CropLife Australia

April
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Strategic Examination of Research and Development

Strategic Examination of Research and Development: Discussion Paper

CropLife Australia Submission

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Executive Summary

Australia's ability to remain a global leader in innovation hinges on a vibrant and forward-thinking research and development (R&D) ecosystem. This submission outlines the critical obstacles currently impeding our R&D competitiveness—and provides a roadmap for turning these challenges into opportunities. Although the nation benefits from world-class universities, a strong scientific tradition, and robust public policy frameworks, key systemic issues persist.

Australia's limited domestic market often compels innovators to look internationally, curtailing local commercialisation benefits. Regulatory obstacles—especially for gene technologies and genetically modified (GM) crops—add delays, inflate costs, and generate uncertainty for investors. Short-term, fragmented funding and infrastructure exacerbate inefficiencies, while insufficient intellectual property provisions discourage the introduction of cutting-edge solutions. Additionally, untapped opportunities in talent development and cross-sector partnerships hold back the commercialisation of Australian research breakthroughs.

Despite these hurdles, the overall picture is not bleak. Australia has a burgeoning bioeconomy, strong public support for scientific research, and a proven capacity to adopt and scale new technologies. By modernising regulatory frameworks, coordinating government funding, and empowering a skilled, interconnected workforce, the nation can seize emerging global opportunities—thereby amplifying the return on each dollar invested in R&D.

The reforms and actions proposed in this document focus on streamlining regulations, bolstering intellectual property protections, extending the length and scope of funding, cultivating public–private collaborations, and promoting the retention of specialised talent. Taken together, these measures can recalibrate Australia's R&D landscape to deliver robust economic growth, innovative solutions to pressing challenges, and an enduring competitive edge on the global stage.

Key Observations

- **Small Market, Global Competition:** A limited domestic market reduces the capacity to gain a commercially viable return on R&D investment, forcing local businesses to seek overseas opportunities early in their development.
- **Regulatory Complexities:** Cumbersome or outdated regulatory frameworks can deter investment, slow technology approvals, and create uncertainty for innovators.
- **Fragmented Funding & Infrastructure:** Overlapping public programs and short-term grants can dilute research efforts and hinder the sustainability of large-scale or long-term projects.
- **Intellectual Property Gaps:** Misaligned IP protections, particularly for agricultural chemicals and biotechnology, reduce incentives for companies to launch cutting-edge products in Australia.
- **Talent Retention & Collaboration:** A robust workforce and closer partnerships between industry, government, and academia are essential to overcoming the "valley of death" that blocks promising research from commercial success.

Key Recommendations

1. **Strengthen Regulatory Modernisation**
   - Expedite overdue reforms of the National Gene Technology Scheme and finalise FSANZ Proposal P1055 for new breeding techniques.
2. **Enhance Funding Efficiency & Scope**
   - Guarantee Commonwealth, state, and territory initiatives are developed to reduce duplication and align objectives.
   - Extend R&D program lengths to nurture higher-risk, higher-reward projects that yield significant economic returns.
3. **Remove Barriers & Duplication**
   - Increase inter-agency collaboration, domestically and internationally, to reduce delays and overlapping assessments.
4. **Foster Collaborative R&D Ecosystems**
   - Incentivise multi-institution collaborations and the specialisation in public research facilities to avoid duplicative efforts.
5. **Bolster Intellectual Property Regimes**
   - Align patent extensions for agricultural chemicals and biotechnology with pharmaceutical standards to compensate for regulatory delays.
   - Strengthen data protection to encourage global data-sharing initiatives and attract greater investment in Australia's small market.

1. Introduction

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators and suppliers of crop protection products (organic, synthetic and biologically based pesticides) and agricultural biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, companies and accordingly, CropLife advocates for policy positions that ensure the agricultural sector that is internationally competitive through globally leading productivity and sustainability. Both of these are achieved through access to world-class technological innovation and products of the plant science sector.

CropLife welcomes the opportunity to engage with the 'Strategic Examination of R&D discussion paper'. We commend the Australian Government for recognising the importance of proactive steps to support research and development across the nation. It is well established that investment in R&D not only delivers impressive returns on capital but also provides solutions to emerging challenges and underpins Australia's long-term prosperity.

However, these conclusions are not new, nor are the challenges Australia faces in this regard. Australia has seen a wealth of studies highlighting the same core challenges our R&D landscape faces, along with a range of potential solutions.[1,2,3] Despite the abundance of evidence and sound guidance, many of the systemic issues remain unresolved. These challenges include the impact of a relatively small domestic market, the complexities introduced by globalised business operations, and the need for efficient, science-based regulatory frameworks. They also extend to the coordination required among universities, industry, and government to maximise returns on existing investments. By addressing these issues in a decisive manner, Australia can position itself as a global leader in agricultural innovation, protect its international competitiveness, and ensure a vibrant, sustainable future for the sector.

