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"Whole of Government" jurisdictional position on preferred regulatory framework option and responses to key consultation questions outlined in the Consultation Regulation Impact Statement (Consultation RIS) and Explanatory Paper entitled *"Modernising and Future-proofing the National Gene Technology Scheme"*.

The Department of Primary Industries and Regional Development (DPIRD) is the Western Australian (WA) Government's lead agency for gene technology. DPIRD, on behalf of the WA Gene Technology Interdepartmental Committee (WAGTIDC) makes this "Whole of Government" jurisdictional position on a preferred regulatory framework and responses to key consultation questions outlined in the Consultation RIS and Explanatory Paper entitled *"Modernising and Future-proofing the National Gene Technology Scheme"*. The WAGTIDC include representatives from DPIRD and other WA Government agencies (WA Department of Health, and Department of Biodiversity, Conservation and Attractions).

While recognising that Australia's National Gene Technology Scheme (the Scheme), and its activities involving Genetically Modified Organisms (GMOs), are subject to regulatory oversight using a risk-based approach, the regulation of the Scheme is a joint responsibility of all state and territory governments and the Commonwealth Government, outlined in the Intergovernmental Gene Technology Agreement 2001 (the Agreement).

The Consultation RIS describes three regulatory framework options:

- **Option A: Status quo** – No changes to the current scope or activities of the Gene Technology Regulator
- **Option B: Risk-tiering model** – Dealings with GMOs would be categorised according to their indicative risk
- **Option C: Matrix model** – The nature of the dealing with the GMO would be the determinative factor for categorisation.

This combined "Whole of Government" response has a preference for **Option B** – A proportionate Regulatory Model to address key priority recommendations of the 2018 Third Review of the National Gene Technology Scheme (the Scheme Review). These include:

- Recommendations 4 and 6 – Update existing definitions in the *Commonwealth Gene Technology Act 2000* to clarify the scope of regulation in light of on-going technological advances.
- Recommendation 9 – Introduce a new risk tiering framework that ensures regulation remains commensurate with the level of risk and flexibility to move GMOs between authorisation pathways based on identification of new risks, a history of safe use and other additional factors.
- Recommendation 10 – Reduce regulatory burden through streamlining processes and current regulatory requirements where appropriate.

Option B aims to retain current levels of oversight for some items outlined under the Commonwealth *Gene Technology Act 2000* (the Act); apply 'outcome-based' legislation to other parts of the Act; and support the Act with a level of delegated legislation. Under this option, the Act (which is the primary legislation) will include some prescriptive elements and broad over-arching principles, with high-level policy and technical issues delegated into subordinate legislation (delegated legislation), and

rule-making on scientific, technical and procedural information delegated to the Gene Technology Regulator (GTR).

The primary benefit of delegation into secondary legislation, and other legislative instruments (Option B), whereby regulations are made by decision-makers, proportionate with risk, is in facilitating competing needs for clarity, flexibility, transparency, and adaptable decision making regarding how regulation is applied to reflect new and emerging scientific technologies into the future, whilst upholding and maintaining the fundamental object of the Act. If required, any legislative reforms would need to be structured in a way ensuring the joint Commonwealth/State/Territory nature of the national scheme is maintained under the Gene Technology Agreement.

Importantly, this option does not represent reduced oversight or a reduced level of regulation and maintains a precautionary approach. Other benefits of this option enable Australia to maintain its process-based regulatory trigger for entry into the regulatory scheme and provide a more suitable framework for the rule-maker (e.g. Minister or the GTR) to respond to a changing technological environment in a shorter time-frame. At the same time Option B is likely to best meet stakeholder expectations regarding clarity of regulation and flexibility in the Scheme whilst maintaining the public trust of the Scheme.

Option B involves a reduced level of oversight by the Commonwealth Parliament for some highly technical elements of the Scheme and will have minimal resource impacts on the GTR. However, under Option B, all high-level policy decisions delegated to secondary legislation will still be required to be approved through multiple governments (and portfolios) through the Legislative and Governance Forum on Gene Technology and will still be considered disallowable through the Commonwealth Parliament.

Responses to Consultation RIS

Key consultation questions – Option A

- **Are there additional impacts of Option A that need to be taken into account?**
  It is unclear what level of impact Option A would have on following:
  1. Impact on new technologies entering into the market.
  2. Impact on prolonging uncertainty of capturing new developments under regulations.
  3. Impact on compliance and monitoring enforcement of new technologies.

