[redacted] **Response to the public consultation on proposed amendments to the Gene Technology Regulations 2001**

https://consultations.health.gov.au/best-practice-regulation/draft-amendments-to-the-gene-technology-regulation/supporting_documents/consultation-on-the-gene-technology-amendment-regulations-2pdf

Attention: gene.technology.implementation@health.gov.au	
Question	**[redacted] Response to Question**
Key changes of note	
1. Do you have any comments or concerns with regards to the proposed changes to the structure of the GT Regulations generally?	[redacted] welcomes the opportunity to comment on the proposed changes to the Gene Technology Regulations. [redacted] agrees with the retention of Section 50(A)(1)(b) Controls to restrict the dissemination or persistence of the GMO and its genetic material in the environment. Under the current Act, section 50A applies to 'limited and controlled release' applications. The draft Bill proposes to repeal section 50A, however it is intended that the concept of 'limited and controlled release' should be retained in the proposed Amendment Regulations.
Part 1 - General definitions	
2. Do you consider that any other terms are unclear and/or require definition?	[redacted] provides the following feedback on the proposed definitions. The new definition of a gene drive dealing is unclear. The proposed definition requires a GMO capable of sexual reproduction and sexual progeny inheriting a particular nucleotide sequence higher than Mendelian frequency. This predominantly applies to organisms capable of sexual reproduction including plants and some insect vectors. Clonal expansion of somatic cells would not constitute sexual reproduction. The Baby KJ (CRISPR) technology would not constitute a gene drive dealing under this proposed definition. The definition of a novel dealing is unclear. "Novel dealings would be defined as GMO that is derived from a parent organism that is novel, or a GMO that displays a novel trait that occurs because of gene technology". This seems to mirror Gene drive definition where a GMO is capable of sexual reproduction and progeny gives rise to carried forward modifications. Under the current GT Regulations, Schedule 1A excludes certain techniques (e.g., certain forms of cell fusion, somatic cell nuclear transfer) from the definition of gene technology. However, when excluded techniques are used in combination with included techniques as part of a manufacturing process for a GMO therapeutic, the overall process may still constitute gene technology. [redacted] proposes that NND4 and P4 have a boundary criterion of detectable, residual viral vector with a qualified, sensitive assay. The risk group classification needs to apply to the final therapeutic product rather than the parent organism to be consistent with the risk-based objectives of the Draft Bill.

Part 2 - Interpretation and general operation	
3. Are stakeholders satisfied with the proposal of certain risks being excluded from the requirement of ministerial and Regulator consideration if they are already considered under another scheme?	[redacted] agrees Subsection 15A(2) of the draft bill should exclude safety risks to patients addressed by the TGA. [redacted] agrees public consultations should be narrowed to novel or high-risk GMOs not otherwise controlled, based on risk-based criteria. With reference to 'Table 1: Licence class descriptions and proposed consultation requirements', [redacted] agrees that Therapeutic Goods are to be excluded from public consultation, and Clinical trials that do not involve a novel or high-risk parent organism or a novel trait would also not require GTAAC consultation. [redacted] agrees with Section 51 of the Draft Bill and a Federal Gazette style system for notifications from the Regulator. The proposed amendments seek to retain facility certification requirements but extend the definition to contained dealing to include facilities agreed in writing by the Regulator. It is not specified but could allow permits and NNND-1-4 to be in permitted facilities including hospitals and CAR-T infusion suites. However, as it stands this could rely on Regulator discretion. The criteria in which a hospital would meet PC1 needs to be mandated.
Part 3 - GMO licences	
4. Do you consider the concept of a designated dealing clear?	[redacted] is concerned the concept of a designated dealing is not sufficiently clear for practical implementation. There is uncertainty about how existing and future dealings map to the new categories, how items are added to or removed from the designated list, and how consultation will occur for such changes. [redacted] would like to better understand the criteria's objectives. It would be beneficial to see worked examples (including therapeutics and gene drive-related applications), and a transparent process for listing/unlisting, including stakeholder consultation. There is also a need to clarify transitional arrangements with explicit grandfathering of existing instruments until expiry, and guidance on how current permits/licences transition.
5. Do you have any concerns with the proposed consultations process for the RARMPs?	[redacted] believes the consultation process with the Regulator for RARMPs lacks clarity on how therapeutic goods are treated and how any changes to risk management plans will be communicated and tracked for existing products. It would be helpful to define the interface between RARMPs and therapeutic goods pathways with examples.
6. Do you have any concerns with revised timeframes?	[redacted] requests the amended timelines be considered in line with the current statutory timelines of the TGA. As outlined in 'Table 2 Proposed alternative licence application consideration periods, in business days', a 400 business day timeframe for gene drive organisms outside containment is approximately 80 working weeks (over 18 months). This exceeds all current TGA and international regulatory timelines. While appropriate for deliberate environmental release of gene drive organisms capable of replicating, if any therapeutic product were inadvertently classified as involving a gene drive mechanism, the 400-day timeline would be commercially

