DRAFT GENE TECHNOLOGY AMENDMENT BILL

Consultation Paper

November 2024

Australian Seed Federation

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Australian Seed Federation
SOWING SEEDS

ABN 66 003 160 638

8 November 2024

Gene Technology Implementation Team
Department of Health
GPO Box 9848
CANBERRA ACT 2601

By email: gene.technology.implementation@health.gov.au

Dear Gene Technology Implementation Team,

RE: Proposed amendments to the Gene Technology Act 2000

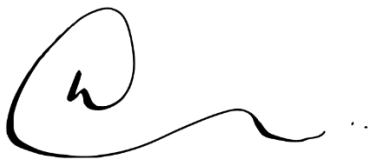
The seed industry is an essential driver of innovation, enabling the development of crops that power agricultural productivity, advance sustainability, and bolster global food security.

The membership of the Australian Seed Federation (ASF) covers the full seed supply chain and includes plant breeders, seed growers, seed processors and seed marketers. Some of our membership is involved in gene technology and new breeding techniques.

We welcome the opportunity to comment on the Proposed amendments to the Gene Technology Act 2000.

In this submission, the ASF advocates for a regulatory framework with a cohesive national and international approach that future-proofs the industry's ability to provide farmers with cutting-edge seed technologies. Our goal is to ensure ASF members can continue to deliver world-class solutions that meet both present and future agricultural needs.

Yours sincerely



Katherine Delbridge
Chief Executive Officer

The seed industry is an essential driver of innovation, enabling the development of crops that power agricultural productivity, advance sustainability, and bolster global food security. Around the world, governments are grappling with policies to support the latest plant breeding breakthroughs. Yet, progress has been slow, and plant breeders remain constrained by complex regulatory barriers.

These hurdles are compounded by a lack of global regulatory harmonisation, a source of mounting frustration for a global industry primed with solutions. Plant breeders stand ready to equip farmers with innovations that target pests and diseases, enhance resilience to environmental stresses, and deliver higher-quality, higher-yield crops — all while aligning with evolving consumer expectations.

In this submission, the Australian Seed Federation (ASF) advocates for a regulatory framework with a cohesive national and international approach that future-proofs the industry's ability to provide farmers with cutting-edge seed technologies. Our goal is to ensure ASF members can continue to deliver world-class solutions that meet both present and future agricultural needs.

Chapter 1: Scope of Regulation

1. Do the proposed amendments to the definitions of 'deal with', 'gene technology' and 'genetically modified organism' provide sufficient clarity about what is captured under the Scheme? 2. Do you consider the proposed amendments to key definitions provide greater clarity with respect to the scope of regulation?

The ASF concurs that the rapid advancements in gene technology have outpaced the definitions in the GT Act, which now struggle to accurately define the scope of regulated GMO activities.

In previous consultations during the Third Review, the ASF highlighted that technology-based definitions bring inherent limitations. This issue was recently addressed in FSANZ's Proposal P1055, which opted for a more proportionate, product-focused approach.

Plant varieties developed through the latest breeding methods should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through earlier breeding methods. This should be the starting point for the regulatory reform.

The fact that a product results from 'gene technology' is, in itself, insufficient to determine its risk to human health, safety, or the environment. Consequently, if a product falls under the gene technology definition but meets criteria for negligible or low risk, there must be a mechanism for early exemption from the regulatory scheme.

Similar molecular changes can arise from vastly different technologies, or natural processes, leading to comparable risk profiles. Therefore, it is impractical to regulate products solely because they fit a broad 'gene technology' definition. Above all, a responsive regulatory framework is essential to avoid being outpaced by innovation and to support the ongoing advancement of safe, beneficial technologies.

3. Do you consider the proposed amendments to key definitions help to future-proof the Scheme?

The proposed amendments to key definitions aim to bring greater clarity to the scope of regulation and help future-proof the Scheme. However, these amendments may not achieve the intended clarity or adaptability, potentially limiting the Scheme's responsiveness to future technological developments.

The criteria for determining regulatory oversight must remain appropriate for plant products developed through a wide range of innovative breeding techniques. For example, genome editing can create mutations (e.g., deletions, substitutions, chromosomal rearrangements) and gene duplications that are also achievable with traditional breeding methods. Such products should therefore fall outside the scope of GMO/biotechnology regulatory oversight. Flexibility is essential to account for advancements in scientific knowledge and its applications.

Chapter 2: Risks considered under the Scheme

4. Is the mechanism in proposed section 15A suitable to manage circumstances where dealings with GMOs may also be regulated under other regulatory schemes?

