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Comments on Phase 1 of the Gene Tech (GT) Scheme Review implementation

Background

This Review and its implementation are subject to the direction and influence of The Australian Government Guide to Regulation.[1] It is a position paper that echoes the deregulation ideology of the Institute of Public Affairs.[2] The Guide is,

> *"intended to be read by every member of the Australian Public Service involved in policy making," that will be, "supplemented by regular Guidance Notes from the Department of the Prime Minister and Cabinet," published on a webpage about the government's deregulation program and badged 'cutting red tape'.*[3]

In his opening remarks in the Guide, the then Parliamentary Secretary to Prime Minister Tony Abbott, Josh Frydenberg MP, wrote in March 2014,

> *"The Government's rigorous approach to policy making seeks to ensure that regulation is never adopted as the default solution, but rather introduced as a means of last resort."*[4]

The Department, "responsible for overseeing the Australian Government's deregulation agenda" advises that its

> *"Efforts to reduce compliance burden will continue."*[5]

Our participation in this process should not be treated as a validation of what is most reprehensible about this review – undermining the capacity of the Gene Technology Act 2000 and the Gene Technology Regulations 2001 to protect human health and the environment from the hazards and potential risks posed by genetically modified organisms (GMOs).

The Gene Technology Act 2000 and the GT Regulations 2001 are to be amended to serve a neoliberal ideology that prioritises and frames deregulation and corporate control as public goods. Yet the public interest and the public are almost completely excluded from regulatory systems and processes. The Government's deregulatory program accelerates despite multiple global existential crises. The Government's refusal to acknowledge or act on these

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[1] Prime Minister and Cabinet (2014) *Australian Government Guide to Regulation*, https://www.pmc.gov.au/sites/default/files/publications/Australian_Government_Guide_to_Regulation.pdf
[2] Deregulation, Institute of Public Affairs. https://ipa.org.au/tag/deregulation/page/2
[3] The Australian Government, Deregulation Agenda.
[4] Prime Minister and Cabinet (2014), p. i.
[5] Australia's Approach to Deregulation, The Department of Employment, Skills, Small and Family Business. https://www.employment.gov.au/australias-approach-deregulation

existential crises is an unprecedented dereliction of its responsibility to protect our health, economy, and environment.

Introduction

The ecological systems on which all life and human societies depend are approaching catastrophic collapse. We humans have so mismanaged the Earth that multitudes of other species are going extinct and we may soon follow. This is a direct result of the failure of successive governments globally to effectively regulate the destructive activities of large multinational corporations. Yet with GT processes and products we are embarking on further uncontrolled global experiments with little evidence or comprehension of what they may also disrupt.

The object of the Gene Technology Act is clearly outlined: "to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs".[6] In his second reading speech when the Act was introduced the then Health Minister Dr Wooldridge further emphasised this priority:

> *"Another matter on which there is complete agreement from the industry and environmental and consumer groups is that the need for the protection of the health of the community and the protection of the Australian environment are to come before all other considerations."*[7]

The Precautionary Principle is also embedded 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."*[8]

The GT Scheme's top priority must be to serve the public instead of private, corporate interests. Yet the GT Scheme Review and its implementation use the same failed, corporate-dominated concepts, approaches and ideologies to implement recommendations that are not in the public interest.

We do not support more of the same or business as usual, as the review and Phase 1 Implementation documents encourage us all to do. Neither pays attention to the broader implications and impacts of the processes and products that the scheme purports to regulate and also promote. Cliched references to the promised benefits of the technology - presumably economic benefits - used as the primary measure of human welfare – are not balanced with any acknowledgement or analysis of the down-sides, pitfalls and hazards of what Australian governments and Office of Gene Technology Regulator propose.

