Australian Government
Department of Health

National Gene Technology Scheme: Consultation Regulation Impact Statement and Explanatory Paper

Frequently asked questions

Modernising and future-proofing the Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme

Questions about the consultation process

There seems to be questions in the RIS and the Explanatory paper. Do we answer both sets?

Yes, please. You don't have to answer every question, but certainly have a look at the questions in both documents. The Consultation RIS and the Explanatory paper serve two different purposes. The Consultation RIS provides a high-level overview of the policy options, while the Explanatory paper offers technical information on how the options in the Consultation RIS could operate in practice.

The answers that you provide in response to both documents will inform the next steps in the implementation process.

When will the details of new authorisation pathways be worked out, such as timeframes, data requirements, and processes to be followed by the regulator? And will regulated stakeholders be involved during the design of the system?

The aim of this consultation process is to identify a preferred option to implement Review recommendations. Once Gene Technology Ministers endorse a preferred option, then the details of such option can be designed.

We will use information provided by stakeholders during this consultation to work out the details of the preferred option and to prepare draft legislation. There will be an opportunity for stakeholders to comment on draft legislation in the future, and the associated Regulations and guidance materials.

There are a number of factors that feed into how long this process may take. Firstly, the number and complexity of submissions we receive, as we will need to analyse that to determine whether we will be considering just Options B and C, or whether another viable option comes out from the submissions.

Secondly, states and territories need to be consulted because of the Gene Technology intergovernmental agreement and we need the views of the ministers of all nine jurisdictions. Once the jurisdictions have completed their necessary processes, the preferred option will be presented to the ministers for policy approval to move forward. Considering the timing of those necessary processes, we are aiming to have policy authority in place towards the middle of this year, then we can look at drafting the legislation.

We are hoping to have completed the drafting of the legislation later this year. If that happens, we could be consulting on such drafting in late 2021 or early 2022. Consultation on draft legislation would be supported with a document containing operational details so that organisations can see how the changes may work in practice. This could look similar to this consultation, where detail is provided in an Explanatory Paper.

How can regulated stakeholders provide quantitative data on the impacts of the different options if the timeframes and requirements for the different authorisation pathways have not been defined yet?

We need to provide Gene Technology Ministers with some information about the cost that the options are going to have on regulated stakeholders. We believe that the proposed options would deliver savings for regulated organisations, since some of the current processes would be streamlined. We would like regulated organisations to let us know if that is the case, and to provide data that backs this up.

We have provided you with some scenarios that you may use to provide feedback (see slides 34-36 of the presentation). Since some of the details of the authorisation pathways are to be refined, you can provide quantitative data about the costs of the options pro-rata, that is, per hour or per month. For instance, you can provide the amount of dollars per hour that your organisation spend when preparing and submitting a current application to the OGTR. In that way, we know how much money is saved when the timing for preparing an application is reduced by, for instance, 2 hours.

You can also provide information on how much money your organisation spends when waiting on a regulatory decision for a year or six months. This would allow us to work out how much money would be saved per month that a regulatory decision is brought forward.

Who will be consulted on the setting of categorisations of GMO dealings?

This is a step that will happen after the current consultation. Once we have a decision on the broader framework we can consider the detail of things like the setting of categories, and there will be another level of consultation on that detail.

Proposed changes to regulations are consulted on through the normal legislative process and, as is current practice now, stakeholders will also be provided an opportunity to comment on proposed guidelines. At each step, there will be an opportunity for consultation, with submissions being considered during the development of the new scheme.

Throughout this review we have been open and transparent about what we are doing and the steps along the way to make sure that the broad spectrum of stakeholders are involved in the process.

Can you comment on the process that would need to follow this consultation to developing the delegated legislation required for Options B/C?

Information received through this consultation process will inform a Decision Regulation Impact Statement (Decision RIS). The Decision RIS is the document that the ministers will use to determine a preferred option to progress the implementation of review recommendations.

