CropLife Australia

May
2024

Inquiry into Food and Beverage Manufacturing in Australia

House of Representatives Standing Committee on Industry, Science and Resources

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, Australian and International companies and accordingly, CropLife advocates for policy positions that deliver whole of industry and national benefit. Our focus is, however, specifically on an Australian agricultural sector that is internationally competitive through globally leading productivity and sustainability. Both of which are achieved through access to world-class technological innovation and products of the plant science sector.

CropLife welcomes the opportunity to contribute to this Inquiry by the House of Representatives Standing Committee on Industry, Science and Resources. With the global population expected to reach 9.8 billion by 2025[1], increasing Australia's capability to add value to our primary production provides the opportunity to grow the bioeconomy's contribution to our nation's prosperity. Analysis undertaken by AlphaBeta for Food Innovation Australia Ltd, identified the opportunity to increase the value-add provided by the Australia's food and agribusiness sector to $200 billion by 2030. Growth of this magnitude would result in the creation of an additional 300,000 jobs in the sector over the period 2019-2030.[2]

As part of positioning the Australian economy to capture this benefit, it is important that government policy settings and regulatory frameworks support the confidence necessary to underpin commercial investment decisions by members of the plant science industry. This is essential to providing Australian farmers with the technologies that will enable them to maintain and expand Australia's food production to meet the needs of our domestic food processing industry.

Ensuring these policy settings are fit for the future has never been more important with the pace of change impacting food production never having been greater. Under these stresses, farmers are being called upon to produce more food on less land and to do so in the face of environmental challenges headlined by climate change and increasing expansion of pests like fall armyworm. At the same time, changes in market tastes and new opportunities for domestic food manufacturing has created the opportunity for Australian farmers to diversify production into new crops. However, this can only be achieved where locally adapted crop varieties can be developed and environmental stresses, like plant disease, can be managed in the farming system.

---

1 United Nations, 'World Population Projected to Reach 9.8 Billion in 2050 and 11.2 Billion in 2100', United Nations, accessed 24 April 2024, https://www.un.org/en/desa/world-population-projected-reach-98-billion-2050-and-112-billion-2100.

2 Food & Agribusiness Growth Centre, *Capturing the prize: The A$200 billon opportunity in 2030 for the Australian food and agribusiness sector* (October 2020).

Likewise, Australian food and beverage manufacturers are competing against manufacturers based in nations with future-oriented regulatory schemes that create greater stability for investment in innovation. The development of innovative food production processes, like molecular farming, is being driven by start-up businesses reliant on sources of equity investment. Clear, consistent and modern regulatory pathways that allow these products to proceed to consumer markets are essential to attracting the investment necessary for R&D, production commercialisation and to scale up to production.

Supporting a highly efficient, productive and prosperous food and beverage manufacturing sector in Australia is dependent on implementing policies that embrace the role of innovation in the bioeconomy, especially in Australia's farming sector. These policies need to provide farmers and food and beverage manufacturers with access to the latest technological developments and provide them with clear access to local and international markets.

By harnessing these technologies, Australia can enhance agricultural productivity, improve nutritional content, develop novel products and address environmental and sustainability challenges. In turn, this will ensure that the Australian-based food and beverage manufacturing sector maintains consistent and competitive access to ingredients required for largescale production. The potential of these technologies is currently constrained by outdated regulatory frameworks that delay the deployment and commercialisation of innovative products. **Targeted modernisation and harmonisation of critical regulatory structures is necessary to foster innovation and grow our agricultural bioeconomy while ensuring sustainable practices and food security are significantly improved.**

A HIGHLY EFFICIENT & INNOVATIVE SECTOR

The efficiency and productivity of Australia's farming sector directly leads to improvements in food and beverage production, but our world-leading position remains reliant on innovative technologies and practices. Amongst these is a wealth of crop and protection products (CPP), novel and genetically modified (GM) varieties of economically critical crops, and rapid adoption of industry best-practices.