For instance, there is no reflection, debate or discussion on how a minimalist, 'streamlined', less regulated system will facilitate the expansion and intensity of biotechnology's role in commodifying all living organisms (including humans); how scant oversight and supervision will enable biohackers to apply their various levels of expertise and scientific knowledge in less formal laboratory settings; where transhumanism, eugenics and other ideologies may

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[6] *Gene Technology Act 2000*
[7] House of Representatives (2000) *Gene Technology Bill 2000: Second Reading Speech*, Thursday, 22 June 2000
[8] *Gene Technology Act 2000*

lead; how corporations will use biotechnologies and their products to intensify their enclosure, ownership and control of public biological assets, using patents; weaponisation of biotech innovations, about which several credible warnings have already been issued.[9]

The Regulator is being made into little more than a handmaid for industry and the privatised science that serves the GT industry's ambitions to further commodify all living things – animals, plants, microbes and humans.

This implementation document adopts industry's language, goals and ethics as its own. It is predicated primarily on reducing what is claimed to be a regulatory burden on industry, but that burden is chiefly the essential burden of proof for the safety and efficacy of its products before they are deployed. It uses industry's cliched euphemisms – flexibility, efficiency, principles-based regulation and streamlining – to promote further destruction of a compromised regulatory system that has, nevertheless, operated reasonably well for the past 20 years and could continue to do so without the radical changes now proposed.

An honest, thorough and critical review of the Act and how it functions would show some aspects of the GT Act 2000 have worked reasonably well, despite many public concerns about its failings. For example:

- IBCs regulate labs and their use well
- States regulating GM on market grounds
- Field trials without major known disasters (except the Tasmanian canola trials)

From a public interest perspective, the 3rd GT Scheme Review was not a legitimate consultation or review of the performance of the Gene Technology Act 2000 and the GT Regulations 2001, and this implementation is similarly flawed.

In fact, the Review process itself represents the greatest threat to the integrity of the Act in its relatively short history. The biotechnology industry is making a concerted push globally to deregulate second-generation GM techniques and their products to the fullest extent possible. The GT industry reluctantly acceded to Australia's regulatory system but the legal framework didn't deliver the ethical, scientific or public support that the industry hoped would emerge from agreeing to regulatory measures. Now its push for deregulation of new GM techniques attempts to ensure that new GMOs can be released by stealth. The Regulator and Government are complicit in this regulatory dismantling.

Our governments should recognise that the biotech sector will not self-regulate for the public good, but they appear not to have learnt anything from the Banking and Aged Care Royal Commissions and other Inquiries into the failures and harm that usually follow deregulation.

This Phase 1 Implementation document asks the wrong questions as it forces us to implicitly accept a model of business and deregulation that is unacceptable and far more destructive than good. Several recurring issues arise from our review of this implementation document and the Review:

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[9] Stephenson, J. (2001) Biowarfare Warning, The World in Medicine. February 14, *JAMA*, **285(6):**725. doi:10.1001/jama.285.6.725-JWM10001-3-1 or https://jamanetwork.com/journals/jama/article-abstract/1844076

1. A fundamental gutting of the Act and Regulations so they will no longer regulate or assess many new GM techniques and products – existing and still to be discovered - thus allowing industry to operate invisibly and without public knowledge or expert surveillance.
2. Lack of a critical review of the function and workings of the Act.
3. A significant industry bias throughout.
4. A dangerous reliance on and use of industry-funded, 'privatised' science.
5. Failure to distinguish industry data from independent, peer-reviewed science.
6. Failure to recognise or discuss the public interest.
7. Failure to implement the precautionary principle.
8. Failure to ensure that data gaps are filled as part of safety assessments, not ignored or filled using 'best guesses' and so-called 'regulatory science'.
9. Failure to critique the deregulatory model and the risks and harms it causes.
10. Failure to review decisions, when new science questions the safety of the product or the thoroughness of an assessment.
11. Disingenuous rationale for the amendment of definitions.
12. Use of industry euphemisms such as flexibility, efficiency, streamlining, burden, etc. to support a deregulatory agenda.
13. Ignoring the extent to which corporate control, over regulators and science, is affecting the capacity of governments to act democratically.
14. Failure to analyse the review provisions of the Act and the reality that citizens have far fewer legal rights of review than industry.
15. The false assumption that this public comment process enables the public to genuinely engage and participate.
16. Decisions and positions that consistently favour industry are deliberate and are evidence of what Harvard academic Lawrence Lessig describes as "institutional corruption".