- **Please provide further information, including quantitative data, on the costs associated with maintaining the status quo?**
  N/A

- **To what extent would maintaining the status quo stifle innovation?**
  There will be limited incentive for investment in Australia that stifles innovation in a range of portfolios including agriculture, pharmaceuticals and medical applications. This is detrimental to future economic development in Australia and maintenance of its international competitiveness.

- **What are the benefits of maintaining the status quo?**

The status quo approach would enable a continuation of current processes, retaining familiarity and transparency for various stakeholders, as well as perhaps a sense of public trust in tried and tested processes. But there are no addition benefits to the Gene Technology Scheme by maintaining the status quo.

Key consultation questions – Option B

- **Would Option B address the identified policy problems?**
  Yes.

- **Please outline any additional impacts of Option B that have not been identified in the current impact analysis.**
  While Options B and C share a number of similarities in context, there is no definition about "history of safe use" either in the Consultation RIS or in the explanatory paper. Depending on the definition, there could be additional possible impacts identified in Option B. The impacts of Gene Drive Organisms and organisms created by using gene editing techniques could have been included in the current impact analysis as those organisms are generally categorised as not common GMOs.

- **Please provide further information, including quantitative data, on any costs and benefits to your organisation associated with Option B.**
  N/A

- **Please outline any risks or additional considerations that need to be taken into account with regard to this option.**
  1. Requirement for a nationally agreed definition on "history of safe use".
  2. Option B may not be considered as appealing long-term for some industry stakeholders as Option C but WAGTIDC believes it does represent the most practicable and graduated way to ensure effective risk proportionate regulation, while providing clarity to stakeholders.
  3. The Consultation RIS outlines under Option B that the Institutional Biosafety Committees (IBCs) would largely operate in the same capacity as currently. However, the WAGTIDC noted that under new authorisation pathways the IBCs are required to make assessments on both low risk contained dealings and also low risk dealings involving the intentional release of a GMO into the environment applications. The committee questioned whether current IBC scientific and technical expertise will be adequate to undertake assessments on applications including dealings involving the intentional release of a GMO into the environment. In order to ensure national consistency across the different sectors in the gene technology space (agriculture, health and environmental) considerable work would be required from the OGTR to educate and train IBCs about their responsibilities and potential risks they must manage. At the same time, the regulated entities and IBCs would need to properly resource their increased compliance responsibilities like developing procedures and record keeping ensuring the national level of standards are maintained.

- **How might Option B promote science innovation?**
  Option B is well suited for a highly scientific and technical subject area such as gene technology. The gene technology applications are broad and the outcomes extremely varied, depending on the sector undertaking the work. As an example, cotton farming vs vaccine production. The

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WAGTIDC believes that Option B can achieve all objectives of government action outlined in the Consultation RIS and it has the potential to strengthen the regulatory framework to be responsive to emerging technologies and promote science innovation.

Key consultation questions – Option C

- **Does Option C address the policy problems identified in the C-RIS?**
  Option C addresses some policy problems identified in the Consultation RIS with a full coverage, whilst some others are only partially addressed.

- **Please outline any additional impacts of Option C that have not been identified in the current impact analysis.**
  N/A

- **Please provide further information, including quantitative data, on the costs and benefits to your organisation associated with Option C.**
  N/A

- **Please outline any risks or additional considerations that need to be taken into account with regard to this option.**
  Option C is able to achieve all objectives of government action as outlined in the Consultation RIS except of objective 5 as the regulatory framework would not be simplified under this option, rather it would increase in complexity. This option requires a significant governance change to enact this model and these risks were not considered in the Consultation RIS. The WAGTIDC believes this outcome based regulatory model is more suited for a 'product based' trigger for entry into the regulatory scheme and this is inconsistent with the Scheme review recommendation 8 which calls for a 'process–based' trigger to be maintained. After careful consideration, the WAGTIDC determined that regulated entities are not yet ready for such a significant change at present.

- **Does Option C promote science innovation? If so, how?**
  Option C offers a high degree of flexibility for the Scheme. However, Option C presents a matrix whereby the primary consideration for categorisation is the nature of the dealing. Any risk associated with that dealing is a secondary consideration that would inform where the dealing falls in the matrix once the relevant category is established. Further, Option C would continue to be as ambiguous as Option A (status quo) when it comes to categorisation of GMO dealings. Consultation RIS defines that there would be circumstances in which a GMO dealing may fall under more than one category. In those cases, stakeholders would have to apply for more than one licence under Option C, while under Option B one application would suffice. Based on the above-mentioned inefficiencies and increase complexity in this model there is a probability that this option will stifle science innovation rather than promote it.