	and clinically untenable. Similarly, the 200 business day timeframe (approximately 10 months) for general release GMOs with public consultation is very close in time to TGA statutory registration timelines (255 business days) put at risk potential TGA registration delay while pending OGTR approval.
7. Do you have any concerns around the proposed range of dealings that will be required to be licensed?	[redacted] believes the proposed range may capture low-risk or well-characterized dealings, increasing burden without clear safety benefit, and it is difficult to determine where some of our existing and planned examples fit. [redacted] proposes a transparent, risk-proportional framework with clear criteria and examples, ensure grandfathering for existing instruments, and consider streamlined pathways or class licences for routine, low-risk dealings. Further guidance to help stakeholders determine licensing requirements for therapeutics, clinical trials, and gene drive-related activities would be beneficial.
Part 3 - Permits	
8. Do you have any concerns with dealings that are proposed to be authorised by a GMO permit?	[redacted] concerns with the proposed dealings to be authorized by a permit are outlined below. *Statutory timeframes*: The draft does not provide statutory timeframes comparable to existing DNIR (90 business days) and DIR (150 business days) standards, creating uncertainty for planning and investment purposes. There is confusion around timelines where gene drive technologies intersect with therapeutic goods. [redacted] requests to establish statutory timeframes for Part 3 permits, including stop-the-clock rules. We recommend 20 business days for P3 (SAS-aligned) permits and 60 business days for P2 clinical trials, with explicit guidance for gene drive and therapeutic good scenarios to avoid ambiguity. For example, permit for a adenoviral-vector vaccine clinical trial should fit P2 with a 60-day standard if prior human data exist. *Eligibility clarity (P2/P3/P4)*: P2's requirement of "previously authorised by the Regulator" would exclude first-in-class trials. The eligibility should be expanded to include prior human data from an equivalent regulator (FDA/EMA) or TGA, consistent with biologicals CTA/CTN pathways. P3/P4 wording appears limited to administration at the site; permits must cover the entire supply chain (import, transport, cold-chain storage, bedside preparation, administration, waste disposal). For example: Special-access lentiviral-based cell therapy should be P3 end-to-end, not P3 for administration plus separate ND for logistics. *Risk group interpretation*: Classify based on the final replication-defective product (e.g., self-inactivating lentiviral vectors) rather than the parent organism's risk group, to avoid unnecessary escalation to a licence. For example: *In vivo* cell therapy using a lentiviral vector should be assessed on the modified product's non-infectious status, not the parent HIV risk group. *Grandfathering and transition*: Explicitly grandfather existing DIR/DNIR instruments until expiry, with voluntary opt-in to new pathways at renewal, and publish mapping guidance for transitions. For example: Existing DIRs for LAIV and DNIRs for adenoviral-vector vaccine manufacturing should remain valid without reapplication.