Once the preferred option is decided, work on the drafting of the legislation that would implement such option can start, including any delegated legislation. Further consultation with the public would be part of the drafting process.

Questions regarding the proposed options

Why are the merits of the existing system - Option A - not canvassed in the documentation?

The merits of the current system were identified in the final report of the Third Review (the review) of the National Gene Technology Scheme. The purpose of the review was to look at the current system and identify any issues that needed addressing. The alternative options currently under consideration address the issues posed by the current framework as identified in the review.

What are the similarities and differences between Options B and C?

As described in the RIS and explanatory paper, Options B and C share the following similarities:

- *Updated definitions* – both options present the same proposed changes to definitions in the legislation that clarify whether new technological developments are within the scope of regulation. The proposed changes also ensure that the legislation is flexible enough to enable the Scheme to respond rapidly to advances in gene technology.
- *Streamlined authorisation pathways* – each option presents a new system of authorisation pathways that differs from the status quo in the incorporation of streamlined authorisation pathways for GMO dealings that are low risk, have a history of safe use, or are under the remit of other product regulators.
- *Essential enablers* – upgrades to the OGTR IT system to deliver an automatic data management system and integrated portal and an improved user interface for stakeholders.
- *Technical changes* – both options propose largely minor and machinery changes to enable existing processes to be streamlined and the complexity of the legislation to be simplified.

The key differences in the options are in respect of the new authorisation pathways:

- Option B presents a risk tiering model, in which GMO dealings are classified into authorisation pathways according to the level of indicative risk.
- In contrast, 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.

Could the outcome be a hybrid of options B & C?

Yes, the outcome could be a hybrid of Options B and C. This is why we are seeking your feedback. We really need technical information in your answers to the questions found in the Consultation RIS and in the Explanatory paper to understand how the options will work for you operationally. The information you give us will help us determine the costs and the regulatory impacts of the options. It may well be that there is a hybrid option or another option that will be put forward in that final Decision RIS document.

Is it necessary to separate out contained use in Option C? Is it not possible to separate medical applications from other applications in Option C without the contained used category?

The main distinction between Option B and Option C is that Option C separates contained dealings and dealings involving intentional release. Option C also adds a third authorisation stream for clinical trials and medical applications. If Option C did not differentiate contained dealings and dealings involving environmental release, there's not much difference left to Option B. You can provide comments if you think there are improvements to the options described in the consultation documents.

Will the clinical trial medical applications path under Option C still require an assessment of whether the dealing is contained?

This is related to the previous question about clinical trials in Option C. The main problem solved by separating clinical trials from the other two authorisation streams in Option C is that determining whether something is contained or not is particularly difficult for some clinical applications.

However, if Option C is chosen for implementation, some consideration of the likelihood of environmental release will be involved when we work through the nuances of the risk indicators and the factors that should determine what authorisation pathway applies for particular clinical trials and medical applications. While it will be one of the risk indicators that's considered, it will no longer be the first question asked to determine what authorisation category applies.

Would Option C provide a faster track for clinical trial GMOs compared to having all applications in one lump in Option B?

Not necessarily. However, Option B may potentially provide more flexibility than Option C.

The criteria for licensed dealings under Options B and C would be exactly the same. Under Option C, the dealings are further categorised and broken down based on whether the proposed dealings are contained, e.g. in a research facility, or if the dealings involve release into the environment, or involve clinical trials or medical applications.

A potential benefit for Option B is that if the applicant has a long-term business plan, and knows that they’re going to be importing the GMO, starting laboratory work within a contained setting, and then progressing to clinical trials, and moving towards commercialisation - that could all be catered for under one licence. If an applicant has a sound plan and provides the required data to the OGTR, that licence can be varied depending upon where the applicant is up to within the development line.

Option B could be more flexible than the current system where applicants may need to return to the OGTR for two or three different authorisations. Under the current setting, if you’re importing a GMO, you might do that under a NLRD. If you’re subsequently conducting dealings within a laboratory, the dealings could be authorised under a DNIR. Then, when you are ready for commercialisation, OGTR may authorise that under a DIR. Under Option B, OGTR could authorise those different dealings under one licence.