The proposed mechanism offers several benefits, including reduced regulatory overlap and duplication between the Scheme and other regulatory systems, which can help lower costs and increase efficiency for both the Gene Technology Regulator (GTR) and regulated entities. By clarifying the responsibilities of the GTR and other regulators, the mechanism ensures that risks are assessed by the most suitable regulatory body. It also supports a risk-proportionate approach, allowing the GTR to focus regulatory efforts on risks not already managed by other schemes, while maintaining essential safeguards for human health, safety, and the environment.

However, there are concerns that the mechanism may lead to regulatory gaps if certain risks fall outside the oversight of either the GTR or other bodies. The mechanism could also increase the complexity of the regulatory framework, as it requires clear determinations about which risks each scheme covers. This may introduce uncertainty for regulated entities if responsibilities are not clearly delineated.

The proposed changes to public consultation on risk assessment and risk management plans (RARMPs) for certain GMO license applications aim to enhance efficiency and transparency. Public input would be required for applications involving environmental release of a GMO or GMOs from parent organisms new to Australia, with the Gene Technology Regulator (GTR) retaining discretion for additional consultations if in the public interest.

The ASF is largely supportive given the changes would increase transparency, improve decision-making by incorporating diverse perspectives, and maintain safeguards by involving state and federal stakeholders. However, there must not be unintended time delays due to the added consultation steps.

The Consultation Paper refers to “novelty” for determining consultation requirements but lacks a clear definition. Further clarification on novelty, including criteria for consulting on traits new to Australia, would be beneficial.

Chapter 3: Authorisation Pathways

6. Are the provisions dealing with GMO permits sufficiently clear?

The draft Bill’s provisions on GMO permits are generally clear, aiming to streamline the authorisation process by introducing a permit system with standardised, rather than case-by-case, conditions. However, there is a lot of detail that still needs to be seen in the regulations. This system

would apply to specific GMO dealings providing more predictability for regulated entities. However, practical concerns exist, such as the absence of applicable conditions during a permit or license suspension, which could create oversight gaps, and challenges with notifying individuals covered by a license or permit about relevant conditions.

While the permit system could expedite approvals for gene-edited crops with minor genomic modifications, ASF would again like to raise that its process-focused framework may not align with other domestic and international systems that are increasingly product-focused. This misalignment could create regulatory uncertainties, hinder biotech innovation, and limit access to new crop varieties. The lack of international harmonisation risks affecting Australia's competitiveness and adoption of cutting-edge biotech solutions, potentially contradicting the Bill's goals of fostering a modern, flexible, and responsive regulatory framework.

10. What should be considered for regulations to prescribe criteria for GMO dealings eligible for inclusion on the GMO Register?

The proposed expansion of the GMO Register has the potential to enhance flexibility and reduce the regulatory burden, provided it is implemented with clear criteria and robust management practices. While the amendments aim to include a broader range of minimal-risk GMO dealings, there are several important considerations to ensure effective regulation.

Firstly, it is essential to emphasise that even though dealings on the GMO Register are classified as low-risk, they remain GMOs and require responsible oversight in respect of potential risks to human health, safety, and the environment, as well as address market and trade implications.

Additionally, the criteria for determining eligibility for inclusion on the GMO Register must be clear and transparent. It is crucial that the decision-making process extends beyond just evaluating risks to human health and the environment. Consideration must also be given to intellectual property rights, particularly when GMOs are added to the Register without a license holder's request. Clarity on any IP obligations is necessary to protect stakeholder interests and support fair market practices.

The current proposal does not require stakeholder consultation before placing GMOs on the Register, which could lead to unintended consequences in terms of market acceptance and compliance. Introducing a requirement for stakeholder input in the decision-making process would enhance transparency and ensure that all potential impacts are considered before GMOs are included.

Overall, the proposed changes to the GMO Register should not only streamline the regulatory framework but also maintain safeguards. This will ensure that the system remains risk-proportionate, supports innovation, and aligns with broader regulatory and market needs.

Chapters 4 and 5: Compliance, Monitoring and Enforcement & Certification and Accreditation

15. Do you have any concerns with the practical implementation of proposed amendments to certification and accreditation?

Accreditation conditions will need to be clearly defined and communicated to accredited organisations / individuals. Any ambiguity in these conditions could result in unintentional non-compliance, which might unfairly trigger penalties under the new offence provision.