Responses to Questions

Q1: What other objectives might guide the updating of definitions?

The core object of the Act should remain protecting the health and safety of people and the environment. To this end the Review should:

1) Retain broad definitions, of GM, GMOs, and GM dealings etc.

The explanatory statement for the Gene Technology Regulations states that:

> *"The definition of 'genetically modified organism' in the GT Act was intentionally cast very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly changing technology."*[10]

Recent amendments to the Gene Technology Regulations clearly undermine the intent of the Act and Regulations, which is that all GMOs be assessed for safety. They also represent an over reach by the OGTR and the government, by changing the policy settings of the Scheme without legislative oversight.

[10] *Gene Technology Regulations 2001 2001 No. 106: Explanatory Statement*

The definitions should be wide enough in scope to ensure that all existing GM techniques (including SDN-1, RNAi and null segregants) and all future GM processes and products come within the ambit of the GT Acts, in all jurisdictions. The Acts should require notification to the OGTR and product regulators of all GM dealings, for open, transparent, public and expert assessment, licensing and monitoring.

2) Make the precautionary principle central to the Act and Regulations.

The OGTR must be required to exercise precaution, to minimise the sorts of disasters that arise when regulatory regimes overlook the hazards and potential risks that can result from ill-considered decisions. The principle must be framed so our regulators fully and robustly apply it in all regulatory assessments, decisions and actions. The precautionary principle serves everyone's interests best in the long run, so it must not be sacrificed to the self-serving, deregulatory corporate agenda. Prevention of harm is always quicker, cheaper and more effective for society as a whole than trying afterwards to treat or compensate victims of unsafe products.

The Act would benefit from a stronger expression of the scientific basis for the decisions the Regulator makes. Now, the Regulator can and does rely on industry data in assessments and approvals. Decisions regarding risk, approval, release conditions, monitoring, approval reviews, etc. should be based on independent and peer reviewed science.

Corporations have been fully aware – often long in advance of commercialisation – that their products were hazardous, yet have hidden the evidence of harm - for profit. Major reviews, such as the European Environmental Agency's *Late Lessons from Early Warnings*[11], illustrate the enormous societal costs of allowing market forces and corporate ambitions to dominate decision-making, in place of independent science and precaution.

3) Ensure the Regulator cannot alter the policy settings of the Scheme

The OGTR must not have the power to amend definitions, to effectively alter the meaning of GMO by way of regulation. It is critical that Parliament's legislative oversight is brought to all substantive changes in the Act, including definitions, to ensure they are made in the public interest.

Such decisions should also be open to challenge on their merits via open standing provisions for the public.

4) Recognise planned extinction techniques including gene drives as completely unacceptable, both ecologically and ethically

Gene drives pose the same biosafety risks that other GMOs carry, and considerably more. Gene drives are designed to spread rapidly through whole populations of target species but could also jump to others.

Because of their serious and potentially irreversible threats to biodiversity, national

[11] European Environment Agency (2013) *Late lessons from early warnings: science, precaution, innovation*, https://www.eea.europa.eu/publications/late-lessons-2

sovereignty, peace and food security, Southern countries and over 170 organisations have called for a UN moratorium on gene drives.[12] Leading proponents of gene drives have also now said that they are too risky to release into the wild.[13]

Their potential dual uses for military purposes should also be acknowledged. The Phase 1 document ignores the large extent to which the military is developing and funding the research into emerging GM extinction techniques.