[1] Industry Innovation and Science Australia, 'Barriers to collaboration and commercialisation' (Report, September 2023) <https://www.industry.gov.au/sites/default/files/2023-11/barriers-to-collaboration-and-commercialisation-iisa.pdf>
[2] Australian Government Department of Industry, 'Science and Resources, Australia's RNA Blueprint: Understanding our ribonucleic acid (RNA) potential' (Report, July 2024) <https://www.industry.gov.au/publications/australias-rna-blueprint>
[3] Science & Technology Australia, 'STEM Career Pathways' (Report for the National Science and Technology Council, 2023) <https://www.chiefscientist.gov.au/sites/default/files/2024-02/STEM%20Career%20Pathways%20-%20STA%20for%20NSTC_0.pdf>

2. Challenges

The discussion paper makes for solemn reading and paints a concerning picture for Australia's future economic prosperity. Each $1 investment in R&D returns $3.50 to the Australian economy.[4] Therefore, it is critical to ensure Australia continues to develop a robust R&D sector.

However, while there is no shortage of ideas and research talent, a number of systemic challenges threaten to undermine Australia's ability to harness the full benefits of research and innovation. From the difficulties posed by a relatively small domestic market, through to the complexities of globalised business operations and the hurdles in government-controlled pathways, these factors can significantly affect how, where, and whether R&D efforts take root. Additionally, the interplay between academic institutions, industry partners, and regulatory frameworks must be carefully managed to maintain momentum and attract both local and international investment. Despite these externalities or more nebulous and entrenched problems, there remain several options available to Australian Commonwealth or State and Territory Governments to improve domestic R&D.

2.1 Globalisation

Concern: To attract R&D investment, Australia must compete globally.

R&D is an expensive pursuit that requires highly specialised staff, facilities and equipment, and therefore requires significant investment of resources and time to develop internal capacity. As such, companies will look to invest in areas that provide a stable operating environment where they can attract the personnel needed or will look towards solutions, such as contract research organisations (CROs), where they can undertake R&D without the normal overheads. As a result, Australia is competing globally for R&D investment.

Large companies often have operations in multiple countries. For instance, the Australian, Brazilian, or German divisions of a multinational may vie internally for R&D funding based on each region's prevailing conditions such as research capacity, regulatory environment and closeness to market. Meanwhile, small to medium enterprises typically have very limited footprints and may not have the resources, sufficient suitable labour, or the balance sheet strength for large R&D projects. These businesses may instead engage CROs located anywhere in the world, making this a more financially viable option. Finally, regardless of company size, academic partnerships can also span borders, although proximity has its advantages.

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[4] CSIRO Futures, 'Quantifying Australia's returns to innovation' (Report, November 2021) <https://www.csiro.au/en/work-with-us/services/consultancy-strategic-advice-services/csiro-futures/innovation-business-growth/quantifying-australias-returns-to-innovation>

While globalisation brings many benefits to Australia, it also exposes local enterprises to fierce global competition for R&D investment—even among businesses that are solely Australian-based. Thus, any discussion of Australian R&D investment must ask 'what advantages and benefits does Australia offer?'.

2.2 Small Market Size

Concern: Australia's small market limits return on investment and our capacity across multiples facets.

Australia's relatively small population constrains local demand for new products and services. For many businesses, this smaller market can make it harder to justify substantial R&D expenditure, particularly if they cannot quickly tap into larger overseas markets. This limitation can slow the pace of innovation, deter inward investment in Australian R&D, and create a cycle in which local companies must either scale globally early in their life cycle or risk being unable to recoup their development costs.

It is important to note that our reduced market size impacts almost all areas of concern. With a small domestic market, a return on investment may not be possible, the facilities and personnel may not be available, and the costs associated with regulation may be burdensome.

2.3 Government-Controller Barriers

Concern: Investment in R&D needs a return that can only be achieved with a pathway to market.

Investment in R&D needs a viable pathway to market, yet navigating regulatory systems, approvals, and funding mechanisms can be onerous. Innovation takes time and requires considerable up-front investment, so prolonged or uncertain approval processes, inconsistent policy support, and fragmented government programmes create risk and deter investors or drive them to jurisdictions where a return on investment can be captured. Without a clear, predictable, and efficient path to commercialisation, private and public R&D investments may fail to reach their potential. This challenge is especially acute for emerging technologies that do not fit neatly within existing regulatory frameworks.

2.4 R&D Ecosystems

Concern: A comprehensive ecosystem is needed that guarantees investors have access a collaborative ecosystem and the human capital needed for R&D.

A robust ecosystem is vital so that researchers, investors, and industry can collaborate seamlessly. Australia has world-class universities and research agencies, but insufficient industry linkages, inadequate intellectual property provisions, and limited venture capital can hamper commercial outcomes. Skills shortages—particularly in STEM fields—exacerbate these challenges, as businesses struggle to find or retain

specialised talent. When gaps in coordination arise or when talent and capital remain scarce, promising research may stall or move offshore, undermining long-term economic benefits.

2.5 Investment

Concern: Greater Government investment is needed, and the existing investments need to be leveraged to maximise outcomes.

Commonwealth investment of $14.4 billion in R&D is broad and spread thinly[5] and below that of other OECD nations[6]. It is also important to consider that the largest share of this funding is the R&D tax incentive funding. Although these incentives are critical for domestic R&D, their inclusion in Commonwealth funding is misleading and may result in this funding being counted twice.

Even when funding is available, Australia needs to ensure that resources are targeted and managed for maximum impact. This also requires examining the perverse outcomes from any investment. For example, Government priorities or processes that concentrate funding or biases in project selection may result highly duplicative research or activities that not suited to the Australian system. Moreover, poor strategic planning, and the inconsistent adherence to such plans, especially in research institutions, can lead to duplication of effort and missed opportunities.