If an organisation obtains a Clinical Trial licence under Option C will an additional DIR or DNIR licence be required to conduct dealings in a commercial setting, or will commercial dealings fall under medical applications?

It depends on whether you're doing activities with a GMO in containment, for instance in a research facility, or whether you are doing activities that involve intentional release of the GMO into the environment.

For example, under Option C if you wanted to do clinical trials and it was in a research facility, you could obtain a licence under the contained dealings pathway, and then as you move into commercialisation, that may become a full assessment licence under clinical trials and medical applications. Under Option C there is the potential for complexity because judgements are needed about whether the activities with the GMO are going to be contained or whether they're going to involve release into the environment. There would be quite a few complexities in practically implementing Option C that people would need to be aware of and we are seeking comments in regards to this matter in your submissions.

What is the advantage of option C over option B? A 'priori' option C seems to create more complexity.

The advantage of Option C is that regulated stakeholders will be more familiar with the system, because they all have familiarity with current contained dealings and dealings involving intentional release. Option B is a much simpler system. These two options are presented for stakeholders to have an opinion and inform us of what they prefer.

There is a potential for complexity under Option C when you look from research through to commercial development of a product. For example, importing a GMO to the country could be done as a notification (under an NLRD for contained work at the moment), and a licence may be required for some research within the facility (DNIR currently). To move from laboratory work into a clinical trial might require another licence, and these all remain discrete boxes within Option C.

An issue now, which will continue to be an issue under option C, is that different types of authorisations might be needed depending on what you're doing. By comparison, Option B is simpler. Commercial entities often work to a three to five year plan, knowing where they're proposing to go with an organism. Depending on how your research then develops you might only need one approval, and then that can be varied over time rather than having to issue different sets of licences with different time frames that allow you to do different things.

Option B should provide more flexibility so, if you have planned your work that might only need one or two approaches to the OGTR rather than three or four. This has implications around resourcing and the end costs, which we're looking at through this consultation process.

What are the triggers and decision procedures for choosing an expedited process or a permit to release a GMO?

The Explanatory paper touches on potential triggers and decision points, however the details are still to be fully developed. The case studies in the Explanatory paper outline what types

of triggers could potentially be used. As an example, with regard to the permit category, we could consider the history of safe use and how familiar the OGTR is with the particular crop type and the new traits introduced in that crop type and whether standard conditions could be developed for that particular scenario.

The Explanatory paper provides an idea of the types of dealings that could potentially fit within a particular category. The triggers and decision points still need to be developed further.

Impact of the options on Institutional Biosafety Committee

What do the proposed options mean for an Institutional Biosafety Committee (IBC)?

Under both Options B and C, the role of the IBCs pretty much remains unchanged. IBCs would still be looking at the proposed activities with a GMO, making a determination about whether it fits within the non-notifiable classification or notifiable as you currently do by looking through the Regulations and looking at the exempt list and NLRDs. Similarly with the licencing options, IBCs would look at what the proposals are, and what type of licence category it might fit in to.

OGTR will be providing good guidance material, e.g. guidelines that underpin the changes depending on which proposals are agreed by Ministers, as well as opportunities for training. OGTR will be providing training to IBCs so that people become familiar with the way that the dealings and the categories operate.

Given the additional responsibilities that could be placed on IBCs, would the Department or the Regulator provide a greater level of training to assist with assessment and ongoing monitoring and compliance?

The short answer is yes.

The Explanatory paper covers in some detail the critical enablers for implementing recommendations, and a new IT system for OGTR was one of those. That would be a really important mechanism to support the work of IBCs. It would provide a portal for notifications, information sharing, and could provide some good solid guidance for IBCs.

We are also interested in receiving feedback if any of the options will increase the workload of IBCs, and if IBCs are comfortable with taking the workload.

