

Judith Collins' new Gene Technology Bill – A sticky, unconstitutional mess?

JR Bruning. The Daily Telegraph New Zealand. December 15, 2024.

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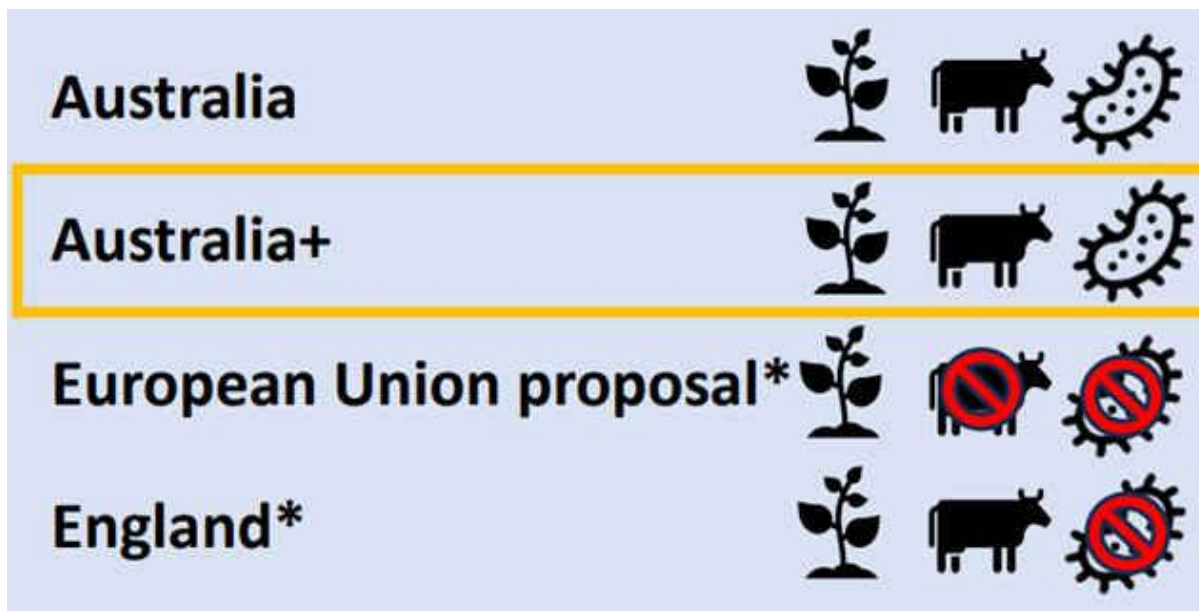
The Hon Judith Collins the Attorney General's [Gene Technology Bill](#) has just been published. Collins claims that the Bill will:

'create an authorisation framework to regulate gene technologies and GMOs and manage any risks they pose to human health and safety and to the environment by imposing risk-proportionate conditions'

Collins plans to take a hybrid approach where higher-risk activities will be regulated using a process-based approach, while lower-risk activities will be exempted.

The new regulatory agency would massively deregulate gene technologies and genetically modified organisms (GMOs). How so? A wide spectrum of gene-edited organisms will be automatically exempted from regulation because they are lower or 'minimal-risk'. There is no scientific rationale and policy explaining how 'minimal risk' was decided and how non-regulated organisms were decided. The policy has been cut and pasted from Australia.

What could be affected by the current deregulation proposal? Everything from livestock to fish to arable food crops to indigenous food and medicine crops to insects and microbiota. European exemptions only [apply to plants](#), New Zealand would follow Australia to potentially exempt all plants and all living creatures, from plants to animals to insects and microbes ([page 55/150](#)).



No economic analysis has been undertaken, and the [impact assessment](#) does not address risk to New Zealand, because it is gospel that minimal or low-risk organisms will not cause adverse or unintended effects.

When the regulator is established, MBIE have recommended ([page 80/150](#)) that the regulator won't have to conduct economic analyses then either.

