment of these approaches within the Australian context. The content of this paper was informed by desktop research and consultation with CSIRO scientists.

More sophisticated approaches to biological management will be critical to protect Australia's natural assets and support productive, resilient and sustainable industries.

Australia boasts strong agricultural and tourism industries worth a combined $150 billion annually. These industries are integral to both domestic and global markets. Biological management is imperative for safeguarding these industries and Australia's unique environmental assets from biological threats.

Traditional approaches to biological management, including the use of conventional pesticides, have been effective for Australia. However, there are several factors driving changes to the threats themselves, as well as the types of approaches deemed suitable for their management (Figure 1).

Figure 1: Factors driving the demand for different biological management approaches

Resistance development

Biological threats are increasingly developing resistance to pesticides (e.g., diamondback moth, silverleaf whitefly, fall armyworm, and multiple weeds).

Global climatic changes

Changing climates will alter biological threat relationships affecting factors such as pest geography, disease epidemiology and host resilience (e.g., warmer temperatures are expanding the geographic range of buffalo flies).

Environmental impacts

Drift of pesticides away from intended targets, the persistence of residues and potential off-target effects remain notable areas of environmental concern.

Trade policies and barriers

The European Union has prohibited the use and import of products grown with certain conventional chemical control methods.

Consumer demands

Australian consumer demand for organic food is growing at a rate of 20–30% per year, with consumers advocating for more sustainable biological management practices.

Technology driven productivity

Advancements in detection, analysis, modelling and deployment are accelerating the development and use of next-generation biological management approaches.

Next generation approaches are emerging that could offer solutions to the evolving needs of biological management.

Five next generation approaches were considered which leverage advancements in biochemistry, genomics, engineering biology and computational technologies to produce more targeted and effective outcomes. As noted in Figure 2, several of the approaches explored have technically and commercially mature examples globally; however, these often relate to a small number of target species and contexts of use and require further development for application within the Australian context. While suitable regulatory pathways exist in Australia for all five of the approaches assessed, only two had examples that had gone through the full approval process.

Each next generation approach was found to have wide applicability across different threats, sectors, and stages of biological management. Technologies like advanced bioinformatics, advanced deployment techniques and *ex vivo* models were found to be key enablers to the successful development and deployment of these approaches.

Figure 2: Snapshot of assessment ratings for next generation approaches (criteria definitions in Appendix 1)

	CRITERIA							
	Technology readiness level (max. global)	**Commercial readiness index (max. global)**	**Large-scale deployment (Australia)**	**Regulation (Australia)**	**Applicability**	**Sector**	**Stage**	**Example threats**
Biopesticides and biostimulants	9	6	< 5 years	Demonstrated	Diseases Pests (invertebrates) Weeds	Environment Horticulture	Exclusion Management Containment	• Green peach aphid • Powdery mildew • *Septoria tritici* blotch
Pheromones and behaviours modifiers	9	6	< 5 years	Demonstrated	Pests (invertebrates) Weeds	Forestry Horticulture Livestock	Management Containment Surveillance	• Diamondback moth • Fall armyworm • Parkinsonia
Gene silencing	9	6	5–15 years	Pathway exists	All threats	All sectors	Exclusion Management Containment	• Cotton bollworm • Fall armyworm • Myrtle rust fungus
Sex biasing systems	9	3	5–15 years	Pathway exists	Diseases (via vectors) Pests (all)	All sectors	Management Containment	• Fall armyworm • Mosquito species • Silver carp
Gene drives	5	1	By 2050	Pathway exists	All threats	All sectors	Exclusion Management Containment	• Invasive rodents • Mosquito species • European rabbit

Australia needs a clearer plan for the future of biological management.

While the need for more sophisticated approaches is already here, their development and large-scale deployment could be more than a decade away for some applications. These timelines are driven by several challenges, including the increased technical complexity of next generation approaches, limited large-scale production systems, low end-user and investor awareness and understanding, the need for enhanced monitoring and data sharing, and the need for more sustained funding.

There is an urgent need for Australia to have a clear plan for how next generation approaches will be sustainably invested in, tailored for the Australian context, and made accessible for those who need them. CSIRO considers this an activity of national importance and is seeking partners to support further analysis against the objectives and example research questions outlined below.

Objective 1: Support the case for investment in biological management

1. What is the value of biological management to Australia and what is the potential future value of next generation approaches?
2. What are well quantified examples of successful biological management in Australia?
3. How does Australia's investment in biological management compare to other countries?

Objective 2: Develop a 2050 vision and strategy for biological management in Australia

1. What is the maturity of next generation approaches across different contexts of use and applications that will be beneficial for biological management in Australia?
2. What might the use and combination of traditional and next generation approaches look like in 2050, and how does this differ from the current state?
3. Which next generation approaches are Australia best placed to focus on based on local threats and capability (e.g., research, development, commercialisation, production, and large-scale deployment)?

Objective 3: Develop priority actions to support a 2050 vision

1. What are the key technical barriers that could delay or prevent the development and adoption of next generation approaches in Australia?
2. What are the key non-technical and system-level barriers that could delay or prevent the development and adoption of next generation approaches in Australia?
3. What infrastructure and skill gaps exist that will be required to support the production, deployment and monitoring of next generation approaches in Australia?
4. How can regulators be supported to improve efficiency, adaptability, and coordination, while maintaining robust and independent oversight in a fast-changing technological and threat landscape?
5. How might industry, government, and other stakeholder groups (e.g., philanthropic organisations) prioritise and better align or complement their investments to support a 2050 vision and strategy?
6. What new business and collaboration models might help to ensure value is captured by all stakeholders along the development pathway of next generation approaches?

Glossary

TERM	DEFINITION
Biological agent	In the context of this report, biological agents are compounds of biological origin (RNA, proteins or metabolites) and organisms (including viruses) with or without genetic modification that can be used to alter the survival, interactions or impact of a biological threat.
Biological management	The controls, measures and approaches (including biological agents) used to manage the risk of biological threats entering, emerging, establishing or spreading in Australia.
Biological threat	Established and exotic diseases (including zoonotic diseases and disease vectors), pests (invertebrate and vertebrate), and weeds that pose a risk to Australia's agricultural industries, plants, animals, ecosystems and cultural heritage.
Commercial readiness index (CRI)	A measure of commercial maturity of a technology or product, indicating its readiness for commercial deployment and market launch, from hypothetical commercial proposition (CRI 1) to bankable asset class (CRI 6).[1]
Containment stage	The process of minimising, restricting or controlling the spread of a biological threat within a defined or limited area to prevent further spread. This also includes eradicating or permanently eliminating a biological threat from an area.
Established threat	A biological threat that occurs in Australia and cannot be eradicated. An established biological threat may be widely distributed across Australia or regionally distributed.
Exclusion stage	Preventing the introduction of an exotic biological threat that does not normally occur in Australia (or other defined area).
Exotic threat	A biological threat that is not currently known to be present in Australia, or if present, is subject to a nationally agreed eradication program.
Integrated management (IM)	A multidisciplinary biological management approach that considers the biological threat, affected species, and ecological context alongside environmental, economic and social aspects. This guides the combination of biological, chemical, physical and cultural interventions, from deployment of a biological agent and selective application of conventional compounds to the use of refuge areas.[2]
Management stage	Preventing or avoiding the spread of a biological threat once it has been introduced, often focusing on limiting the threat to tolerable levels within a population or area.
Surveillance stage	Activities to investigate the presence or prevalence of a pest or disease in a plant or animal population and its environment.
Technology readiness level (TRL)	A tool for tracking progress of a technology through the stages of its research and development, from fundamental early-stage research (TRL 1) to proven system launch and operations (TRL 9).[3]
Traditional biocontrol	Intentional introduction of a natural enemy (or several) usually from a geographically distant place. Traditional biocontrol includes classical, augmentative and conservation biological control.

1 Australian Renewable Energy Agency (2014) Commercial Readiness Index for Renewable Energy Sectors. Commonwealth of Australia, Canberra. <https://arena.gov.au/assets/2014/02/Commercial-Readiness-Index.pdf> (accessed 27 November 2024).

2 Food and Agriculture Organization of the United Nations (2024) Integrated Pest Management. <https://www.fao.org/pest-and-pesticide-management/ipm/integrated-pest-management/en/> (accessed 15 November 2024); Horne P, Page J (2008) Integrated Pest Management for Crops and Pastures. Landlinks Press, Melbourne.

3 Australian Renewable Energy Agency (2014) Technology readiness levels for renewable energy sectors. Commonwealth of Australia, Canberra. <https://arena.gov.au/assets/2014/02/Technology-Readiness-Levels.pdf> (accessed 27 November 2024).

Introduction

Biological management is critical for safeguarding Australia's agricultural and tourism industries, and unique environment, from biological threats.

Australia's rich and diverse natural environments are crucial to the nation's economic, social and cultural wellbeing. Australia's agricultural, fisheries and forestry industries provide over $100 billion in annual value and play an important role in international trade, with over 70% of produce exported.[4] Further, Australia's terrestrial, coastal and marine ecosystems are home to over 700,000 species of animals and plants (many of which are unique to the country) and supports tourism industries that generate $50 billion annually.[5] The environment also holds critical importance for the cultural heritage of Aboriginal and Torres Strait Islander peoples and is significant to the Australian way of life.

Established and exotic biological threats (diseases, pests and weeds) pose substantial economic, social and environmental risks to Australia (Figure 3). The cost of established biological threats in Australia exceeds $24 billion annually; 70% of this cost is attributable to agricultural damages and losses, and 30% to management expenses.[6] Additionally, private expenditure of Australian agricultural producers to control weeds is over $4.3 billion annually; approximately 10% of the total local value of production.[7]

Potential incursions from exotic biological threats pose further substantial risks to Australia. For example, a multi-state outbreak of foot and mouth disease could result in severe direct economic losses to the livestock and meat processing sector of around $80 billion over a ten-year period,[8] while the Khapra beetle (*Trogoderma granarium*) could cost Australia $15.5 billion over 20 years if it became established.[9] Biological threats also pose significant social and environmental costs, including eroding biodiversity and disrupting cultural practices, which are difficult to quantify in economic terms.[10]

4 ABARES (2024) Snapshot of Australia Agriculture. Australian Bureau of Agricultural and Resource Economics and Sciences. <https://www.agriculture.gov.au/abares/products/insights/snapshot-of-australian-agriculture> (accessed 19 November 2024).

5 ABS (2023) Australian National Accounts: Tourism Satellite Account. Australian Bureau of Statistics. <https://www.abs.gov.au/statistics/economy/national-accounts/australian-national-accounts-tourism-satellite-account/latest-release> (accessed 19 November 2024); Murphy H, van Leeuwen S (2021) Australia state of the environment 2021: biodiversity, independent report to the Australian Government Minister for the Environment. Commonwealth of Australia, Canberra. <https://soe.dcceew.gov.au/overview/environment/biodiversity> (accessed 19 November 2024).

6 Bradshaw et al. (2021) Detailed assessment of the reported economic costs of invasive species in Australia. NeoBiota 67, 511–550

7 Hafi et al. (2023) Cost of established pests animals and weeds to Australian agricultural producers. ABARES, Canberra. <https://www.agriculture.gov.au/abares/research-topics/biosecurity/biosecurity-economics/cost-of-established-pest-animals-and-weeds-to-australian-agricultural-producers> (accessed 10 December 2024).

8 DAFF (2022) National Biosecurity Strategy. Department of Agriculture, Fisheries and Forestry, Canberra. <https://www.biosecurity.gov.au/sites/default/files/2024-02/national-biosecurity-strategy.pdf> (accessed 10 December 2024).

9 DAFF (2023) About FMD and the risk. Australian Government Department of Agriculture, Fisheries and Forestry. <https://www.agriculture.gov.au/biosecurity-trade/pests-diseases-weeds/animal/fmd/aboutfmd#australias-response-policy-for-fmd> (accessed 19 November 2024).

10 Bradshaw et al. (2016) Massive yet grossly underestimated global costs of invasive insects. Nature Communications 7: e12986.

Figure 3: Examples of economic, social and environmental costs of biological threats to Australia

ECONOMIC COSTS	SOCIAL AND ENVIRONMENTAL COSTS
• Unchecked spread of red imported fire ants (*Solenopsis invicta*) has been predicted to cost $2 billion annually in agricultural losses, negative impacts on tourism and damage to infrastructure.[11] • European rabbits (*Oryctolagus cuniculus*) cause annual revenue losses of $114 million in sheep meat, wool and beef production, and $82 million in control expenses.[12] • Blackberry weeds (*Rubus fruticosus aggregate*), which form dense and impenetrable thickets, cost Australia $103 million annually in control and production losses.[13] • Annual rye grass (*Lolium rigidum*) costs Australia $34.1 million annually in agricultural losses.[14]	• Invasive species are a leading cause of biodiversity loss and are thought to impact 1,257 threatened native species.[15] • Decline in agricultural production due to biological threats can lead to disruptions in the food supply chain and food insecurity.[16] • Damage to the natural environment caused by biological threats discourages tourism and outdoor recreation.[17] • Some pests and zoonotic diseases also pose human health risks. For example, red imported fire ant bites can cause injury and death,[18] and Japanese encephalitis virus can cause serious illness and death.[19]

Biological threats, and the required biological management approaches, are evolving.

