GENETIC BIOCONTROL TECHNOLOGY FOR VERTEBRATE PESTS: DECISION FRAMEWORK SUMMARY

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Genetic Biocontrol Technology for Vertebrate Pests: Decision Framework Summary

Section 1: Introduction

Invasive vertebrate pest species are the primary threat facing Australia's unique fauna and flora, with cats, rodents, pigs, rabbits and foxes accounting for 95% of the total cost of mammalian pests (US$20.19 billion, 1960-2017). Vertebrate pests are responsible for agricultural production losses of more than $750M annually, increasing at a rate that is outstripping the capacity of current solutions. Emerging genetic biocontrol technologies have great potential for improved effectiveness of vertebrate pest management in Australia. Realisation of this potential requires implementation of a coordinated approach to research and development for application of genetic biocontrol technologies into vertebrates.

> *Genetic biocontrol technologies provide opportunities for the control and potential eradication of pest species. The term 'genetic biocontrol' refers to techniques that alter the genes of an organism to control pest species in the environment by modifying biological processes to disrupt the reproduction dynamics of the pest population resulting in skewed sex ratios or sterile offspring. The establishment of a decision and implementation framework with coordinated approaches will boost current and future efforts to develop advanced biocontrol applications and encourage investment in a science roadmap that has the potential to deliver substantial economic and environmental benefit to Australia.*

Here, we present an investment and decision-making framework for a coordinated development of genetic biocontrol technologies. The framework presents a path for the development of genetic biocontrol technologies, considering:

1. Current national and international investments in this area,
2. The science knowledge gaps that need to be filled in the journey from problem identification, technology proof-of-concept to realised implementation, and
3. Differences in priorities and investment appetite from various key private and public organisations involved in pest species management.

A coordinated research and development investment framework for implementation by relevant stakeholders in the biosecurity sector will maximise the benefits of genetic biocontrol for high impact established pests.

Further information supporting this approach is available via an in-depth report that considers related published literature and describes and interprets discussions with a broad range of stakeholders during engagement surveys, discussions and facilitated workshops.

Section 2: Investment Case for Genetic Biocontrol Technology

An investment decision framework for an integrated approach to the development of genetic biocontrol technologies for vertebrates requires consideration of:
1. The current investment and management environment for organisations funding, supporting and governing genetic biocontrol options 2. Critical conditions for investment in genetic biocontrol options 3. Enabling conditions for investors to support, sponsor and/or fund genetic biocontrol initiatives

Vertebrate pests effect productivity, access to export markets, public health, and threaten conservation of biodiversity, natural and built environments. These effects lead to increased production costs, export trade restrictions, reduced tourism, loss of biodiversity, greater public health costs and reduced public amenity. Annual losses and government expenditure on pest management estimated for wool, sheep-meat, beef and grain industries was more than $750M in 2013/14. The 2011 mouse plague reportedly caused over $200M in-crop damage alone and the current 2021 plague is shaping up similarly. With the National Farmers Fund's target to exceed $100B in farm gate output by 2030, their Road Map sets a course for more innovative, safe and sustainable practices in agriculture. The financial, environmental, and social costs caused by most pest animal species are difficult to quantify and are not commonly reported but have been estimated to range from $11.8M per annum for invasive European carp, $144M per annum for feral cats and $190M per annum for foxes. Due to the significant social, economic, and environmental impacts, and the current lack of efficient control methods for many vertebrate pests in Australia, development of new technologies is a critical consideration for improving pest management. Most vertebrate pests have no efficient strategic biological control technology options (apart from rabbits and potentially carp), and current control technologies have limited impact or are not suitable for effective landscape-scale control (eg. cane toads, cats).

Total eradication of an established vertebrate pest animal is generally considered not feasible, with some island eradications being notable exceptions. Conventional methods of control currently include fencing, trapping, baiting, shooting and biological control. These conventional methods vary markedly in their efficacy and economies of scale, with few methods effective at the landscape scale. There is an ongoing drive towards developing effective control tools and methods that deliver improved welfare outcomes for both target and non-target animals. Depending on the species, location and extent of the spread, a combination of techniques is typically required for sustained control of vertebrate pests to achieve population management. Importantly, these methods are costly and impractical when considering implementation at the landscape scale, which is required to effectively manage wide-ranging established pests.