The funding of any projects in Australia needs to be mindful of existing infrastructure. Often large or specific facilities are built without clear demand or ongoing funding for maintenance and personnel. Although their existence can eventually drive critical research outcomes[7], greater planning is required. Funding multiple institutes to undertake similar work that requires specialised infrastructure, such as plant growth rooms or farm plots, only dilutes what can be achieved and wastes limited resources duplicating efforts. Priority must be given to projects that leverage existing infrastructure or that are established around core strategic strengths accompanied by plans for collaboration.

By the same token, existing expertise must also be considered.

Furthermore, translating research into commercial ventures remains a persistent challenge. Intellectual property settings may prioritise key performance indicators and controlling an invention, rather than maximising benefit. Promising concepts often fail to reach market due to insufficient funding, mentoring, or infrastructure. Improving

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[5] Department of Industry, Science, Energy and Resources (Cth), 'Strategic Examination of the R&D Tax Incentive: Discussion Paper' (Discussion Paper, Australian Government, 2023) <https://consult.industry.gov.au/strategic-examination-rd-discussion-paper> ('R&D Discussion Paper'), p30.

[6] Ibid, p33.

[7] See, eg, the Australian Synchrotron.

transparency, measurement, and coordination in R&D investment strategies is crucial to ensure returns are realised and to strengthen Australia's position as a leading innovator.

2.6 Specialised Personnel

Concern: Australia risks losing its best and brightest researchers and technical experts—whether because they leave the country or pivot away from specialised fields altogether.

As highlighted in the Discussion Paper, a robust R&D ecosystem depends heavily on retaining a skilled workforce with advanced technical capabilities.[8] When these professionals depart, the nation not only forfeits the return on public investments in their education and training, but also erodes its capacity to innovate and respond to emerging challenges. This 'brain drain' can have far-reaching consequences in critical areas such as biosecurity, public health, disaster management, and logistics. Moreover, without sufficient incentives and infrastructure to support career progression in specialised sectors, Australia's capacity to conduct high-impact R&D—and to benefit from it—may be significantly compromised.

3. Intellectual Property

Recommendation: Align the intellectual property protections for agricultural/veterinary chemicals and biotechnology innovations with the provisions afforded to pharmaceutical products.

Before any agricultural chemical product or crop biotechnology innovation is brought to market, they are subject to mandatory pre-market regulatory assessment and approval. This is similar to the pre-market regulatory assessment of medicines by the Therapeutic Goods Administration. These regulatory schemes contribute to the national interest by providing consumers and businesses with access to technologies that are both safe and beneficial.

With Australia competing in a global market for access to technologies and investment in R&D for innovations in medicines, agricultural chemical products and biotechnology innovations, it is important that the regulatory settings supporting their commercialisation are well designed. These regulatory settings must ensure that global innovators are able to generate a return on the substantial investment they make in the development of these technologies and in their commercial release in Australia. This possibility is adversely impacted by the small size of our domestic market.

In recognition of these objectives, Australia's IP law allows the patent protection provided to a pharmaceutical ingredient to be extended to compensate for the period of

[8] R&D Discussion Paper, above 5, p10-12.

market exclusivity lost during pre-market regulatory assessment. Unfortunately, this recognition is not extended to developers of agricultural chemical and crop biotechnology products, impacting the financial incentive to bring new technologies to Australia in a manner that is on par with other agricultural nations. The effect of this impacts the international competitiveness of Australian farmers.

This was heightened by the 2010–2012 Raising the Bar reforms of Australia's IP arrangements, which amended the *Patents Act 1990* to introduce the process of 'springboarding'. These reforms provide an exemption from patent infringement for activities undertaken for the purpose of obtaining information that is required for regulatory approval of non-pharmaceutical products. This allows generic manufacturers to obtain regulatory approval during the term of the patent, enabling them to compete with the patent holder as soon as the patent expires.

While springboarding new products has relevant benefits (e.g. it can reduce the market cost of products), companies seeking to commercialise new and innovative products should be treated equitably with their generic competitors. Amendments should be made to Australia's IP arrangements to compensate patent owners for the real loss of the value to their patents due to the inability to obtain a commercial return during the assessment period imposed by the mandatory registration process. It is for this reason that when the reforms that enabled 'springboarding' were introduced it was recognised that such a patent extension system should be introduced to ensure a competitive and balanced IP regulatory system was maintained for regulated agricultural chemical products.

This reform to the patent system is needed to provide a pathway to market for new products, signal that we support investment in innovation and ensure Australian-based innovations remain commercially viable. Mechanisms, such as patent extensions that recognise and compensate for the loss of patent protection during regulatory assessment of agricultural chemical or crop biotechnology products, will improve the incentives for companies to invest in Australia.

3.1 Value Capture

Recommendation: Eliminate any existing gaps for capturing value within the current Australian IP system.

A robust IP framework not only protects inventions but also ensures innovators can capture sufficient value to reward their initial investment and incentivise future R&D. In agriculture, value capture extends beyond traditional patents to include mechanisms such as Plant Breeders' Rights (PBRs), which are used by plant breeding companies to generate the revenue streams that provide a return on the investment in the time and cost of breeding a new plant variety. Properly structured IP protections—covering novel traits, plant varieties, and biotechnological processes—provide innovators with a

predictable return on investment, incentivising further research and leading to a steady pipeline of advanced agricultural products.