Would eligibility for a 'permit status' be self-assessed by the local IBC, or be assessed by an OGTR committee (like GTTAC)? If by committee, would that not still entail potential delays?

We still need to build eligibility criteria for the different categories of licences, which includes full assessments, expedited assessments, and permits. For a permit, a large part of the application process may be self-assessment with the criteria fairly well explained, and we would be providing training to IBCs in terms of how to interpret guidelines and determine classifications within the new authorisation categories.

For any decisions that the IBCs will need to make, based on new categorisations, there will be training, there will be guidelines developed, and we will provide assistance.

Applicants will need to identify if they are applying for a permit, expedited or full licence, and it will be the Regulator deciding whether to accept those applications and whether to issue an authorisation.

Interface between OGTR and other regulators

The draft RIS, or Regulation Impact Statement, proposes that the Australian Gene Technology Regulator can streamline its approval where another Australian regulator has approved the use of the GMO. This is important to ensure timely access and minimise duplication. However, other regulators have different purposes or objectives, which may not consider the particular risks and objectives of the Scheme. How are these differences in approach and objectives being taken into account to avoid inadvertent regulatory gaps?

Part of this consultation process is talking to the other regulators about the options. It's an opportunity for us to look at OGTR's processes where they interface with the other regulators such as the Australian Pesticides and Veterinary Medicines Authority, Food Standards Australia New Zealand, and the TGA.

At the moment there is a first principles review of the APVMA and the AgVet regulatory system and a review of the food regulation system and the work of FSANZ. It's an ideal opportunity to talk to all of those regulators about how OGTR's work interfaces with what product regulators do and try to streamline and future-proof some of our administrative arrangements. This work has been underway over the last 12 months, and we're hoping this will come together when implementing the option that gets approved through the Gene Technology Ministers' Meeting.

In regards to the changes to the approval process for DIRs and relying on other organisations to approve things, like the APVMA example, this assumes that those other organisations have the necessary knowledge about GMOs to make these decisions. Does the OGTR feel confident in this assumption or will there need to be a lot of education for these other organisations?

For the interface between OGTR and other regulators, we are proposing a model where a particular stakeholder doesn't have to make two applications to two different agencies. Ideally there would be one application. In the case of a veterinary vaccine, that application would go to the APVMA. Any assessment around the GMO and the risks associated with that GMO could be done here at the OGTR, where the OGTR then becomes an advice giver to the APVMA.

It's not necessarily that we're removing ourselves from any form of risk assessment at all, we're still going to be considered as an advice giver, but we don't want to have to process two sets of applications when the APVMA might be doing the bulk of the risk assessment

and we're just informing that decision by using our technical capability and conducting part of the GMO risk assessment.

This fits right into the streamlining recommendation.

To do a field trial for a veterinary vaccine, submit the application to APVMA and not OGTR. OGTR is to provide advice to APVMA. Is this for both Option B and Option C?

This is a topic also being considered through the current AgVet Review. Together, we are looking at how to streamline applications so that one agency assesses an application, supported by advice provided by the other agency. This would likely operate the same way for both Option B and Option C.

Under the proposed Option B, plus C, if we're looking to use a GMO vaccine that has not being used before in Australia, how would we determine which regulatory Scheme, OGTR, or TGA to use?

We're not proposing that there's any change in terms of applications being made to the TGA or OGTR, because for medical applications the two regulators look at different elements of the evaluation.

Impact of the proposed options on jurisdictions

Under Option B, how will the Tasmanian moratorium be applied if the classification of contained dealings is removed?

It is not envisaged that the moratorium rules would change. If the Tasmanian moratorium act requires changes - that will be discussed at a later time through our senior officials committee once Ministers have endorsed an option.

If intentional release is prohibited in Tasmania, is there a risk in Option C that non-identifiable-- non-notifiable intentional release dealings clash with state legislation?