On the date the Bill was released, December 10, Collins released the [Departmental Disclosure Statement](#) which contains the links to regulatory impact statements and it's favourite reports which complement Collin's Bill. The claims about the regulator being 'evidence-based' and 'risk proportionate' don't and can't stack up. All the exemptions are cut and pasted from Australia.

The [Gene Technology Bill](#) aims to provide 'risk proportionate regulation' and 'a flexible legislative framework able to accommodate future technological and policy developments without frequent amendment'. But for this, the information used to inform the legislation that would give the regulatory agency it's powers would be scientifically robust. Methods-based risk assessment and analysis would have been held to ensure that the underlying principles and concepts were robust.

It hasn't been done, and no-one is permitted to criticise the underlying policy documents.

The proposed deregulation of GMOs is so extreme that Judith Collin's current proposal would turn New Zealand from best practice, tightly regulated jurisdiction, to one of the weakest in the western world.

But the question is, will members of Parliament bow to the party whips, and rubber stamp the legislation, or will they use the resources at their disposal to understand why Europe is currently at a standstill, because the European Commission wants more content in the legislation that will strengthen regulations and increase transparency and traceability?

GAMING POLICY: TALK TO THE BILL – NOT THE UNDERLYING SCIENCE

What's key here is to understand that the scientific understandings (or 'facts') are drafted into and inferred, in underlying policy. The new Bill is based upon scientific understandings, concepts, or presumptions. None of the policy documentation that has been released reflects the weight of evidence in the peer reviewed literature and the extent of debate – and nuance – in other jurisdictions, including Europe.

Collins [never intended to permit](#) broader debate on the underlying science and the implications of earlier court findings. MBIE earlier advised the public that they had to [wait for the Bill](#) to be published before they can feedback.

Broad and impartial consultation [is important](#) at an early stage, but stakeholder consultation has been selective. Most people on the [technical, Māori and industry groups](#) come from institutions with a significant commitment to biotechnology research. Collins is determined to [prioritise biotech research funding](#). Funding to research biotech *risk* has never been allocated.

Somewhat ironically, the [Science Media Centre's 'experts'](#) who have commented on the legislation, are mainly from the very institutes who will benefit from deregulation.

There is a game being played here. MBIE and Collins throw this new Bill to members of Parliament (MPs) and present all the underlying policy at the same time, as finished business. People (including [sceptical farmers](#)) can only genuflect (religiously) to Collins' Bill and MBIE's policy documentation where the predetermined principles and concepts sit. There are no resources and no time for MPs to ask for an independent review to critically assess Australia's policies. They are taken as gospel truth.

Before voting on the Bill, MPs might like to talk to Professor Jack Heinemann who has been studying [outdoor releases](#), how risk increases as [technologies that enable rapid deployment onto the market](#) and into the environment scale up, and the gnarly problem of [risk to non-target organisms](#). Heinemann was an expert witness in a recent [South African court decision](#). But he's left out in the cold. We presume it is because he advocates for process-based pre-market assessment of all techniques of genetic modification rather than [exclusion by biological characteristics](#), where a line-in-the-sand is drawn for what might be distinguishable, or not distinguishable as a GMO.

When the Bill is finally released for comment, the public will only be permitted to speak directly to the text drafted into the Bill. Any comments which argue that the underlying scientific concepts have been too narrow, or have not addressed important issues of science and scientific knowledge, will be deliberately excluded by Select Committee. Any criticism on the underlying information that *created the basis* for the legislation, would be 'out of scope'. Submitters (in a [technique that is increasingly common](#)) get told their input is out of scope because they do not directly relate to the *content* of that proposed Bill.

Once the legislation is in place the only pathway to object to an environmental release in the Bill is if a proposal (s.122) relates to an 'organism that uses an indigenous species as a host organism.' Otherwise it's a closed shop.