Plant breeding, for instance, often demands extensive field testing, regulatory compliance, and years of iterative development to achieve robust, high-yield varieties suitable for local conditions. Without adequate mechanisms that support recouping investment in IP creation, developers may be unable to justify the substantial upfront costs required for plant breeding. This ultimately discourages private-sector participation in R&D, slows the rate of technological advancement and narrows the scope of investment to areas that are supported by operable value capture mechanisms, limiting Australian growers' access to the latest innovations.

It is critical than any gaps within value capture provisions within the Australian IP system be closed. This includes implementing mechanisms that restrict the ability of those who benefit from utilising protected technology to avoid paying for the use of these innovations. Opportunities for end-users to avoid paying for the use of technology limits future investment in innovation and unfairly places the burden of remunerating research, development and commercialisation costs upon those in industry who elect to comply with laws.

By ensuring that IP rights appropriately capture the value of new innovation, Australia can encourage greater private-sector involvement in agricultural research. Moreover, mechanisms that facilitate the collection of royalties or licensing fees create a virtuous cycle of reinvestment in future research, strengthening the nation's capacity to deliver high-impact innovations. A well-designed system of value capture also reduces the financial uncertainty associated with long development timelines and regulatory approval processes.

When innovators are confident that uptake of their technology will be appropriately remunerated through value capture mechanisms, whether through royalties, such as end-point royalties, licence agreements or sales, the functionality of the market for innovation will mature. This results in improved investment in ambitious projects that tackle emerging challenges, such as food security, climate resilience and disease resistance. It will also create greater competition between innovation providers that will accelerate technology delivery to farmers. This holistic approach to value capture underpins the economic feasibility of innovation, ensuring that Australian producers have access to cutting-edge solutions that keep them ahead in global markets.

4. Regulation

A science-based risk-proportionate regulatory system administered by a truly independent regulator is critical to provide certainty. An investor in Australia R&D needs to be assured that our regulatory system, both for commercial products and the

research facilities, are guided by a transparent process that maintains public confidence without saddling innovators with undue costs or delays.

A regulatory system that embraces science-based best practices and risk-proportionate assessment opens the door to innovation and investment. For example, Argentina's regulatory reforms in 2015–2016 lowered the barriers to innovation in biotechnology, especially for gene-edited crops. By eliminating the costly and lengthy GMO approval process for certain products indistinguishable from those developed through conventional breeding, the new rules opened the door to a wider range of developers. In the first four years of implementing the policy, Argentina saw a surge of NBT product submissions from universities, public research institutes, and small companies.[9] This highlights that with functional regulatory policies in place, there is a marked increase in products progressing through the relevant system. Once a global leader, it is critical that Australia reforms its aging gene technology regulatory systems.

4.1 Science-based Regulation

Recommendation: Ensure Australian regulatory frameworks remain firmly embedded in science-based risk-proportionate practices.

Regulating GM crops at a state level undermines the National Regulatory Scheme for Gene Technology. As recommended in the Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture, the remaining state and territory (Tasmania and the Australian Capital Territory) governments should remove their moratoria on GM crops. All states and territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs.

The circumvention of the national scheme is facilitated by section 21(1)(aa) of the *Gene Technology Act 2000*, which states:

> *The Ministerial Council may issue policy principles in relation to the following: recognising areas, if any, designated under State law, for the purpose of preserving the identity of one or both of the following:*
>
> *(i) GM crops;*
>
> *(ii) Non-GM crops;*
>
> *for marketing purposes.*

Section 21(1)(aa) allowed the then Gene Technology Ministerial Council to introduce the Gene Technology (Recognition of Designated Areas) Principle 2003. In doing so, states and territories have the power to disallow the cultivation of GM crops for marketing purposes.

The principle was used by Western Australia, South Australia, Tasmania, Victoria, New South Wales and the Australian Capital Territory to legislate for moratoria on the

[9] John D Smith, 'Innovations in Bioengineering' (2020) 8 *Frontiers in Bioengineering and Biotechnology* 00303 <https://doi.org/10.3389/fbioe.2020.00303>.

commercial cultivation of GMOs, leading to what was identified in the March 2015 Harper Competition Policy Review as a significant example of a regulatory restriction on competition.[10]

Section 21(1)(aa) is a costly disincentive for private investment in Australian agriculture. It has been demonstrated to be unnecessary for preserving the identity of GM and non-GM crops and it removes farmer choice, with Australian farmers missing out on millions in additional farm income.[11,12,13]

Since their introduction, moratoriums remain only for the ACT, Tasmania and Kangaroo Island (SA).

CropLife recommends the repeal of s21(1)(aa) in the Commonwealth *Gene Technology Act 2000*, the repeal of the corresponding section in state and territory acts, and the immediate disallowance by the responsible Minister of the Gene Technology (Recognition of Designated Areas) Principle 2003.

4.2 Remove Regulatory Delays

Recommendation: Guarantee regulatory reforms are rapidly implemented.

Australia needs to take urgent action to avoid being left behind. Failure to maintain science-based regulatory frameworks and to progress reforms in a timely manner has a chilling effect on R&D investment and the growth of the national bioeconomy. The only thing worse than failing to provide modern regulatory frameworks is the ongoing commercial uncertainty created by protracted and unresolved regulatory review.