Genetic biocontrol represents a transformational tool with the potential to address the high impacts of established pests of national significance in the absence of effective management methods. This is a strong driver for investment in coordinated research and development into this new and promising opportunity. Managing biosecurity is critical to a sustainable and productive agricultural sector and healthy environment. Governments at the national, state and territory levels; industry; non-government organisations (NGOs); indigenous communities and private landholders all have a long history of investing both collaboratively and individually in pest animal management. Effective management of established pests is required for Australia to meet its international obligations with respect to international trade and prevention of further biodiversity loss. The Intergovernmental Agreement on Biosecurity (IGAB, IGAB2) is signed by all jurisdictions in Australia. This agreement outlines national biosecurity goals and objectives and clarifies roles, responsibilities, and governance arrangements.

Where vertebrate pests significantly impact multiple industries and/or multiple jurisdictions, it becomes more difficult and costly for the private sector to provide effective coordinated management. The National Biosecurity Committee (NBC) established under the IGAB is responsible for managing a national strategic approach to biosecurity threats relating to, among other things, plant and animal pests and diseases, the impact of these on agricultural production, the environment, community well-being and social amenity. A core objective of the NBC is to promote cooperation, coordination, consistency, and synergies across and between Australian governments. The NBC is well placed to provide national leadership on the coordination of research and development of genetic biocontrol technologies for pest vertebrate management.

Targeted engagement with key stakeholders (interviews and workshops with Commonwealth and state governments, researchers, industry, and non-government organisations) has highlighted important factors that may influence stakeholder support for, and investment in, the development of genetic biocontrol technologies. While technical hurdles such as *proof of concept* and demonstrating the safety and efficacy of genetic biocontrol technologies (e.g. ability to contain a release, species-specificity) are yet to be addressed; a range of important factors for inclusion in a decision-making framework were identified. These include broad-ranging community engagement and mitigation of social, environmental and business/trade risks. Future development of genetic biocontrol technologies needs to be facilitated through a coordinated implementation framework that takes into account current national and international investments in this area, differences in appetite and funding sources by various private and public stakeholders, and the science knowledge gaps that need to be filled in the journey from contextualised problem formulation, technology proof-of-concept to realistic implementation.

Section 3: Decision and implementation framework for genetic biocontrol of vertebrate pest species in Australia – considerations.

3.1 National coordination and engagement

A broad range of stakeholders from a variety of sectors have an interest in the development and use of genetic biocontrol technologies including researchers, land managers, community organisations, and regulatory bodies. Direct research in genetic biocontrol technologies in Australia, to date, is typically undertaken by University and CSIRO researchers. However, additional research into the supporting information (population genetics, ecology, bioethics, social acceptability, etc) is undertaken by a much larger group of stakeholders, sometimes unknown to each other. With a growing research portfolio in genetic biocontrol, the Centre for Invasive Species Solutions together with its CSIRO and university partners is now providing national coordination of vertebrate pest genetic biocontrol research. This includes strategic planning to develop this business case and decision prioritisation framework, as well as investment in proof-of-concept research on mammal and fish model species. The decision prioritisation project is oversighted by the CISS Vertebrate Pests Genetic Biocontrol Steering Committee, which is chaired by a WA government expert and whose membership includes representatives from government (Australian Government, NSW and WA), conservation land trusts, CISS, CSIRO and key researchers. This prioritisation framework will inform National Biosecurity Committee in its priority development of a national framework for biocontrol investment and application contributing to the strategic outcome: A consistent approach to biosecurity risk prioritisation and investment across the system.

In addition, there is a sizable international effort in genetic biocontrol technology development, particularly targeting insect vectors of disease, rodents, and social acceptability of genetic technologies more generally.

The complex stakeholder and researcher environment means there would be substantial benefits from a centralised system for integration, coordination and communication of genetic biocontrol knowledge. A structure with functions similar to a Community of Practice - or Reference Panel, would be an effective mechanism by which to broker both knowledge and partnerships in genetic biocontrol. Key accountability features of a panel would include: independence from unilateral influence, transparency, and inclusion of a broad range of stakeholder groups. A key feature of the panel would be to provide an accessible, respected repository of knowledge around regulatory processes and requirements. Ideally, the panel would not duplicate existing structures, but could be embedded within and overseen by a national government committee (e.g. National Biosecurity Committee). The panel could build on the national coordination and strategic planning delivered through the Centre for Invasive Species Solutions Vertebrate Pests Genetic Biocontrol Steering Committee.

