Queensland University of Technology (QUT) is grateful for the opportunity to provide feedback on the Consultation Regulatory Impact Statement (consultation RIS) Modernising and future-proofing the National Gene Technology Scheme. QUT agrees that a proportionate regulatory model is required, that is flexible, streamlined, and able to adapt in a timely manner to changes in the field of gene technology. It is also important that the model is not overly complex so that it can be understood by applicants and IBCs, including lay members. After consideration of the proposed Options, QUT’s preference is Option B: Risk-tiering model. QUT provides the following specific feedback in response to the consultation RIS and associated explanatory paper.

Time is a key factor in the research sector. Delays obtaining approval affect researchers’ ability to meet project milestones, obtain grant funding, and publish novel research in a highly competitive environment. Delays also significantly impact the candidature of research students. Proposals that increase efficiency and reduce turnaround times, are therefore very welcome.

Organisations will inevitably incur some costs associated with implementing a new system, irrespective of which option is chosen. This will include, for example, costs developing detailed guidance and procedures for applicants and the IBC. Beyond that, the cost impact will depend on how the options are implemented in practice.

As we understand, Options B and C share key goals:  to better proportion regulation to risk, to find efficiencies, and to future-proof the scheme by allowing greater flexibility. The consultation RIS rightly notes that environmental release is only one determinant of risk, and it is a limitation of the status quo (Option A) that the authorisation pathway is determined in this narrow way. Options B and C therefore take a broader view of risk, and so enable more proportionate methods of authorisation.  We prefer option B to C on the grounds that it appears to allow the greatest flexibility, and therefore the greatest potential to realise benefits in reducing timeframes.

However, we have some concerns about whether Options B and C will require organisations to undertake more complex decision making in advance of submission to the Regulator. For example, will we be required to identify the correct form when we apply for a permit rather than an expedited approval? We may incur additional costs and time in undertaking these decisions. Moreover, we will incur greater costs in the event that we get it wrong and may be required to resubmit the application on a different form through a different pathway.

To mitigate these risks, it is imperative that the scheme provides clear criteria to determine the appropriate pathway.  The explanatory paper states that, “…eligibility criteria for each pathway would be defined through *specific listings or risk criteria*.”  This is crucial. These must be clear and simple to “[protect] IBCs and researchers from difficult judgements as to whether a GMO is being dealt with in the right way.”

# Delegated legislation

We agree that the use of delegated legislation will allow for changes to be implemented in a timelier manner. Currently guidance and other documentation is used to fill the gap until gene technology legislation can be updated, which can cause confusion. Similar models of delegated legislation are used in other government entities, and for the most part work well. It is important that the public and stakeholders are involved in both the generation of delegated legislation and the process for updating it. The OGTR has a strong history of engaging stakeholders and ensuring public consult, and we hope that this will continue. It will be crucial to the success of the proposed options, and to all of the items we discuss below.

# Non-notifiable and notifiable dealings

QUT supports the change of ‘exempt’ dealings to ‘non-notifiable’ dealings. The term exempt can cause confusion, with some believing it referred to a dealing being exempt from being a GMO, rather than exempt from licencing requirements. We also support the expansion of the dealing pathway to include other GMO dealings.

QUT also supports the change of ‘NLRD’ to ‘notifiable’ dealings. The term clearly describes the requirements for these dealings and is not dissimilar to the current name, so there should be little confusion to the change. Again, QUT supports the expansion of the category to include other GMO dealings.

The success of these changes will depend on clear guidance as to how non-notifiable, and notifiable dealings need to be undertaken (e.g. contained vs not contained, required facility containment level). Currently all NLRD and exempt dealings require the dealing to be contained. If the expansion of notifiable dealings may include intentional release, this will need to be very clear in the delegated legislation so that applicants and IBCs know what is or is not allowed for each dealing. IBCs may have difficulty overseeing notifiable dealings involving intentional release, as this is not something they have previously had oversight of.

