POLICY TAKEAWAYS

UQ Centre for Policy Futures

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Emerging Issues in the Regulation of Synthetic Biology in Australia

On 2 September 2021, the Centre for Policy Futures, in collaboration with the CSIRO Future Science Platform on Responsible Innovation and the Centre of Excellence in Synthetic Biology held the workshop, Emerging Issues in the Regulation of Synthetic Biology in Australia. The workshop brought decision-makers, businesses and academia together for a discussion on the policy contexts shaping synthetic biology applications. The event focused on the processes and challenges of designing fit-for-purpose policy frameworks, including the need for consistency and clarity of terms and definitions.

Moderated by Dr Artem Anyshchenko, the panel of speakers included:
Dr Paul Bertsch, Science Director, Land & Water, CSIRO
Dr Raj Bhula, Gene Technology Regulator
Dr Lisa Kelly, GM Team Leader, Food Safety Australia New Zealand (FSANZ)

Key Takeaways

1. Synthetic biology involves the design and construction of new biological parts, devices, and systems, as well as the re-design of existing, natural biological systems for useful purposes (ACOLA).

2. SynBio enables advanced biomanufacturing that could help address global food and sustainability challenges, for example, through the development of sustainable alternatives to animal proteins, non-toxic agricultural chemicals, waste management and resource recovery solutions, mineral processing and a variety of other applications.

3. CSIRO estimates that an Australian SynBio industry could be worth $27 billion and create 44,000 new jobs by 2040. Like all disruptive technologies, however, rapid adoption of SynBio could also pose risks to certain industries.

4. Gene Technology Regulations seek primarily to protect the environment and health and safety of people, particularly with regards to agriculture and food. Since 2006, the on-going National Gene Technology Scheme Review (under its third review since 2017) has sought to modernise and future-proof Australia's gene technology framework by, among other things, updating definitions and terms, clarifying the scope of regulation, and streamlining processes and requirements.

5. In 2019, amendments to the *Gene Technology Act 2000 Act* sought to clarify the regulation of specific gene technologies in line with technological developments. Among other things, a key amendment was the exemption of organisms modified using SDN-1 gene editing methods.

6. In July 2021, the Gene Technology Ministers' Meeting considered a Decision Regulation Impact Statement and endorsed Risk Tiering Model as the preferred option to address key recommendations of the Third Review of the National Gene Technology Scheme. The risk tiering model seeks to provide greater flexibility in the authorisation of GMOs and ensure that the level of regulatory oversight is proportionate to the level of risk.

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