4.2.1 Third Review of the National Gene Technology Scheme

Recommendation: Finalise implementing recommendations stemming from the Third review of the National Gene Technology Scheme.

The Third Review of the National Gene Technology Scheme commenced in 2017 but over seven years later, the recommendations made by the review remain unimplemented. In October 2018, the Legislative and Governance Forum on Gene Technology met to endorse the Third Review and its 27 recommendations. Forum Ministers said these recommendations will enhance and strengthen the Scheme,

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[10] Harper I, Anderson P, McCluskey S, O'Bryan M, 'Competition Policy Review Final Report' (Report, Commonwealth of Australia, March 2015) <https://treasury.gov.au/publication/p2015-cpr-final-report>
[11] Kym Anderson, *Independent Review of the South Australian GM Food Crop Moratorium* (Report prepared for SA Minister for Primary Industries and Regional Development, March 2019).
[12] Andrew Whitelaw, Matt Dalgleish and Olivia Agar, *Analysis of price premiums under the South Australian GM moratorium* (Report produced by Mecardo and commissioned by Grain Producers South Australia and the Agricultural Biotechnology Council of Australia, March 2018).
[13] Macquarie Franklin, *Market Advantages of Tasmania's GMO-free Status* (Report commissioned by the Department of Economic Development, Tourism & the Arts (Tas), April 2012).

crucial to ensuring it addresses future developments and challenges across health, medicine, agriculture, plants and animals.

The implementation delay has left the Scheme lagging in numerous areas of accumulated scientific evidence, undermining Australia's global reputation as a leader in agricultural innovation and biotechnology investment. This stagnation has had a chilling effect on R&D investment and has delayed the introduction of advanced biotechnologies essential for the sector's sustainability and growth. The delay is so significant that we are now two years overdue for a fourth review of the scheme.

Progress towards implementation has been made by the Department of Health and Aged Care (DHAC) in the past 12 months, including the release of the draft Gene Technology Bill. However, the lack of certainty on when the reform process will be complete leaves industry without the certainty necessary to plan for the investment needed to support R&D and commercialisation. By comparison, the New Zealand Government has recently released its Gene Technology Bill to establish an entirely new regulatory scheme for gene technology in a little over 12-months. This Bill will incorporate the recommendations made as part of the Australian Third Review of the National Gene Technology Scheme.

The amendments to the National Gene Technology Scheme provided by the Australian Gene Technology Bill remain modest. While the introduction of risk tiering is an important step forward, the scheme will not adequately provide Australia with a future-proofed regulatory framework. Although the continuation of process-based triggers, as opposed to an outcomes-based system, needlessly burdens innovators, this was agreed upon in the review. However, as it stands the amendments will not adequately implement all the recommendations. Furthermore, the definitions governing the organisms under the framework remain overly restrictive, limiting innovation and the integration of emerging technologies.

4.2.2 Updating the Food Code for New Breeding Techniques

Recommendation: Finalise the updating of the food standards code for new breeding techniques (FSANZ Proposal P1055).

Commencing in June 2017 and with the final report being published December 2019, FSANZ undertook a review of food derived using new breeding techniques (NBTs). Subsequently, proposal P1055 was commenced by FSANZ to amend definitions of food produced using gene technology in the Australia New Zealand Food Standards Code (the Code). With the recent completion of the proposal P1055 public consultation, it is critical that these amendments to the Code be finalised as soon as possible.

CropLife supports updates to the Code that result in foods being regulated in a manner proportionate to the risk they pose. The recognition that NBT foods have the same characteristics as conventional foods and therefore should be regulated in the same

manner as conventionally produced food is welcomed. This is consistent with current scientific knowledge and understanding, as elaborated in FSANZ's detailed safety assessment of NBTs. Furthermore, this approach is in line with progressive approaches being implemented in other international jurisdictions.

As noted in our submission to the second P1055 call for comment, the proposed definition amendments are a significant step towards a science-based regulatory system but still fall short in the development of a risk-proportionate outcome-based system. The proposed definitions potentially regulate food as GM even if they are indistinguishable from those developed through conventional breeding. This includes the classifying intragenesis as GM, despite its similarity to naturally occurring processes.

An outcome-based, rather than process-based, risk-proportionate regulatory approach ensures Australian consumers benefit from biotechnology innovations by having rapid access to food that is potentially both cheaper and better for the environment. Furthermore, continued delays in updating the code are having a chilling effect on innovation and investment in the bioeconomy. With the rapid global expansion of NBT-related products, many of our largest trading partners are leaping ahead by introducing modernised regulatory frameworks.

CropLife would like to acknowledge the considerable body of work undertaken as part of P1055 with respect to the analysis and summary of stakeholder concerns and the relevant scientific literature that relates to the proposed changes.

CropLife recommends that sufficient resourcing and support is provided to FSANZ to ensure the timely completion of P1055. This will provide industry with the certainty necessary to introduce additional products to the comparably small Australian market and thus provide access to Australian consumers.

4.3 Ensure Appropriate & Proportional Cost Recovery

Recommendation: Ensure any cost recovery initiatives are appropriate, proportional and do not inhibit innovation.