With the change from NLRD and exempt dealings to notifiable and non-notifiable, and the associated expansion of each authorisation pathway, will IBCs be required to re-assess current dealings under the new criteria, as has been the case with past changes to the gene technology scheme. If so, we anticipate an initial increase in IBC workload while current dealings are re-assessed. This workload will vary from IBC to IBC depending on the number and complexity of their current dealings. When the new criteria are released IBCs will require time and in-house training to familiarise themselves with the details. It is likely that IBCs will spend more time assessing and classifying dealings until they become familiar with the new criteria and authorisation pathways. There may also be an increased IBC workload with dealings from higher categories moving into the notifiable dealing pathway. Please note that while exempt/non-notifiable dealings do not require assessment from an IBC, many organisations request their IBCs assess these dealings to determine the correct classification, as individual applicants are not normally familiar enough with the legislation to correctly categorise their dealings. This is an internal procedure by organisations to minimise non-compliance.

# Scope for allowing “variations” to notifiable dealings

As part of the modernising and future-proofing of the gene technology scheme we ask that consideration be given to allow IBCs to approve variations to notifiable dealings. Provided a variation is reviewed by an IBC and approved before work commences, there is little risk. Variations might include the addition of new facilities, new classes of authorised persons, or new traits/dealings if they are within the scope of the approved project. In practice, the review of an original application with the proposed changes clearly identifiable (e.g. tracked changes), is the same as reviewing a new application, so poses no additional risk. This suggestion would reduce administrative burden for applicants and IBCs, and is consistent with the aims of the review. It may also reduce risks of non-compliance if dealings covered on the original approval are not re-labelled etc to note they are now covered under a new approval. Variations to notifiable dealings could still be reported to the Regulator annually.

# Licences

QUT acknowledges the need for certain dealings to remain licensed by the OGTR, to ensure appropriate assessment of risks and oversight. It is however very important that criteria clearly define what dealings can be applied for in each of the licence categories, permit, expedited and full assessment. If this is not clear, or it is assessed on a case-by-case basis, it will potentially increase the time required to obtain approvals. For example, if a permit is assessed for administrative, financial and compliance checks only, the application form is not likely to require as much information from the applicant when compared to an expedited assessment, or a full assessment application. If a permit application is refused following assessment or allocated to a more appropriate licence type, additional information is likely to be required from the applicant so the dealing can be assessed. This additional information would presumably need to be reviewed by the IBC before submitting to the OGTR. This will add additional time delays and administrative burden on applicants and IBCs, rather than speeding up and simplifying the application process. This also adds uncertainty to applicants as they will be unaware of the potential time frames to obtain their approval. This scenario can be mitigated if criteria for each of the licence categories is very clear and can easily be applied by applicants and IBCs.

While option B is more streamlined, it is unlikely there could be a single application form for each licence category. Presumably, different information will be required in an application for a plant field trial compared to a clinical trial. We are not sure how this would work in practice – e.g. whether it would involve a complex smart-form that change questions depending in the nature of the dealing. We have some concern that the proposed flexibility may necessitate a lengthy application form and some applicants will be confused as to what sections do or do not apply to their dealing.

We agree that categorising by dealing type, as in option C, can be difficult and there are dealings that would not clearly fall into a single category. However, categorisation as some point in the process, at least for licences, may be unavoidable.

Would the proposed licence system allow streamlining of dealings as they progress? For example, suppose an applicant applies for a permit to work with a GM plant in the lab (currently DNIR), the work progresses, and they now want to test the plants in a field study (currently DIR). The change in work would require a new DIR application through the IBC and OGTR, and a new licence issued which can take a long time. Once issued, the applicant works under two licence approvals. In the proposed model, if they already had a permit or expedited approval for work, would they be able to vary the licence to now do field work? Would this be faster than submitting a new application, as the background of the project (host plant, gene traits, etc) have already been assessed? This would increase efficiency for the applicant and the IBC and presumably the OGTR if they could build on previous risk assessments undertaken for the first licence. It also means the applicant works under one approval which covers all the work.

It is noted that urgent applications such as those for access to the special access scheme can be actioned in a timelier matter by including these dealings in the permit licence category. How will other ‘urgent’ applications be dealt with in a timely manner, for example research or vaccines in response to a pandemic? Presumably, these would not fit within the permit or expedited licence category as not much may be known about them.

