AusBiotech submission in response to the Department of Health consultation on: *Modernising and future-proofing the National Gene Technology Scheme*

Proposed regulatory framework to support implementation of the Third Review of the Scheme

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17 March 2021

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Introduction

AusBiotech is pleased to have the opportunity to make a submission to the Department of Health's consultation on the *Modernising and future-proofing the National Gene Technology Scheme* (the Scheme). AusBiotech has actively engaged on consultations on the Scheme throughout its Third Review, and seeks to build on the strong work accomplished to date while supporting its ability to prepare for Australia's gene technology future.

This submission represents AusBiotech members engaged in delivering economic benefits to Australia through the commercialisation of biotechnologies and medical technologies.

AusBiotech is a well-connected national network of over 3,000 members in the life sciences industry, which includes bio-therapeutics, medical technology, and agricultural technology (agritech) biotechnology sectors. The industry consists of more than 1,000 biotechnology companies and employs in excess of 87,000 Australians. Our members span the pipeline from bench through business to bedside.

AusBiotech is in a unique position to represent both agritech as well emerging medical developments, such as regenerative medicine. The submission represents a collation of comments and submissions from AusBiotech members, including the AusBiotech Regenerative Medicine Advisory Group, engaged in delivering economic benefits to Australia through the commercialisation of biotechnology across both sectors.

Agritech and food science technology (foodtech) contributes to Australia's food development process, from farm to plate. The agritech and foodtech industry strives to enhance seeds and crops, improve diet and provide functional foods for preventative health. With the global population expected to reach 9.7 billion by 2050, agricultural technologists and food science researchers must develop tools to reach growing population's needs.

Australia has a proud history of agricultural innovation. It is critical for the competitiveness of our industry that Australia maintains the capacity to support innovation and deliver its outcomes (i.e. commercialisation) to ensure that Australia maintains its global leadership in developing technologies that will benefit all Australians. Therefore, we must maintain and build upon the work that has already been done to date on the Scheme.

Australia also has a strong and active regenerative medicine (RM) industry with internationally-recognised basic and translational research, clinical trials framework and clinical centres, more than 30 companies in Australia developing products and more than 30 clinical trials in progress. It is expected that the emerging and global RM market will reach AU$120 billion in revenues by 2035. If Australia captures just five per cent share of this global market, this would represent $6 billion in annual revenue and create approximately 6,000 jobs. It is important that as this important burgeoning technology is fostered, we provide a system that will complement it and enable it to grow.

Recommendations

The strength of the National Gene Technology Scheme is that regulation is built on the principle of managing risk first, and in a transparent and evidence-based manner. AusBiotech continues to support this principle, and therefore supports Option B: *Risk-tiering model – dealings with GMOs would be categorised according to their indicative risk*.

AusBiotech welcomes the early consideration of how the regulatory framework that was originally designed for GMO plants can accommodate emerging gene technology fields, such as RM, that do not fit into the current system.

The OGTR has already experienced RM's increasing importance, with a growing number of licences under the Gene Technology Act being granted for medical and other uses. The industry and the Australian Government recognises, and is investing in, its potential, with the aim of promoting Australia as a global leader in clinical trials and medical research.

Therefore, it is important that any proposed changes are effective and do not present unnecessary barriers for the progress of biotech research and development, which contribute to the wellbeing of the Australian and global community and the environment.

As RM is an emerging field full of potential, it is still early in its development. The whole ecosystem, including companies and regulators world-wide, is still learning and changing.

In Australia, the medical health and research industry seek an efficient and effective system that will provide the strength of our existing well-reputed regulatory framework, while also the ability to bolster the internal regulatory capabilities. The benefit of the proposed Option C is that is provides a clear delineation of the review of materials for clinical trials and medical developments, allowing for better integration into Therapeutics Good Administration (TGA) processes, with a view to improving assessments and review times.

However, this focus can also be attained in other ways. For example, the organisational design of the OGTR could enable a team of experts to focus on this area, rather than changing the structure of the regulatory framework in order to accommodate. Combining a new risk-tiering framework that ensures regulation remains commensurate with risk together with a dedicated team that holds expertise on emerging technologies and focused on improving assessments and review times, could also result in the same outcome with less disruption.