While CropLife supports cost recovery, we are concerned that the introduction of cost recovery on OGTR activities, or unwarranted increases for FSANZ and APVMA, will adversely impact Australia's development as a global agricultural innovation hub. The bioeconomy is still very much in its infancy but if Australia is to carve out a slice of this lucrative market, we need to remove barriers to R&D for both the commercial sector and academia.

It is also important to acknowledge the need for ongoing Government funding for Australia's regulatory agencies. Each agency undertakes considerable work for the

public good. Relying on commercial funding for these activities will significantly raise costs and inhibit innovation.

The current discussion surrounding OGTR cost recovery suggests a series of models that will greatly raise the costs of undertaking research, testing novel products in the Australian environment, and subsequently commercialising them. With countries globally, including many of our biggest trading partners and competitors, fighting to attract R&D investment and partnerships with their academic sector through generous incentives, it is vexing that Australia would take the opposite approach. Our concern is further compounded when one considers the Government rhetoric surrounding the importance of growing the bioeconomy.

CropLife recommends that moves towards cost recovery at the OGTR be postponed allowing the Australian biotechnology sector to develop. Moreover, CropLife recommends adequate funding be provided to the OGTR to ensure that all applications continue to be reviewed promptly.

4.4 Eliminate Inter-Agency Duplication

Recommendation: Ensure close collaboration between regulatory agencies for aligned assessments.

Regulatory duplication can significantly delay the commercialisation of cutting-edge technologies and create additional administrative burdens for innovators. When multiple agencies assess the same product or process, overlapping requirements and inconsistent timelines increase costs and uncertainties. This, in turn, can discourage investment in Australian R&D and slow the delivery of potential benefits—whether in agriculture, medicine, or the broader economy.

An excellent recent example of effective inter-agency collaboration is the simultaneous assessment of a GM banana developed for resistance to Fusarium wilt tropical race 4 by the Queensland University of Technology.[14] The OGTR and FSANZ worked in tandem to review the GM banana, streamlining data requests and coordinating approvals. This alignment not only reduced duplication of effort but also provided greater certainty for the project's proponents. By receiving timely, coordinated feedback, researchers and investors were better able to manage resources and prepare for eventual commercialisation. Such collaboration could also be expanded to other regulatory agencies. For example, between the APVMA and OGTR. This is critical for GM crop varieties with herbicide resistance traits—a space that has seen significant delays.

[14] See, eg, Office of the Gene Technology Regulator, 'DIR 199:Commercial release of banana genetically modified for resistance to Fusarium wilt tropical race 4 (TR4)' (Website, Accessed March 2025) <https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-199>.

This kind of inter-agency cooperation should be the norm rather than the exception. When agencies proactively share information, standardise protocols, and synchronise review timelines, Australia's regulatory frameworks become more transparent and efficient. This fosters an environment that attracts global innovators, secures funding for local research projects, and brings novel technologies and products to market sooner—without compromising safety or integrity. By prioritising cohesive, science-based regulatory approaches, Australia can strengthen its leadership in agricultural, environmental, and medical innovation.

5. International Harmonisation & Assessment

5.1 Intellectual Property

Recommendation: Strengthen Australia's IP and data protection frameworks for agricultural pesticides and biotechnology to align with international standards, reducing duplicative data requirements and expediting market access for innovative solutions.

Effective intellectual property (IP) protections are essential for fostering research and development in plant science, ensuring that innovative technologies reach Australian farmers in a timely and commercially viable manner. Improving Australia's IP arrangements for pesticides and biotechnology will strengthen commercial incentives for companies to invest in the timely registration of these technologies, with the full range of potential uses (ie: crop and pest combinations) included at initial registration.

Australia's small market size already presents a significant challenge to attracting investment in new agricultural technologies. Considering ongoing uncertainties regarding approval timelines at the Australian Pesticides and Veterinary Medicines Authority (APVMA), many registrants will elect to submit only the most certain and viable application dossiers to prevent any potential delay in registration.

In addition to the patent protection provisions outlined above, there are provisions for protecting commercially confidential information (CCI) that is used to support the approval or registrations of pesticides. These are data generated to satisfy the statutory criteria of manufacturing quality (chemistry and stability), safety, efficacy, and trade. These go beyond the technical specifications protected by patents, but are equally important to patent protections. The "limitation of use"[15] provisions are designed to encourage innovation. Generally, Australian data protection and limitations of use provisions are substantially weaker than those of competing nations.

[15] Australian Pesticides and Veterinary Medicines Authority, 'Limits on Use and Disclosure of Information' (Web Page) <https://www.apvma.gov.au/registrations-and-permits/limits-on-use-and-disclosure-information>.

Aligning Australia's data protection measures with international jurisdictions would also play a crucial role in reducing the costs associated with generating duplicative scientific data. Stronger data protection would facilitate collaboration with global minor use programs, making it more economically feasible to commercialise new pesticides in Australia.

For example, Australia's weaker data protection measures compared to the United States and Canada pose a barrier to negotiating access to valuable scientific data generated by international research initiatives like the Agricultural Handler Exposure Task Force (AHETF). The shorter data protection periods in Australia undermine the commercial value of the investment made by AHETF members, discouraging data-sharing agreements and increasing the cost of bringing new solutions to Australian farmers.

By strengthening intellectual property protections and harmonising data protection policies with key trading partners, Australia can create a regulatory environment that encourages investment in cutting-edge agricultural innovations. This will not only benefit the research and development sector but also support Australian growers by improving access to safer, more effective, and environmentally sustainable crop protection solutions.