Traditional biocontrol approaches and conventional pesticides have been effective biological management strategies for Australia. However, there are several factors driving changes to the threats themselves, as well as the types of approaches deemed suitable for their management (Figure 4). These drivers include climate change, technology advancements, resistance development to chemical and biological control methods, and the environmental impacts of some traditional biocontrol approaches. Additionally, changing international trade and nature positive policies, alongside consumer demand, are pushing for more sustainable approaches to biological management.

Next generation approaches to biological management will be critical in protecting Australia's natural assets and supporting productive, resilient and sustainable industries over the next 25 years.

Together, the factors from Figure 4 are escalating risks to long-term productivity, resilience and sustainability for Australia. While the degree and pace at which these factors will influence biological management needs by 2050 is uncertain, scenario analysis has shown that investment and uptake in disruptive agritech will be key to positioning Australia for a sustainable and prosperous future.[20]

11 Scott-Orr H, Gruber M, Zacharin W (2021) National Red Imported Fire Ant Eradication Program Strategic Review August 2021. Queensland Department of Agriculture and Fisheries, Brisbane.

12 Hafi et al. (2023) Cost of established pests animals and weeds to Australian agricultural producers. ABARES, Canberra.

13 Invasive Plants and Animals Committee (2016) Australian Weeds Strategy 2017–2027. Commonwealth Department of Agriculture and Water Resources, Canberra.

14 CropLife Australia (2018) List of Herbicide Resistant Weeds in Australia. <https://www.croplife.org.au/wp-content/uploads/2017/06/2018-Herbicide-Resistant-Weeds.pdf> (accessed 19 November 2024).

15 Cresswell et al. (2021) Australia state of the environment 2021: overview. Commonwealth of Australia, Canberra. <https://soe.dcceew.gov.au/overview/outlook-and-impacts#impacts> (accessed 19 November 2024).

16 Rojas-Reyes J, Rivera-Cadavid L, Peña-Orozco DL (2024) Disruptions in the food supply chain: A literature review. Heliyon 10(14), e34730.

17 Bradbeer S, Zarah P (2022) Impacts of Aquatic Plant Invasions on Tourism and Recreation. In Tourism, Recreation and Biological Invasions. (Eds Barros et al.) 97–108. Centre for Agriculture and Bioscience International, UK.

18 Ngoc-Le M, Campbell R (2024) Red Imported Fire Ants and Queensland electorates. The Australia Institute, Canberra.

19 DoHAC (2023) Japanese Encephalitis. Australian Government Department of Health and Aged Care. <https://www.health.gov.au/diseases/japanese-encephalitis> (accessed 19 November 2024).

20 CSIRO (2024) Ag2050 Scenarios Report. Commonwealth Scientific and Industrial Research Organisation, Canberra.

Next generation approaches are emerging that leverage advancements in biochemistry, genomics, engineering biology and computational technologies to produce more targeted and effective outcomes. While the need for more sophisticated approaches is already here, their development and large-scale deployment may be more than a decade away for some applications due to the evolving complexity of biological threats and the large timelines and costs of developing novel biological agents.[21] Given this, there is an urgent need for Australia to have a clear plan for how next generation approaches will be sustainably invested in, tailored to the Australian context, and made accessible for those who need them.

To help frame these plans, this discussion paper examines the benefits and challenges of five next generation approaches for biological management and outlines strategically significant questions that require further analysis at the national level.

Figure 4: Factors driving the demand for different biological management approaches[22]

Resistance development

Biological threats are increasingly developing resistance to pesticides (e.g., diamondback moth, silverleaf whitefly, fall armyworm, and multiple weeds).

Global climatic changes

Changing climates will alter biological threat relationships affecting factors such as pest geography, disease epidemiology and host resilience (e.g., warmer temperatures are expanding the geographic range of buffalo flies).

Environmental impacts

Drift of pesticides away from intended targets, the persistence of residues and potential off-target effects remain notable areas of environmental concern.

Trade policies and barriers

The European Union has prohibited the use and import of products grown with certain conventional chemical control methods.

Consumer demands

Australian consumer demand for organic food is growing at a rate of 20–30% per year, with consumers advocating for more sustainable biological management practices.

Technology driven productivity

Advancements in detection, analysis, modelling and deployment are accelerating the development and use of next-generation biological management approaches.

21 AgbioInvestor (2022) Time and Cost to Develop a New GM Trait. <https://croplife.org/wp-content/uploads/2022/05/AgbioInvestor-Trait-RD-Branded-Report-Final-20220512.pdf > (accessed 19 November 2024); AgbioInvestor (2024) Time and Cost of New Agrochemical product Discovery, Development and Registration. <https://croplife.org/wp-content/uploads/2024/02/Time-and-Cost-To-Market-CP-2024.pdf> (accessed 18 November 2024).

22 GRDC (2016) A Status report on Insecticide Resistance in Australia. Australian Government Grains Research & Development Corporation; NSW Department of Primary Industries (2023) Climate Vulnerability Assessment: Buffalo fly factsheet. <https://www.dpi.nsw.gov.au/__data/assets/pdf_file/0011/1499834/Climate-Vulnerability-Assessment-Factsheet-Buffalo-fly.pdf> (accessed 10 December 2024); Miller GT (2004) Sustaining the Earth, 6th ed. Thompson Learning, California US; European Parliament (2024) Pesticides: No residues of EU-banned products in imported food. <https://www.europarl.europa.eu/news/en/press-room/20240917IPR24036/pesticides-no-residues-of-eu-banned-products-in-imported-food> (accessed 10 December 2024); BetterHealth (2024) Organic Food. Victorian Government Department of Health. <https://www.betterhealth.vic.gov.au/health/healthyliving/organic-food> (accessed 10 December 2024).

Next generation approaches

This section introduces five next generation approaches that are likely to be key to biological management in Australia by 2050 (Table 1). These summaries provide a preliminary analysis of the underlying technology and mechanisms of each approach, high-level benefits, examples of challenges that require additional work to support technical and commercial progress, and ratings against an assessment framework to help compare approaches (see Appendix 1). While there are areas of overlap between the approaches, the approach categories were selected for ease of communication with a diverse audience.

The indicative ratings and narrative produced in this discussion paper were informed by CSIRO scientists and desktop research, and as such should only be used to inform discussion. More comprehensive consultation and analysis, as outlined in Next steps, is required to support government and industry decision-making.

Table 1: Next generation approaches assessed in this discussion paper

APPROACH	DESCRIPTION
Biopesticides and biostimulants	Biopesticides (including biofungicides, bioinsecticides and bioherbicides) are biological compounds that can be used to supress diseases, pests and weeds, while biostimulants are biological compounds used to enhance plant growth and resilience. For example, by stimulating defence mechanisms.
Pheromones and behaviour modifiers	Pheromones and behaviour modifiers are chemical signals that trigger specific behaviours or physiological responses in certain organisms, such as attracting or repelling target organisms, disrupting mating processes or altering threat behaviours.
Gene silencing	Gene silencing techniques interrupt expression of functional genes to help suppress key disease and pest processes. Alternatively, target genes can be related to a host trait, with silencing providing resistance against a biological threat or improving an attribute of interest.
Sex biasing systems	Sex biasing systems encompass several technologies that can replace, decrease or favour one sex of a species, hindering reproduction and controlling population numbers (suppression strategy), or driving a specific trait into a population without reducing population numbers (replacement strategy).
Gene drives	Gene drives are genetic elements that leverage a self-spreading mechanism to increase the likelihood of passing a genetic element to offspring. This increases the prevalence of genetic elements (and any associated traits or effects) across a population, which can be relevant for suppression or modification of threat impacts.[23]

23 Alphey et al. (2020) Standardizing the definition of gene drive. Proceedings of the National Academy of Sciences 117, 30864.

Biopesticides and biostimulants

Max. TRL (Global)	Max. CRI (Global)	Large-scale deployment (Aus)	Regulation (Aus)	Applicability	Sector	Stage	Example threats
9	6	Feasible in 5 years or less	Demonstrated	Diseases Pests (invertebrates) Weeds	Environment Horticulture	Exclusion Management Containment	• Green peach aphid • Powdery mildew • *Septoria tritici* blotch

Description and applications

Biopesticides can be used to supress diseases, invertebrate pests and weeds, while biostimulants can be used to enhance plant pest and disease resilience by stimulating defence mechanisms. Biostimulants can also enhance plant growth, nutritional efficiency and climate tolerance; however, this discussion paper focuses on biostimulants in the context of biological management. These biological compounds contain active constituents or microbial populations to deliver these impacts. Biopesticides and biostimulants can be derived from, or be synthetic analogues of, naturally occurring biochemicals, natural products, minerals and microbes.

Biopesticides and biostimulants can be deployed on or surrounding biological targets at various biological management stages, but the specific stages will depend on the type of biological agent used and the target biological threat. For example, some biopesticides are preventative and valuable for exclusion but are ineffective once an infection has occurred, while others are most effective during management and containment stages against pests and diseases that are present.[24]

Biopesticides and biostimulants can range from being species-specific to being effective against multiple biological threats, and there are often synergies gained when using them together.[25] For example, the combination of chitosan (a biostimulant) and various biopesticides suppressed fungal populations more effectively than when used separately.[26] Biopesticides can also be used alongside conventional pesticides in an integrated management (IM) approach. IM approaches often promote rotating biopesticides and conventional pesticides to reduce overall pesticide load.[27] Biopesticides that exert multiple modes of action can reduce the development of resistance in diseases, invertebrate pests, and weeds making them ideal for long term sustainable biological management.[28]

24 Pilcher et al. (2023) Biopesticides for Crop Disease Management. Crop Protection Network, Iowa US.

25 Zulfiqar et al. (2024) Biostimulants: A sufficiently effective tool for sustainable agriculture in the era of climate change? Plant Physiology and Biochemistry 211, 108699.

26 DeGenring L, Peter L, Poleatewich A (2023) Integration of Chitosan and Biopesticides to Suppress Pre-Harvest Diseases of Apple. Horticulturae 10(12), 1242; Benhamou et al. (1998) Induction of resistance against Fusarium wilt of tomato by combination of chitosan with an endophytic bacterial strain: ultrastructure and cytochemistry of the host response. Planta 204, 153–168.

27 Koul O (2023) Chapter 1 – Biopesticides: commercial opportunities and challenges. In Development and Commercialization of Biopesticides. (Ed. Koul O). 1–23. Academic Press Publishing, Massachusetts US; Popp et al. (2013) Pesticide productivity and food security. Agronomy for Sustainable Development 33, 243–255.

28 Marrone PG (2010) Chapter 13 – Barriers to adoption of biological control agents and biological pesticides. In Integrated Pest Management. (Eds Radcliffe et al.) 163–178. Cambridge University Press, Cambridge UK.

Current state

Biopesticides and biostimulants are technologically and commercially mature next generation approaches (TRL 9; CRI 6). The use of biopesticides and biostimulants has been increasing as an alternative to conventional pesticides. The value of the global biopesticide market has increased from USD $4.5 billion in 2017 to USD $8.7 billion in 2022, and the compound annual growth rate during that time period was 14% compared to 4.5% for conventional pesticides.[29]

Select biopesticides and biostimulants are available in Australia, however the majority of these are produced overseas.[30] Commercially mature products developed internationally could be deployed at large-scale in Australia within 5 years or less, but there is a lack of products tailored to the Australian context. Currently *Bacillus thuringiensis* products make up over 90% of the commercially available biopesticides in Australia.[31]

Development considerations

The development of novel biopesticides and biostimulants will vary, but commercial scale up is estimated to be between 5 and 15 years.[32] For example, HayRite, a microbial pesticide that stops fungal growth on hay, took 14 years to develop and commercialise in Australia.[33]

Regulation

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the primary regulatory body responsible for the regulation of biopesticides and biostimulants. Biological-derived products including microbial products undergo additional and different data requirements compared to conventional pesticides. Genetically modified microbial products require additional approval from the Office of the Gene Technology Regulator (OGTR).[34] Biosecurity regulations in Australia restrict the import of biological agents from overseas and require approval from the Department of Agriculture, Fisheries and Forestry (DAFF).[35]

Few biostimulants in Australia are marketed for biological management; rather they are often marketed as plant growth promoters or soil conditioners, which do not require APVMA registration.[36] For example, Kodiak, which contains the active ingredient *Bacillus subtilis GBO3*, is sold as a biological fungicide in the United States (US) but in Australia is sold as a microbial inoculant under the product name Companion.[37]

29 Chen J (2018) Biopesticides: Global Markets to 2022. Report code: CHM029G. BCC Research, Boston US.

30 Dart P, Shao Z, Schenk PM (2023) Chapter 16 – Biopesticides: commercialization in Australia: potential and challenges. In Development and Commercialization of Biopesticides. (Ed. Koul O). 345–374. Academic Press Publishing, Massachusetts US.

31 Dart P, Shao Z, Schenk PM (2023) Chapter 16 – Biopesticides: commercialization in Australia: potential and challenges. In Development and Commercialization of Biopesticides. (Ed. Koul O). 345–374. Academic Press Publishing, Massachusetts US; Ragasruthi et al. (2021) Bacillus thuringiensis biopesticide: Navigating success, challenges, and future horizons in sustainable pest control. Science of the Total Environment 954(1), 176594.

32 Douthwaite B, Langewald J, Harris, J (2001) Development and commercialization of the Green Muscle biopesticide. International Institute of Tropical Agriculture, Nigeria.