Part 3 - Notifiable dealings	
9. Do you have any concerns in relation to the proposed notifiable dealings classes?	[redacted] concerns with the proposed classes for notifiable dealings are outlined below. *Scope of NDs and overlap with permits*: it is unclear whether NDs would be required in addition to permits for import, transport, and storage. Avoid dual authorisations by either explicitly expanding P2/P3 to cover logistics or clarifying when NDs substitute for those supply-chain steps. For example: a vaccine manufacturing by a local partner could map to ND2 for contained larger-scale operations; logistics for special-access cell therapies should be within the P3 permit rather than separate ND. *Risk-proportionality and facility requirements*: ND classes should have objective criteria and examples mapped to typical therapeutic dealings (ND1 small-scale in PC2; ND2 manufacturing containment; ND4 ex vivo cell therapies). For ND4, specify "detectable residual infectious vector" using qualified, sensitive assays; theoretical trace nucleic acids should not disqualify. For example: *Ex vivo* CAR-T cell therapies as ND4 where residual infectious vector is not detectable; hospital administration remains contained. *Administrative predictability*: Publish a decision guide showing when dealings fall under ND1–ND4 vs P2/P3/P4, including trials and commercial supply. For example: Starting materials and regulatory stability-testing stocks held in PC2 facilities should be illustrated as ND1.
Part 3 - Non-notifiable dealings	
10. Do you have any concerns in relation to the proposed non-notifiable dealings classes?	[redacted] concerns with the proposed classes for non-notifiable dealings are outlined below. *Definition and boundaries*: NNDs need clear definitions and worked examples to prevent inadvertent reclassification. If NNDs mirror current exempt dealings, confirm hospital contexts and whether commercial supply chains can be covered where no intentional environmental release occurs. For example: Pre-registration contingency stock held in PC2 storage should be treated as NND1-equivalent, consistent with prior exempt arrangements. *Interaction with permits*: Clarify whether NNDs can fully cover import/transport/storage when P3/P4 cover administration, or whether a single authorisation should cover end-to-end activities. Avoid requiring both NND and permit for the same therapeutic episode. For example: For special-access *in vivo* cell therapy, the P3 authorisation should include logistics to prevent duplicative NND requirements. *Risk tests for* ex vivo *therapies:* For NND4, define the threshold as "detectable residual infectious viral vector" via qualified assays; without this, ex vivo CAR-T could be unnecessarily pushed into P3 or a licence. For example: *Ex vivo* CAR-T should remain NND4 when residual infectious vector is not detected.

11. Do you consider the language 'not involving intentional release into the environment' appropriate for NNDs?	[redacted] considers the language is appropriate provided it is precisely defined for clinical and hospital contexts. Contained therapeutic use, including import, transport, storage, bedside preparation, administration, and waste disposal under approved conditions, should not be treated as intentional release into the environment. The regulation should clarify that risk is assessed on the modified therapeutic product (for example, replication-defective, non-infectious constructs) rather than the parent organism and include examples that distinguish contained hospital use from deliberate environmental release.
Any other feedback	[redacted] is keen to see the GMO Regulations align with other countries and jurisdictions as closely as practicable. This will ensure novel clinical research continues to be conducted in Australia in the future. For example, in the UK, comparable timelines for submissions under The Genetically Modified Organisms (Contained Use) Regulations 2014 are as follows: For a class I GMO (e.g., AAV vector), if prior site notification, then dosing can start immediately after the risk assessment has been approved by local clinical site GM Safety Committee (15 – 45 days). For low hazard, class 1 (such as AAV) for new site notification, HSE to contact site within 10 days and dosing can commence (receiving final clearance within 45 days). Class 2: up to 55 days without prior notification; up to 10 days if prior site notification. Class 3-4: up to 100 days without prior site notification; up to 55 days if prior site notification. There is a public register if information about all notifications concerning contained uses, including the nature of the work to be carried out at the premises, the purpose of individual contained uses and the characteristics of the GMOs involved. Reference: https://www.hse.gov.uk/biosafety/gmo/index.htm