The scientific basis, and any inherent risks, are taken as fully known and not up for debate. The constant altering of the line-in-the-sand (instead of a process-based approach) means that primary Act is designed to allow endless reshaping of that line-in-the-sand through [secondary legislation](#):

The powers to make delegated legislation described in response to this question are necessary due to the nature of gene technology, which means that the regime needs to address highly technical, detailed, and operational matters best reserved for regulations and other secondary legislation. Furthermore, delegated legislative powers are appropriate as they allow incorporation of advancements in scientific knowledge without having to amend primary legislation. Such powers are also necessary to allow the Regulator to perform its functions.

What an authoritarian game.

NEW ZEALAND & AUSTRALIA – THE 'WILD WEST' OF GMO REGULATION?

An [8-page media pack](#) was all we could view until December 10. It contains a disingenuous Myths and Facts section talking about 'super humans'. It neglected to discuss what could and might happen when a 'low-risk gene edited' GMO species interacts in an ecosystem with another species with similar genetics and biological pathways.

MBIE and Collins claim the legislation is piggy-backing off Australian policy, inferring that if it's good enough for the Aussies, it's good enough for us.

Will we see best global practice? We suspect there has been no review of globally hesitant jurisdictions. This is strange for a country that traditionally has been obsessive about biosecurity risk.

Do officials have any idea of the [extent of policy debate](#) in Europe, historically the region with the tightest regulations, or are they being directed to follow north and south America, who traditionally have the most lax regulations? MBIE's [Regulatory Impact Statement](#) downplays European Commission hesitancy and certainly doesn't explore any of [Europe's proposed amendments](#).

MBIE and Collins promise health and safety without doing any safety or risk assessment.

As a recent Official Information Act [response reveals](#), MBIE are firmly aware that they don't have the scientific expertise. We know that the NZEPA aren't really happy that MBIE, an agency without any practical risk assessment experience, would have such powers.

[According to](#) Simon Rae Policy Director, Emerging Technologies, it's '[good regulatory practice](#)' to remove the precautionary principle which is enshrined in [European](#) law and [important treaties](#). (I've sent in an Official Information Act request to understand how Rae came to that conclusion.)

MBIE's [July 2024 Regulatory Impact Statement](#) called the provisions which emphasise decision-makers should take a precautionary approach as being 'out-of-date'.

Europe must be incredibly 'out-of-date' as their GMO legislation specifies that they must have '[full regard](#) for the precautionary principle'. Poor dears.

[The response also revealed](#) that no economic analysis has been undertaken, Collins does not want debate on MBIE's scientific claims. Neither MBIE and Collins have considered important findings from the [Royal Commission into Genetic Modification](#). The Royal Commission recommended a practical three-pronged approach including the establishment of a Parliamentary Commissioner on Biotechnology, a Bioethics Council and a biotechnology strategy. None of these initiatives are in operation in 2024.

INDISTINGUISHABLE AND 'MINIMAL-RISK'

The following documents were released on December 10, 2024:

- [2023 Interim Regulatory Impact Statement](#) – discusses risk tier framework.
- [2024, July. MBIE Regulatory Impact Statement – Reform of Gene Technology Regulation.](#)
- [Regulation of Gene Technologies – Policy Decisions \[PDF 937KB\] 60 pages.](#)
- [Regulation of gene technologies – policy decisions – Minute of Decision 7 pages.](#)
- [Regulation of Gene Technologies – Policy Decisions: Proactive Release of Advice 150 pages.](#)

Under the proposed new FSANZ and New Zealand laws, patented GMOs (animals, plants, microbiota – pick your flora or fauna, and go for it) can have DNA sequences added into the genome and then removed, resulting in widespread genome alterations, including the desired trait or traits.

However, unless novel DNA is deliberately inserted or a novel protein/s is produced, FSANZ propose that they won't be regulated as a GMO. They will be viewed as similar (comparative) to naturally bred organisms. This could be the minimal or low risk 'idea' or it could be something else such as size and numbers of modifications to the genome. It looks like the parameters will be stuck in secondary legislation where they can be altered like a high school skirt length.