Key consultation questions

- **In your opinion, what Option offers the greatest net benefit? Please provide reasons supporting your choice.**
  Option B.
  Option B fully address all identified policy problems outlined in the Consultation RIS and it will have the following advantages:

1. Option B is a risk-tiering model and dealings with GMOs would be classified into three authorisation pathways according to their indicative risk.
2. Includes a balance of flexibility and certainty/clarity to the regulatory framework.
3. More responsive to the rapidly evolving advances in the field of gene technology.
4. Moderate change for regulated entities and moderate lead-in time for implementation.
5. Enables Australia to maintain its process based regulatory trigger for entry into the regulatory scheme and provide a more suitable framework for the rule-maker (e.g. Minister or the GTR) to respond to a changing technological environment in a shorter time frame.
6. Option B streamlines authorisations under the Scheme with limited disruption to the existing structure of the authorisations that stakeholders are familiar with.
7. It will likely be best to meet stakeholder expectations regarding clarity of regulation and flexibility in the Scheme whilst maintaining the public trust of the Scheme.
8. Ensures national consistency across the different sectors in the gene technology space (agriculture, health and environmental).

Responses to Explanatory Paper

Key consultation questions – definition of gene technology

- **Does the proposed definition of gene technology address the issues identified?**
  Yes.

- **Does the proposed definition of gene technology introduce any new issues?**
  At present our response would be no, no new issues are introduced. Yet the WAGTIDC believes that continuing to exclude the process of “homologous recombination” in the definition does potentially pose an issue. This is due to certain gene-modifying technologies (e.g. CRISPR-Cas9) having homologous-directed repair as a possible mechanism in the methodology. Homologous-directed repair can be enhanced to employ genetically-modified segments of DNA for homologous recombination.

  The WAGTIC is also cognisant that with the ongoing technological advances into the future one can expect that new issues could arise with the revised definition of gene technology.

- **Are there any other desirable changes to the definition of gene technology that would address the issues identified in the Third Review and the objectives agreed by the Forum (e.g. to increase flexibility, future-proof the legislation, etc.)?**
  Broad definitions with more easily amended rules will be desirable to adopt to frequently changing circumstances that gives more flexibility and to future proof the legislation. There must be an agreed mechanism that the Regulator can make swift adjustments to definition of gene technology to bring clarity in the short-term frequency. Any changes to definitions should take into account concurrent work, including relevant domestic reviews and in going work internationally as out line in the recommendation 4 of the third review. The WAGTIDC understands that in both Australian and international contexts, the value of having definitional consistency across the board but full international harmonisation is unlikely in the near future as each county has very different legislative framework and approaches to the regulation of GMOs.

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- **Would interpretative guidance on the definition of *gene technology* issued by the Regulator be adequate, or should the Regulator have the capacity to make binding determinations that something is or is not a technique for the modification of genes or genetic material?**
  Interpretive guidance on the definition of *gene technology* issued by the Regulator would be adequate at this point in time with relevant consultation and making sure that regulatory creep is avoided. Without more detailed information and consultation, the WAGTIDC is unable to comment on binding determinations.

Key consultation questions – definition of GMO

- **Does the proposed definition of *GMO* address the issues identified?**
  The WAGTIDC supports the new definition.

- **Does the proposed definition of *GMO* introduce any new issues?**
  The WAGTIDC notes that there is ongoing consideration of whether all humans should be considered **not** to be GMOs. The WAGTIDC is supportive of this, particularly for the scenario in which a person receives genetic modification to their germline cells, a possibility that is now more readily possible due to emerging technologies such as CRISPR-Cas9. Currently, a person who has their germline cells modified in this way would be considered a GMO.

- **Are there any other desirable changes to the definition of GMO which would address the issues identified in the Third Review and the objectives agreed by the Forum (e.g. to increase flexibility, future-proof the legislation, etc.) noting that the Review also recommended that a process-based trigger be maintained as the entry point for the Scheme at the present, to allow for any potential risks associated with new technologies to be initially considered within the scope of the Scheme (refer recommendation 8)?**
  The WAGTIDC recommends that the any changes to definitions or changes to the regulatory trigger should take into account concurrent work, including relevant domestic reviews and on-going work internationally. In the long term, the scheme must maintain best practice regulation through participation in international harmonisation activities and collaboration with relevant national gene technology regulators and other product regulators towards achieving harmonised consensus across the board.