Comparing this proposal to the current system, there is nothing in the non-notifiable intentional release category at the moment. Whereas if we're looking to translate our existing Regulations into the different proposed authorisation categories, the non-notifiable contained dealings match really well with exempt dealings. Same with notifiable and contained matching with NLRD. There is no current equivalent to Option C's notifiable and intentional release category, and if that's something that people envisage as being a problem, then we want to hear from them.

Impact of the proposed options for specific types of dealings

Are you still going to require all the same information currently required for NLRDs?

The information that's reported to the Regulator in accredited organisation annual reports, or real-time reporting, is required for the GMO Record. That's an important transparency measure for the Gene Technology Scheme, and making any changes to the scope of information provided to the Regulator would impact on what information can be published on the OGTR website and made publicly available.

If, for an IBC, the types of information that need to be recorded and reported are an important aspect of regulatory burden, that's something we're interested in hearing about. Is there a particular type of information that you're proposing should be handled differently? That would be of interest to us.

Do we still have the choice of annual submission of notifiable dealings or are these expected to be submitted in real time with annual reporting eliminated?

The current arrangements are that organisations can notify NLRDs to the Regulator in real time or annually. It's a choice of what is easiest for organisations. If that's an important factor for managing the regulatory burden of the Scheme on you, that's something that we'd be very interested to hear about. We're looking to use IT system improvements to ease regulatory burden and make reporting easier and more efficient for everybody involved, and real experience from the user end is something that would be very informative to us.

Are there proposals to review and downgrade any dealings currently categorised as NLRD using a risk-based decision? For example, is there a possibility of moving GM mice from NLRD to Exempt Dealing?

There are not specific proposals at the moment, because we're looking first at which regulatory approach should be implemented. As outlined already, developing the details of how the approach would be implemented will be the next stage of this process.

This specific proposal about GM mice has come up in OGTR's previous technical reviews of the Gene Technology Regulations. It hasn't previously been agreed to downgrade dealings with GM mice from NLRDs to exempt dealings, and a very strong argument would need to be put forward by anyone proposing this change.

What timeframes were you envisaging for the issue of a permit, say for a small scale GM crop field trial?

That will probably depend on how much information OGTR already has as a basis for assessment. For example, adding to existing or previously licenced field trial work, where OGTR can rely on that previous information, will require a shorter timeframe. For permits, there will be set criteria that applicants will be able to self-assess against. For example, whether OGTR has assessed the GMO or the trait before, whether there are standard conditions that we could apply to that parent species. These are still details that we would need to work through once we've got a pathway.

Once applicants have done a self-assessment, the Regulator would take a view as to whether an application truly fits in the permit category. An important focus of permit applications would be checking applicant suitability, regardless of what layers of risk

assessment rely on previous assessments to inform the issuing of the licence in the permit form.

Can you please run us through an example of what could happen under B or C for, let's say, an application for a field trial commercial release of a crop modified using based editing or any other gene editing method that is not already excluded from the scope of regulation, but leading to a crop that could have been obtained via conventional breeding.

This question is about the next layer of details that will be worked through in future stages of implementation. The Explanatory paper and the consultation RIS don't go into details of how specific technologies might be approached in the various risk tiering options. If this is something that you've got views about, you're very welcome to submit them. As implementation details are developed, we will consider whether there are specific technologies that warrant lower regulatory oversight, and whether field trials of crops modified through newly developed methods need the same level of oversight as other GM crops.

Is it intended to regulate bio foundries or gene synthesis facilities that would be creating genes and genomes, but not necessarily putting them into organisms?

This question goes to the proposals that we're putting forward around definitions. We are considering some modification to the definitions of gene technology, genetically modified organisms, and dealings. The explanatory document details what we're proposing around those three different definitions, which you could consider against what it is that you would be proposing to do.

How will options B&C regulate newly created novel synthetic GMOs that have never existed before, especially their release into the environment?