3.2 Clear pipeline from Proof of Concept to priority pest species

For most established vertebrate pests, landscape scale control options are currently lacking, and there are some concerns with use of the smaller scale techniques on animal welfare grounds. The landscape scale potential of genetic biocontrol systems and application across multiple vertebrate pests offers great benefit. Therefore, a coordinated approach to investment will be required that maximises progress in development from laboratory systems to field application, recognising that progress for some model species (e.g. mice) is more advanced than for others. The framework developed is based on a combination of published data, expert opinion, and stakeholder input to establish investment priorities for proof of concept for genetic biocontrol in vertebrate pests including a roadmap to implementation.

While feral cats may be regarded as Australia's most intractable environmental vertebrate pest species, both their biology and the sociocultural association between (domestic) cats and humans are challenges requiring considerable ecological and social research to understand the nature of these barriers and their influence on suitability and social acceptability. In consultation with stakeholders, while cats were a priority target, there was a shared understanding among pest research and management stakeholders that early investment funding into genetic biocontrol R&D would necessarily focus on model species. This was particularly expressed by Australian terrestrial conservation organisations who consider feral cats as the greatest pest threat, but not the ideal model animal for proof of concept nor as the initial target candidate. Instead, stakeholders considered carp and cane toads as good initial target candidates, believing these species to be more socially acceptable candidates for genetic biocontrol technology. This is also evidenced and supported by CSIRO's National-level population survey where support for genetic intervention showed cane toads and carp within the top three species of interest. From a practicality/feasibility perspective, carp and cane toads (like mice and rabbits that were also ranked higher than feral cats in this exercise) are also small, easily housed, and have had recent investment in genetic R&D.

The relative rankings of target pest species when compared using several criteria required for acceptable and successful use of genetic biotechnologies is illustrated in Table 1. The ranking reflects scoring against several technical criteria (e.g. knowledge gaps, current genetic biological control knowledge, related model species), social (e.g. social acceptability, effectiveness of current control, Moro et al. 2018) and ecological and economic imperatives revealed by pest research and management stakeholders. Importantly, research around gene editing has already begun in Australia using mice, cane toads and zebrafish

Table 1. Priority ranking of pest animals as potential targets for genetic biocontrol technologies. Scores derived from Stakeholder Workshops* and from Moro et al. (2018) *Global Ecology and Conservation* 13. Rankings from lowest importance/applicability/availability (0) to highest (3).

CRITERIA	Rodent	Carp	Cane toad	Rabbit	Cat	Fox
Ecological Imperative*	1	2	2	3	3	1
Economic priority*	2	1	0	3	0	1
Social acceptability*	3	3	3	2	1	2
Current control not effective	1	2	3	1	3	2
Biology/ecology knowledge	2	2	1	2	0	1
Technical development	3	2	3	0	0	0
Current genetic biocontrol knowledge	2	2	1	2	0	0
Close model species	3	3	3	2	0	0
OVERALL RANK	17	17	16	15	7	7

Importantly, stakeholders require a clear pipeline from model animal laboratory studies to real world implementation in other pest species, e.g. a 5–10-year strategy. This needs to include explicit stage gates for investment/research decisions along the length of the development process.

An R&D pipeline towards genetic biocontrol of key vertebrate pest species in Australia can be broadly divided into four phases for each target species of interest (see Figures 3a&b);

1. Proof of concept in a model animal species
2. Acquisition of essential background data and closing of knowledge gaps for the target species
3. Transfer of the technology to the target species, and
4. Implementation and rollout in target species.

All phases must be accompanied by ongoing engagement with regulators and relevant key stakeholders including the publics.