11. Do you understand the obligations and responsibilities that flow from the proposed offences and civil penalties relevant to your scope of regulated activities? 12. Do the proposed new enforcement powers strike a suitable balance with the risk tiering framework, which would increase flexibility and enable a greater range of authorisations with reduced up-front assessment?

The Office of the Gene Technology Regulator (OGTR) should be aware that the introduction of any new offences could result in the creation of a more punitive environment, which might discourage open communication between the OGTR and those accredited. The emphasis on penalising breaches may limit the willingness of organisations to seek guidance or voluntarily disclose potential compliance issues.

Penalties for breaches must be proportionate to the nature and risk level of the violation. If penalties are perceived as too severe relative to the breach, it may be seen as overly punitive, especially for minor infractions that do not pose significant risks to human health or the environment.

Increased compliance burden could require additional resources for monitoring, auditing, and record-keeping, which might be challenging for smaller companies with limited capacity. There must not be any disadvantage.

Any enforcement of the new measures must be consistent and transparent. Any perceived inconsistency could lead to concerns about fairness and trust in the regulatory framework.

16. Should it continue to be a requirement for the accreditation of an organisation that the organisation has appropriate indemnity arrangements in place for the members of its Institutional Biosafety Committee(s)? If so, what type of indemnity arrangements should be regarded as appropriate?

It is appropriate to maintain indemnity arrangements for members of Institutional Biosafety Committees (IBCs).

Chapter 6: Use and Disclosure of Information

18. Do the proposed amendments relating to CCI strike the right balance between protecting the valuable information of those involved in the research and development of GMOs and transparency relating to the regulation of GMOs?

The ASF is broadly supportive of the changes to Confidential Commercial Information (CCI) handling as it offers a more risk-based and protective framework for industry while striving to maintain transparency and consistency. However, attention must be given to the practical implementation of these amendments to avoid unintended consequences, such as delays, reduced transparency, or inequitable burdens across different-sized entities.

Streamlining the handling of CCI should make the regulatory process faster and less burdensome for both applicants and the OGTR. Focusing only on information with genuine commercial sensitivity reduces administrative complexity.

By redefining CCI to include two definitions, "trade secrets" and "commercially valuable information," the amendments aim to protect sensitive business data more precisely, limiting unnecessary disclosures. This can help maintain trust among industry participants and encourage

innovation. However, clear guidelines and consistent application will be needed to ensure definitions are not subjective to avoid unnecessary legal challenges and ensure fair treatment.

19. Are the proposals for use and disclosure of Regulator Information sufficiently clear?

The changes should help to clarify CCI's interaction with other information-access laws, like the Freedom of Information Act, reducing legal uncertainty.

The Regulator's assessment of CCI before publication, particularly during public consultations on Risk Assessment and Risk Management Plans (RARMPs), ensures that only non-sensitive information is made public. This maintains transparency while protecting sensitive business interests.

The ASF is cognisant that the process of assessing CCI claims before publication could introduce delays, especially if claim assessments become contentious or complex. This could affect the timeliness of public consultations and decision-making.

Balancing CCI protection with Freedom of Information Act requests may be challenging and is something that must be considered.

20. Do stakeholders have any concerns with the revised definition of CCI noting the change in scope from the existing definition?

Smaller companies may find the CCI claims process resource-intensive, especially if it involves legal or procedural complexities. Ensuring clarity and support for claim submissions will be important to prevent disadvantages for smaller players.

Chapters 7 and 8: Minor, Technical and Consequential Amendments & Application, Savings and Transitional Provisions

22. Are there any concerns about the scope and process proposed for rules made by the Regulator?

Ultimately, the scope appears broad to enable responsive regulation. Transparency in the rule-making process and stakeholder consultation remains critical to maintaining trust and achieving balanced implementation in this process.

The ASF believes that the Regulator is the one who is better placed through Rules to do risk-tiering and decide whether a breeding method results in varieties that are similar or indistinguishable from varieties that could have been produced through earlier breeding methods. This will introduce more flexibility and adaptability into the Scheme.

23. Are there provisions in the GT Act as amended that would be difficult for regulated entities to apply or that would operate unfairly?

Changes to authorisation pathways, particularly reclassification of notifiable dealings and revised statutory conditions, could create compliance challenges, especially for smaller entities. Ensuring clear guidance and support will be key to fair application.

24. Are there any concerns about the proposed approaches to transition to the reformed scheme?

The proposed 12-month transition is generally reasonable, but the reclassification of some existing dealings and authorisations may place unexpected administrative burdens on regulated entities.

Additional transitional support and communication should be considered as it will be important to minimise disruption.