In the Explanatory paper, we explore some of the proposed changes to definitions in more detail. The proposed changes relate to the definitions of gene technology, genetically modified organism, and deal with. The Explanatory paper details how proposed changes to these definitions could capture novel synthetic GMOs under regulation.

IT SYSTEM

Will OGTR's updated IT system be linked with other regulatory agencies? And, will the OGTR’s new IT infrastructure/portal be as secure and/or based on e.g. TGA web based Business Services portal?

There is a lot of work to be done to determine the particular requirements for an IT system and we would be very interested in working with our regulatory counterparts in particular to see what they have already built and what we can learn or borrow from them. One of the

expected challenges of building an IT system would be interoperability between different IT systems, which can be problematic.

We will definitely investigate how we could link IT systems with some of our counterpart agencies as we move forward.

How will the updated IT system work for applications that need to be reviewed by an IBC prior to submission to the OGTR, and have you considered the impact this may have on individual organisations and their electronic submission systems to their IBC?

The requirements and details of the new IT system are yet to be determined, and we're at the early stages of exploring what would be required. We will certainly consult with stakeholders and in particular with IBCs to make sure it is a very functional and usable system.

We are envisioning a type of portal system where we could interface with IBCs in a very streamlined, usable way. We will need to have consideration for the types of systems currently used within organisations and how those systems would interface with this new IT system.

Miscellaneous questions

What would be the impact on the everyday life of the OGTR of Option B and C? Would CDES (Contained Dealings and Evaluation Section) and PES (Plant Evaluation Section) be split into different sections for example?

It is too early to tell. OGTR's current operations, as our workloads have shifted more from cropping applications to medical and clinical trials, involve the evaluators working across both sections. Evaluators are upskilling, they're being trained in different forms of risk assessment, and doing different work.

Does recommendation 22 (of the Review's Final Report) identify a cost recovery model where organisations will be charged by the application or notification?

Recommendation 22 of the Review recommended that further consideration to be given to the most appropriate funding mechanism to support the ongoing operation of the Scheme and the Gene Technology Regulator's activities. However, this consideration cannot happen until a preferred option has been identified and endorsed. That would be not an effective and efficient use of resources. So our first aim is to actually establish what the new or revised model of future-proofed and modernised regulatory system would look like, and then we can do further work on cost recovery as required after that.

Page 7 of the Consultation RIS states "initially agreed to an Action Plan". Given this proportionate regulatory model being considered, has the Action Plan been discarded?

No, the action plan has not been discarded but it has certainly been revised and updated to reflect the current situation. When that action plan was first agreed to by ministers, at the end of 2018, they prioritised some recommendations.

Since then, there's been a recognition of the interrelated nature of a lot of the recommendations, so rather than implementing legislative changes that apply to only one prioritised recommendation at a time, we are implementing several recommendations at the same time.

We're still delivering the recommendations in line with the action plan, but the action plan is being revised in terms of how it will be timed and coordinated. We will provide the action plan after it has been revised. We are still working within the parameters set out in the initial 2018-23 action plan.

Is 'streamlining' in the documents synonymous with 'fast-tracking' applications?

No. Streamlining refers to a broad range of improvements to make the scheme more efficient and effective. All the issues that were explored in the review (e.g. duplication of effort, systems which are not properly integrated) will be considered and addressed appropriately to make sure that we have a system where we put regulatory effort where the most risk is.

Streamlining also involves building improved IT systems that add efficiencies such as reducing the time taken to complete administrative tasks or data entry by hand. Moving to a new, more efficient IT system is also considered streamlining.

Will the new model retain the mechanism enabling review/updating of the Gene Technology Regulations?

Yes. The legislation under the new model would remain reviewable and updates could be made to the legislation. However, Option B and Option C would make greater use of delegated legislation, which can be reviewed and updated through a simpler process than amending the current Gene Technology Regulations. This means the new model would bring more agility and responsiveness, and an improved ability to keep pace with technology. Our technical reviews currently take a considerable amount of time to progress and, under the new model, that could be a more frequent and regular consideration.