A 2023 Deloitte Access Economics report[3] estimates that crucially, CPPs underpin a substantial portion of agricultural productivity, directly contributing to $30.2 billion of Australian agricultural output in 2020-21. This represents 70 per cent of the total value of crop production. Furthermore, the utilisation of CPPs extends beyond agriculture, providing benefits in non-agricultural sectors such as gardens, sports ovals and public spaces, enhancing accessibility, amenity and health benefits.

Notably, practices enabled by herbicides and herbicide-resistant GM crops, such as no-till farming, have demonstrated environmental benefits by reducing soil erosion by 80 per cent and protecting water quality. Evidence suggests that without CPPs, there could be a substantial decline in global fruit, vegetable and cereal production, underscoring the vital role of these technologies in sustaining agricultural productivity and food security. The report indicates that without implementing CPPs in some key crops, there could be a global decline by 78 per cent in fruit production, 54 per cent in vegetable production and 32 per cent in cereal production. As such, CPPs are important to maintaining and growing production of these commodities that are a cornerstone of advanced food manufacturing.

[3] Deloitte Access Economics (2023) *Economic contribution of crop protection products in Australia*, https://www.croplife.org.au/wp-content/uploads/2023/08/CropLife-economic-contribution-final-draft-report-Deloitte-Aug-2023.pdf

EMERGING TECHNOLOGIES

Necessity, our need to produce more from less, has been the mother of invention in the food production sector over the past decade. Global embrace of this innovation has accelerated since 2020. Spurred on by the pandemic-induced logistics shock, an increasing number of countries are implementing programs to become food self-sufficient.[4] The flurry of developments has seen technologies emerge like precision genomic editing for many key foods, cellular agriculture that includes cell cultivation, precision fermentation and molecular farming and innovative pest control techniques.

Biotechnology

Gene editing, epitomised by technologies such as CRISPR, is a cornerstone of synthetic biology and the emerging global bioeconomy. The technology promises to rewrite the rulebook for multiple industries, ranging from healthcare to agriculture. Although to realise the CSIRO vision of "[s]ynthetic biology has the potential to unlock $27 billion in annual revenue and 44,000 jobs in Australia by 2040",[5] regulatory modernisation and certainty is needed.

The gene editing revolution has been brought about by scientists harnessing naturally occurring enzymes that cut genetic material, site directed nucleases (SDNs), to offer precise modifications to the genome of target organisms. Building on traditional genetic modification (GM) techniques, SDNs have facilitated the development of crops and animals with enhanced traits such as increased yield, pest resistance and improved nutritional profiles. Unlike conventional breeding or traditional GM technology, gene editing allows for quicker and more precise alterations, holding significant promise for the food and beverage sector.

SDNs are typically broken down into three categories:

- SDN-1 employs only a targeted nuclease that relies on cellular repair processes to introduce mutations at the target location. This technique is typically used to switch off specific genes such as the one responsible for cows growing horns.
- SDN-2 also includes the targeted nuclease but also DNA templates that guide a cell to repair the target gene in a specific minor way. This can be used to repair a broken gene, like many of those in human disease, or to introduce a minor change.
- SDN-3, rather than the DNA template used in SDN-2, includes a long DNA sequence that through cellular repair will be introduced into the cell's genome. Like traditional GM techniques, this allows the introduction of novel genes. However, due to the precision of SDNs, the introduction of any novel information is highly efficient and occurs at a precise location.

[4] See, eg, Singapore Food Agency, '30 by 30', accessed 24 April 2024, https://www.ourfoodfuture.gov.sg/30by30.

[5] CSIRO Futures (2021) 'A National Synthetic Biology Roadmap: Identifying commercial and economic opportunities for Australia' CSIRO, Canberra.

Each of these techniques can be used to create novel crops and foods that are indistinguishable, right down to the genetic level, from those developed through conventional breeding. This means that the 12,000-year-old process of breeding plants and animals for agricultural purposes, that still takes decades for each new variety, is rapidly accelerated with greater accuracy. The increased speed and accuracy of plant breeding, facilitated by gene editing technologies, lowers breeding costs and offers great opportunities for the development of custom varieties that incorporate specific traits or are adapted to specific environmental conditions. This offers great scope to increase the adaptation of Australian food production to climate change and to increase production of niche varieties to support domestic food and beverage manufacturing.