5) Ensure all GMOs are assessed for safety irrespective of their uses

No rationale is provided, nor any deficits in the existing Act explained, when a justification for amending the definitions is claimed to be that "technological advances have led to an expansion in applications and uses in other areas, including in medicine and industrial production."

Alhough second-generation GM techniques are used for non-agricultural purposes, that does not explain or justify amendments to definitions. The Review document also offered no justification so it remains a non sequitur.

The Scheme Review and the Technical Regulatory Amendments confirm that a significant purpose of these definitional debates is to define several techniques as non-GM, to remove them from the scope of the Act. As justification for the changes that the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019 made, it was claimed that the deregulated SDN-1, RNAi and null segregant techniques are precise, have no off-target effects, or that traits aren't inherited. Yet, despite scientific evidence showing most of these claims to be false, the regulations were still pushed through to weaken the scale and scope of the GT regulatory system. We reiterate that under the existing definition of GMO in the GT Act 2000, these techniques produce GMOs. This should continue to be so.

Q2: How might we improve the regulatory flexibility of definitions within the National Gene Technology Scheme, whilst maintaining protections for human health and the environment?

The explanatory statement for the Gene Technology Regulations states that:

> *"The definition of 'genetically modified organism' in the GT Act was intentionally cast very broadly to ensure that the definition did not become outdated and ineffectual in response to rapidly changing technology."*[14]

Recent amendments to the Gene Technology Regulations clearly undermine the intent of the Act and Regulations, which is that all GMOs be assessed for safety. The suggestion that 'the regulatory flexibility of definitions' could be 'improved' is another attempt at deregulation - which we strongly oppose.

The Implementation Document claims that:,

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[12] For reporting on the call for a moratorium on Gene Drives at CBD COP13 in Cancun December 2016 see http://www.etcgroup.org/content/160-global-groups-call-moratorium-new-genetic-extinction-technology-unconvention and https://www.scientificamerican.com/article/gene-drive-moratorium-shot-down-at-un-meeting/

[13] Zimmer, C. (2017) 'Gene Drives' Are Too Risky for Field Trials, Scientists Say, 16/11/17, https://www.nytimes.com/2017/11/16/science/gene-drives-crispr.html

[14] *Gene Technology Regulations 2001 2001 No. 106: Explanatory Statement*

> *"The Review found that some definitions in the Gene Technology Act 2000 and Gene Technology Regulations 2001 may not appropriately classify a range of advances in technology."*[15]

As already outlined, the intent of the Act is that all GMOs be regulated. Furthermore, the Precautionary Principle is also embedded 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."*[16]

Under such a precautionary regime, it is entirely appropriate that new GM techniques such as CRISPR, with no history of safe use - and very little research into their potential hazards and risks – are comprehensively assessed for safety.

The further deregulation and self-regulation that the Review and its Implementation propose would further erode and compromise the capacity of the GT Act to achieve its main object of protecting public health, safety and the environment.

The Implementation Document claims that:

> *"The aim is to update these definitions to appropriately capture and regulate genetically modified organisms that may pose a risk to the health and safety of people and the environment, while not over-regulating organisms that pose little or no risk (taking into account likely exposure and appropriate controls). Recent amendments to the Gene Technology Regulations have taken steps towards this goal."*[17]

This claim is false and misleading. The Regulatory Amendments effectively deregulated a whole suite of techniques that would rightly remain within the Act's definition of GMOs and its regulatory ambit, if precaution were being exercised. The deregulation is an abrogation of governments' regulatory, legal and social responsibilities, to suit the profit driven purposes of the global GT industry. The deregulated methods are widely acknowledged within the scientific community as being GM, imprecise and unpredictable.[18]

The Federal Government and the OGTR should commit to maintaining the broad scope of the Act, to protect human health and environment.