33 Brown S, Dart P (2005) Testing hay treated with mould inhibiting, biocontrol inoculum. Australian Government Rural Industries Research and Development Corporation, Publication No. 05/103, Canberra.

34 APVMA (2024) Guideline for the regulation of biological agricultural products. Australian Pesticides and Veterinary Medicines Authority, Canberra. <https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/biological> (accessed 27 November 2024).

35 CropLife Australia (2021) The official Australian reference guide for organic, synthetic and biological pesticides. <https://www.croplife.org.au/wp-content/uploads/2021/03/The-Official-Australian-Reference-Guide-to-Pesticides.pdf> (accessed 25 November 2025).

36 Dart P, Shao Z, Schenk PM (2023) Chapter 16 – Biopesticides: commercialization in Australia: potential and challenges. In Development and Commercialization of Biopesticides. (Ed. Koul O). 345–374. Academic Press Publishing, Massachusetts US.

37 Dart P, Shao Z, Schenk PM (2023) Chapter 16 – Biopesticides: commercialization in Australia: potential and challenges. In Development and Commercialization of Biopesticides. (Ed. Koul O). 345–374. Academic Press Publishing, Massachusetts US.

Challenges

Stability: Climate variables such as temperature, UV radiation and humidity affect the stability of biopesticides and biostimulants, highlighting the necessity for field trials across different agroecological regions and seasons. Further, microbial products generally demonstrate less stability than conventional pesticides and other biopesticides, meaning they require specific storage conditions and delivery innovations.[38]

Application costs: Currently, the use of biopesticides is more costly than conventional pesticides. This higher cost is largely due to the small-scale production of biopesticides, which limits their availability and increases their price.[39] Manufacturing biopesticides also requires dedicated infrastructure. For example, producing microbial biopesticides requires large fermentation facilities.

End use adoption barriers: Biopesticides often need to be integrated with other technologies to maximise biological management.[40] Consulted stakeholders expressed that more educational initiatives targeted at end-users are needed to raise awareness, help with the development and deployment of biopesticides, and integrate them into existing and IM approaches.

CASE STUDY 1: A microbial pesticide that targets the Queensland fruit fly

The Queensland fruit fly (*Bactrocera tryoni*) is Australia's primary fruit fly pest and damages a wide variety of fruit and vegetable crops by laying eggs inside the produce.[41] At present, control measures are aimed at adult stages in the fly, with no measures available to target larvae once they exit the fruit and pupate in soil.

Research funded by Agriculture Victoria is investigating the potential use of a microbial biopesticide that has been shown to achieve an average mortality rate of 93% in laboratory tests of larvae populations.[42] The fungal-based biopesticide is highly specific to the Queensland fruit fly and offers little to no environmental toxicity. Since this biopesticide consists of living microorganisms, current research is focused on developing an appropriate formulation before it can undergo regulation and commercialisation.

38 Thakur et al. (2020) Chapter 15 – Microbial pesticides: Current status and advancement for sustainable agriculture and environment. In New and Future Developments in Microbial Biotechnology and Bioengineering. (Eds Rastegari et al.) 242–282. Elsevier Publishing, Amsterdam, Netherlands.

39 Koul O (2023) Chapter 1 – Biopesticides: commercial opportunities and challenges. In Development and Commercialization of Biopesticides. (Ed. Koul O). 1–23. Academic Press Publishing, Massachusetts US; Singh et al. (2024) Chapter 13 – Alternatives to chemical pesticides: Current trends and future implications. In Pesticides in the Environment. (Eds Sharma et al.) 307–334. Elsevier Publishing, Amsterdam, Netherlands.

40 Baker et al. (2020) Biological control and integrated pest management in organic and conventional systems. Biological Control 140, 104095; Fenibo et al. (2022) The Potential and Green Chemistry Attributes of Biopesticides. Sustainability 14(21), 14441.

41 Zamek et al. (2021) Parasitoids of Queensland Fruit Fly Bactrocera tryoni in Australia and Prospects for Improved Biological Control. Insects 3(4), 1056–1083.

42 Prince et al. (2024) Metarhizium spp. isolates effective against Queensland fruit fly juvenile life stages in soil. Public Library of Science One 19(1), e0297341.

Pheromones and behaviour modifiers

Max. TRL (Global)	Max. CRI (Global)	Large-scale deployment (Aus)	Regulation (Aus)	Applicability	Sector	Stage	Example threats
9	6	Feasible in 5 years or less	Demonstrated	Pests (invertebrates) Weeds	Forestry Horticulture Livestock	Management Containment Surveillance	• Diamondback moth • Fall armyworm • Parkinsonia

Description and application

Pheromones and behaviour modifiers are chemical signals that trigger specific behaviours or physiological responses, such as attracting or repelling target organisms, disrupting mating processes or altering threat behaviours. These approaches are used across horticulture, livestock and forestry sectors to manage pests and weeds. Pheromones and behaviour modifiers can be released as sprays that overwhelm and disorient pests, as bait in traps to capture pests, or to attract beneficial insects to eat target weeds.[43]

Pheromones and behaviour modifiers are an important component of IM and can reduce or replace the use of conventional pesticides and insecticides. They can also be used alongside conventional pesticides and other next generation approaches.[44] Using pheromones to bait and subsequently monitor pest populations greatly improves the timing of insecticide application and can lower overall conventional pesticides use.[45] Further, pheromones and insecticides can be used in traps to attract and kill insect pests simultaneously. The use of pheromones and insecticide together ensures a more targeted application of insecticide, thereby reducing the risk of off-target effects and environmental contamination.[46]

Pheromones and behaviour modifiers have low environmental risks and are a sustainable solution for long term pest and weed management. Pheromones typically have high species-specificity,[47] which reduces and minimises the impact on non-target organisms and the environment. Pheromones are also effective in small amounts and do not persist in the environment, which allows for their deployment close to crop harvesting without concerns they will enter the food supply.[48] Additionally, since pheromones and behaviour modifiers mimic natural communication, pests are unlikely to develop resistance.[49]

Current state

Pheromones and behaviour modifiers are technologically and commercially mature in international markets (TRL 9; CRI 6). The approach is currently most mature for invertebrate pests. Australian producers can purchase and use international pheromone and behaviour modifier products that have been registered with the APVMA. Large-scale deployment of pheromones and behaviour modifiers are feasible in Australia within 5 years or less, however, currently available products are limited and are concentrated towards agricultural invertebrate pests and weeds that have global commercial value.

Development considerations

Since the development and use of pheromones and behaviour modifiers are geared for species-specificity, research of pheromones and behaviour modifiers for one species does not typically lend itself to development for another species. Deep behavioural research is necessary for individual organisms. Australian-specific research is particularly important as pest species in different geographies may not respond to the same pheromones. For example, bark beetle populations (*Ips pini*) and fall armyworm populations (*Spodoptera frugiperda*) from different geographic regions exhibit varying responses to the same pheromones.[50]

43 Gaffke et al. (2021) Using Chemical Ecology to Enhance Weed Biological Control. Insects 12(8), 695; Larsson MC (2016) Pheromones and Other Semiochemicals for Monitoring Rare and Endangered Species. Journal of Chemical Ecology 42, 853–868.

44 Gaffke et al. (2021) Using Chemical Ecology to Enhance Weed Biological Control. Insects 12(8), 695.

45 Mishra et al. (2020) Insect Pheromones and Its Applications in Management of Pest Population. In Natural Materials and Products from Insects. (Eds Kumar D, Shahid M) 121–136. Springer Publishing, Cham, Switzerland.

46 Reddy GVP, Guerrero A (2010) New Pheromones and Insect Control Strategies. Vitamins & Hormones 83, 493–519.

47 Brennan PA, Zufall F (2006) Pheromonal communication in vertebrates. Nature 444, 308–315; Yew JY, Chung H (2015) Insect pheromones: An overview of function, form, and discovery. Progress in Lipid Research 59, 88.

48 Emden HF, Service MW (2004) Pheromones. In Pest and Vector Control. 204–214. Cambridge University Press, Cambridge UK.

49 Fernández et al. (2022) Insect pest management in the age of synthetic biology. Plant Biotechnology Journal 21(1) 25–36; Rizvi et al. (2021) Latest Developments in Insect Sex Pheromone Research and Its Application in Agricultural Pest Management 12(6) 484.

50 Akinbuluma et al. (2024) Region-Specific Variation in the Electrophysiological Responses of Spodoptera frugiperda to Synthetic Sex Pheromone Compounds. Journal of Chemical Ecology 50(11), 631–642; Emden HF, Service MW (2004) Pheromones. In Pest and Vector Control. 204–214. Cambridge University Press, Cambridge UK.

Regulation

Pheromones and behaviour modifiers have demonstrated regulatory pathways in Australia under the APVMA.[51] Pheromones and behaviour modifiers imported into Australia also require permits from DAFF.[52]

Challenges

Development costs: Synthesising an effective pheromone or behaviour modifier requires iterative testing and can be costly.[53] The development of pheromones and behaviour modifiers is complex and needs to be optimised to suit location, season and species. Formulation effectiveness is also dependent on the chemical and isomeric ratios, as well as time and rate of release.

Replacement costs: Pheromones and behaviour modifiers are short-lived and need to be replaced periodically, which can be labour intensive and increase the overall cost of pest management.[54]

Domestic capacity: There is a limited domestic capacity and expertise for researching, producing and commercialising pheromones.[55] Significant investments need to be made to ensure the development and widespread adoption of Australian-relevant pheromones and behaviour modifiers as biological management approaches.

CASE STUDY 2: Using pheromone traps to monitor fall armyworm populations

The fall armyworm (*Spodoptera frugiperda*) is estimated to cost $14–39 million in Western Australia alone due to the damage and significant crop losses on maize, sweet corn and sorghum.[56] This exotic pest was first detected in Australia between January and February 2020 but is now considered established across Queensland, the Northern Territory, New South Wales and Western Australia, as eradication has been deemed unfeasible.[57]

Insecticides are currently the first line of defence for biological management, however, fall armyworm populations are already showing signs of resistance to many groups of pesticides. While assessments of pheromone lure efficacies in Australian agricultural settings are ongoing, state-run initiatives in Queensland, New South Wales and Western Australia have deployed several pheromone traps to monitor fall armyworm populations that are helping to inform crop planting strategies.[58] Their insights have informed the planting of crops earlier in the season, which has reduced fall armyworm damage with significant positive outcomes.[59]

51 APVMA (2024) Guideline for the regulation of biological agricultural products. Australian Pesticides and Veterinary Medicines Authority. <https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/biological> (accessed 25 November 2024)

52 DAFF (2024) Biological control agents. Australian Government Department of Agriculture, Fisheries and Forestry, Canberra. <https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis/biological-control-agents> (accessed 25 November 2024.)

53 Villarreal et al. (2023) Chapter 3 – Development and commercialization of pheromone-based biopesticides: a global perspective. In Development and Commercialization of Biopesticides. (Ed. Koul O). 37–56. Academic Press Publishing, Massachusetts US.

54 Alam et al. (2023) Emerging trends in insect sex pheromones and traps for sustainable management of key agricultural pests in Asia: beyond insecticides—a comprehensive review. International Journal of Tropical Insect Science 43, 1867–1882.

55 Begum et al. (2017) Development of Australian commercial producers of invertebrate biological control agents. Biocontrol 62, 525–533.

56 Cook et al. (2021) What will Fall Armyworm Cost Western Australian Agriculture? Journal of Economic Entomology 114(4), 1613–1621.

57 Plant Health Australia (2020) Fall Armyworm Continuity Plan for the Australian Grains Industry, Version 1 (November 2020). <https://grainsbiosecurity.com.au/app/uploads/2021/02/Fall-Armworm-Continuity-Plan-2.pdf> (accessed 25 November 2024)

58 Grains Research & Development Corporation (2023) Fall armyworm: impact by crop, management strategy and resistance. <https://grdc.com.au/resources-and-publications/grdc-update-papers/tab-content/grdc-update-papers/2023/03/fall-armyworm-iimpact-by-crop-management-strategy-and-resistance> (accessed 27 November); New South Wales Local Land services (2021) Fall Armyworm update. <https://www.lls.nsw.gov.au/regions/riverina/articles,-plans-and-publications/fall-armyworm-update-in-nsw-oct-2021> (accessed 17 November 2024); Western Australia Department of Primary Industries and Regional Development (2024) Fall armyworm in Western Australia. <https://www.agric.wa.gov.au/fall-armyworm-western-australia?page=0%2C1> (accessed 27 November 2024).

59 GRDC (2023) Fall armyworm: impact by crop, management strategy and resistance. Australian Government Grains Research and Development Corporation, Canberra. <https://grdc.com.au/resources-and-publications/grdc-update-papers/tab-content/grdc-update-papers/2023/03/fall-armyworm-iimpact-by-crop-management-strategy-and-resistance> (accessed 10 December 2024).

