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Re: Third GT Scheme Review - Proposed regulatory framework for implementation – Phase 2

Thank you for the opportunity to comment.

Introduction

Our participation in this implementation process does not mean we concur with the twenty-seven recommendations of the GT Scheme Review, as some tend to undermine the capacity of the Gene Technology Act 2000 and the Gene Technology Regulations 2001 (amended) to fulfill their chief objectives of protecting human health and environments. Effectively minimizing the hazards and risks of Genetically Manipulated Organisms (GMOs) – microbes, plants, animals and humans – especially in open environments must, from our point of view, remain the primary reason for the GT Scheme. We there consider that science and industry promotion, regulatory streamlining, fast-tracking applications and lightening the burden of proof for which applicants are responsible are external to the regulatory system and its legitimate concerns.

The GT Scheme Review and its implementation, which propose legislative and regulatory amendments, also serve the Federal Government's neoliberal deregulation agenda.[1] This ideological program would dismantle, disempower and deregulate many of the regulatory institutions and mechanisms that should provide community protection, by promoting corporate control and vested scientific ambitions as public benefits.

The "Objectives of government action" to which the RIS refers are this government's ideologically driven deregulatory agenda in all areas of public administration and regulation. We resoundingly and unequivocally reject this abnegation of the government's responsibility to Australia's citizens, to protect the public's health, safety, and environments against personal and existential threats, through the regulation of research, development and commercial GT activities.

Government and its fellow travelers seek if possible to "align regulation with comparable international regulatory schemes and enable the better utilisation of international assessment information,' where it suits science and industry. Government has not, for instance, signed or ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity that seeks to protect biological diversity from the potential risks that GMOs resulting from modern biotechnology pose. The Protocol now has 173 states parties and Australia should join them.[2]

The present implementation proposals assume the GT Scheme will continue to be "governed by a Ministerial Council, known as the Legislative and Governance Forum on Gene Technology (the Forum) … comprised of Ministers with responsibility for gene technology from every state and territory and the Commonwealth."

Yet the Forum has now been rebadged as the Gene Technology Ministers' Meeting (GTMM), which the Implementation documents hold out as providing essential checks and balances on the revised Scheme and its operations. It is one of those intergovernmental bodies that the Conran Report to National Cabinet recommends should be "time-limited and when needed – to convene

[1] Deregulation agenda, DSIER. https://www.industry.gov.au/about-us/deregulation-agenda
[2] Parties to the Cartagena Protocol https://bch.cbd.int/protocol/parties/

only for specific tasks with specified, sun-setting timeframes of no longer than 12 months."[3]

Ministers, as the governing body of the Australian Gene Technology Scheme, have rarely reported meeting or exercising their powers to make joint policies on GT issues or exercise any oversight on the OGTR's work.

We are concerned that the intergovernmental Gene Technology Agreement could be further radically amended to diminish the GTMM's oversight functions. Such co-operative multi-government oversight is far from certain as a bulwark against the unfettered exercise of federal government power into the future. The proposals present reform proposals would also invest many additional and expanded powers in the GTR, and it appears that the decisions made under these powers would not be subject to public review or appeal. That is unacceptable.

Strong precautionary regulators and regulations should first and foremost serve the public not private or professional interests and ambitions. Being regulated must not be framed as a burden on industry or science, to be minimized or disabled. The RIS should explain in advance how it is intended that the "Other Technical Changes (to the legislation) would reduce regulatory and administrative burden."

It is essential and legitimate that the burden of proof for the safety and efficacy of their enterprises fall squarely on applicants. They must demonstrate to the GTR and the public, with convincing and substantial scientific evidence, that their production processes and living GT products are safe and efficacious. They must also create benefits that far outweigh the risks, hazards and costs for society of being allowed to undertake the proposed biotechnology enterprises. Such proofs, that meet clear standards of scientific and social honesty and probity, must count as the necessary conditions for being granted a social licence to conduct biotech operations.