Cellular Agriculture

The rapid expansion of both the scale and scope of cellular agriculture has created a highly diverse range of products capable of enhancing our existing food production sector. Typically involving culturing large volumes of a given cell to produce a very wide range of products that includes foods and feed, medicines and textiles.

Areas of cellular agriculture include cell cultivation that involves culturing animal cells to make products such as meat, seafood, leather and fat; or from plants to make products like coffee and chocolate. It also includes precision fermentation that harnesses microorganisms (such as fungi and bacteria) to produce specific functional ingredients used in numerous food and agricultural products such as egg and dairy proteins, fats and oils. This also builds on the long history of synthetic production of key products like insulin, rennet and industrial enzymes. Finally, molecular farming is an emerging technology that uses plants and the power of photosynthesis to produce targeted functional ingredients, including proteins and fats.

Sustainability, Value Adding & Reducing Waste in Australian Agriculture

Faced with significant headwinds from a changing and unpredictable climate, a cost of living and food security crisis, and the rising cost of inputs, Australian food producers are facing some of the most complex conditions in their history. However, despite this, we are developing critical innovations to overcome these issues one at a time. Moreover, on the horizon there are numerous developments that will ensure Australia remains one of the world's most efficient food producers.

Aquaculture of ocean fish typically relies on omega-3 fatty acids that are largely sourced from wild-caught ocean fish. However, this is at or past sustainable harvesting capacity. By using an Australian developed variety of canola bio-enhanced to produce omega-3, global aquaculture can become greatly more sustainable. This canola variety has now received regulatory approval to support Norway's large aquaculture sector.[6] This variety, when grown as a rotational crop, results in improved performance of subsequently grown crops.

[6] AquaTerra Omega3, 'Norway Approves AquaTerra Omega-3 Oil for Use in Aquafeed', accessed 24 April 2024, https://aquaterraomega3.com/norway-approves-aquaterra-omega-3-oil-for-use-in-aquafeed/.

Given Australia's vast tracts of land, gene-edited organisms could revolutionise the nation's energy sector. However, a lack of clear regulatory frameworks can act as a deterrent to investors eyeing this burgeoning space. With biomass value-adding listed as a key ingredient in Australia's sustainable aviation fuel ambitions[7], innovation is critical.

There are also numerous exciting developments within the development pipeline that include a vast range of crops that can grow with less water, in smaller areas, are more nutritious, and have improved resistance to agricultural pests. For example, the OTGR recently approved a University of Adelaide field trial for wheat and barley varieties[8] that looks to improve overall yield and specifically water/nutrient use efficiency.

[7] CSIRO, 'Sustainable Aviation Fuel', accessed 24 April 2024, https://www.csiro.au/en/news/All/Articles/2023/September/sustainable-aviation-fuel.

[8] Commonwealth of Australia, Office of the Gene Technology Regulatory, 'DIR 201 Limited and controlled release of wheat and barley genetically modified for yield enhancement', accessed 15 April 2024, https://www.ogtr.gov.au/gmo-dealings/dealings-involving-intentional-release/dir-201.

TIMELY & COST-EFFECTIVE PATHWAYS TO MARKET

There is substantial investment from the Australian Government, industry and growers in Australia's 15 Rural Research and Development Corporations (RDCs). This is set against a broader background of large programs and initiatives, each funding groups of projects, aimed at developing the genetics that will drive Australian agriculture forward. However, to realise the potential of this investment, a clearly defined pathway from lab to field is desperately needed. The greatest risk is that these Australian-developed innovations will be purchased cheaply and introduced into foreign markets. These innovations would then be competing directly with Australian farmers.