Gene silencing

Max. TRL (Global)	Max. CRI (Global)	Large-scale deployment (Aus)	Regulation (Aus)	Applicability	Sector	Stage	Example threats
9	6	Feasible in 5–15 years	Pathway exists	All threats	All sectors	Exclusion Management Containment	• Cotton bollworm • Fall armyworm • Myrtle rust fungus

Description and application

Gene silencing helps suppress key processes in a biological threat by interrupting gene expression. This approach can also be applied to host traits, with silencing providing resistance against a pest or disease (e.g., by inactivating a component or pathway that influences host susceptibility) or improving an attribute of interest (e.g., tolerance to an environmental condition). Traditionally, gene silencing is associated with RNA interference (RNAi);[60] however, it can also involve using CRISPR-Cas editing to impede a downstream process or introduce a sequence change.[61]

Gene silencing approaches can be deployed in two ways. The first is integrating nucleotide sequences (and any necessary proteins) via genetic modification into the organism of interest, resulting in their endogenous production. The second is external application and delivery of the sequence without the need for genetic modification (e.g., through feeding, spraying or injection of a carrier compound or a viral vector).[62]

Gene silencing relies on customisable sequences that target a particular gene and have limited persistence in the environment, making the technology highly specific and adaptable. Its underlying mechanisms can also be used for all threat types and sectors, and most stages of biological management. However, efficacy varies by species, development stage and deployment method.[63]

Gene silencing can be used alongside or in combination with conventional pesticides or herbicides, traditional biocontrol and next generation approaches to enable complementary strategies. For example, it can be used to target traits related to pesticide or herbicide resistance in a target species, or otherwise increase the susceptibility of the target to a conventional chemical compound. This approach can also be used alongside selective breeding and conventional genetic modification to introduce traits that confer resistance against a pest or disease. Combining gene silencing with other biological management approaches can help to simultaneously achieve protection against multiple species, which is a key practical consideration for end-users.

Current state

Gene silencing is technologically and commercially mature in select applications (TRL 9; CRI 6), with the overall field still scaling up. RNAi (both endogenous production and external delivery) is already used across multiple plant species to modify traits of interest for improved crop production and for protection against invertebrate pests. In 2023 the US Environmental Protection Agency registered the world's first spray-based RNAi product (Ledprona) which silences an essential gene in the Colorado potato beetle (*Leptinotarsa decemlineata*).[64] In Australia, the OGTR has approved products that use gene silencing for crop improvement,[65] with product applications for biological management not yet approved.

60 Zotti et al. (2018) RNA interference technology in crop protection against arthropod pests, pathogens and nematodes. Pest Management Science 74, 1239.

61 Simon SA, Meyers BC (2011) Small RNA-mediated epigenetic modifications in plants. Current Opinion in Plant Biology 14, 148; Wang JY, Doudna JA (2023) CRISPR technology: A decade of genome editing is only the beginning. Science 379.

62 These two methods are sometimes referred to as host-induced gene silencing (HIGS) and spray-induced gene silencing (SIGS), respectively. Christiaens et al. (2020) Double-Stranded RNA Technology to Control Insect Pests: Current Status and Challenges. Frontiers in Plant Science 11.

63 Deployment via external production and delivery may be more compatible with the management and containment stages, given the need for repeated applications. Cooper et al. (2019) Molecular mechanisms influencing efficiency of RNA interference in insects. Pest Management Science 75, 18.

64 EPA (2023) EPA Registers Novel Pesticide Technology for Potato Crops. United States Environmental Protection Agency. <https://www.epa.gov/pesticides/epa-registers-novel-pesticide-technology-potato-crops> (accessed 18 November 2024).

65 Wood et al. (2018) Seed- specific RNAi in safflower generates a superhigh oleic oil with extended oxidative stability. Plant Biotechnology Journal 16, 1788; OGTR (2018) DIR 158 Commercial release of safflower genetically modified for high oleic acid composition. Australian Government Department of Health and Aged Care, Office of the Gene Technology Regulator. <https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-158> (accessed 18 November 2024); Alsop E (2022) Demand for SHO safflower looks bright. Grain Central. <https://www.graincentral.com/cropping/demand-for-sho-safflower-looks-bright/> (accessed 18 November 2024).

Gene silencing via CRISPR-Cas editing is similarly advanced, with specific plant and animal applications focused on improving economically relevant traits approved for commercial use in countries like Japan and the US.[66]

The current availability of commercial products that use gene silencing, both domestically and internationally, suggests that this approach could be deployed at scale for biological management in Australia within 5–15 years. Some of the key factors determining the overall timeline will be the pace at which products are tailored for Australian threats, submitted and approved for use by Australian regulators, and reach cost-competitive production at scale.

Development considerations

Existing products that involve gene silencing could be imported into Australia and deployed once approved for use by local regulators. However, the high species-specificity of gene silencing means that new products will often have to be developed for the Australian context. Spray-based applications that do not involve genetic modification face similar development pathways to those of chemical active ingredients, albeit with potentially shorter development and regulatory timelines according to consulted stakeholders. A survey of agrochemical companies on the cost of developing new chemical active ingredients reported a mean cost of USD 301 million from discovery to registration, with a lead time of 12.3 years from initial synthesis to first sale.[67] Deploying novel varieties that continuously produce the gene silencing agent (RNA or CRISPR-Cas) or rely on the permanent disruption of a gene, requires genetic modification. In that context, gene silencing is closer to the development costs of genetically modified organisms. As a baseline reference, a 2022 survey of agrochemical companies reported that the mean cost of developing a new genetic trait in plants (from discovery to regulatory approval) was USD 115 million, with a mean time of 16.5 years.[68]

After development and approval, costs are predominantly driven by production and use. Synthesis of dsRNA (for RNAi gene silencing via external delivery) has historically been more expensive than production of traditional chemical compounds, but some companies have reportedly reached competitive levels under production at scale (USD 0.5–1 per gram).[69]

Regulation

Gene silencing approaches are regulated in Australia, but specific pathways and requirements can vary. An external RNA sequence that is not translated, does not produce an infectious agent, and does not involve genetic modification is not considered a gene technology. This would be regulated as an agricultural chemical product by the APVMA, albeit with potentially different data requirements compared to a conventional pesticide. This is the case for spray-based products applied topically for pest management. Gene silencing applications that do not meet these conditions are additionally regulated by the OGTR.[70]

---

66 Pairwise (2023) Pairwise Introduces Conscious™ Greens into U.S. Restaurants. News. <https://www.pairwise.com/news/pairwise-introduces-conscious-greens-into-u.s.-restaurants> (accessed 27 November 2024); Kishimoto et al. (2018) Production of a breed of red sea bream Pagrus major with an increase of skeletal muscle mass and reduced body length by genome editing with CRISPR/Cas9. Aquaculture 495; Nature Biotechnology (2022) Japan embraces CRISPR-edited fish. 40, 10.

67 The survey included responses from 5 companies that are part of CropLife International and considered new active ingredients over the 2014–2019 period. AgbioInvestor (2024) Time and Cost of New Agrochemical product Discovery, Development and Registration. A study on Behalf of Crop Life International. <https://croplife.org/wp-content/uploads/2024/02/Time-and-Cost-To-Market-CP-2024.pdf> (accessed 18 November 2024).

68 The survey included responses from 4 companies that are part of CropLife International and considered traits introduced over the 2017–2022 period. AgbioInvestor (2022) Time and Cost to Develop a New GM Trait. A study on Behalf of Crop Life International. <https://croplife.org/wp-content/uploads/2022/05/AgbioInvestor-Trait-RD-Branded-Report-Final-20220512.pdf > (accessed 19 November 2024).

69 Rank AP, Koch A (2021) Lab-to-Field Transition of RNA Spray Applications – How Far Are We? Frontiers in Plant Science 12; Stokstad E (2024) The perfect pesticide? RNA kills crop-destroying beetles with unprecedented accuracy. Science (1979) 384, 1398.

70 Fletcher et al. (2020) A Perspective on RNAi-Based Biopesticides. Frontiers in Plant Science 11; Menezes et al. (2022) RNAi-Based Biocontrol of Pests to Improve the Productivity and Welfare of Livestock Production. Applied Biosciences 1, 229.

Challenges

Variable efficacy: Efficacy can be affected by the stability of the gene silencing agent, delivery method, and the genetic background and intrinsic susceptibility of the species (from degrading enzyme activity to physiological conditions).[71]

Degradation: Applications based on external delivery face fast degradation in the environment, which may limit the duration of impact if a product is applied on its own.[72] However, this also means the product will have limited persistence in the environment.

Resistance: Organisms can develop resistance to gene silencing approaches, just like traditional chemicals and traits derived from genetic modification.[73]

Potential for off-target activity: Gene silencing can attract environmental and social concerns, specifically on the potential for off-target effects.[74] While the use of bioinformatic prediction and experimental assessment can minimise off-target effects,[75] greater engagement with stakeholders will be critical in ensuring social acceptability.

Economic implications of consumer perceptions: Perception of gene silencing use in food products is aligned to broader attitudes towards biotechnology related interventions. For instance, two studies on purchasing attitudes found that consumers could require a price discount for food items produced using RNAi, as compared to conventionally produced items. However, the magnitude of the discount was lower than the one required for beef produced using antibiotics and for rice genetically modifiedfor pest resistance.[76]

CASE STUDY 3: A gene silencing approach to myrtle rust fungus in Australia

The myrtle rust fungus (*Austropuccinia psidii*) poses significant risk to one of the largest plant families in Australia, which includes species of environmental, cultural and economic significance (e.g., eucalyptus, lemon myrtle and other native forest species). At least 15 Australian rainforest tree species are considered at risk of extinction in the wild due to myrtle rust fungus, and multiple additional species are at risk of infection.[77]

Researchers from the University of Queensland and the Queensland Department of Agriculture and Fisheries have successfully trialled the use of an RNAi intervention to prevent and treat infections by the myrtle rust fungus in glasshouse conditions. The use of a targeted dsRNA delivered by spray avoids the use of conventional fungicides that have limited efficacy and potential off-target effects in other organisms.[78] This application highlights the potential for gene silencing in Australian forestry and environmental applications, protecting commercial crops, supporting threatened populations in the wild, and managing incursions from other highly pathogenic rust fungi.

71 Cooper et al. (2019) Molecular mechanisms influencing efficiency of RNA interference in insects. Pest Management Science 75, 18.

72 Bachman et al. (2020) Environmental Fate and Dissipation of Applied dsRNA in Soil, Aquatic Systems, and Plants. Frontiers in Plant Science 11.

73 Mishra et al. (2021) Selection for high levels of resistance to double-stranded RNA (dsRNA) in Colorado potato beetle (Leptinotarsa decemlineata Say) using non-transgenic foliar delivery. Scientific Reports 11, 6523.

74 Svoboda P (2020) Key Mechanistic Principles and Considerations Concerning RNA Interference. Frontiers in Plant Science 11.

75 Fletcher et al. (2020) A Perspective on RNAi-Based Biopesticides. Frontiers in Plant Science 11; Sturme et al. (2022) Occurrence and Nature of Off-Target Modifications by CRISPR-Cas Genome Editing in Plants. ACS Agricultural Science & Technology 2, 192.

76 Grant et al. (n.d.) Consumer Responses to the Use of NBTs in the Production of Food: A Systematic Literature Review. Australian National University. <https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/NBT%20Literature%20Review.pdf> (accessed 18 November 2024); Britton LL, Tonsor GT (2019) Consumers' willingness to pay for beef products derived from RNA interference technology. Food Quality and Preference 75, 187; Shew et al. (2017) New innovations in agricultural biotech: Consumer acceptance of topical RNAi in rice production. Food Control 81, 189.

77 DCCEEW (2024) Myrtle rust (Austropuccinia psidii). Australian Government Department of Climate Change, Energy, the Environment and Water – Diseases, Fungi and parasites in Australia. <https://www.dcceew.gov.au/environment/invasive-species/diseases-fungi-and-parasites/myrtle-rust> (accessed 18 November 2024).

78 Degnan et al. (2023) Double-stranded RNA prevents and cures infection by rust fungi. Communications Biology 6, 1234.

Sex biasing systems

Max. TRL (Global)	Max. CRI (Global)	Large-scale deployment (Aus)	Regulation (Aus)	Applicability	Sector	Stage	Example threats
9	3	Feasible in 5–15 years	Pathway exists	Diseases (via vectors) Pests (all)	All sectors	Management Containment	• Fall armyworm • Mosquito species • Silver carp

Description and application

Sex biasing systems encompass several technologies that can replace, decrease or favour one sex of a species, with the aim of hindering reproduction and controlling population numbers (suppression strategy), or driving a specific trait into a population without reducing population numbers (replacement strategy).

Sex biasing systems can be categorised into genetically modified and non-genetically modified controls. Genetically modified controls include introducing genetic material from another species, gene drives and some forms of RNAi-based gene silencing. Gene drives can have other applications beyond sex biasing and are discussed further in the Gene drives analysis. These methods can be applied to any organism, but to date have been demonstrated in invertebrates, lower vertebrates and select mammals with simple sex differentiation pathways.

Non-genetically modified controls include bacterial, hormonal and thermal treatments. These methods are only applicable to certain species. For example, the *Wolbachia* bacteria that prevents mating in mosquitoes only affect insects.[79] Similarly, thermal and hormonal treatments are limited to ectothermic vertebrates in which their sex determination can be affected by environmental variables.[80]

Sex biasing systems can be used in place of the conventional sterile insect technique,[81] which uses irradiation to induce chromosomal damage and produce sterile males. Irradiation-induced damage can reduce overall fitness and mating competitiveness in sterile males, so the use of genetically modified controls that precisely target fertility genes without compromising overall fitness can be more effective.[82]

Next generation sex biasing systems are more cost effective than conventional methods, especially when coupled with gene drives that can autonomously propagate through a population without the need for ongoing additional releases.[83] Non-genetically modified sex biasing approaches will generally require more frequent application or release of the technology.[84]

79 Iturbe–Ormaetxe et al. (2011) Wolbachia and the biological control of mosquito-borne disease. Embo Reports 12(6) 508–518.