Principal Concerns and Proposals

- The Gene Technology Forum of Ministers must remain operational and capable of critically reviewing and recasting the OGTR's regulatory procedures and decisions for the foreseeable future. The Forum is essential to the effective operation of the GT Scheme to meet changing and challenging future conditions, especially scientific and technical innovation. We seek an unequivocal assurance that the Forum will be exempt from the federal government's deregulation program;
- Options B and C would both give the GT Regulator far too much unfettered discretion and power to make and amend regulations, without clear processes for independent and influential external criticism, review and appeal by affected parties, the public at large, and experts;
- The members of interested and affected communities, and independent experts, must have more open access and central roles in the GT Scheme's regulatory processes. As the new GT Scheme is proposed, it appears they would have minimal scope to participate, or to influence any regulatory decisions and changes that are made;
- While we agree that Option A is somewhat out of date - as many genetic manipulation techniques, their uses, and living products are set to radically change - we also strongly favour keeping the GT Act and Regulations substantially intact as many of their robust provisions have worked well for participants, standing the tests of time and use over 20 years;
- The Precautionary Principle in the Act, which states that: "where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation,"[4] must remain and should be more central to how the OGTR treats evidence and uncertainty.
- All biotech innovations should continue to be regulated without exception, until they have a long and established history of safe use in contained environments. Dealings involving release must be backed with robust peer-reviewed and published, independent scientific evidence. The

[3] Review of COAG Councils and Ministerial Forums Report to National Cabinet Peter Conran AM October 2020, PM&C. https://www.pmc.gov.au/sites/default/files/final-report-review-coag-councils-ministerial-forums.pdf
[4] Gene Technology Act 2000, Section 4 (aa).

standards of acceptable evidence must be clearly enunciated and supporting data must show that the risks and hazards of release are fully known, understood and manageable;

- Only corporate and other entities which are suitable, legally liable, trustworthy, responsible and fully accountable should be accredited to undertake the management of approved GMOs, especially any dealings that involve intentional releases;
- The GT Scheme must ensure that anyone making or advising on regulatory decisions has no conflicts of interest and are free from political pressure or lobbying that may influence their decisions in any way;
- Those recruited to committees or advisory panels that offer expert advice to the regulators must be absolutely free of professional or commercial conflicts of interest;
- Option B is superficially attractive for its simplicity, however, a one size fits all scheme will not enable the OGTR to adequately regulate the multiple arenas in which a broad and diverse spectrum of GMOs may in future be researched, developed and deployed;
- We do not favour making risk the dominant determinant for allocating dealings to one dealing category or another as this elevates risk and its management to a dominant position, ahead of the exercise of precaution and the prevention of harm;
- Option A has worked well with its focus on different dealings. Its most robust and reliable features should be maintained in whatever replaces it. Allocating dealings to risk assessment and management categories is inherent in the status quo and Option C follows this lead.
- Option C takes the more nuanced approach to assessment and approval pathways, that the Scheme relies on to be fully effective and to make key distinctions between:
    - contained dealings – for research and industrial purposes;
    - dealings where GMOs are 'intentionally' released into our environments – in field trials, commercially or for diverse other purposes; or
    - clinical dealings – where the claimed ambiguities of potential contained or uncontained uses should be amenable to case-by-case assessment, regulation and management.
- Despite the expected upswing in gene technology innovations and applications in future, mechanisms for genuine public participation in the work of the GT Scheme remain lacking. The Scheme could include a public forum (maybe somewhat like an IBC) in which the OGTR, applicants, independent experts and the public would regularly and directly engage in discussing policy and practical matters. Heinemann and others propose a model for "critical control points … where technical experts can collaborate with publics with different expertise to identify and manage the technology"[5];
- We agree that a precautionary approach is necessary to capture all novel organisms that may be created using synthetic biology under GT regulations. All should be classed as exotic in every open environment so their live release must not be permitted, as it would breach biosecurity and biosafety provisions.

Key consultation questions

In your opinion, what Option offers the greatest net benefit? Please provide reasons supporting your choice.

- On balance, GeneEthics overwhelmingly favours Option C. It still differentiates risks, but does not make risks and risk-tiering the core focus or dominant theme of the Scheme. The GT Scheme should focus most importantly on exercising precaution, to provide greater assurance that human and animal health goals are achieved and diverse environments are protected. It can best do this with an emphasis on refining the processes and pathways for foolproof notification, assessment, regulation, approval and monitoring of all GMO dealings. It needs to sufficiently flexible and broad in scope to deal with extremely diverse GT proposals, for instance, release live GMOs into open environments, work in high security laboratories with

[5] Heinemann JA; et al. 2021, Differentiated impacts of human interventions on nature: Scaling the conversation on regulation of gene technologies, Elem Sci Anth, 9: 1. DOI: https://doi.org/10.1525/elementa.2021.00086

dangerous pathogens, or to licence human clinical trials.[6] Option B would obsess over risk without sufficiently considering the variety GMOs, the contexts in which they may exist and the multiple pathways to their approval and deployment.

Key consultation questions – Option A

Are there additional impacts of Option A that need to be taken into account?