Despite the enormous promise of existing and emerging technologies, timely and cost-effective pathways to market in Australia remain a critical stumbling block. The thinness afforded by Australia's small market size means availability of crucial innovations are frequently delayed or just simply do not materialise. This problem is widespread with costs and delays in one area compounding impacts in other areas. These barriers to market include:

- **Costs of Crop Protection Product Assessment:** For example, registration of CPPs in Australia is often not commercially viable as our small market has regulatory costs comparable to the US or Europe – which are each around seven times larger than the local market.
- **Costs of Novel Food Applications:** Food Standards Australia New Zealand (FSANZ) presently classifies cellular agriculture applications as a major procedure and thus there is an approximate cost of $200,000(AUD) for an application. No other international jurisdiction charges for novel food assessments This serves to make Australia a less attractive market and is a critical barrier to pre-revenue companies seeking to scale a new product.
- **National Gene Technology Scheme Delays:** The Third Review of the National Gene Technology Scheme (the Third Review) is now entering its seventh year without a clear timeline to implementation.
- **Delays in Reviewing Gene Edited Foods:** FSANZ commenced Proposal P1055[9], reviewing the definitions for gene technology and new breeding techniques, early in 2020. Like the Third Review, delays in finalising P1055 have created a holding pattern for introduction of gene edited products with innovators waiting on the final decision. It is noteworthy that in 2021, the OTGR exempted SDN-1 derived organisms from classification as genetically modified organisms (GMOs). This decision stemmed from OTGR technical review that commenced in 2016.

[9] FSANZ 'Proposal P1055 - Definitions for gene technology and new breeding techniques' accessed 18 April 2024, https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques.

COMMERCIAL SUPPORT

In recognition of both the importance and impact of the regulatory approval process and the need for a return on the substantial investments of money and time expended on the generation of new pharmaceuticals, many countries have introduced a system of patent term extensions in relation to patents that protect regulated pharmaceutical products. This is already demonstrated in Australia; s70 of the Patents Act 1990 provides for patent term extensions for pharmaceutical products of up to five years in appropriate circumstances.

While CropLife is composed of both patent holding and generic companies and advocates for an accessible and competitive generic market, reform to the patent system is needed to equitably deal with product spring boarding. Mechanisms, such as patent extensions, need to be put into place to recognise the loss of patent protection value that occurs when agricultural chemical or crop biotechnology products are undergoing mandatory regulatory assessment.

These amendments, if made to Australia's IP arrangements, would compensate through time extension patent owners for the real inability to realise a commercial return during the assessment period imposed by the mandatory registration process. In turn, this would encourage increased agricultural science investment and innovation in the Australian market. Australian agriculture, and specifically farmers, would benefit as a result.

While a new crop protection product may gain registration in Australia, it often isn't approved for all potential applications. For instance, a pesticide might be approved for use on citrus and apples but not on bananas and avocados. Each specific use requires separate registration that relies upon the development of specific data to ensure the safety and efficacy of the product for that use in the Australian environment. The cost associated with generating the data package necessary for regulatory assessment means that even if a product proves profitable for a major crop like wheat, it might not be financially viable for registration on other crops or pests, despite being well-suited for them. This trend of 'partial registration' is becoming more common with initial registrations. Introducing a patent credit system not only enhances the commercial feasibility of more products for registration in Australia but also expands the range of approved applications for these products.

Given the crucial nature of crop protection products underpinning the production of food crops in Australia, and that the commercial production of carrots, onion, strawberries and potatoes would not be possible without them,[10] increasing the attractiveness of the Australian market is vital.

[10] Deloitte Access Economics, 'Economic Contribution of Crop Protection Products in Australia', August 2023, https://www.croplife.org.au/resources/reports/economic-contribution-of-cropprotection-products-in-australia/

The protection of commercial investment through patent credits has demonstrably increased R&D investment and commercialisation of pharmaceutical drugs in jurisdictions where it has been enacted (See Figure 1)