80 Bhattacharyya et al. (2020) Using YY supermales to destabilize invasive fish populations. Theoretical Population Biology 134, 1–14.

81 DAFF (2023) Sterile Insect Technique use in Australia. Australia Government Department of Agriculture, Fisheries and Forestry, Canberra. <https://www.agriculture.gov.au/biosecurity-trade/pests-diseases-weeds/fruit-flies-australia/management/sterile-insect-technique> (accessed 10 December 2024).

82 Kandul et al. (2019) Transforming insect population control with precision guided sterile males with demonstration in flies. Nature Communication 10(84).

83 Faber et al. (2021) Novel combination of CRISPR-based gene drives eliminates resistance and localises spread. Scientific Reports 11, 3719.

84 Teem et al. (2020) Genetic Biocontrol for Invasive Species. Frontiers in Bioengineering and Biotechnology 8, 452.

Current state

Sex biasing systems in the context of biological management are technologically mature and nearing commercial scale up (TRL 9; CRI 3). Oxitec recently conducted field trials in Brazil and Paraguay for a genetically modified, self-limiting fall army worm. Other Oxitec Friendly™ applications in development include the diamondback moth and the Mediterranean fruit fly.[85]

Applications in human health are more advanced and commercially mature (CRI 5). Oxitec Friendly™ mosquitoes targeting dengue have been approved for field trials in several countries, and in November 2024, the OGTR received an application for the commercial release of Oxitec Friendly™ mosquitoes in Queensland to manage dengue.[86]

Other sex biasing systems for the control of dengue include the release of *Wolbachia*-infected mosquitoes in Australia. This approach is currently undergoing field trials in Northern Queensland to assess their feasibility as a biological management strategy and large-scale deployment could be feasible in 5 years or less.[87] Self-sustaining genetically modified technology will likely take a minimum of 15 years before large-scale deployment is feasible the Australian context.

Development considerations

Research on long-term effects in the environment are needed for self-sustaining technologies to be deemed safe by gene technology regulators and ensure wider social acceptability.[88] Even then, the technology will likely be limited to insects, proving more difficult in higher vertebrates. The development and deployment of sex biasing in higher order vertebrates is likely to be 25 years away (TRL 4). It is unclear how effective sex biasing systems could be against higher vertebrates, as the effectiveness of the sex biasing systems is dependent on the generation time of each species. For example, sex biasing systems in mosquitoes can take effect within one year,[89] while in rabbits it could take close to 17 years to affect half the population.[90]

Regulation

Clear regulatory pathways exist for most sex biasing systems; however, it remains to be demonstrated for self-sustaining genetically modified approaches. Sex biasing systems require regulation and approval by the APVMA, with genetically modified sex biasing systems requiring additional OGTR regulation and approval.[91] Sex biasing systems that involve importing a new species into Australia will also require approval from DAFF.

85 Oxitec (2017) Solution of Tackle Growing Diamondback Moth Pest Issue Begins Field Trials. <https://www.oxitec.com/en/news/oxitecs-innovative-solution-to-tackle-growing-diamondback-moth-pest-issue-begins-field-trials> (accessed 11 December 2024); Oxitec (2019) Study of Oxitec Friendly Mediterranean Fruit Fly Technology Shows Successful Suppression of Wild-type Population While Protecting Fruit Quality and Potential Marketable Yield. <https://www.oxitec.com/en/news/new-study-of-oxitecs-friendly-mediterranean-fruit-fly-technology-shows-successful-suppression-of-wild-type-population-while-protecting-fruit-quality-and-potential-marketable-yield> (accessed 11 December 2024).

86 OGTR (2024) Commercial release of a GM mosquito strain to help prevent dengue outbreaks <https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-207> (accessed 25 November 2024); Oxitec (2022) Oxitec Announces 2022 US Pilot Plans for Mosquito Technology. <https://www.oxitec.com/en/news/oxitec-announces-2022-us-pilot-plans-for-mosquito-technology> (accessed 25 November 2024); Oxitec (2016) Panama. <https://www.oxitec.com/panama> (accessed 25 November 2024); Oxitec (2024) Djibouti Breaks New Ground in the Fight Against Malaria. <https://www.oxitec.com/en/news/oxitec-djiboutirelease> (accessed 25 November 2024); Oxitec (2024) Oxitec and Orkin Enter into National Partnership to Combat Dengue-Spreading Mosquitoes <https://www.oxitec.com/en/news/oxitec-orkin> (accessed 25 November 2024).

87 Ritchie SA (2018). Wolbachia and the near cessation of dengue outbreaks in Northen Australia despite continued dengue importations via travellers. Journal of travel medicine 25(1), tay084.

88 Collins JP (2018) Gene drives in our future: challenges of and opportunities for using a self-sustaining technology in pest and vector management. BioMed Central Proceedings 12(Suppl 8), 9.

89 Lounibos LP, Escher EL (2008) Sex Ratios of Mosquitoes from Long-Term Censuses of Florida Tree Holes. Journal of American Mosquito Control Association 24(1), 11–15.

90 Birand A, Cassey P, Ross J V., Thomas PQ, Prowse TAA (2022) Scalability of genetic biocontrols for eradicating invasive alien mammals. NeoBiota 74, 93; Cottingham E (2023) What are gene drives, and how can they help eradicate invasive species in Australia? ABC News, 28 November. <https://www.abc.net.au/news/science/2023-11-28/gene-drives-explainer-feral-cats-invasive-species-genetic/102953190> (accessed 10 December 2024).

91 OGTR (2021) Overview of the status of organisms modified using gene editing and other new technologies. Australian Government Department of Health and Aged Care, Office of the Gene Technology Regulator, Canberra. <https://www.ogtr.gov.au/resources/publications/overview-status-organisms-modified-using-gene-editing-and-other-new-technologies> (accessed 27 November 2024).

Challenges

Potential for evolutionary changes: Genetically modified sex biasing systems will require long-term research and continuous monitoring due to various biological challenges. These include the potential emergence of resistance to gene drives,[92] and the potential evolution of hosts (and in the case of *Wolbachia*, evolution of the bacteria),[93] which could render these approaches ineffective.

Ecological risks: There may be ecological risks to ecosystems and non-target species associated with altering sex ratios in an established population. The release of sterile pests may also cause damage to the ecosystem in the short term.[94] Benefit analyses are needed to quantify and evaluate these risks.[95]

Infrastructure needs: The deployment of sex biasing systems will require specialised mass rearing facilities, which presents potential logistical and technical barriers.[96] Additional analysis will be needed to determine if existing insect rearing facilities can be modified to support next generation technologies or if new infrastructure is needed.

CASE STUDY 4: Sex biasing systems for the biological management of fall armyworm

The fall armyworm has emerged as a significant threat to Australian agriculture since its first detection in 2020. The pest has spread across Queensland, the Northen Territory, New South Wales and Western Australia,[97] and primarily impacts maize, corn, sorghum and cotton crops.[98]

Oxitec Friendly™ genetically modified self-limiting fall armyworms are released on target crops where they mate with wildtype populations. Any resulting female offspring are non-viable, which gradually reduces pest population numbers. The genetically modified population disappears completely after three generations and as such does not persist in the environment.[99] Successful field trials have already been conducted in Brazil, with the approach offering a promising mitigation strategy for fall armyworm in the Australian context.[100]

92 Fuchs et al. (2021) Resistance to a CRISPR-based gene drive at an evolutionarily conserved site is revealed by mimicking genotype fixation. Public Library of Science Genetics 17(10), e1009740.

93 Ross et al. (2020) Evolutionary Ecology of Wolbachia Releases for Disease Control. Annual Review of Genetics 53, 93–116.

94 Jiang et al. (2018) Production of YY Supermale and XY Physiological Female Common Carp for Potential Eradication of this Invasive Species. Journal of the World Aquaculture Society 49(2), 315–327.

95 Hartley S, Taitingfong R, Fidelman P (2022) The principles driving gene drives for conservation. Environmental Science & Policy 135, 36–45.

96 Madhav et al. (2024) Culex-Transmitted Diseases: Mechanisms, Impact, and Future Control Strategies using Wolbachia. Viruses 16(7), 1134.

97 Plant Health Australia (2020) Fall Armyworm Continuity Plan for the Australia Grains Industry. <https://grainsbiosecurity.com.au/app/uploads/2021/02/Fall-Armworm-Continuity-Plan-2.pdf> (accessed 25 November 2024).

98 Cook et al. (2021) What will Fall Armyworm Cost Western Australian Agriculture? Journal of Economic Entomology 114(4), 1613–1621.

99 Reavey et al. (2022) Self-limiting fall armyworm: a new approach in development for sustainable crop protection and resistance management. BMC Biotechnology 22, 5.

100 Oxitec (2024) Australia's National Science Agency and Oxitec Launch Venture Targeting Invasive Pests Threatening Health and Agricultural Sustainability Across Australia and Oceania. <https://www.oxitec.com/en/news/oxitecaustralialaunch> (accessed 10 December 2024).

Gene drives

Max. TRL (Global)	Max. CRI (Global)	Large-scale deployment (Aus)	Regulation (Aus)	Applicability	Sector	Stage	Example threats
5	1	Feasible by 2050	Pathway exists	All threats	All sectors	Exclusion Management Containment	• Invasive rodents • Mosquito species • European rabbit

Description and application

Gene drives are genetic elements that leverage a self-spreading mechanism to have a higher likelihood of being passed to offspring. This increases the prevalence of the elements (and any associated traits or effects) across a population. For example, a gene drive could be used to increase the vulnerability of an insect population to a pesticide, or to skew the sex ratio in a population as part of a suppression strategy.[101] The latter use is covered in more detail in the Sex biasing systems analysis.

Gene drives are designed to be species-specific, both in terms of mechanism (by targeting a defined sequence) and in terms of spread (via sexual reproduction). Gene drives can be subdivided according to their objective (suppression or modification of a population), mechanism, threshold for achieving change in a population, spatial range, and persistence (self-eliminating or self-sustaining).[102] In principle, gene drives can be applied to all threat types and sectors. However, the approach is more suitable for organisms that undergo sexual reproduction, which includes a range of animal, plant and fungal species. Groups with primarily asexual reproduction are not as compatible with conventional gene drives, but adaptation is possible.[103]

The use of gene drives in population suppression strategies provides an alternative to conventional pesticides, traditional biocontrol approaches, and release of sterile or non-viable individuals. Gene drives can also complement these approaches, which have limited persistence of effects,[104] are geographically constrained, and can pose risks to non-target species due to lower specificity.[105]

Current state

The maturity of gene drives varies by species (TRL 5). In general, implementation for agricultural invertebrates, vertebrates and plants are earlier in the development cycle, while applications for mosquito species are the most advanced.[106] For example, a gene drive that limits the reproduction of *Anopheles gambiae* (a mosquito species and malaria vector) has been tested in large indoor cages.[107] However, gene drives have not yet reached the field trial stage, which is key for the transition into operational applications. The deployment of gene drives in Australia for biological management is likely to be farther in time than the other approaches, potentially 15 to 25 years from now. This is the result of a comparatively lower technological readiness, the still pending need for testing in a relevant and contained field setting, and the expected regulatory and stakeholder engagement requirements.

101 Buchman et al. (2018) Synthetically engineered *Medea* gene drive system in the worldwide crop pest Drosophila suzukii. Proceedings of the National Academy of Sciences 115, 4725; Meccariello et al. (2021) Engineered sex ratio distortion by X-shredding in the global agricultural pest Ceratitis capitata. BMC Biology 19, 78.

102 Overcash J, Golnar A (2022) Facilitating the Conversation: Gene Drive Classification. Health Security 20, 16. This subdivision is based on the classification proposed by Overcash and Golnar 2022. A standardised classification is needed to accommodate the many possible gene drive variants derived from changes to individual elements (e.g., a different effector or mechanism of action).

103 Valderrama et al. (2019) A bacterial gene-drive system efficiently edits and inactivates a high copy number antibiotic resistance locus. Nature Communications 10, 5726.

104 Buchman et al. (2018) Synthetically engineered *Medea* gene drive system in the worldwide crop pest *Drosophila suzukii*. Proceedings of the National Academy of Sciences 115, 4725.

105 Croghan et al. (2023) Benefits and risks of gene drives for invasive plant management - the case for common tansy. Frontiers in Agronomy 5.

106 Yadav et al. (2023) CRISPR/Cas9-based split homing gene drive targeting *doublesex* for population suppression of the global fruit pest *Drosophila suzukii*. Proceedings of the National Academy of Sciences 120; Hammond et al. (2021) Gene-drive suppression of mosquito populations in large cages as a bridge between lab and field. Nature Communications 12, 4589; Anderson et al. (2024) A multiplexed, confinable CRISPR/Cas9 gene drive can propagate in caged Aedes aegypti populations. Nature Communications 15, 729; Gierus et al. (2022) Leveraging a natural murine meiotic drive to suppress invasive populations. Proceedings of the National Academy of Sciences 119; Liu et al. (2024) Overriding Mendelian inheritance in Arabidopsis with a CRISPR toxin–antidote gene drive that impairs pollen germination. Nature Plants 10, 910; Oberhofer et al. (2024) Cleave and Rescue gamete killers create conditions for gene drive in plants. Nature Plants 10, 936.