Critically, for medicines, any developments undertaken must be done in coordination with TGA requirements. The TGA is globally-recognised, with well-established processes and regulations governing these activities for safety and efficacy in Australia. Leveraging required and existing risk management plans and controls, governance, and suitable reporting would reduce overlap on applications, and thereby improve review timeliness, and reduce unnecessary duplication of effort and regulatory burden. This has been a successful approach for the TGA in other areas.

If the OGTR introduces a risk-tiering model, AusBiotech would welcome acknowledgement of further streamlining, fast tracking or risk-rating reduction where an application meets the risk management criteria through demonstration of oversight and controls. For example: a clinical trial with a Human Research Ethics Committee (HREC) established, or if an application has established post-market surveillance reporting in place.

It also seeks further details of how additional pathways (or risk-tiering) for clinical trials and medical developments would align with assessments undertaken by other major regulatory bodies, such as European Medicines Agency (through the ATMP framework), or the US Food and Drug Administration.

Aligning the Scheme's developments for medical developments to TGA requirements would reduce the cost of regulation and enhance the competitiveness of the Australian biotech industry, without compromising the objective of the Gene Technology Act.

An enhanced Option B would be suitable for all regulated communities and sectors in Australia and ensure the Scheme remains flexible, fit for purpose and futureproof. This would prove critical for both agricultural and medical research and for Australia in general, as this would ensure the benefits from new innovations reach Australian and global communities.

Definition amendments
Clarification of the terms Genetically Modified Organism (GMO) and Gene technology are welcomed and AusBiotech encourages that they are maintained in line with technological advances. While there is no globally harmonised definition of gene technology or GMO, an awareness and understanding of these broader terms remains important and consistency where appropriate is urged.

AusBiotech strongly opposes using the word "creation" in any of the Gene Technology Act's revised definitions, including as a way of encapsulating technological advancements.

New and evolving gene editing techniques and tools (e.g. CRISPR) allow editing of genes with a level of precision that increases its applications across the health, agricultural, and industrial sectors. Any definitions should lean into technological intention and back the robust evidence-based model, and avoid the often triggering and misunderstood word 'creation'.

AusBiotech supports the proposed changes to 'deal with', as it provides greater clarity.
It is also recommended that containment conditions for use of gene technology in a clinical trial be better defined to guide applicants through the process.

Page 12 of the Explanatory paper notes that to avoid regulatory creep, consideration of legally-binding determination or guidance could be considered to update definitions. AusBiotech strongly recommends that due to the rapid rate of change being experienced in gene technology in medical development, as well as agritech research and development, guidance is the more appropriate avenue. While the overall process should be legally-binding, guidance offers the opportunity for agile updates. As noted earlier, the RM sector is still early in its development and while the whole ecosystem, including companies and regulators world-wide, is still learning, this would be the preferred approach. It would also provide transparency, clarity and greater understanding for the agritech sector as it continues to innovate.

Licenced dealings: expedited assessment
The CRIS notes that licensed dealings would be further classified into three types on the basis of risk to enable further streamlining of lower risk applications, including expedited assessment.

AusBiotech supports this risk-based approach in principle, however, recommends that it is important that qualification criteria for this assessment is made extremely clear, and that it is only used in very specific circumstances. Clear guidelines for qualification will ensure that the mechanism remains focused on its intended use, and is not open for abuse by applicants that do not meet the criteria. Clear guidelines will also reduce administrative burden for industry and the regulator.

Technology advancements/essential enablers
AusBiotech encourages an automated data management system to improve the regulator's capability and capacity to manage the Scheme.

We recommend that any portal/user interface places the reliance back on the sponsor to keep the information up to date for ongoing licencing. A system such as this reduces burden on the OGTR, and ensures better compliance of sponsors/applicants to remain compliant.

The system could simultaneously provide a public guide of previously reviewed and licenced materials, which may assist applicants in their proposals. The information would need to carefully ensure it did not disclose confidential or proprietary information.

In addition, a GMO Registry of dealings that rank risk in order, to streamline new applications, could allow focus of assessments on those materials that pose a potentially new exposure. AusBiotech recommends that including a dealing on the GMO Register be an administrative decision made by written instrument, rather than being made by legislative instrument, thereby reducing regulatory burden.