5.2 Regulatory Framework Harmonisation & Collaboration

Recommendation: Strengthen formal inter-agency collaboration, data sharing, and review processes while ensuring our frameworks harmonise with international science-based best practice.

International alignment and collaboration not only greatly improves regulator efficiency, it strengthens our commercial attractiveness by providing common pathways to market. Facilitating approvals across multiple jurisdictions, with limited or no need for additional applications or data, allows Australia to overcome some of the adverse impacts of our small market size.

A standout example of beneficial regulatory collaboration is the partnership between Food Standards Australia New Zealand (FSANZ) and Health Canada in assessing genetically modified (GM) foods. Both agencies maintain high scientific standards and rigorous processes for evaluating the safety of novel food products before they enter the market. By sharing data, methodologies, and best practices, FSANZ and Health Canada have been able to:

- Reduce Duplication: Through mutual exchange of scientific findings and dossiers, each agency can streamline its review process. This means fewer repeated assessments of the same scientific evidence, leading to more efficient use of resources and faster approval times for safe and beneficial GM products.

- Maintain High Standards: Collaboration ensures that any new evidence or concerns identified by one regulator are quickly communicated to the other. This continuous exchange of insights strengthens the rigour of both agencies' assessments, ultimately providing consumers with greater confidence in the safety of approved products.
- Encourage Innovation: When innovators recognise that approval in one country can facilitate or accelerate the process in another, it incentivises further investment in R&D. Companies are more likely to develop or introduce novel GM foods in Australia if they know that parallel processes with Canada—and the potential for reduced regulatory barriers—exist.

This form of collaboration represents a powerful model for how Australia can work with other advanced regulatory agencies around the world. Formal agreements, shared review processes, and regular engagement on emerging scientific issues all help maintain a level playing field and boost investor confidence in Australian-based R&D activities.

6. R&D Requires Personnel

6.1 Industry PhDs

Recommendation: Extend support for industry-led PhD projects.

The discussion paper noted that industry employers are sceptical of the value of PhDs or the alignment of their skillsets with needs, and that researchers have limited networks with people in other sectors. However, these conclusions do not appear to be supported. There is a wealth of studies highlighting the value of industry-based PhDs, particularly in developing the professional networks and applicable skills that graduates acquire. For example, 76% of industry-based PhD students went on to work in the same industry[16], 80% of industrial PhD students acquired employment in the private sector after the conclusion of their degrees[17], and the likelihood of successful PhD completion increased if the industry had funding involved in the project[18]. In Australia, industry

[16] Gustavsson, L, C Nuur and J Söderlind, 'An impact analysis of regional industry–university interactions: the case of industrial PhD schools' (2016) 30(1) *Industry and Higher Education* 41–51.
[17] Kolmos, A, LB Kofoed and XY Du, 'PhD students' work conditions and study environment in university- and industry-based PhD programmes' (2008) 33(5–6) *European Journal of Engineering Education* 539–550.
[18] Salimi, N, R Bekkers and K Frenken, 'Success factors in university–industry PhD projects' (2016) 43(6) *Science and Public Policy* 812–830.

PhDs offer candidates a wider range of skills and place the onus of universities to advertise and raise awareness of the value of industry-based PhDs.[19,20]

Industry-PhDs are also currently a core piece of multiple Australian Research Council (ARC) Industrial Transformation Training Centres that see widespread partnership with a wide range of entities.[21] These partnerships foster inter-sector relationships and provide direct industry experience for students.

Furthermore, such PhDs also result in an increase in university to private sector networks, which may aid in alleviating the issue of the current limited networks of university-based researchers. If as is stated in the discussion paper that initiatives to encourage industry-based PhDs are small and narrow in their scope, then they clearly need expansion and promotion.

6.2 Staff Mobility

Recommendation: Incentivise staff mobility between industry, academia, and government sectors.

Staff mobility between academia, industry, and government research agencies can help close skill gaps, accelerate technology transfer, and enhance professional development. Encouraging secondments, joint appointments, or sabbatical-like opportunities allows researchers to gain firsthand knowledge of industry needs while enabling companies to tap into the latest academic expertise. This could also be achieved through metrics within block grant funding for the university sector.

Promoting staff mobility helps cultivate a well-rounded workforce capable of bridging the “valley of death” where many innovations fail to move from the lab to the marketplace. It can also help to disrupt entrenched barriers to inter-sector collaboration.

[19] Roberts, AG, ‘Industry and PhD engagement programs: inspiring collaboration and driving knowledge exchange’ (2018) 22(4) *Perspectives: Policy and Practice in Higher Education* 115–123.
[20] Bröchner, J and AA Sezer, ‘Effects of construction industry support for PhD projects: the case of a Swedish scheme’ (2020) 34(6) *Industry and Higher Education* 391–400.
[21] Australian Research Council, ‘Industrial Transformation Training Centres’ (Webpage, Accessed April 2025) <https://www.arc.gov.au/funding-research/funding-schemes/linkage-program/industrial-transformation-research-program/industrial-transformation-training-centres>

7. Maximising Existing Investment

Supporting additional R&D investment is critical. However, as noted above, Australia must also maximise the benefits of existing investments to enhance returns, drive innovation, and provide potential investors with the certainty needed to commit new resources. Strengthening efficiencies in the public research sector, expanding the role of state and territory funding, improving the longevity and stability of R&D programs, and fostering robust industry partnerships will be vital to this mission.