107 Hammond et al. (2021) Gene-drive suppression of mosquito populations in large cages as a bridge between lab and field. Nature Communications 12, 4589.

Development considerations

The unique characteristics of each species in terms of development, reproduction or ecological interaction has a direct impact on the efficacy of a gene drive, as well as on the timeline and cost for its development. For instance, gene drive development and population-level impact will be slower in species that have longer development times, which will also attract higher costs from husbandry and management in containment facilities.[108] The impact of unique species traits also mean gene drives will be highly species-specific, requiring a complete development process for a new threat.

Gene drives involve genetic modification. As highlighted in the Gene silencing analysis, the mean cost of developing a novel genetic trait in plants is above USD 100 million and can take over 15 years from discovery to regulatory approval.[109] This serves only as a baseline given the lower maturity stage of gene drives. Gene drives could incur higher costs and longer timelines than other genetic modification events given the current maturity of the technology, its development requirements and the extent of regulatory assessment. Certain applications, like those on mosquito species of relevance to human health, could see faster progress.

Once developed and approved for release, deployment will require large-scale rearing of organisms that carry the gene drive, releasing them into the environment in a way that supports the suppression or modification objective, and continuous monitoring over time (of the population and the local ecosystem). These activities attract their own ongoing costs, but consulted experts noted that overall expenses for target species could diminish over time due to reductions in the use of traditional approaches.

Regulation

An applicable regulatory framework already exists in Australia, with the OGTR qualifying that 'all dealings involving a genetically modified gene drive organism are currently regulated under the National Gene Technology Scheme and require a licence'.[110] A dedicated assessment process has also been proposed as part of the draft National Gene Drive Policy Guide,[111] but remains to be tested as no application has been submitted for the environmental release of a gene drive in Australia at the time of writing.

Where the gene drive itself has pesticidal activity and is not found normally in the organism, or results in the production of a pesticidal substance that is new to an organism (e.g., as part of its cargo), there will also be regulation from the APVMA as a biological agricultural product.[112]

Challenges

Resistance and potential off-target effects: Resistance to a gene drive could arise, limiting effectiveness and leading to its disappearance. Alternatively, a gene drive's effect may result in unexpected behavioural or reproductive changes at the population level, altering its intended spread. Mutations and effects on other genes could also alter other relevant characteristics in the population.[113] Minimising off-target activity while maintaining efficiency will require gene drive designs and strategies that closely control the timing and tissue-specificity of activity.[114] Moreover, controlling a gene drive, as is the case for population control approaches in general, will also require mechanisms that can limit its persistence in time or inactivate it after release.[115]

108 Esvelt et al. (2014) Concerning RNA-guided gene drives for the alteration of wild populations. eLife 3.

109 AgbioInvestor (2022) Time and Cost to Develop a New GM Trait. A study on Behalf of Crop Life International. <https://croplife.org/wp-content/uploads/2022/05/AgbioInvestor-Trait-RD-Branded-Report-Final-20220512.pdf> (accessed 19 November 2024).

110 The National Gene Technology Scheme (2024) About the National Gene Drive Policy Guide. <https://www.genetechnology.gov.au/about-the-national-scheme/about-national-gene-drive-policy-guide> (accessed 19 November 2024).

111 DOHAC (2023) National Gene Drive Policy Guide, December 2023. Commonwealth of Australia (Department of Health and Aged Care). 9–10. <https://www.genetechnology.gov.au/sites/default/files/2024-01/draft-national-gene-drive-policy-guide.pdf> (accessed 19 November 2024).

112 APVMA (2024) Guideline for the regulation of biological agricultural products. Australian Pesticides and Veterinary Medicines Authority. <https://www.apvma.gov.au/registrations-and-permits/data-requirements/agricultural-data-guidelines/biological> (accessed 20 November 2024).

113 Kuzma J (2022) Gene drives: Environmental impacts, sustainability, and governance. In Ensuring the environmental sustainability of emerging technologies. (Ed. MV Florin) 5–9. EPFL International Risk Governance Center, Lausanne.

114 Verkuijl et al. (2022) The Challenges in Developing Efficient and Robust Synthetic Homing Endonuclease Gene Drives. Frontiers in Bioengineering and Biotechnology 10.

115 Xu et al. (2020) Active Genetic Neutralizing Elements for Halting or Deleting Gene Drives. Molecular Cell 80, 246; Noble et al. (2019) Daisy-chain gene drives for the alteration of local populations. Proceedings of the National Academy of Sciences 116, 8275.

Ecosystem implications: Resulting changes in the population could alter relationships at the ecosystem level, indirectly impacting other species (e.g., decreased competition or food web disruptions).[116] This represents a potential challenge for all highly effective biological management approaches, not just gene drives. However, stakeholders have noted that it could be compounded by difficulty in stopping self-sustaining gene drives.

Complex IP landscape: Some gene drive approaches rely on genetic technologies that are subject to overlapping patents from different entities, which can complicate both development and deployment due to multiple licensing requirements and freedom to operate considerations.[117] This is particularly prominent in CRISPR-Cas, which could prompt developers to use other technologies or self-spreading strategies in their gene drive approach.

CASE STUDY 5: Developing a gene drive with potential for mouse population control

The house mouse (*Mus musculus*) is a prevalent, widespread invasive species in Australia. Growth of its populations under favourable conditions (mouse plagues) have repeatedly caused large economic impacts, stemming from damage to commercial crops and infrastructure, as well as the control measures used. For instance, a survey of farmers found that the 2020–21 mouse plague in New South Wales and Victoria was estimated to cost an average of $140,000 per grower.[118]

In 2022, researchers from Australian and US institutions reported the development of a gene drive strategy that targets a female fertility gene.[119] This approach progressively reduces the number of fertile females, with accompanying modelling showing that it could successfully achieve population suppression in vulnerable ecosystems (e.g., islands). While additional testing and development will be necessary, the strategy could provide a complement or alternative to traditional bait-based approaches, which have efficacy and specificity challenges.[120]

116 Kuzma J (2022) Gene drives: Environmental impacts, sustainability, and governance. In Ensuring the environmental sustainability of emerging technologies. (Ed. Florin MV) 5–9. EPFL International Risk Governance Center, Lausanne.

117 WIPO (2024) CRISPR-Cas: Navigating the Patent Landscape to Explore Boundless Applications. <https://www.wipo.int/en/web/global-health/w/news/2024/crispr-cas-navigating-the-patent-landscape-to-explore-boundless-applications> (accessed 4 December 2024); Kim et al. (2024) New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector - Position Statement of the Max Planck Institute for Innovation and Competition. GRUR International 73, 323.

118 Brown PR, Henry S (2022) Impacts of House Mice on Sustainable Fodder Storage in Australia. Agronomy 12, 254.

119 Gierus et al. (2022) Leveraging a natural murine meiotic drive to suppress invasive populations. Proceedings of the National Academy of Sciences 119; National Gene Technology Scheme (2024) Hypothetical gene drive environmental release case studies. <https://www.genetechnology.gov.au/resources/publications/hypothetical-gene-drive-environmental-release-case-studies> (accessed 19 November 2024).

120 Smith D, Neindorf B (2022) University of Adelaide researchers developing gene drive technology to combat invasive mice. ABC Rural, 10 November. <https://www.abc.net.au/news/2022-11-10/university-of-adelaide-gene-drive-technology-mice-control/101639638> (accessed 19 November 2024).

Enabling technologies

Next generation approaches play a direct role in suppressing or controlling the spread of biological threats; however, a range of enabling technologies are also needed to support the efficient development and deployment of these approaches. This section introduces three enabling technologies that will contribute to biological management in Australia by 2050: advanced bioinformatics, advanced deployment techniques and *ex vivo* models.

Advanced bioinformatics

Description and application

Advanced bioinformatics are computational and statistical approaches that encode, process and analyse detailed biological information. These approaches are enabled by omics technologies, each underpinned by distinct analytical techniques and tools.[121]

Omics technologies rely on collecting a sample from a relevant environment (e.g., a tissue fragment, soil, water) and processing it to obtain key data. From that data, advanced bioinformatics can assist with monitoring changes in a species of interest, like the emergence of resistance;[122] detecting the presence of a species in an area (environmental genomics);[123] identifying potential targets for novel biological agents and designing targeted constructs (e.g., RNAi or gene drive);[124] assessing the mode of action and effect of a biological agent;[125] or predicting broader outcomes of an intervention (e.g., population-level models).[126]

Omics technologies can be highly specific and enable the fast processing, targeted analysis and linking of diverse levels of information, which can inform the prioritisation of traditionally time-intensive laboratory activities. They also have a longstanding history of use in research and commercial settings and are versatile enough to be used across biological threats for Australia, from viruses and disease-causing fungi to invasive plants and pest insects.[127] For example, the Australian Pest Genome Partnership is a cross-institutional collaboration (part of the broader Applied Genomics Initiative) that aims to provide genomic data for pest and invasive species relevant to Australia.[128] The datasets are intended to be publicly available with accompanying processing workflows (both for lab bench and *in silico* activities) and analysis tools.[129]

121 Dai X, Shen L (2022) Advances and Trends in Omics Technology Development. Frontiers in Medicine 9, 911861.

122 Taylor et al. (2021) Genome evolution in an agricultural pest following adoption of transgenic crops. Proceedings of the National Academy of Sciences 118.

123 Deiner et al. (2017) Environmental DNA metabarcoding: Transforming how we survey animal and plant communities. Molecular Ecology 26, 5872.

124 Noriega et al. (2019) Transcriptome and gene expression analysis of three developmental stages of the coffee berry borer, Hypothenemus hampei. Scientific Reports 9, 12804; Singh et al. (2019) Using de novo transcriptome assembly and analysis to study RNAi in Phenacoccus solenopsis Tinsley (Hemiptera: Pseudococcidae). Scientific Reports 9, 13710.

125 Xu et al. (2022) Application of transcriptomic analysis to unveil the toxicity mechanisms of fall armyworm response after exposure to sublethal chlorantraniliprole. Ecotoxicology and Environmental Safety 230, 113145.

126 Greenbaum et al. (2021) Designing gene drives to limit spillover to non-target populations. Public Library of Science Genetics 17, e1009278.

127 Batovska et al. (2024) The Australian Biosecurity Genomic Database: a new resource for high-throughput sequencing analysis based on the National Notifiable Disease List of Terrestrial Animals. Database 2024, baae084; Bioplatforms Australia (n.d.) Integrated Pest Management Omics Initiative. Projects. <https://bioplatforms.com/projects/integrated-pest-management-omics-initiative/> (accessed 19 November 2024).

128 CSIRO (n.d.) A few stories from AGI. Applied Genomics Initiative. <https://appliedgenomics.csiro.au/projects/> (accessed 19 November 2024).

129 Australian Pest Genome Partnership (n.d.) Applied genomics Initiative. <https://appliedgenomics.csiro.au/projects/apgp/> (accessed 19 November 2024); CSIRO (2023) New CSIRO project to crack the codes of Australia's most invasive species. <https://www.csiro.au/en/news/All/News/2023/April/New-CSIRO-project-to-crack-the-codes-of-Australias-most-invasive-species> (accessed 19 November 2024).

Development and use

Using advanced bioinformatics involves direct costs across labour, computation (on local infrastructure or on third-party servers), and access to dedicated processing tools. Some of these tools are open source but may require technical expertise, while others are more user friendly but attract higher prices.[130]

There are also indirect costs across sample collection and processing, reagents and consumables, infrastructure and equipment, and data analysis. However, these costs also apply to the alternatives to advanced bioinformatics, like traditional environmental surveys, cultivation and trial approaches.

Challenges

Accuracy: Data accuracy depends on the technical resolution of the equipment used to process samples and the software that transforms the detected signals into data.[131]

Implications of data collection and use: Extensive reliance on biological data requires ongoing discussion and engagement regarding reliability, availability of data, the ethics of data collection methods, the national security implications of access to threat species data, benefit-sharing structures, and data sovereignty for Aboriginal and Torres Strait Islander Peoples.[132]

Translating data into decisions: The fast pace of change in bioinformatics and growing data generation capacity are turning the interpretation and application of findings in decision-making into bottlenecks. To realise the full value of vast amounts of data, adequate training of end-users is needed, from senior decision-makers to personnel interacting with species of interest.

CASE STUDY 6: Using advanced bioinformatics to support post-entry quarantine facilities

Over 4 million plants are imported into Australia annually, with those of medium biosecurity risk or above undergoing assessment and in some circumstances treatment in post-entry quarantine facilities.[133] Plants posing high biosecurity risk can spend significant periods of time growing in the facilities to support adequate testing, resulting in delayed release of the material, increased costs and logistical challenges at scale.

To address this challenge, a group of Australia and New Zealand researchers developed a web-based bioinformatics workflow to detect plant viruses and viroids using RNA sequencing data.[134] The approach was trialled at large scale in quarantined imported plants and the results matched conventional methods in use at post-entry quarantine facilities, highlighting the potential to streamline testing and screen for multiple threats simultaneously without specific targeting.