- We agree that in several respects the status quo needs amendment but do not sacrifice its best and most enduring features in the breakneck rush to respond to speculative future demands.

Please provide further information, including quantitative data, on the costs associated with maintaining the status quo.

- The benefits that the status quo has brought to the community must not be ignored.

To what extent would maintaining the status quo stifle innovation?

- Appropriate regulation always promotes innovation as it enables applicants to get their social licence to operate. A regulatory system that seeks to promote innovation through fast-tracking and creating paths to market for products will do a disservice to its core purposes and will not serve the community well.

What are the benefits of maintaining the status quo?

- We acknowledge the need for change in the public interest.

Key consultation questions – Option B

Would Option B address the identified policy problems?

- No. See our reflections on the RIS following below for reasons why.

Please outline any additional impacts of Option B that have not been identified in the current impact analysis.

- Option B is a single pathway proposal that does not adequately differentiate the diverse contexts in which GMOs may be produced and deployed. It would more likely create the confusion and ambiguity that the RIS claims would result from Option C.

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

- See our reflections on the RIS following.

Please outline any risks or additional considerations that need to be taken into account with regard to this option.

- See our reflections on the RIS following.

How might Option B promote science innovation?

- Promoting science innovation is an inappropriate criterion for determining the policy settings for the GT Scheme. Option B is more likely to stunt innovation, especially where the commercial and scientific risks of innovation may be large, less manageable, uncertain or unknown.

[6] Australian Centre for Disease Preparedness, Geelong, Vic. https://www.csiro.au/en/Research/Facilities/AAHL#header-search

Key consultation questions – Option C

Does Option C address the policy problems identified in the Consultation RIS?

- Yes. We disagree with Attachment B's assertions that Option C:
  - only partially addresses the Authorisation pathways problem; and
  - that its authorisation pathways are more complex than necessary to achieve the goals of the Scheme
- Option C is more nuanced and robust than B, so has the potential to effectively manage the vast array of diverse GT proposals which it may in future be called on to regulate.

Please outline any additional impacts of Option C that have not been identified in the current impact analysis.

- See our reflections on the RIS following.

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.

- See our reflections on the RIS following.

Does Option C promote science innovation? If so, how?

- Promoting science innovation is an inappropriate criterion for determining the policy settings for the GT Scheme.

Reflections on the RIS

Options B and C appear to give the OGTR unacceptable levels of unfettered, unreviewable and un-appealable powers to make and change regulations, with insufficient independent review. We oppose this. For instance, the proposal document says:

- Under Option B, **the GT Regulator would have the ability to make legislative instruments that specify the eligibility criteria for each authorisation pathway** according to scientific information about risk. The primary legislation would specify mandatory matters that the GT Regulator must consider prior to changing the eligibility criteria, as well as who must be consulted. Without public access and appeal rights, we are not reassured by these checks on GTR power.

- it is proposed that under Options B and C: … **the GT Regulator's determination to include a dealing on the GMO Register would become an administrative decision made by written instrument, instead of being made by a legislative instrument.** Government and public oversight would be possible through the consultation steps that the GT Regulator would have to undertake before making a determination. Again, we are not reassured by these token checks on GTR power.

- **As for Option B, the relevant criteria establishing the levels of authorisations within each of the categories would be** achieved through delegated legislation[7] made by the GT Regulator**, to facilitate sufficient flexibility to move organisms between the authorisation pathways as new scientific or regulatory evidence becomes available.** Again, we seek greater assurances of checks on unfettered GTR powers.

[7] Delegated legislation https://www.aph.gov.au/About_Parliament/House_of_Representatives/Powers_practice_and_procedure/Practice7/HTML/Chapter10/Delegated_legislation

The GTR does not need such sweeping powers to operate effectively and they are against the public interest, which demands that democratic processes, critical reviews and due process are essential to effective regulation and governance.

“Delegated legislation can be made and amended more quickly than primary legislation”

- Hasty legislative amendments without independent review are not acceptable as such unfettered powers may be used to fast track R&D and commercial deployments without due process?

“Delegated legislation is a term which covers legislation made by government agencies and the Governor-General under authority of Acts of Parliaments, which delegate this power to agencies.”

- We oppose such regulatory change being possible without reference to the Forum, parliament or the Minister. Rights to review and appeal in the public interest would also be lost.

“The Gene Technology Scheme responds slowly to advances in the field of gene technology” and the antidote is to “provide certainty on regulatory scope in a timely manner.”

- Scant evidence is provided to support the fast-tracking theme of the paper. Option C appears to provide the better definition of scope but whether it would speed processing remains to be seen.

