Question and Answers

On 25 September 2024, an information webinar on proposed changes to the *Gene Technology Act 2000* (GT Act) was held. Read some of the answers to questions raised during the webinar session below. The questions have been grouped into topics they relate to.

Consultation process and related materials

Q Is a revised document with tracked changes available?

A Yes. We have loaded the compilation draft Gene Technology Amendment Bill with tracked changes onto the consultation hub.

Assessments with regulatory overlap

Q Subsection 15A is proposed to reduce regulatory overlap with other regulators. Will guidance be given about what data assessment performed by the TGA or APVMA etc will be acceptable by the OGTR?

A This proposed amendment relates to identifying the risks that are assessed by different regulators, and more detail will appear in the amendment regulations currently being developed. It should be noted that applicants will not be directly involved in this process; the information and advice exchanged between OGTR and other regulators will occur as part of the assessment.

Q Will food or material fermentations that use GMOs be assessed? Note FSANZ says it will exclude any consideration of such processes.

A Food that might be the result of a fermentation process, falls under the regulatory remit of Food Standards Australia and New Zealand. The scope of the GT Act does not include the assessment of food safety risks. Depending on the fermentation process and whether a GMO is being used for fermentation - the GT Regulator would assess that part of the process, but not the end product, which would be the food.

Q If personalised therapies are developed that involve genetic modification, will the technology be approved, or will it require approval of each implementation of the tech since they will be different?

A If the therapy involves genetic modification of some sort, then it falls under the remit of the scheme. Which means that some kind of approval would be needed, whether it is part of a clinical trial or generating that therapy.

It is proposed that the definition of GMO will be amended to clarify that human beings are not GMOs. When considering application of techniques that modify the cells of a human, those humans would not be GMOs, and provided that the therapeutic is not itself a GMO, then regulatory authorisation would not be needed from OGTR. This would be different if the therapeutic is a GMO.

Authorisation Pathways

Q What types of dealings will fall into lower authorisation pathways or have less regulation under the changes?

A The consultation paper includes examples of the types of GMO dealings that would be included in the lower risk tiers. More detail on the specific requirements of each authorisation pathway will be set out and subject to future consultation on the Gene Technology Regulations that are under development.

Q How will you ensure a future proofed GT Act?

A The proposed changes to definitions within the GT Act and the addition of risk-tiering aim to future-proof the scheme. As new technologies emerge and there is increased knowledge and history of safe use – applications may move into different authorisation pathways. For example, as there is increased knowledge of a particular dealing with a GMO, it may move from requiring a GMO licence to requiring a GMO permit. This would ensure risk proportionate regulation.

Timeframes and transition period

Q Can you please explain how applications under review with the OGTR will be impacted by the amendments. Do we expect an impact on the timeline for approval of the application?

A With regards to applications made before the amendments would commence, that are not yet decided at the time of commencement, there is a section of the consultation paper that specifically refers to how those applications will be

handled. The intention is to not have any periods in the transition where applications cannot be made and where the regulator is unable to decide on applications.

It is intended that there will be a steady flow of applications being made and decisions being made throughout, so applicants are minimally inconvenienced.

With regards to decision time frames for licence applications following the proposed changes, there is a section of the consultation paper that explains how the proposed amendments will set out application decision time frames. It is important to note this includes the ability for the gene technology regulations to specify alternate time frames for licence applications. Stakeholders can expect more detail about licence decision time frames as part of a future consultation process on the regulations.

In terms of timelines, once the legislation is passed through the parliament, it is currently proposed that there is a 12 month commencement period before it will take effect, and that gives states and territories opportunity to pass mirror legislation or enact the Commonwealth legislation in their jurisdictions, and for stakeholders to prepare for this to take effect.

Q What do you think the timeframe is for these changes to go through Parliament? When will the consultation period for the new Regulations/Rules start etc? I assume there will be a lot of detail in these documents.