The Implementation Document claims that:

> *"it is not a system that responds efficiently to change. Any amendments – to the Act or the Regulations – take time, making it difficult to manage risk by quickly changing the scope of what is, or isn't, regulated."*

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[15] *Implementing recommendations of the third review of the National Gene technology Scheme*: phase 1,,p. 2.
[16] *Gene Technology Act 2000*
[17] *Ibid.* P2.
[18] ENSSER Statement: New genetic modification techniques and their products pose risks that need to be assessed, 8/11/19, https://ensser.org/publications/2019-publications/ensser-statement-new-genetic-modification-techniques-and-their-products-pose-risks-that-need-to-be-assessed/

If the precautionary principle were applied, then risk would be managed by taking the time needed to properly consider the impacts and risks of reducing or increasing the stringency of regulation.

But our governments and Regulator seek to pave the way, and reduce the time to market for GT products, using streamlining, risk tiering and deregulation. This means reduced rigour, scale and scope of assessments and generally gives the GT industry an even freer hand to self-assess and self-regulate. Examples abound, of corporate self-regulation leading to unacceptable impacts on public health, safety and the environment. When regulators abdicate their responsibilities to private interests, they risk losing credibility.

Q3: What other issues should be taken into account when considering how best to ensure that humans are not regulated as GMOs?

Australia should follow other nations by legislating a national prohibition on human germ-line editing. Human germline editing is not only highly risky, it also raises profound moral and ethical questions that society has not yet had an opportunity to properly discuss.

Making deliberate, irreversible decisions about modifying the genetic makeup of all of someone's descendants is an act of supreme hubris. The human traits that our societies now preference may well be highly dysfunctional or anathema to future generations.

Q4: Given the benefits and challenges of defining terms in legislation, what other mechanisms might be used to provide the clarity required?

Definitional precision may be important in some circumstances but, more crucially, the broad objective of the Act is to bring all GT techniques and products into the ambit of regulation. The recent Regulatory Amendments did the opposite, making the definitions uncertain and unclear and potentially opening the Act to numerous premature and reckless claims for exclusions based on compromised science, ideological influence and political donations.

We support clarification of some definitions, including 'history of safe use', to ensure that regulatory decisions made under the Act are based on independent science. Replicable laboratory and field data must be collected and assessed before a history of safe use can be established, including evidence from long term monitoring that can be used to evaluate how new gene constructs behave, propagate and interact within complex systems. Ecological and epidemiological expertise is essential to such assessments, but it remains absent from the regulatory system as it now exists. This deficit should be remedied by legislation.

Q5: Are there any other key objectives/considerations that should be taken into account in designing a risk-proportionate approach to regulation?

The core object of the Act should remain protecting the health and safety of people and the environment.

Disturbingly, the implementation document frames the primary goals and motivations of the review as a process of deregulation, reducing so-called 'regulatory burden', reassessing hazards and risks on the run, and fast tracking amendments to legislation. For instance,

> *"Regulatory burden is only partially improved by risk tiering if there is no way to efficiently move between tiers or categories. Long timeframes for legislative change mean that it is not possible to quickly adapt to technological advances."*[19]

It is entirely appropriate that organisms produced using new GM techniques such as CRISPR, with no history of safe use - and very little research into their potential risks – are comprehensively assessed for safety. Risk and hazard research inevitably lags behind the development of new technologies – with CRISPR being a good example. Since the OGTR's Technical Review of the Gene Technology Regulations, a number of peer reviewed studies have been published which undermine the OGTR's claims that this and similar techniques pose no greater risk than natural breeding.[20]

The government's recent deregulation of these techniques based on conflicted advice from industry scientists is exposing us all to unnecessary and unjustifiable hazards and risks.

In our view, 'regulatory burden' can only be reasonably interpreted as the burden of proof that every applicant has, to produce robust scientific and forward-looking evidence that its GMO will not harm the environment or public health and safety.

But industry and governments apply ideologies that see all regulatory and assessment processes as 'regulatory burden', even though these are also the processes via which the creators and owners of new GM methods may acquire community agreement to operate and earn a social licence to make and sell their novel products.