130 Sebby K (2022) What is the cost of bioinformatics? A look at bioinformatics pricing and costs. <https://medium.com/truwl/what-is-the-cost-of-bioinformatics-a-look-at-bioinformatics-pricing-and-costs-1e4c1c3bcb4f> (accessed 19 November 2024).

131 Alfaro et al. (2021) The emerging landscape of single-molecule protein sequencing technologies. Nature Methods 18, 604; Mann M (2024) Measuring sequencing accuracy. <https://sapac.illumina.com/science/technology/next-generation-sequencing/plan-experiments/quality-scores.html> (accessed 19 November 2024); Liu-Wei et al. (2024) Sequencing accuracy and systematic errors of nanopore direct RNA sequencing. BMC Genomics 25, 528.

132 Handsley-Davis et al. (2020) Researchers using environmental DNA must engage ethically with Indigenous communities. Nature Ecology & Evolution 5, 146; Hoffmann WA (2016) Benefit-Sharing. In Encyclopedia of Global Bioethics. (Ed. Have H) 246–256. Springer International Publishing, Cham, Switzerland; Janke et al. (2021) Australia state of the environment 2021: Indigenous, independent report to the Australian Government Minister for the Environment. 54–60. Commonwealth of Australia, Canberra. <https://soe.dcceew.gov.au/sites/default/files/2022-07/soe2021-Indigenous.pdf> (accessed 19 November 2024); Plant Health Australia (2024) Australian Plant Pest Database. <https://www.appd.net.au/> (accessed 19 November 2024).

133 Whattam et al. (2021) Evolution of Plant Virus Diagnostics Used in Australian Post Entry Quarantine. Plants 10, 1430.

134 Gauthier et al. (2022) Side-by-Side Comparison of Post-Entry Quarantine and High Throughput Sequencing Methods for Virus and Viroid Diagnosis. Biology 11, 263; Lelwala et al. (2022) Implementation of GA-VirReport, a Web-Based Bioinformatics Toolkit for Post-Entry Quarantine Screening of Virus and Viroids in Plants. Viruses 14, 1480.

Advanced deployment techniques

Description and application

Advanced deployment techniques encompass a range of methods and technologies that aid in the release of biological agents, usually with a focus on increased precision and control. Biological agents can be deployed in two potentially complementary ways that are directly influenced by the biology of the biological threat of interest: direct integration via genetic modification and release into the environment.

Direct integration involves using genetic modification to ensure the continuous production and effect of the biological agent. Direct integration approaches can be designed to link the expression of the biological agent to a specific development stage, biological attribute (e.g., presence of a genetic element or selective expression in only one sex) or environmental context, which enables an additional layer of control.

Release into the environment is typically transient in nature and involves the use of both physicochemical and delivery technologies. Physicochemical technologies aim to optimise the stability of the biological agent and the mode of interaction with the organism of interest through the formulation of the biological agent (e.g., simple alternative formulations or viral vectors, liposomes, polymers, and other nanoscale carriers).[135] These technologies can contribute towards protection from degradation, progressive release, more efficient application or increased specificity by using components that interact selectively with the target organism.[136] Delivery technologies help biological agents reach its target. This includes spraying, dipping, drenching or mass release of organisms, drones, ground equipment and sensors that enable them, and auto-dissemination techniques.[137] Some delivery technologies support specificity through advanced sensing and analysis capabilities that link the application of a biological agent to the identification of features of interest in the field.[138]

Development and use

The average costs and timelines for developing a novel genetic modification trait and a new active ingredient for crop protection are presented in the analyses for Gene drives and Gene silencing. These are relevant to the deployment strategies that rely on genetic modification and physicochemical technologies for transient application.

The cost of using a new delivery technology versus an established alternative varies significantly. For example, a 2020 economic assessment based on an olive orchard found that the application cost of a drone was higher than conventional ground equipment (EUR 33.8 per ha versus EUR 26 per ha).[139] The costs and benefits of spray technologies have also been assessed. A 2019 Grains Research and Development Corporation (GRDC) case study across four Australian farms adopting optical spot spray technologies found that annual operating costs ranged between \$3.65 and \$13.50 per ha, while annual gains (in terms of cost savings) were between \$12.38 and \$29 per ha.[140]

135 Stejskal et al. (2021) Synthetic and Natural Insecticides: Gas, Liquid, Gel and Solid Formulations for Stored-Product and Food-Industry Pest Control. Insects 12, 590; Wilson et al. (2020) A novel formulation technology for baculoviruses protects biopesticide from degradation by ultraviolet radiation. Scientific Reports 10, 13301.

136 APVMA (2015) Nanotechnologies for pesticides and veterinary medicines: regulatory considerations. Australian Pesticides and Veterinary Medicines Authority, Canberra. <https://www.apvma.gov.au/sites/default/files/publication/15626-nanotechnologies-pesticides-veterinary-medicines_regulatory-considerations_july2015.pdf> (accessed 19 November 2024).

137 Lake et al. (2021) First drone releases of the biological control agent *Neomusotima conspurcatalis* on Old World climbing fern. Biocontrol Science and Technology 31, 97; Vijayakumar et al. (2023) Smart spraying technologies for precision weed management: A review. Smart Agricultural Technology 6, 100337; Unlu et al. (2017) Effectiveness of autodissemination stations containing pyriproxyfen in reducing immature Aedes albopictus populations. Parasites & Vectors 10, 139.

138 Bilberry GJ (2019) Green on green camera spraying – a game changer on our doorstep? Grains Research & Development Corporation. <https://grdc.com.au/resources-and-publications/grdc-update-papers/tab-content/grdc-update-papers/2019/02/green-on-green-camera-spraying-a-game-changer-on-our-doorstep3> (accessed 19 November 2024); Elliston A, (2024) Rolling out green-on-green spot spraying. Grains Research & Development Corporation. <https://groundcover.grdc.com.au/innovation/precision-agriculture-and-machinery/rolling-out-green-on-green-spot-spraying> (accessed 19 November 2025).

139 Martinez-Guanter et al. (2020) Spray and economics assessment of a UAV-based ultra-low-volume application in olive and citrus orchards. Precision Agriculture 21, 226.

140 GRDC (2019) Case study: Optical spot spraying. Grains Research & Development Corporation. <Optical-Spot-Spraying-Case-Study-updated-05052020.pdf> (accessed 19 November 2024).

Challenges

Resistance: Continuous production of a biological agent within an organism can facilitate the emergence of resistance without adequate management measures. This is related to increased exposure of the biological threat to the biological agent, which increases the likelihood of selecting for resistant individuals.[141]

Increased persistence and potential for exposure: Increased durability, solubility or prolonged release due to the physicochemical technologies used in formulations may increase the risk of environmental persistence, exposure of non-target species, and higher residue levels, which carry environmental, social and regulatory considerations.[142]

Testing, training and support: The equipment used in delivery technologies require training data representative of the context of use; testing to ensure it maintains the application levels required for efficacy; adequate training for operating personnel; and supporting infrastructure that may not be available in all locations.[143]

CASE STUDY 7: A versatile carrier material for gene silencing in agricultural pests

Silverleaf whitefly (*Bemisia tabaci*) is a major pest species worldwide with a large range of host plant species, including a range of economically relevant fibres (cotton), vegetable crops (e.g., tomatoes and legumes), and ornamentals.[144] Silverleaf whitefly populations have been reported to develop resistance to multiple conventional pesticides and can cause damage in various ways – from direct feeding on plant sap that reduces yields to injecting toxic compounds, promoting mould growth, and transmitting plant viruses.[145]

A group of researchers at the University of Queensland developed a novel carrier material for dsRNA targeting silverleaf whitefly that is applied via foliar spray to cotton plants. The carrier, known as BioClay, is a system of clay nanosheets that loads the dsRNA and additional adjuvants to protect them from degradation and enable progressive release, supporting an increase in silverleaf whitefly mortality compared to dsRNA on its own.[146] A similar approach of using clay particle carriers to protect dsRNA has also been tested on cattle hide, for possible topical applications in livestock.[147]

141 US EPA (n.d.) Insect Resistance Management for Bt Plant – Incorporated Protectants. US EPA. <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/insect-resistance-management-bt-plant-incorporated#overview> (accessed 21 November 2024).

142 APVMA (2015) Nanotechnologies for pesticides and veterinary medicines: regulatory considerations. Australian Pesticides and Veterinary Medicines Authority, Canberra. <https://www.apvma.gov.au/sites/default/files/publication/15626-nanotechnologies-pesticides-veterinary-medicines_regulatory-considerations_july2015.pdf> (accessed 19 November 2024); Fojtová et al. (2019) Nanoformulations can significantly affect pesticide degradation and uptake by earthworms and plants. Environmental Chemistry 16, 470.

143 Carrasco-Escobar et al. (2022) The use of drones for mosquito surveillance and control. Parasites & Vectors 15, 473.

144 Agriculture Victoria (2023) Silverleaf white fly. Priority pest insects and mites. <https://agriculture.vic.gov.au/biosecurity/pest-insects-and-mites/priority-pest-insects-and-mites/silverleaf-white-fly> (accessed 19 November 2024).

145 Hopkinson et al. (2023) Insecticide resistance management of *Bemisia tabaci* (Hemiptera: Aleyrodidae) in Australian cotton – pyriproxyfen, spirotetramat and buprofezin. Pest Management Science 79, 1829; Business Queensland (2024) Silverleaf whitefly. Horticultural insect pests. <https://www.business.qld.gov.au/industries/farms-fishing-forestry/agriculture/biosecurity/plants/insects/horticultural/silverleaf-whitefly> (accessed 19 November 2024).

146 Mitter et al. (2017) Clay nanosheets for topical delivery of RNAi for sustained protection against plant viruses. Nature Plants 3, 16207; Jain et al. (2022) Foliar application of clay-delivered RNA interference for whitefly control. Nature Plants 8, 535.

147 Mody et al. (2020) Topical RNAi for Sustainable Animal Health. In Proceedings of The Third International Tropical Agriculture Conference (TROPAG 2019). 11–13 November. Brisbane, Queensland.

Ex vivo models

Description and application

Ex vivo models are representations of biological systems that are established from cells or tissues of a species of interest. The cells or tissues are cultured under controlled conditions and can be used to assess the effects of an intervention, study cell dynamics and mechanisms of action or resistance, and determine optimal dosage and delivery forms.[148]

Ex vivo models can support decisions around the appropriateness, and any subsequent design, of next generation approaches by modelling target species response. Their ability to rapidly assess large sets of biological agents and conditions can also reduce the number of candidates that go through to whole organism toxicology studies, providing both ethical and cost benefits. Moreover, their species-specificity and often detailed characterisation increases the relevance of tests and can help assess potential effects in other organisms that may be exposed to a candidate.[149]

Ex vivo models cannot fully replicate the diversity of cell populations, or the interactions and environmental dynamics associated with an organism, which limits the extrapolation of findings. Thus, *in vivo* and field studies are still required to verify the effectiveness of a novel biological management agent. Further detail on the use and challenges of *ex vivo* models can be found in CSIRO's 2023 Non-animal models report.[150]

Development and use

If the required storage, culturing, visualisation and support infrastructure is in place, the costs of establishing a new *ex vivo* model are driven by primary tissue collection, processing, consumables, and the involvement of highly skilled personnel. The time required will vary depending on the species, the *ex vivo* model, and the availability of protocols to guide the culture, taking multiple months.[151] Once established, the validation step for a new model can add significantly to the overall development timeline.

CASE STUDY 8: A new *ex vivo* model to assess biological management of European rabbit

Feral European rabbits (*Oryctolagus cuniculus*) are an invasive species with broad ecological impacts, from competition with native species to land and vegetation damage. They also pose significant economic implications, with costs to Australian agricultural producers estimated to be $197 million per year.[152]

In 2023, a team of CSIRO scientists in collaboration with US researchers reported the development of new organoid liver models from European rabbits and other Australian pest species including hares, mice and feral cats. The *ex vivo* models were established from bile duct stem cells in which the replication of multiple lagoviruses (biological agents potentially lethal to European rabbits) was possible.[153] The models could serve to facilitate the selection of control agents and evaluate the effect of changes in the viruses, the evolving resistance of a rabbit population, and the species-specificity of a particular lagovirus when compared to cell cultures derived from other organisms.

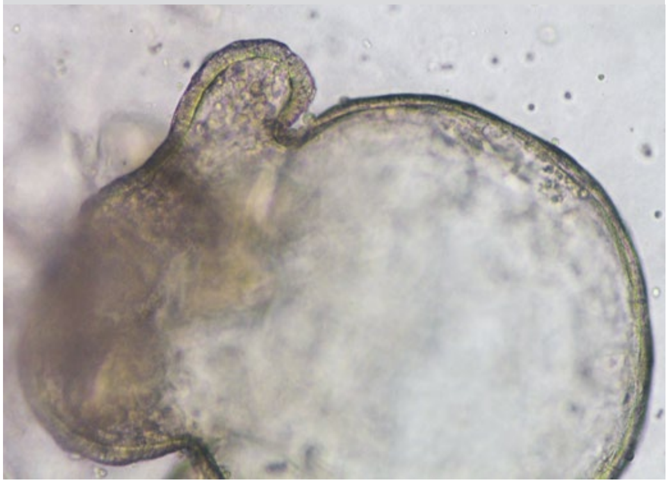


Image: Rabbit liver organoid, serendipitously shaped like a rabbit (Source: Egi Kardia, CSIRO)

148 CSIRO (2023) Non-animal models: a strategy for maturing Australia's medical product development capabilities. Commonwealth Scientific and Industrial Research Organisation, Canberra.