A Once the public consultation closes, we will be working as quickly as we can to analyse feedback received and make any necessary changes. This will also involve working within the standard Commonwealth Government legislation process. Drafting of legislation is required before it gets submitted to parliament for approval, and the timing for introduction of the Bill into parliament will be in line with Government priorities.

Another factor that impacts timeframes is the upcoming federal election that is due to occur before late May next year. This will involve a caretaker period and the dissolution of parliament for an election.

Regarding the proposed amendments to the regulations and the rules, there will be another consultation process, which will provide a significant amount of detail. This will again require us to work within the published legislation development processes, and priorities as determined by the Government.

Q What is the timeframe for the subsequent reg changes (rather than the bill amendment) to be released, or for that consultation period?

A We are working as quickly as we can to prepare for public consultation on the proposed amendment regulations and rules. We will provide more notice once we have more information.

Fees and Charges

Q Will any fees be imposed on applications to the OGTR?

A The current GT Act has the capability to charge fees for services. This is maintained in this new exposure draft Bill but has been extended with the new range of activities that would be available. There have not been any new decisions to introduce fees and charges at this point. Before adding new fees and charges in the future, there would be a separate consultation process as is required under the Government Guideline.

Other

Q With the human exception - although a person cannot be a GMO, a therapeutic may be a GMO & be under the remit of the GT Act. This depends on what is an organism which depends on what you define as a biological entity in the GT Act. Is there a plan to define what biological entity is?

A Biological entity is a term used in the definition of organism in the GT Act, and the Bill does not include any proposals to amend that definition of organism or any of the terms used within it.

Q What risks have you identified as possibly emerging from these amendments?

A The purpose of the amendments is to ensure that the regulations are flexible and not adding to regulatory burden. We have published the Decision Regulatory Impact Statement, where we have considered what the impact of the proposed changes to the regulations will be and have outlined potential impacts on stakeholders and applicants.

One of the key risks emerging from the amendments could be that there are unintended consequences for regulated entities. If we receive clear feedback during the consultation process, we will be able to minimise any unintended consequences.

The objective of the GT Act is to protect human health and the environment from the risks posed by dealings with certain GMOs. These reforms aim to ensure that these goals are maintained. This has been something at the forefront of consideration throughout the development of the amendments. The proposed amendments to the current Gene Technology Act aim to improve regulation and reflect the 25 years' experience with managing risks to human health and the environment.

Q Can the definition of "organism" be clarified? for example, are immortalised cell lines considered organisms for the purpose of the regulation?

A The proposed Bill does not include any amendments to the definition of the word organism, as defined in Section 10 ten the GT Act. If there is a view that this definition requires more clarity, then that would be something suitable to put in a submission, along with supporting information.

Q Considering smaller organisations with a limited number of OGTR certified spaces, and tightly resourced teams, what if any impacts do you foresee on the operations of these types of organisations through the proposed changes to the Act?

A If the organisation in question is currently undertaking notifiable low risk dealings or exempt dealings, it is anticipated that there would be minimal impact.

GMO dealings that are currently notifiable low risk dealings will predominantly be moved over to notifiable dealings. Dealings that are currently exempt dealings will predominantly become non-notifiable dealings. In both instances, there would not be substantial changes to how an applicant would need to undertake these dealings or the location of where the dealings need to be done. All applications to undertake dealings with GMOs will be assessed based on specific circumstances. The consultation paper, particularly the sections relevant to transitioning to the draft Amendment Bill may be useful.

Q Will the proposed changes clarify that animals vaccinated with mRNA vaccines are not GMOs? Or is that a regulatory question?

A A regulation change would be involved in clarifying whether animals vaccinated with MRNA vaccines are not GMOs. This would not rely on the proposed amendments to GT Act. That could be done as a regulation change.

Q Do the amendments intend to address the discrepancy with WA's GT legislation not being a corresponding law?

A Commonwealth legislation cannot address those matters. That is something that can be considered by the WA Government.