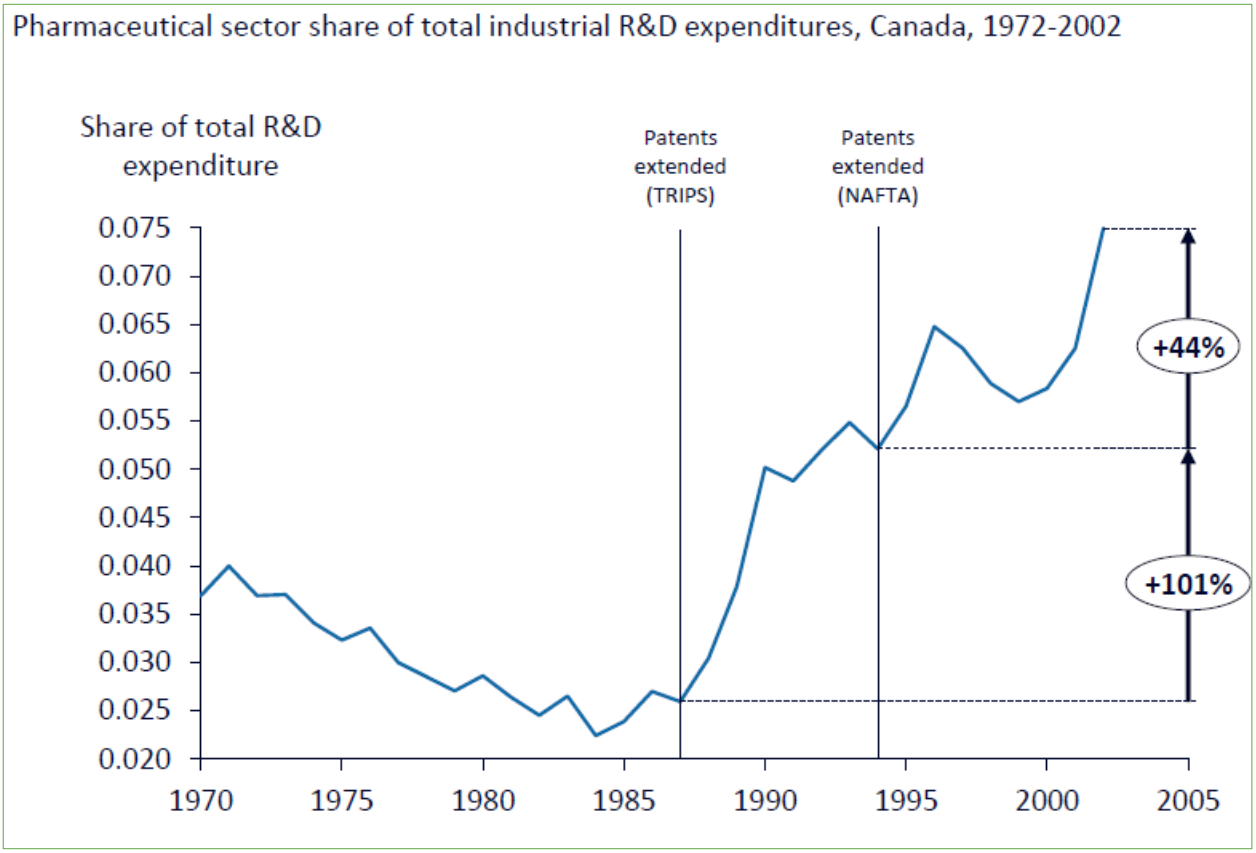

Figure 1: Grootendorst, P. and Matteo, L. (2007). The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada. National Institutes of Health

The case for a patent credit scheme for CPPs in Australia is strong, significantly stronger than that for pharmaceutical drugs. This is because of the additional costs associated with achieving regulatory approval for each registered use outlined above combined with the seasonal nature of CPP use in Australian agriculture. The impact of seasonality means that if regulatory assessment is not completed within an adequate period prior to the season in which the product is intended to be used, the registrant will be unable to commence sales until the following season. Where this happens, the registrant can miss an entire year of the product's patent before they are able to commence recouping the substantial costs of research, development and registration, reducing the incentive to bring newer innovations to Australia. A patent credit scheme would offset this period of time by extending the operation of the patent, reducing the commercial disincentive that Australia faces against nations with higher demand for CPP use due to the size of their agriculture industries.

Figure 2 illustrates this benefit in increased registration that would result from the implementation of a patent credit scheme for CPPs in Australia.