Key consultation questions – definition of deal with

- **Does consolidating the definition of deal with into the concepts of make, supply and use address the issues identified?**
  The WAGTIDC supports the new definition.

- **Does consolidating the definition of deal with introduce any new issues?**
  It is hard to make a definite conclusion at this point in time on new issues but the WAGTIDC believes that the proposed new definition sufficiently describes activities that apply to all GMOs not only activities that are relevant to agriculture.

- **Is it preferable to consider the role of other regulators through the consideration of risk in the new pathways described in Chapter 4, or should the intersection be addressed through a revised definition of deal with?**

The WAGTIDC preferred that the intersection be addressed through a revised definition of deal with by the OGTR rather than going through other regulators.

Key consultation questions – Non-notifiable dealings

- **What types of dealings would be appropriate to include in the non-notifiable pathway for Option B?**
  An exempt dealing for contained research conducted in very well understood organisms, using well-established processes for creating and studying GMOs as described in the *Gene Technology Regulations 2001* (GT Regulations) would be appropriate. In addition, some of the specific dealings that are currently contained and categorised as Notifiable Low Risk Dealings (NLRDs) could become non-notifiable if assessed to pose very low risk.

- **For each of the three categories for Option C, what types of dealings would be appropriate to include in the non-notifiable pathway?**
  N/A

- **What are the relevant risk indicators (to be established in the GT Act) that could guide the Regulator's determination of what is a very low risk dealing?**
  The risk indicators such as containment, history of safe use, parent organism, nature of modification, experience in applying management conditions and the involvement of other regulators could be considered to define what is a very low risk dealing.

- **What are the advantages and disadvantages of categorising dealings using existing concepts (e.g. contained dealings and intentional release) that do not account for risk or modern technology?**
  The existing concept may have advantages to some stakeholders in the agriculture sector whist the same concept may disadvantage and become complex for dealings with, for example, clinical trials involving vaccines and therapeutic goods, animals or microbes that require an approach that enables the regulation to better align with the indicative risk posed by the dealing.

- **Under Option C, what are the advantages and disadvantages of first categorising the dealing in the context of the non-notifiable dealing authorisation pathway?**
  N/A

Key consultation questions – Notifiable dealings

- **What types of dealings would be appropriate to include in the notifiable pathway for Option B?**
  The NLRDs that are currently described in Parts 1 and 2 of Schedule 3 in the GT Regulations that are undertaken in regulator approved containment facilities. In addition, the Consultation RIS proposed that this authorisation pathway could include other low risk dealings that are also regulated by other Australian regulators, as an example GMO veterinary vaccines that are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The WAGTIDC is unable to support the proposal at this point of time without having additional information and consultation.

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- **For each of the three categories for Option C, what types of dealings would be appropriate to include in the notifiable pathway?**
  N/A

- **What are the relevant risk indicators (principles) that could be considered in determining what a low risk dealing is for the purposes of categorisation as a notifiable dealing?**
  The WAGTIDC believes that the current risk indicators defined in the GT Regulations may be sufficient to determine what a low risk dealing is.

- **Under Option C, what are the advantages and disadvantages of first categorising the dealing in the context of the notifiable dealing authorisation pathway?**
  N/A

Key consultation questions – Licensed dealings

- **What risk indicators would inform the split between a permit, an expedited assessment or a full assessment for Option B?**
  The WAGTIDC supports the risk indicators outlined in the table at page 20 of the Consultation RIS.

- **For Option C, what risk indicators would inform the split between a permit, an expedited assessment or a full assessment for the categories 'dealings involving intentional release' and 'clinical trials and medical applications'?**
  N/A

- **Under Option C, what are the advantages and disadvantages of first categorising the dealing before using risk indicators to determine the relevant licence type?**
  N/A

Key consultation questions – Essential enablers

- **What current processes (that are unnecessarily burdensome) could be resolved by an improved IT system?**
  At present WA government agencies' involvement on GMO research activities are minimum to nil and therefore they are unable to provide feedback on unnecessarily burdensome processes. However, the WAGTIDC supports an upgrade of the OGTR's IT system to enable an automatic data management system.

- **What other advantages could be gained from the implementation of an automatic data management system?**
  The GTIDC supports the advantages outlined in the explanatory paper.

Key consultation questions – Streamlining and other technical changes

- **Are there other opportunities to streamline or improve the clarity of the legislation?**
  The WAGTIDC supports the technical changes proposed to support the reforms and to improve the legislative scheme.