Effective genetic biocontrol approaches have not yet been demonstrated for vertebrate species. Work is currently underway in Australia aimed at demonstrating proof of concept of genetic population control in zebrafish (as a fish model species) and laboratory mice (mammalian model system). There is broad agreement that the successful demonstration of this technology in vertebrate model species is a prerequisite for potential future development and application of this technology to control other high-profile mammalian pest animals such as rabbits, feral cats or foxes, or pest fish like carp or tilapia. The immediate (next 5 year) R&D strategy into genetic biocontrol therefore needs to focus on facilitating the delivery of proof-of-concept in the respective model species (Phase 1a), while at the same time providing essential underpinning background data for other target species (Phase 1b). Only when proof of concept is successful in model species should the technology be transferred to a suitable target species (Phase 2).

3.2.1 Model System

Selection of the most appropriate model system for genetic biocontrol development to demonstrate 'proof of concept' hinges on two critical features:

i) the availability of techniques for building and introducing a genetic biocontrol tool into the germline of the species, and
ii) the generation interval of the species, i.e. the time it takes to reach sexual maturity and thus pass on and/or show the functional control trait.

For these reasons the mouse and the zebrafish are ideal model systems for mammalian and aquatic pests respectively, in which to develop and assess genetic biocontrol systems. Their small body size, established husbandry protocols, and short generation interval have established them as the dominant model organisms in the field of animal biology (Figure 1). Their fast development optimises the capacity to demonstrate successful transmission of genes, and subsequently the effect of introducing a single or small number of animals carrying the genetic biocontrol tool into a captive or isolated population (to mirror demonstrated effects in insect pests). Pilot genetic biocontrol studies using mice are already yielding data and are the subject of funding both nationally and internationally, including the development of molecular tools and genetically modified mouse lines, population genetics, ecological population studies and modelling of genetic biocontrol impacts. Similar tools are now under development in zebrafish, as a model for the aquatic pest carp in the Murray-Darling basin, following Federal investment in molecular strategies for fertility control. Rodents were the pests ranked highest by stakeholders as suitable model species for genetic biocontrol during stakeholder engagement workshops.

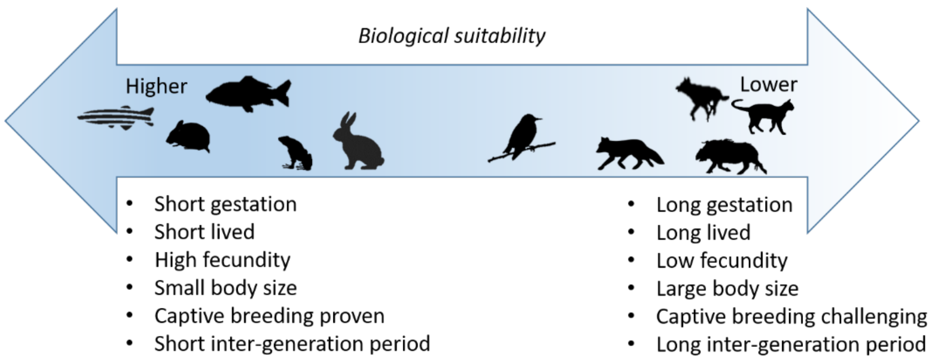

Figure 1: Species that rank highly as proof-of-concept 'model animals' for the initial demonstration of genetic biological control technology in a vertebrate, are not necessarily those with the highest ecological and / or social imperative for the application of new technologies to aid management. Rather, appropriate model species will be those whose reproductive biology and captive keeping requirements are conducive to successful demonstration of genetic biological control technologies in a laboratory setting.

3.2.2 Target Species

While initial advances in development of genetic control systems will focus on model systems, further work to increase biological and ecological knowledge in other target species with high impacts should continue. The list of Established Pests of National Significance includes rabbits, foxes, cats, cane toads, pigs and rodents on islands, all of which have current Threat Abatement Plans in force. Implementation of genetic biocontrol in target species requires key knowledge gaps to be closed. These include understanding of gene flow, density dependant reproduction, mate selection, age and sex-specific fecundity and the impact of geographic and climate factors. There is also a requirement for a reference genome, population genomics data and artificial reproductive techniques to enable integration of the genetic tool (Figure 2). Previous studies supporting the development of virally vectored immunocontraceptive strategies have generated foundational knowledge in the ecology and reproductive biology for a few key species that is still relevant within the current management strategies. Stakeholder investment will be needed for research to fill key knowledge gaps in the development of genetic biocontrol strategies. Such data also provides valuable insights to enable better use of current control measures and may reveal new opportunities/strategies as yet unforeseen.