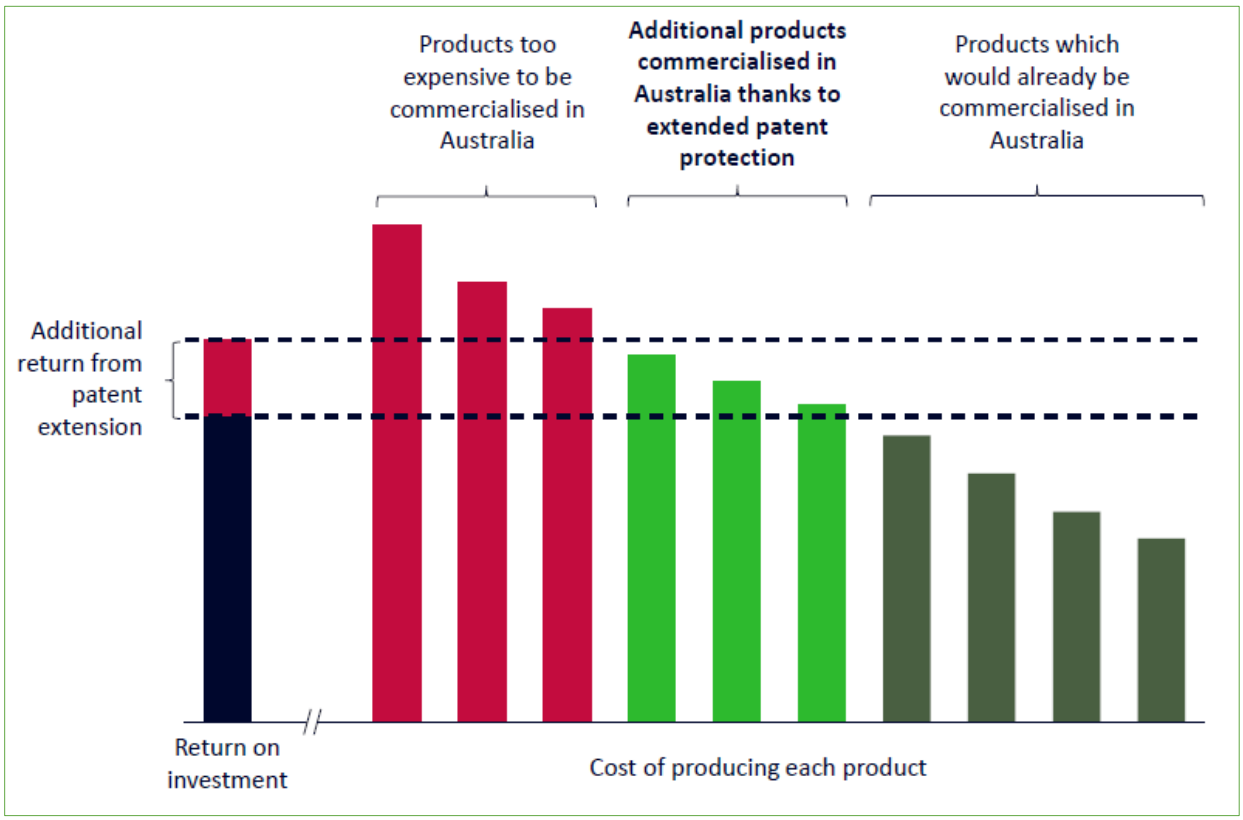

Figure 2: Analysis of impact of a patent credit scheme on the commercialising of crop protection products in Australia (Source: Mandala)

LOST OPPORTUNITIES

To feed the growing world, while also strengthening and diversifying our economy, Australian food and beverage producers need access to constant innovation. While we are fortunate that Australia has been at the forefront of innovation in this sector, we have often failed to capitalise on this leading position. CropLife Australia shares the concerns of many in the sector that this leads to other nations luring away our best and brightest while buying our invention for cents on the dollar.

Companies involved in the global commercialisation of crop biotechnology innovations and products have consistently noted that delays in updating the National Gene Technology Scheme have created significant uncertainty for investment and frustrated farmers that are waiting on access to new innovations.

This point has been echoed by all CropLife Australia members. The absence of certainty was cited as a key factor limiting investment in Australia. Despite global interest and the overall size of the Australian biotechnology sector[11], delays or overregulation could:

> **Stunts Start-ups**: In the absence of a clear regulatory path, Australian entrepreneurs might hesitate to venture into the gene editing domain, potentially curbing the nation's innovative spirit. This is reflected in the limited number of biotechnology start-ups relative to many of our trading partners.
> **Promote Investor Hesitation**: The Australian investment community, though keen on breakthrough technologies, might tread cautiously in an uncertain regulatory environment, slowing down potential financial returns.