As things stand now, neither the Act nor the Regulator are responsive to new scientific findings in a timely way. Nor does the Act require the Regulator to exercise the scientific rigour in assessment, licensing, monitoring or reviewing approvals that would instil confidence in a discretionary risk-tiering system.

The OGTR does not acknowledge hazards but assumes that their impacts and risks, which are not defined in the Act, can be minimised mainly with voluntary industry codes of practice and other unenforceable strategies. Defining risk and the methodologies to assess it require exhaustive review before any risk tiering regimes are considered.

A lack of sufficiently rigorous requirements for evidence, prior to environmental releases, also needs to be addressed as the definition of 'environment' in the Act includes: "(a) ecosystems and their constituent parts; and (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas."[21] So the regulator's main focus on minimizing the risk of adverse impacts in farm environments is far from adequate.

History of safe use may be a useful construct in a risk tiering system, but once again, that requires a clear definition and clear criteria for how to assess, monitor and establish a history of safe use.

A risk-tiering system would require more monitoring and must be based on independent and peer reviewed science. While there may be some GT uses that are lower risk than others,

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[19] *Implementing recommendations of the third review of the National Gene technology Scheme: phase 1*, p. 11.
[20] ENSSER (2019) *ENSSER Statement: New genetic modification techniques and their products pose risks that need to be assessed*, 8/11/19, https://ensser.org/publications/2019-publications/ensser-statement-new-genetic-modification-techniques-and-their-products-pose-risks-that-need-to-be-assessed/
[21] *Gene Technology Act 2000*, Section 10, p. 5.

that conclusion must not be based exclusively on an absence of evidence of harm, especially when scant effort is spent on finding any evidence. Classification as a lower risk must be based on proactive evidence gathering to justify any findings of safety. This basic distinction in science – that an absence of evidence must not be confused with the evidence of absence - is a maxim that regulators appear to routinely ignore.

Also, findings such as a history of safe use, or precision, or 'just like natural mutations' must not be based on advice from expert committees whose members have clear conflicts of interest. We reject the assertion that good policy advice comes from those working at the cutting edge of technical innovation, and that consultation with experts from a broader range of relevant disciplines such as risk assessment, ecology or epidemiology would make it more problematic to reach consensus and conclusions. Working through professional differences of opinion, and bringing collective wisdom to bear on keeping things safe is a necessary part of the precaution that the public rightly expects will be exercised.

The implementation seeks added flexibility to deal with either over or under-regulation, yet the Review Report does not appear to assess whether over or under-regulation is a problem or even whether it occurs. We support mechanisms to expedite the Regulator moving a dealing or previous approval to a higher risk category, particularly when new evidence of harm is found.

As a precaution or in an emergency, it should be possible to make an interim reassignment to a higher risk category while literature is reviewed, data gaps filled and interested parties are invited to contribute. Members of the public must be enabled to alert the Regulator to emerging evidence of hazard, risk or harm, to have their representations received and assessed as the trigger for a risk category change, and to have the outcome of the process published.

Q6: What additional risk tiers could be considered and what criteria could be applied to determining what falls in or out of any required tiers?

Over-simplification appears to be the goal of the implementation process and the GT industry, to serve their mutual interests. Yet risk-tiering would likely increase the complexity of the Act and its implementation. If there is to be risk-tiering then we favour amending existing risk classifications – LRDs, NLRDs, DIRs, DNIRs, etc. for this purpose. Additions to exempt dealings should only be made after wide consultation.

Risk tiering, if implemented, should be based on:

1. Clear criteria for defining and assessing hazard and risk, including rare events and outliers;
2. The precautionary principle (more stringently and clearly defined than that used in the Act and by Australia to try to weaken international conventions)
3. Clear identification of knowledge and data gaps;
4. Objective thresholds for concluding that data is insufficient to justify a decision;
5. Independent and peer reviewed science;
6. Criteria for and analysis of potential cumulative and long term impacts.