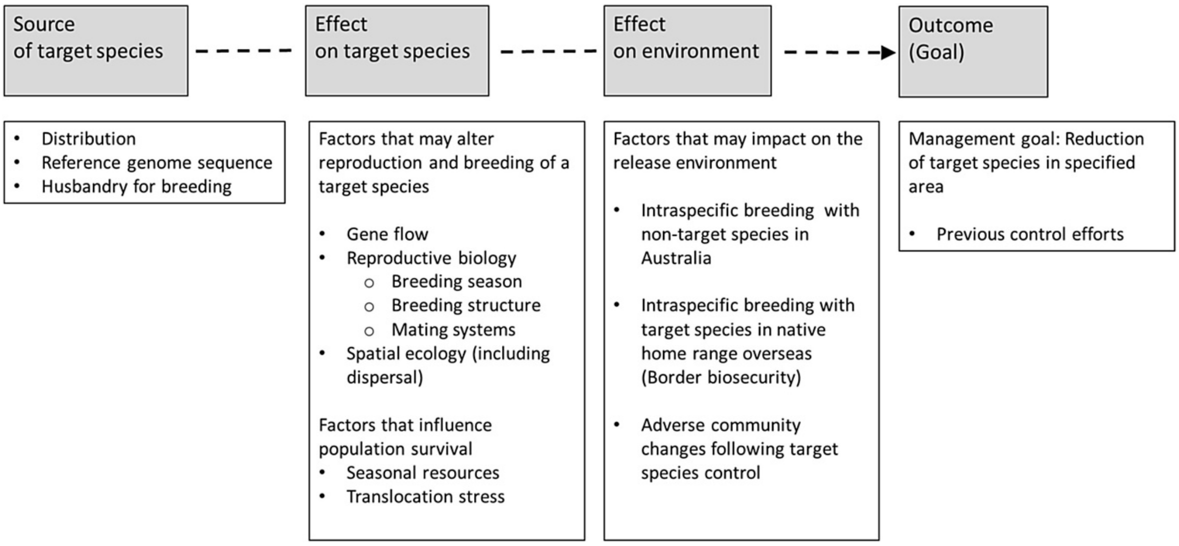

Figure 2: Conceptual model to illustrate the types of biological information required to reduce gaps and uncertainty about the spread and persistence of a gene drive construct focusing on invasive species management. From: Moro et al. (2018) *Global Ecology and Conservation* 13.

It is clear from the priority analysis (Table 1) that the key species on which to focus fall into two categories. For mammalian pests the mouse is an obvious model species for pest rodents (and potentially other mammals), with research pathways established, and a target species with both economic and ecological drivers and the benefit of international collaborative networks (GBIRd. https://www.geneticbiocontrol.org/). An early target mammalian species would be rabbits as they have similar life-history strategies (short-lived, high fecundity), are easily kept in captivity, have had previous investment in field and genetic research and have a high economic and environmental imperative for their control. For aquatic pests, the zebrafish is a closely related model for the carp target species, with advanced knowledge of the species' genetic system. In addition, recent advances have made the cane toad a model system and a target species, with notably high public acceptability for this technology.

As Phase 1a of the Road Map (Figures 3a&b) unfolds and proof of concept is achieved in the model species (years 1 – 5), concurrent work during Phase 1b would fill the critical knowledge gaps. This would immediately proceed to the next research phase (Phase 2, 5-10 years) transferring successful genetic biocontrol designs into target species, controlled environment pen trials (which will require secure facilities) and potentially islands, prior to entering the final implementation and impact assessment phase (Phase 3, 10-20 years).