In a research environment there may not be a decrease in cost or timeframes when seeking a licence since most research is ‘novel’ and as such likely to require a full assessment. We assume that a full assessment would take no longer than the current timeframe for obtaining a DNIR licence. If this is the case, there would be no benefit from decreased time frames, but applicants would be no worse off than under the current system. It is unclear if there would be additional administration for organisation to records and monitor different licence types.

Ultimately dealings will have the same risk assessment applied to them and associated conditions, regardless of the model implemented. A dealing that is suitable for an expedited assessment will still be an expedited assessment under option B and under option C. Option B will have the criteria for each licence type in one clear section, whereas Option C will have criteria for each licence type divided between the different dealing types. Depending on the number of dealings that meet these requirements, it may be cumbersome reviewing a lengthy criteria under Option B to determine if a particular dealing is included in the section. In this case, breaking the dealings into dealing types as per Option C. may make it easier for applicants and IBCs to find a particular dealing within a category. As noted in the consultation RIS, there will be some dealings that fit into more than one category, leading to duplication of dealings listed across the categories and resulting in lengthier delegated legislation. In this case, the number of dealings which meet each of the different licence types may be a factor in determining the best option for licences.

# Option C specific feedback

While option C notes that the risk associated with a dealing is the secondary consideration, the risk level still determines whether the dealing is non-notifiable, notifiable, or licenced (permit, expedited or full assessment). The difference being that dealings are also categorised based on the type of dealing. Categorising dealings based on the type of dealing may be useful in assigning applications to appropriate persons e.g. clinical trial and medical applications being reviewed by members of the IBC with medical application expertise, while dealings involving intentional release of plants in field trials being reviewed by members with expertise in plant research. This could also help the OGTR where there are teams that are experts in those niche areas and the dealing category directs the applications to the right people/resources. However, the number of categories could make the system appear overly complex and difficult to understand (option B certainly appears from diagrams to be simpler and ‘look’ more streamlined). Also noting the difficulties already discussed in assigning an application to a category based on the dealing type.

In option C, why does the contained dealing category only include the expedited licence type? Would there not be cases where a permit could be issued? While there is no release into the environment, is there the potential a full assessment would be required for a dealing as the work poses a risk to human health and not much is known about the organism/traits? It is difficult to think of a non-notifiable dealing that could fit under dealings involving intentional release or clinical trials and medical applications. Is there a reason that notifiable and non-notifiable need to be first categorised into contained, intentional release and medical/clinical trial categories? At any rate, Option B allows more flexibility than Option C in all of these ways.

# Dealings covered by another regulator

In principle, QUT supports cases where dealings with GMOs are regulated under another authority and the Regulator provides advice during the assessment of applications by the other authority. However, we are unsure as to how would this work in practice. It is noted in the consultation RIS that these types of dealings would be classed as notifiable dealings, yet notifiable dealings are assessed by an IBC. If an applicant applies to an IBC, and they approve the work as a notifiable dealing, as the work is being assessed by another regulator and meets this authorisation pathway, this suggests to the applicant that this work may now begin. How does the OGTR become aware of the dealing, and therefore know to consult with the other authority (given IBCs report notifiable dealings annually)? Would the OGTR ‘approve’ certain authorities where they have agreed to notify the OGTR? What if there are other authorities who do not want to have the Regulator provide advice? There is a risk of other authorities ‘overregulating’ GMOs (note this has previously occurred). Is the OGTR able to step in where another authority imposes requirements due to the material being a GMO, but the requirement is above and beyond OGTR requirements? Who would have oversight of these dealings, the OGTR or the other authority, or both?

To enable the system to work there would need to be a list of ‘approved other authorities’ for which the OGTR has determined they assess risks to people and the environment, and there is an agreement in place for OGTR advice to be included in the other authority’s assessment. There would need to be a way for the OGTR to be made aware of these dealings, perhaps through a question on the other authority’s application form, or a notification system through IBCs. Note this would impose more burden on other authorities and/or IBCs. Is there a risk that applicants could apply through another authority and IBCs would not be aware of the GMO dealing? Perhaps instead of these dealings being notifiable, they could be submitted to the OGTR, via the IBC as a specific application type?