MBIE have reframed the new legislative purpose. MBIE plan to solely manage risks posed to human health and the environment. MBIE 'factually' state some forms of gene editing are 'low risk'.

How can MBIE and Collins know that the new legislation will be 'risk-proportionate' and 'evidence-based' (page 2) if risk has never been evaluated in New Zealand?

Members of Parliament voting on the Bill must understand – *what is a risk, what increases risk?*

The horse has to come before the cart. There can be no claim of a low-risk gene editing activity if what is considered 'low-risk' has never been agreed on scientifically by people in New Zealand. Legislation can only be 'risk-proportionate' and 'evidence-based' *after* rigorous scientific enquiry. Risk assessment also involves setting parameters that are based on how we think about and define risk – i.e. what our values are.

A formal claim of a 'low-risk gene editing activity' must come after process-based scientific review.

A [bunch of stuff](#) could happen to the genome, as all the DNA is shuffled about, but this wouldn't have to be declared. [Off-target unanticipated events](#) beyond the small subset of genomic alterations in the genome being edited could happen, like [this](#) or [this](#), but unless it involves GMOs where novel protein/s or novel DNA was *deliberately inserted*, regulators really wouldn't know.

'Exempt' and 'non-notifiable' activities, or exclusions write-out risks and prevent official scrutiny.

Collins has the idea that a lot of new gene edited organisms are 'minimal' or 'indistinguishable' from non-edited, naturally grown and produced organisms – from birds and beasts to plants and microorganisms.

140. Organisms developed using new gene technologies can be indistinguishable in genetic makeup and traits from naturally occurring or organisms produced with conventional techniques. As such, current scientific understanding suggests organisms developed using new techniques do not pose any greater risks to health or the environment. Under this option, indistinguishable products are regulated differently based on the technique used to achieve a modification which may result in regulatory uncertainty for users of gene technologies.

Regulatory Impact Statement, [page 41](#).

Paragraph 140 in the [Regulatory Impact Statement](#) makes two scientific claims. One is incorrect and the other is – fuzzy. First of all, a German government funded [research group](#) recently [demonstrated](#) that it is possible to distinguish GMOs from conventional organisms.

Secondly, '*current scientific understandings suggest that organisms developed using new techniques do not pose greater risks*'. They're basing New Zealand legislation on a suggestion – but will exempt vast swathes from regulation.

Indistinguishable is not defined but it's a fundamental basis for an exempt activity in a 'risk tier' in the Bill:

'Exempt activities will be minimal-risk products of gene editing, for example, products of editing techniques that cannot be distinguished from those produced by conventional processes.'

How did the officials decide on 'minimal risk'? It's not defined in the legislation. How can 'health and safety' be promised? It's all rhetoric.

How the Bill will achieve its purpose and meet its objectives

The regime will replace parts of the Hazardous Substances and New Organisms Act 1996 (the **HSNO Act**) that regulate GMOs with a standalone regime that future-proofs the law. The Bill will—

- establish a Gene Technology Regulator (the **Regulator**) within the Environmental Protection Authority to be the independent decision-maker;
- establish a Technical Advisory Committee and a Māori Advisory Committee to provide the Regulator with expert advice;
- create an authorisation framework to regulate gene technologies and GMOs and manage any risks they pose to human health and safety and to the environment by imposing risk-proportionate conditions;
- create a process to enable the management of risks to Māori kaitiaki relationships with indigenous species;
- enable the Regulator to undertake joint assessments with overseas regulators and to draw on their expertise;
- include definitions of terms such as regulated organism and gene technology that can be clarified to account for potential future changes to gene technologies;
- enable some products of minimal risk gene editing to be exempted from regulation;
- establish offences and penalties for breaches of the regime;
- ensure a nationally consistent approach to regulation of gene technology by removing local authorities' ability to restrict its use;
- ensure New Zealand continues to be able to comply with its international legal obligations.