We believe that the OGTR is currently ill-equipped to undertake unbiased or rigorous risk-tiering. Public and independent professional engagement is therefore essential.

Q7: Is the introduction of additional risk tiers the only way to ensure regulation is proportionate to the level of risk?

No. If there is to be risk-tiering then we favour amending existing risk classifications – LRDs, NLRDs, DIRs, DNIRs, etc. for this purpose. The classification system works reasonably well and the Review has not made a compelling case for new risk categories. We reject any rationale that would add new risk or hazard categories that could be used as a means to facilitate the deregulation of new GT processes and products in future.

Regulators notoriously underestimate levels of hazard and risk. Yet the Review and Implementation documents do not discuss the problems of assessing unpredictable and uncertain hazards and risks, especially with incomplete and imperfect knowledge. All needing proper review are the definition and scope of risk, the implications of rare or unpredictable and unidentifiable events (in the case of new GM processes and products), the methodologies used to assess risk, and the extent of monitoring.

But rather than reviewing the Act as a whole, the Review and the Regulator have solely reviewed the ways the Act can be amended to better serve industry's ambitions. Rather than critique the current laws or audit the state of current environmental releases, the Regulator and reviewers merely assert the Scheme is well regarded. By whom? And on what grounds?

Q8: What principles or criteria should be applied in moving an organism/technique across risk-tiers?

Any power given to the Regulator to move an organism or technique across risk-tiers should be matched by public rights of merit review and open standing provisions.

History tells us that it is highly likely that movement across tiers will almost exclusively be into lower risk tiers. Regulators are incredibly reluctant to increase levels of regulation and only do so occasionally, even when the evidence is overwhelming. There are significant reasons for this (institutional corruption, deregulatory devotion, political and industry pressure, capture and corruption all play a role).

This implementation report notes that,

> *"With the advent of new and cost-effective genetic modification tools that are more precise and easy to use, the use of gene technology in new and diverse fields (including medical and industrial sectors) is expanding world-wide. Introducing flexibility into the Scheme could help to reduce regulatory impediments to the uptake of technological advances."*

The claims of precision have proven to be false. The risks associated with both greater ease of use and greater power are ignored. Until the Regulator understands why these techniques entail significant risk, a risk-tiering approach will always be a deregulatory mechanism. Further, the premise that underpins this statement is that all technological advances are good and must be embraced and approved with haste – based on another false premise that failure to immediately commercialise new technologies leaves a country or industry behind.

Q9: Are there any elements of the Scheme that would NOT benefit from a principles/outcome-based approach?

Principle-based approaches are the latest in a long line of euphemisms for reducing so-called regulatory burden for industry, while pretending to care about the public interest. The concept is inherently lacking clarity, precision or certainty. It is flexible in design and methods of achieving outcomes – and, again, this 'flexibility' serves industry. The principles will be virtually impossible to enforce and subject to numerous abuses under the current Australian deregulatory model. It is a recipe for making a bad system even worse. As there will be no clear standards, there will be no outcomes that cannot be argued as having been achieved. The public will be further excluded from the process, so outcomes will be little more than a 'vibe'. This is an Orwellian approach at its worst.

Q10: What other objectives might guide streamlining of regulatory requirements?

It is not surprising that this Phase 1 implementation spends more time on streamlining (and the other associated euphemisms identified above) than any other aspect of the Gene Tech Scheme. In the interests of industry and privatised science they are prioritised ahead of other more pressing issues in this 2 to 3 year implementation process.

While we support some of the streamlining measures identified in the Review, such as online applications and real time tracking, we do not support others such as devolution of decision-making (either to the Regulator or the IBCs); or reporting to IBCs (which will reduce transparency). It is clear that those in the biotechnology industry consistently perceive the risks associated with their GM activities to be much lower than independent scientists and the broader community.