149 Lynch et al. (2024) High-Throughput Screening to Advance In Vitro Toxicology: Accomplishments, Challenges, and Future Directions. Annual Review of Pharmacology and Toxicology 64, 191.

150 CSIRO (2023) Non-animal models: a strategy for maturing Australia's medical product development capabilities. Commonwealth Scientific and Industrial Research Organisation, Canberra.

151 Strand et al. (2021) Establishing Cell Lines from Fresh or Cryopreserved Tissue from the Great Crested Newt (Triturus cristatus): A Preliminary Protocol. Animals 11, 367; Pinillos et al. (2022) Establishing and characterising a new cell line from Calliphora vicina (diptera: calliphoridae) fly embryonic tissues. Heliyon 8, e10674.

152 Hafi et al. (2023) Cost of established pest animals and weeds to Australian agricultural producers. Australian Bureau of Agricultural and Resource Economics and Sciences, ABARES research report No. 23.29, Canberra. <https://daff.ent.sirsidynix.net.au/client/en_AU/search/asset/1035221/0> (accessed 19 November 2024).

153 Kardia et al. (2023) Hepatobiliary organoids derived from leporids support the replication of hepatotropic lagoviruses. Journal of General Virology 104.

Cross-cutting challenges and next steps

Cross-cutting challenges

The availability of next generation approaches to biological management in Australia by 2050 faces cross-cutting challenges relating to sustainable investment, development, adaptation and clear access pathways. Table 2 describes these areas, which also represent opportunities to ensure biological management helps Australia protect its natural assets and productive industries, adapt to changing consumer and trade demands, and tackle increasingly complex biological threats. The analysis described in Next steps seeks to explore pathways for overcoming these challenges.

Table 2: Cross-cutting challenges of next generation approaches

CHALLENGE	DESCRIPTION
Access to internationally developed approaches, supplies or underlying technologies	Australian access to next generation approaches developed in other countries, or to the supplies and technologies required to develop approaches domestically, can be impacted by clearance processes for importation and trade restrictions linked to strategic partnerships and geopolitical considerations. Some engineering biology technologies that are key to the development or function of next generation approaches also face complex intellectual property implications and freedom to operate landscapes. This could limit their use in domestic research and commercial applications.
End-user and investor awareness and understanding	Lower awareness, understanding, or trust by end-users, investors and decision-making can be barriers to investment, adoption and deployment of biological management approaches. Addressing these areas will require fit-for-purpose explanations of benefits and limitations, user guidelines, and continued engagement with consumers. While Australia has suitable regulatory pathways for next generation approaches, there are few examples of products that have gone through them. Clear examples will be key to guide subsequent regulatory applications and build trust in the regulatory process with input from industry, research, regulators and other stakeholder groups.
Monitoring and data sharing	Limited cross-sector coordination, monitoring of investments and their impact, and data sharing between key stakeholders can hamper the assessment of next generation approaches. These gaps can also affect the integration of lessons back into the development process and advocacy for additional investment.
Production ecosystem and costs	Next generation approaches currently face higher costs than traditional counterparts. This stems from less mature supply chains at scale and limited local infrastructure for development, production and deployment, which reduces affordability for end-users. Greater species-specificity also attracts additional development costs, with dedicated tailoring required to successfully target new biological threats.
Suitable funding structures	Next generation approaches that involve a self-sustaining mechanism, and applications with a clear environmental or social benefit but no clear commercial driver, require sustained investment from alternative, non-commercial funding streams to reach maturity and deployment.
Technical	Next generation biological management approaches can face challenges of stability after deployment due to environmental conditions. Similarly, efficacy can decrease over time due to the emergence of resistance. There is also potential for off-target activity in the organism of interest or other species, and for indirect impacts in a local ecosystem. These challenges are carefully considered during research and development, and benefit from detailed characterisation, monitoring and development of mechanisms for containment and inactivation after deployment.

Next steps

This discussion paper seeks to build a baseline understanding across government and industry of the next generation approaches for biological management and highlight key challenges that require further analysis and coordinated national planning. This foundational knowledge is intended to support key decision-makers in discussions about sustainable investment, development, adaptation and access to these biological management approaches in the Australian context.

The complexity and importance of the identified cross-cutting challenges demonstrate the critical need for further analysis to support those discussions and investment decisions. CSIRO considers this an activity of national importance and is seeking partners to support further analysis against the objectives and example research questions outlined below; these are aligned to the 'sustainable investment' and 'integration supported by technology, research and data' priority areas of the National Biosecurity Strategy.[154]

Objective 1: Support the case for investment in biological management

1. What is the value of biological management to Australia and what is the potential future value of next generation approaches?
2. What are well quantified examples of successful biological management in Australia?
3. How does Australia's investment in biological management compare to other countries?

Objective 2: Develop a 2050 vision and strategy for biological management in Australia

1. What is the maturity of next generation approaches across different contexts of use and applications that will be beneficial for biological management in Australia?
2. What might the use and combination of traditional and next generation approaches look like in 2050, and how does this differ from the current state?
3. Which next generation approaches are Australia best placed to focus on based on local threats and capability (e.g., research, development, commercialisation, production, and large-scale deployment)?

Objective 3: Develop priority actions to support a 2050 vision

1. What are the key technical barriers that could delay or prevent the development and adoption of next generation approaches in Australia?
2. What are the key non-technical and system-level barriers that could delay or prevent the development and adoption of next generation approaches in Australia?
3. What infrastructure and skill gaps exist that will be required to support the production, deployment and monitoring of next generation approaches in Australia?
4. How can regulators be supported to improve efficiency, adaptability, and coordination, while maintaining robust and independent oversight in a fast-changing technological and threat landscape?
5. How might industry, government, and other stakeholder groups (e.g., philanthropic organisations) prioritise and better align or complement their investments to support a 2050 vision and strategy?
6. What new business and collaboration models might help to ensure value is captured by all stakeholders along the development pathway of next generation approaches?

154 DAFF (2022) National Biosecurity Strategy. Department of Agriculture, Fisheries and Forestry, Canberra. <https://www.biosecurity.gov.au/sites/default/files/2024-02/national-biosecurity-strategy.pdf> (accessed 10 December 2024).

Appendix 1 – Assessment criteria

The high-level assessments of the five next generation approaches described in this discussion paper were undertaken using the criteria described in Table 3.

Table 3: Descriptions of criteria used to assess next generation approaches

CRITERIA	DESCRIPTION	RATING
Maximum TRL (Global)	The TRL of the most mature application identified for this approach. TRL is based on global development because technologies that have matured overseas can be adopted in Australia. TRL is explained in more detail in Appendix 2	Low: TRL 1–4 Medium: TRL 5–7 High: TRL 8–9
Maximum CRI (Global)	The CRI of the most mature commercial application identified for this approach. CRI is based on global commercialisation because technologies that have matured overseas can be adopted in Australia. CRI is explained in more detail in Appendix 2	Low: CRI 1–2 Medium: CRI 3–4 High: CRI 5–6
Large-scale deployment (Australia)	Within what timeframe is it most likely that this approach will be deployed at a large scale in Australia? This assessment considered social acceptability and risk, regulation and validation, TRL, CRI, and whether the approach is feasible for the Australian context.	Low: Feasible by 2050 Medium: Feasible in 5–15 years High: Feasible in 5 years or less
Regulation (Australia)	Is there an established and suitable regulatory approval process in Australia? If so, has it been demonstrated by having the relevant next generation approach go through the full approval process?	Low: No suitable pathway exists Medium: Suitable pathway exists but has not been demonstrated High: Suitable pathway exists and has been demonstrated
Applicability	What biological threats (established and exotic) could this approach be used for in the context of biological management?	Diseases (includes zoonotic diseases and disease vectors) Pests (invertebrate and vertebrate) Weeds
Sector	Which sectors could utilise this approach for the purpose of biological management?	Aquaculture Environment Forestry Horticulture Livestock
Stage	What stage(s) of biological management could this approach be used for? Definitions for each stage are included in the Glossary.	Exclusion Management Containment Surveillance
Example threats	What are examples of species, which pose a threat to Australia, that the approach could be used for (currently or by 2050)?	

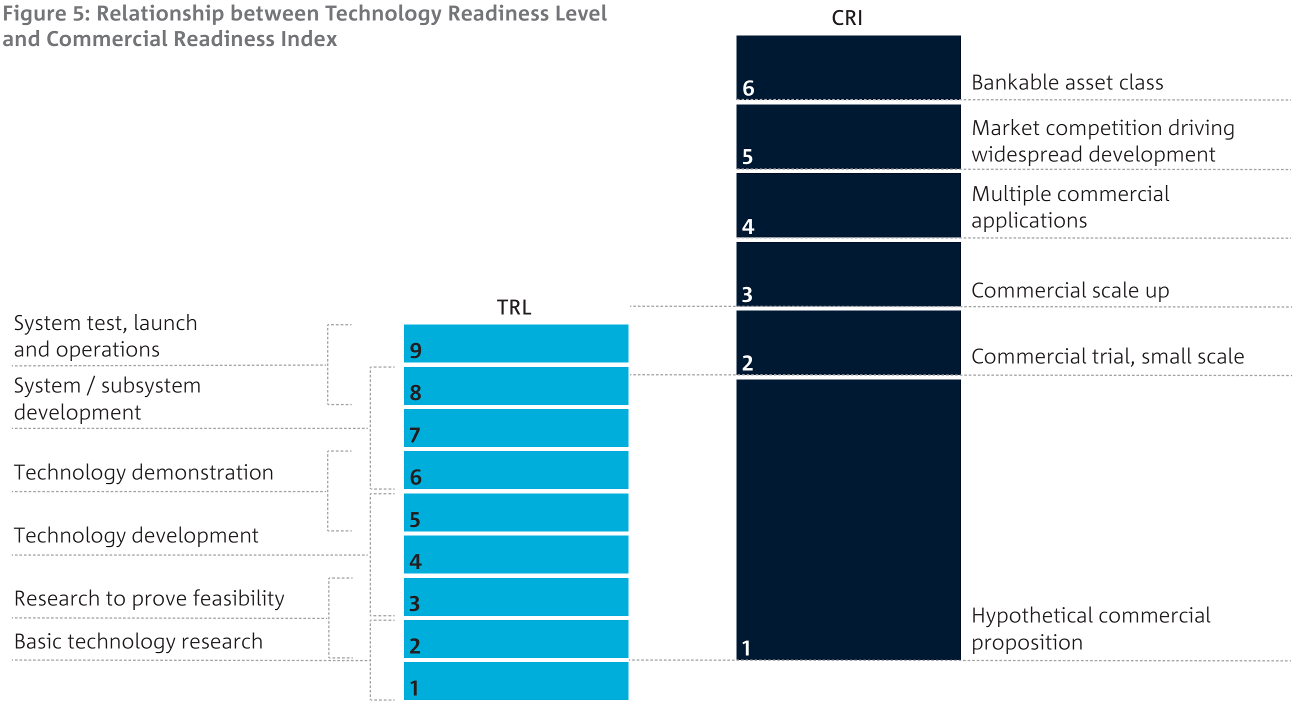
Appendix 2 – Technology readiness level and commercial readiness index

This discussion paper used the TRL and CRI frameworks to describe the maturity of the next generation approaches, and where mentioned the values correspond with the definitions in Table 4. Figure 5 illustrates the relationship between the two frameworks.

Table 4: Technology Readiness Level and Commercial Readiness Index definitions

VALUE	DEFINITION
TRL 1–6 **CRI 1**	**Research, development and demonstration, with a hypothetical commercial proposition:** The technology is technically ready, but commercially unproven. The commercial proposition is driven by advocates with little technical or financial evidence.
TRL 7–9 **CRI 1–2**	**Technically ready but commercially untested:** Small-scale first of a kind commercial testing completed and the project is funded by equity or government support.
CRI 3	**Commercial scale up:** Commercial proposition being driven by technology proponents, market participants and specific policy and emerging debt finance. Publicly discoverable data is driving emerging interest from the finance and regulatory sectors.
CRI 4	**Multiple commercial applications:** Verifiable data on technical and financial performance in the public domain is driving interest from various debt and equity sources, but it still requires government support. Regulatory challenges are being addressed in multiple jurisdictions.
CRI 5	**Market competition driving widespread development:** Competition emerging across the supply chain with commoditisation of key components and financial products driving widespread development.
CRI 6	**Bankable asset class:** Bankable grade asset class with known standards and performance expectations, driven by the same criteria as other mature technologies. Capability, pricing and other typical market forces are driving market uptake and investment.

Figure 5: Relationship between Technology Readiness Level and Commercial Readiness Index



As Australia's national science agency, CSIRO is solving the greatest challenges through innovative science and technology.

CSIRO. Creating a better future for everyone.

Contact us
1300 363 400
+61 3 9545 2176
csiro.au/contact
csiro.au

For further information
Greg Williams
Associate Director, CSIRO Futures
greg.williams@csiro.au
csiro.au/futures

Rose Roche
Principal Research Scientist, Ag2050
rose.roche@csiro.au

Raghu Sathyamurthy
Research Director, Biosecurity
raghu.sathyamurthy@csiro.au

B&M | 24-00489