7.1 The Public Research Sector

Recommendation: Remove duplicative efforts between publicly funded institutes and foster greater collaboration.

It is critical that Australia develops a system that harnesses long-term strategic planning and focus for our public research sector. Individual institutions need the incentives to specialise with respect to facilities and staff, and to collaborate with other institutes and as well as industry.

Australia's public research ecosystem includes numerous universities, Cooperative Research Centres (CRCs), and government agencies (e.g., CSIRO and state-based institutes). While this diversity brings invaluable expertise, it can also lead to overlapping or duplicate efforts. Many institutes compete for similar research grants and industry partnerships, limiting opportunities for synergy and risking inefficient use of public funds. By consolidating or coordinating complementary specialisations, Australia could focus on building well-defined centres of excellence, each with clear mandates and capabilities.

Once again, incentivisation for institute specialisation and collaboration can be achieved via block funding with specific metrics relating to these aspects. This would ensure continued funding for shared facilities even in the absence of project-specific grants. Moreover, it could help to reduce duplication. In addition, stronger incentives for collaboration—such as multi-institutional grants, shared infrastructure, and joint graduate programs—would enable more coherent, large-scale research projects. Reducing duplicative efforts not only cuts costs but also offers industry clearer avenues for engagement, as they can more easily identify the best partners for specific research challenges. Ultimately, a more integrated public research landscape that draws on each organisation's unique strengths will enhance Australia's global standing in R&D and provide a more compelling case for both domestic and international investment.

7.2 State & Territory Funding

Recommendation: Improve synergy between federal, state, and territory R&D funding.

Although the Discussion Paper focuses largely on Commonwealth-led R&D initiatives, it is remiss not to address the importance of state and territory funding in shaping the

national research landscape. State and territory governments often administer their own grants, incentive schemes, and tax offsets to attract and retain R&D-intensive enterprises. These programs can be critical in areas such as regional development, localised industry clusters, and specialised research infrastructure (e.g., precincts or technology parks).

Better coordination between federal, state, and territory funding initiatives could amplify the impact of every dollar invested. Regularly convening cross-jurisdictional working groups, publishing consolidated funding strategies, and establishing shared metrics for success would help align objectives across all levels of government. This not only improves transparency and accountability but also streamlines industry engagement, making it easier for businesses—particularly small to medium enterprises—to access the resources they need to undertake R&D in Australia.

7.3 Program Length

Recommendation: Extend the timing of funding programs to provide certainty for R&D.

R&D programs in Australia are typically subject to short, fixed-term funding cycles. While such timeframes may be sufficient for proof-of-concept studies, they can be insufficient to nurture long-term initiatives, especially in fields requiring extensive trials, regulatory approvals, or capital-intensive infrastructure. Shorter program windows also introduce greater uncertainty for researchers and investors, who may be reluctant to commit resources if subsequent funding is not guaranteed in the long term.

Even the most dynamic companies require long-term strategic planning especially for R&D projects that can take decades for commercial product development. This necessitates a stable R&D ecosystem and partners.

Lengthening or staggering program terms—particularly for research areas with proven strategic importance to the national interest like agriculture—would aid in sustaining critical talent and intellectual capital. By offering long term or rolling funding models, Australia would encourage higher-risk, higher-reward projects that might otherwise remain unexplored domestically. This approach would also reduce administrative burdens associated with constant reapplications, allowing researchers to focus on delivering tangible outcomes and fostering stable relationships with industry partners.

7.4 Industry Partnership

Recommendation: Strengthen incentives and frameworks for industry–research collaboration.

Strong industry partnerships are essential for translating research breakthroughs into market-ready solutions. In many cases, public researchers and private companies operate in silos, limiting opportunities to share expertise and resources. Encouraging industry-based doctoral programs, secondment opportunities for researchers, and co-

funded facilities can bridge these gaps and create a pipeline of commercially relevant ideas. Such approaches also help develop a skilled workforce able to move fluidly between academic research and industry problem-solving.

Moreover, targeted policy tools—such as matched funding, tax incentives for collaborative projects, and dedicated industry liaison offices within universities—could stimulate closer ties between researchers and businesses. Effective partnerships reduce the "valley of death" risk, where promising concepts fail to attract the support necessary for full commercial development. By embedding strong collaboration mechanisms at every stage of the R&D process, Australia can maximise returns on existing public and private investments, ultimately driving economic growth and reinforcing the nation's position as a global leader in innovation.

8. Conclusion

Australia stands at a crossroads in its effort to remain a globally competitive innovator. This submission has highlighted systemic challenges in our R&D landscape—including the small domestic market, regulatory complexities, funding structures, and talent retention—and suggested policy avenues to address them. Although the current environment is challenging, Australia has the building blocks to succeed: world-class universities, a robust regulatory tradition rooted in science, and an emerging bioeconomy rich with potential.

By modernising regulatory frameworks, enshrining agency independence, fostering stronger industry partnerships, coordinating funding across all levels of government, and prioritising long-term investment strategies, Australia can reinvigorate its R&D ecosystem. Such actions will not only protect our international competitiveness but also ensure that new technologies and scientific discoveries continue to enrich the broader economy and society.