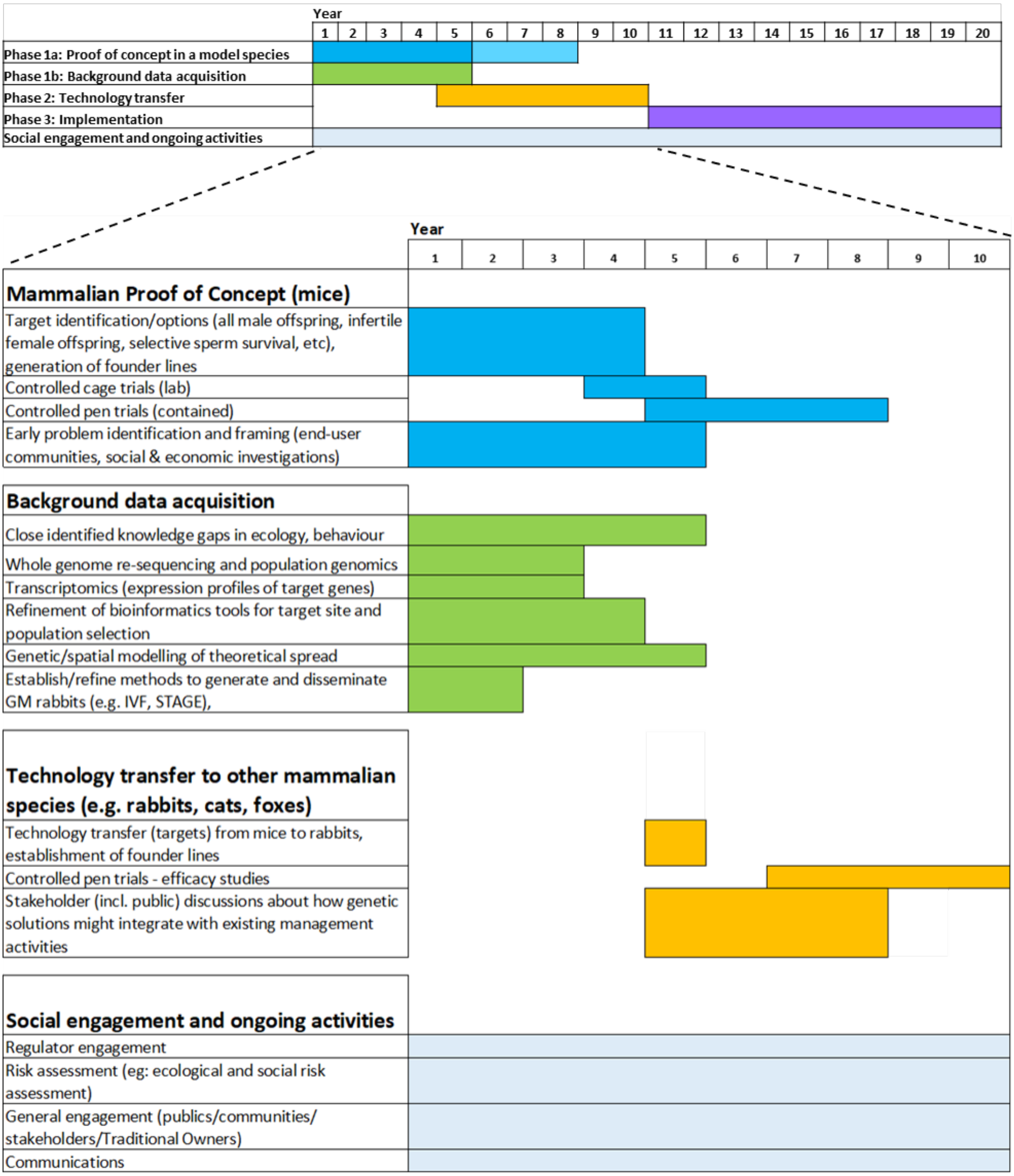

Figure 3a: Broad outline of a potential Roadmap for a mammalian genetic biocontrol.

Figure 3b: Broad outline of a potential Roadmap for amphibian and fish genetic biocontrol.

3.3 Inclusive and on-going engagement

In consultation, stakeholders identified that investment in new technologies for vertebrate pest control must show increased efficacy and humaneness over current techniques, while proving to be safe, generally acceptable to the wider community, and without negative trade impacts. Understanding the institutional decision-making environment and addressing broader social and ecological concerns will be essential for establishing stakeholder support for genetic biotechnology development (Table 2).

Table 2: Themes emerging from structured workshops describing the environments in which decision-makers work (this table first appeared in a corresponding journal paper, Carter et al. (in prep)).