“… uncertainty can stifle innovation, since research organisations and industry are reluctant to invest in new technologies without knowing how these would be regulated.”

- These matters should be of minimal concern to the GT Scheme. This is special pleading in favour of a more compliant regulatory system that will not critically assess applications when they are finally made. We reject industry’s ambit claim for a path to market for proposed products and services, even before speculative R&D has begun and there are no assessments of the ultimate risks they might pose.

There is “a growing trend in the number of applications received for GMO dealings with medical and other uses”.

- Option C best caters for this recalibrating of the most numerous uses of biotechnologies, by establishing clearer authorisation pathways in the GT Act for new GMO applications.

It is claimed that “The Scheme is no longer risk proportionate” but Option C provides robust scope to appropriately regulate the multifarious risks of a great diversity of dealings, including research, development, commercial and industrial processing, and products.

- The RIS offers no evidence for the claim that “to move GMO dealings from one authorisation pathway to another, in response to new information about risk, is a lengthy process that can take up to eight years.”

Under the present GT Scheme, “Dealings involving intentional release (DIR) must be authorised by a licence.”

- This should continue as the issuing of fast-track licences and permits for release are envisaged to be inappropriately less rigorous and to be based on unacceptable assumptions about risk based on past experience with different organisms. Genomes are so complex and the understanding of their functioning still relatively rudimentary that assuming risk levels is unacceptable.

In the Water Test Kit case study, “although the GM bacteria are contained within the device, they may be released if the device is broken when used or disposed of outdoors.”

- This does not challenge the integrity of a rational regulatory regime. Lab security contends with the same issues with their inbuilt protection devices, the Test Kit might be sold only subject to recall or proper disposal as nuclear smoke alarms already are, or the kit could be assessed as suitable for environmental release as this is bound to occur in some cases.

Where specified administrative steps, "could delay availability of an urgently needed treatment" the emergency dealing determinations already in the regulations may be invoked and interface with the TGA's Special access Scheme. The GTR's assessment processes do not appear to have delayed the timely approval of COVID-19 vaccines.

- The "examples of potential duplication between the OGTR and other regulators" are not compelling. After all, the OGTR assesses and approves both the processes and products of gene manipulation whereas the other regulators concern themselves exclusively with products, regardless of their origins. Collaborations between regulators can surely minimise duplication.

"Over 95% of authorisations for dealings with GMOs over the duration of the Scheme have been for NLRDs, a category imposing minimal regulatory burden."

- But experience to date may not be typical of the future, as we enter an era of greater unpredictability with, for instance, sprayable RNAi and nanotech insecticides, multiple synthetic biology applications, gene drives with potential to make species extinct, gain-of-function research in which the virulence and transmissibility of dangerous pathogens is intentionally increased, biohacking and bioweapons R&D, and diverse medical applications such as Mitochondrial DNA transfers, stem cell research, and RNAi vaccines. Many such uses are likely to increase the risks and hazards of Genetic Manipulation techniques and their living products – microbes, plants and animals so strong precautionary regulation is essential.

"Under Option B, the GT Regulator would have the ability to make legislative instruments that specify the eligibility criteria for each authorisation pathway according to scientific information about risk."

- We do not favour the GT Regulator exercising such powers alone, without a provision for independent critical review and appeal. All decision-procedures should be open, transparent and subject to public scrutiny.

"Dealings with GMOs that have been assessed and authorised by reputable regulatory agencies overseas could be eligible for authorisation under lower risk categories. .. streamlined in Australia by using the … overseas risk analysis."

- Implicit in this assertion is the questionable assumption that foreign and local environmental and safety contexts are similar. If overseas regulatory assessments were deemed relevant here, then a negative assessment abroad should count against the success of a similar application here.

It is proposed that the scope of the category Notifiable dealing "could be expanded to allow:– GMO dealings where other regulators assess risks to people and the environment."

- However, the GT process of production would still require a separate assessment, even if another regulator had assessed the final product.

It is proposed that a "Licensed dealing" could be authorized with a permit and that "Through a transparent and consultative process, the GT Regulator would determine the criteria for a permit and specify dealings that are subject to defined conditions … that meet certain criteria regarding use, traits, understanding of parent organism, etc."

- This requires further elaboration and discussion as it accords substantial additional powers to

the GTR, without specifying in any detail who would be consulted and on what terms.

“An expedited assessment would be required for dealings … such that only some components of the proposed dealing need assessment.”