More generally, it is important to note that streamlining of regulatory requirements is not what is needed to build a more effective regulatory system. More fore-sighting capacity (any fore-sighting would be an improvement), greater ethical analysis, and much more emphasis on the public interest are all sorely needed.

Q11: Are there any particular issues to be considered when streamlining any of these regulatory requirements?

See Q10

Q12: What mechanisms or tools would reduce the regulatory burden and administrative burden on the end user interacting with the regulator/regulatory system?

See Q10

Q13: Are there any particular issues to be considered when streamlining any of these regulatory processes?

See Q10

Q14: Are there any other key processes that might be streamlined without impacting the safety of people or the environment?

See Q10

Q15: What specific areas are suitable for harmonisation between regulators? Are there any overlaps that could be removed?

The Legislative and Governance Forum (the Forum) on Gene Technology is the appropriate body to approve any proposed changes to the Scheme. But the work of the Gene Technology Standing Committee[22] and the advice it provides to the Forum Ministers must be much more open and transparent than it now is. These necessary checks and balances are necessary to ensure that any proposed changes to the Act, Regulations or Scheme are open to public scrutiny and are genuinely in the public interest.

States should have the right to oppose any proposed changes to the Scheme – especially those designed to gut GM regulation. The current requirement merely for majority support is anti-democratic. Full consensus from all states to any legislative and regulatory amendments should be necessary. When the Regulations were amended to remove SDN-1, RNAi and null segregants from notification to the OGTR for scrutiny, Tasmania's no vote and South Australia's abstention should have held substantial sway.

The lack of any policy or regulatory settings to deal with issues such as GM crops increasing associated herbicide use concern us. Neither the OGTR nor product regulators appear to have responsibility for adequately assessing such hazards and risks. The turfing that exists between agencies such as AQIS, FSANZ and the Department of Agriculture over who is responsible for preventing the import of unapproved GMOs is also of concern. None of these agencies appear to take responsibility for monitoring or enforcement.

FSANZ's lack of clear guidance on its intentions for the safety assessment and labelling requirements of products produced using new GM techniques such as CRISPR and RNA interference also need resolution in concert with this review implementation process. Whilst the states are responsible for enforcing the Food Standards Code, FSANZ is responsible for providing guidance on new GMOs to help them do this. Instead, the food agency has released various conflicting statements on whether these GMOs are covered by Standard 1.5.2.

We oppose FSANZ adopting the OGTR's current definition of Gene Technology as the recent amendments to the Gene Technology Regulations would exclude from safety assessment and labelling the food products produced using several new GM techniques. This would threaten both public health, safety and shoppers right to know.

When it comes to Australia harmonising its regulations with those of overseas jurisdictions, the precautionary principle should apply - so we harmonise with the strongest – not the weakest – regulatory regimes around the world.

Q16: What are some of the ways in which the role of IBCs could be strengthened to achieve efficiencies in a co-regulatory model?

We oppose devolving certification of PC-1 and PC-2 facilities and the approval of contained dealings exclusively to IBCs. Some IBC's may not be adequately equipped with resources and appropriate expertise to assess the potential risks that GMOs pose. It is therefore important that the OGTR maintains regulatory oversight.

We support the call from IBCs for a targeted educational program to help them improve their

[22] Gene Technology Standing Committee, Australian Government Department of Health https://www1.health.gov.au/internet/main/publishing.nsf/Content/gene-gtstandingcommittee.htm

expertise and confidence in assessing applications.

Q17: What could be some avenues that would empower the Regulator to make decisions about changes to regulatory requirements and processes deemed low-risk?

We oppose the Regulator making unilateral decisions to change any regulatory requirements or to deem processes as low risk. The Regulator has a strong pro-industry bias and its recent decisions have not been evidence based, precautionary or in the public interest. Public review rights need to be strengthened - not weakened - and empowering the Regulator to act without consultation is unacceptable. Any executive powers given to the Regulator, without offsetting powers available to the public, are more closed-shop business as usual and we do not accept that.