INVESTMENT DECISION-MAKING ENVIRONMENT	
Push Factors (towards investment in genetic biocontrol)	Proof of concept; species specificity
	Established contextual (community-based) problem formulation and social license
	Relative advantage (i.e. better than current methods); economic cost and affordability
	Realistic time frame
	Demonstrable effectiveness, safety, conformity
Pull Factors (away from investment in genetic biocontrol)	Effects on market access; international trade implications
	Negative community perceptions
	Loss of confidence in reliability and transparency of data
	Flow-on ecosystem effects
	International mistakes (herein)
	Organised opposition
	Uncertainty: who is investing; is it a national priority
	Fragmented policy and regulatory framework
Current Reality	Opportunities for co-investment and partnership
	Dynamic funding schemes
	Animal welfare priority – real and perceived
	Balancing alternative control options
	Well-defined pathway to impact
	Program and strategy alignment
	Alignment with sustainability goals and industry profiles
Deal breakers/Game changers (factors that would be considered unacceptable and likely to derail investment efforts)	Trade insecurity or market blocks
	Evidence that undermines stakeholder confidence
	Impacts on charismatic non-target species
	Radical failure – environmental escape; ecosystem decline

Testing of an effective genetic biocontrol technology will require rigorous contained trials followed by open field trials. This will be required to provide evidence for consideration in the various stages of regulation and to gain the appropriate approvals and licences to enable implementation of a viable control system for pest animals. The licencing and approval would most certainly require post-deployment monitoring. This would serve two purposes: 1) to determine the impact of the release at the local level on the specific pest animal; 2) to monitor the location, prevalence and density of the genetic biocontrol in the environment.

Genetic biocontrol technology solutions are complex to understand and communicate and require substantive and constructive dialogue with communities likely to be affected. Investment in social science alongside biotechnology development, in addition to well-considered engagement processes which include diverse sections of society, are all required to progress genetic biocontrol solutions for vertebrate pest management. Involvement of Traditional Owners, and broader Aboriginal and Torres Strait Islander communities to co-develop culturally acceptable plans for deployment will be critical and highlights the depth of engagement required in responsible science development.

Section 4: Conclusion

Current conventional control methods fail to prevent the substantial economic, environmental, and social impacts from vertebrate pests across multiple jurisdictions. There is a clear need to support new research and development programs that aim to deliver innovative, transformative, and acceptable methods for established vertebrate pest management. It is important that these research, development and extension activities and associated funding arrangements are supported with a long-term focus.

The potential exists for genetic biocontrol technologies to deliver a game changing advantage to vertebrate pest managers, but the successful development, and implementation of the technology hinges on several critical factors. Development of the Decision-Making Framework has taken the following key factors into consideration.

- The high reproductive output of most pest animals presents a target for development of a transformational new tool (genetic biocontrol) applicable to key pest species in Australia.
- Targeted engagement with stakeholders will attract investment to develop first stage model systems (mice and zebrafish) that will yield valuable data and enable rapid translation to next stage targets (e.g. rabbits, rats and cats).
- Establishment of a group with the functions of a Community of Practice or reference panel will provide coordination and governance and maximise advancement and impact.
- Conducting on-going risk assessment (ecological and social) with input and coordination of R&D activities will provide confidence for researchers, funders, the public and regulators.
- Parallel development of public engagement and communication activities and regulatory oversight will ensure both acceptability and licensing of deployment strategies

Australia has an enviable environment for development of genetic biocontrol technologies. We have excellent scientific technical capability, an established risk assessment community, a sophisticated society able to be engaged, and strong demand for applications given the scale of vertebrate pest impacts. Establishment of a decision and implementation framework with agreed approaches to further development and strong investment in a science roadmap, will realise these current advantages and unlock the significant potential for major advances in genetic biocontrol technologies for vertebrate pest management, ultimately delivering substantial economic, environmental, and social benefits to Australia.

AS AUSTRALIA'S NATIONAL SCIENCE AGENCY AND INNOVATION CATALYST, CSIRO IS SOLVING THE GREATEST CHALLENGES THROUGH INNOVATIVE SCIENCE AND TECHNOLOGY.

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