- Reliance on historical presumptions to approve substantial parts of an application without further assessment is not satisfactory. Nor is it reassuring that using an unspecified “transparent and consultative process the GT Regulator would determine the criteria for dealings that could be eligible for an expedited assessment,”

Applications subject to full assessment “would involve extensive consultations with government agencies, the Gene Technology Technical Advisory Committee and the public.”

- We advocate that the new Scheme provides more scope for real public participation, rather than the mere consultation processes now used. They disempower and alienate the interested public and independent experts who might otherwise engage more fully and productively in OGTR decision-making processes.

“It is proposed that under Options B and C … the GT Regulator’s determination to include a dealing on the GMO Register would become an administrative decision made by written instrument, instead of being made by a legislative instrument. Government and public oversight would be possible through the consultation steps that the GT Regulator would have to undertake before making a determination.”

- This suffers again from the weakness of the proposed “consultation steps”. And, unlike a legislative instrument, the GT Regulator’s administrative decision would not likely be subject to any review or appeal, disenfranchising those who may seek to object. https://www.aph.gov.au/About_Parliament/Senate/

“Under Options B and C, the definition of ‘deal with’ would also be amended to better reflect current activities with GMOs and to make sure that future applications are also captured under regulation.”

- Rather than specifying “a list of activities/GMO applications that are captured under regulation,” it may be more constructive to specify that any person or institution that is licensed to have custody of an approved living GMO, is also fully responsible and accountable for all aspects of its safe and secure stewardship, from its creation to its final fate.

Considering the impacts of Option B, we disagree with the proposal that “authorisation pathways would no longer require a judgment (on the part of IBCs) as to whether the dealing involves the release of a GMO into the environment, nor whether such release is intentional.”

- This would create substantial ambiguity that could not be easily resolved, instead of making such decisions “easier for IBCs.” As the OGTR's frontline agents, IBCs must continue to be directly responsible and accountable for all actual and potential GMO releases. The term ‘intentional' requires further consideration as it imputes motives for actions, which are subjective and therefore always difficult to interpret and adjudicate.

The RIS claims that under Option B “the benefits of gene technology would be made available to the community in shorter timeframes.”

- This means that the risks, hazards and costs would also be delivered faster. We profoundly disagree with the government’s ideological fast-tracking agenda and prefer Option C.

The Biobricks case study does not bolster the claim that “Under Option C it would be uncertain whether this application is for dealings that are contained (since the GM bacteria are contained in the bricks and would not be able to disperse) or for dealings involving intentional release of a GMO

into the environment (because the wall would be built in the open environment)."

- This example is another outlier that does not convincingly argue against Option C. Reformulation of the definitions of 'contained dealing' and 'intentional' may suffice. This release issue, with or without intent, may parallel the biosafety and biosecurity questions that arise when a GM mouse escapes a lab and enters the environment, or laboratory systems such as ventilation or wastewater, fail.

In the case of the vaccine lettuce example, two assessments would be fully justified "one for the field trial and another for the clinical trial."

- The field trial would address agronomic and environmental questions, while the efficacy and safety of the vaccine dose delivered to a laboratory animal or human in the lettuce would logically be assessed separately. Conflating the two assessments under Option B would be messy and unsatisfactory for all concerned. Biofortified fruit or vegetables may fall into a similar category. Growing the plant, animal feeding studies and the human clinical trial should not logically or practically fall into the same category for regulatory purposes, and the risk-dominated Option B should also treat them as discrete dealings.

In arguing against Option C, the RIS claims "the risk-based criteria determining categorisation in Option B provides more flexibility."

- However, we view the three discrete notification, assessment and approval pathways in option C as a much more robust and expansive model for effectively embracing the regulation of all future GMOs than the single track that Option B would provide. Option B oversimplifies scientific, technical and regulatory complexity and would rely more on the best guesses and assumptions that characterise regulatory science, to ascertain presumptive risk levels and allocate projects to different categories. That is not satisfactory.

Conclusions

Overall and on balance we much prefer Option C as the model for progressing amendments to the GT Scheme and its enabling Act and Regulations.

We emphasise the need for strong checks and balances in the system, to ensure good decisions, that concentrations of excessive power cannot compromise.

Public and expert engagement in the GT Scheme should be optimized to prioritise serving the public interest. Avenues for critical review and appeal should be incorporated into the Scheme.

The Precautionary Principle should feature more prominently in the new regulatory approach.

The Scheme should focus on achieving its core purposes. Fast-tracking, streamlining and promotion of science and industry innovations should be far outside the scope and responsibilities of the Scheme. Such concerns would compromise the integrity and standing of the GT Scheme.