In contrast, two recent international examples demonstrate the appetite for this type of investment in other jurisdictions. Start-up enterprises Pairwise[12] and CoverCress[13] represent large investments into US-based gene editing enterprises. Recent equity investment in Pairwise shows renewed commitment from the market, building on an existing $100 million (USD) collaboration between scientific entrepreneurs and the purchase of a 65 per cent stake from Chevron in CoverCress, an important acquisition. All CropLife Crop Biotechnology members noted the wealth of partnerships and investments currently being made internationally but also noted hesitation to invest in gene editing technologies in Australia under current regulatory settings.

Vow, a Sydney-based company specialising in cultured meat, has their cultured quail meat on the menu at the Mandela Club in Singapore, following its regulatory approval by the Singapore Food Agency in April 2024. Despite Food Standards Australia and New Zealand (FSANZ) commencing regulatory assessment of the product for consumption in Australia in January 2023, it is yet to progress to the second consultation stage.

---

[11] Stockhead, 'ASX Health Winners March: A Rebound, Aussie Biotech Sector Is on the Radar of Asian Investors', accessed 24 April 2024, https://stockhead.com.au/health/asx-health-winners-march-a-rebound-aussie-biotech-sector-is-on-the-radar-of-asian-investors/.

[12] Bayer, 'Gene Editing: Pairwise and Bayer start new five-year multi-million Dollar collaboration to further advance short-stature corn', online 29 August 2023, https://www.bayer.com/media/en-us/gene-editing-pairwise-and-bayer-start-new-five-year-multi-million-dollar-collaboration-to-further-advance-short-stature-corn.

[13] Bayer, 'Bayer expands existing investment to acquire majority share in sustainable lower carbon oilseed producer CoverCress Inc.', online 01 August 2022, https://www.bayer.com/media/en-us/bayer-expands-existing-investment-to-acquire-majority-share-in-sustainable-lower-carbon-oilseed-producer-covercress-inc.

While the FSANZ workplan anticipates approval will be finalised by mid-May 2024 it is now likely that the final approval will not be made until at least the end of 2024.

As part of driving an innovative and growing food manufacturing sector in Australia, it should be the ambition of our policy settings to see these start-ups able to commence and maintain their commercial production here. Failure to do so, risks the flight of these innovative businesses and their science savvy entrepreneurs to set up their production facilities and headquarters elsewhere.

SOLUTIONS

With many Australian companies and institutions leading the way on innovation, it is critical that we capitalise and develop a diverse agricultural bioeconomy. If we can achieve this goal, Australia can emerge as a global biotechnology powerhouse ensuring our prosperity and wellbeing. Although additional financial support and investment in the sector is desperately needed, Australia's existing investment in innovation can be maximised through carefully targeted policy changes.

Timely Regulatory Reform

The Third Review of our National Gene Technology Scheme must be implemented as soon as possible. In addition, P1055 must also be finalised. Both are serving as a barrier to investment and innovation. Moreover, it is critical that in the future, the **duration of regulatory reviews be minimised**. Extending the process, especially without clear accountable timelines, greatly harms confidence in our regulatory system and reduces investment in our bioeconomy.

There are numerous opportunities for **inter-agency harmonisation** improvements with respect to assessments, costs and priorities. Building on the example of the simultaneous assessment example of the TR4 resistant GM banana from FSANZ and the OTGR, greater harmonisation would facilitate a rapid response to priorities. For example, if assessments of gene editing by both FSANZ and OGTR were conducted simultaneously, duplication of effort would have been minimised.

CONCLUSION

Australia's reputation as an innovation hub and leading food producer is well-deserved, but our nation stands at a pivotal juncture. Clear and consistent regulations are paramount to leveraging our full financial, ethical and societal potential. As Australia charts its course in the global bioeconomy, it's imperative that regulatory clarity and government policy not only safeguards interests but also propels the nation towards a prosperous future in biotechnology.