# GMO register

QUT supports better usage of the GMO register where the risks of the dealing are negligible based on scientific knowledge and accumulated regulatory experience. We agree this could be changed from a legislative instrument to administrative, provided there is a transparent system involving government, public and stakeholder input. The consultation RIS notes the change in eligibility criteria for a listing on the GMO register, that would allow dealings not previously authorised under the Gene Technology Act to be included. What sort of dealings that have not previously been authorised under the Gene Technology Act could be added to the GMO register? Is this to capture dealings that may have been undertaken overseas and have a history of safe use, but have not previously been seen/used in Australia? If so, this seems to be inconsistent with the consultation RIS that noted overseas risk analyses are likely to be relevant for human health and safety, but risks posed to the environment may differ between countries.

# Definition of ‘gene technology’

QUT support changes to the definition of ‘gene technology’ to include genes or other genetic material that have been created, in addition to those that have been modified. Regarding techniques that are considered gene technology, is inclusion on the regulations the best option? This would limit the ability to add, change or remove techniques (past examples included CRISPR, Talen) and a more flexible option may be better suited. It would make sense for the details of included techniques be listed in delegated legislation so that it can be changed in a timely manner. Binding determinations from the Regulator as to what is or is not a technique are likely to be more definitive and clearer compared to ‘guidance regarding the interpretation’ which may be more subjective and open to different perspectives. It may be that a combination of the two is required depending on what techniques are included or excluded in the definition.

# Definition of ‘genetically modified organism’

QUT support the change to the definition of ‘genetically modified organism’ to cover the creation of organisms by gene technology. As per the case study on page 12 of the explanatory paper, it is not clear where organisms that have been modified for example by a construct, that has subsequently been removed, fit within the definition of genetically modified organisms. Where possible the updated definition of ‘genetically modified organism’ should attempt to clarify where these organisms fit. Alternatively, delegated legislation should specify how these organisms should be classified.

# Definition of ‘deal with’

QUT support the streamlining of the definition deal with, into the three concepts make, supply, and use of the GMO. Where there is overlap of the concepts with other authorities, it is preferable to consider the other authority’s role as part of the risk tiered approach, rather than revising the definition to remove the overlap and inadvertently exclude dealings that should fall under the Gene Technology scheme.

# IT system update

While we welcome an update to the OGTR’s IT system and the efficiencies this will provide, we have concerns over how this will impact organisations’ current systems. Of particular concern is the review and submission of licence applications. The current OGTR licence applications are a document available on the website. In our current system, applicants can be directed to this link where they complete the form and submit it to the IBC. The IBC reviews the application and can request changes, if required, which the applicant makes on the form and resubmits to the IBC. Once the IBC is happy with the application form, it is endorsed and submitted to the OGTR. This works very well from the applicant and IBC point of view. If the licence applications become an online submission, the applicant will require an efficient mechanism to complete the application and then provide it to the IBC for review. For example, the current OGTR online submission forms allow an applicant to generate a PDF of the application which could be provided to an IBC. If the IBC requires changes the applicant must go into the OGTR application form and make the changes, create a new PDF, and then resubmit to the IBC. There is no easy way for the IBC to see what has changed (e.g. via tracked changes) and needs to review the entire document again. Once the IBC has endorsed the application, an authorised person needs to submit the application to the OGTR. This would not normally be the applicant, so the new system must also make it easy for an authorised person to access applicants’ forms. Additionally, the current OGTR application forms require someone to log into an application at least once every 10 business days, otherwise the form is deleted. The time between an applicant applying to the IBC and the IBC reviewing the application can easily be more than 10 business days. If the applicant forgets to log into the OGTR system, their application is deleted and they have to re-enter the information that the IBC has already reviewed. There is also the risk of an un-authorised person applying to the OGTR before an application has been reviewed by the IBC.

# Conclusion

QUT would welcome the opportunity to provide feedback on further items such as delegated legislation following a decision on the preferred model for the scheme.