What will be regulated

The regulatory regime covers gene technology activities (for example, making, breeding, culturing, supplying, importing, or releasing a regulated organism) and regulated organisms (organisms—often referred to as GMOs—that have been modified or constructed by gene technology, but excluding human beings).

Risk tiers and authorisations

Activities will be categorised depending on the nature of the activity: medical, contained, or environmental. For each activity category, the Bill establishes risk tiers to enable proportionate management of risks to human health and safety and to the environment, and associated authorisations. The risk tier framework and risk management approach includes—

- *exempt activities*: minimal-risk products of gene editing, for example, products of editing techniques that result in organisms that cannot be distinguished from those produced by conventional processes;
- *non-notifiable activities*: very low-risk activities that do not require active monitoring by the Regulator, for example, gene therapies that are also regulated by Medsafe;
- *notifiable activities*: low-risk activities that require the Regulator to be notified, for example, laboratory research with mice;
- *licensed activities*: medium- and higher-risk, or uncertain-risk, activities that require a case-by-case assessment before they can be authorised to determine that all risks of the proposed activity can be managed.

In addition, the Bill enables 2 further types of authorisation in specific circumstances, namely—

- *mandatory medical activity authorisations*: for a human medicine that is or contains gene technology that has been approved by at least 2 recognised overseas Gene Technology Regulators;
- *emergency authorisations*: when there is an actual or imminent threat to the health and safety of people or to the environment, for example, threat from a disease outbreak or an industrial spillage. The Minister responsible for the Bill when enacted (the **Minister**) will have the power to grant an emergency authorisation.

Risk assessment and management

A key component of the Bill is to manage any risks gene technologies and GMOs pose to human health and safety and the environment. Any authorised activity may be subject to conditions to manage any risks the Regulator identifies. An example of a condition is that an activity must be carried out in a facility that complies with containment standards. Using conditions to manage risk will allow for an enabling, flexible, and risk-proportionate regulatory approach.

To identify risks, the Regulator will be required to prepare a risk assessment and risk management plan in relation to an application for a licensed activity. The plan will identify and detail any risks posed by the activity to human health and safety and to the environment and ways to manage those risks, which will be given effect to as conditions if the Regulator grants the licence.

The Bill empowers the Regulator to declare some activities to be non-notifiable, notifiable, or pre-assessed licensed activities. The Regulator will identify any risks and ways to manage the risks, which will be given effect to as conditions in the declaration.

Risk assessment will also be one of the mechanisms the Regulator uses to ensure New Zealand complies with its international obligations in respect of modified organisms and management of risks to the conservation and sustainable use of biodiversity arising from GMOs.

Gene Technology Bill, 110-1. Hon Judith Collins

[Link.](#)

No scientific document has been published to categorise what these 'minimal risks' are and how they have been defined, and arrived at. Instead of discussion, MBIE have released this chart ([page 55 of the Proactive Release of Advice](#)):

Gene-editing techniques

		Unguided repair	Guided repair	Genes from within species	Genes from 'foreign' species
Australia		Green	Red	Red	Red
Australia+		Green	Green	Red	Red
European Union proposal*		Green	Green	Green	Red
England*		Green	Green	Green	Red

*Exemptions under the EU proposal would only apply to plants (not animals and plants), while under the new English regulations they only apply to plants and animals (not microorganisms).

Non-regulated technologies and organisms

Null segregants <i>In vitro</i> fertilisation Embryo rescue	Protoplast fusion Zygote implantation Radiation and chemical mutagenesis	RNA interference Epigenetics Gene-editing exemptions (as above)
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Blue = Australia and New Zealand non-regulated technologies (non-exhaustive) Green = Additions from New Zealand statutory determinations and new exemptions (non-exhaustive)

Key considerations and questions for Ministerial discussion

Key Considerations

- There are a range of gene editing techniques and their application to different types of organisms can create different risks.
- International jurisdictions are exempting or proposing to exempt gene editing techniques based on their equivalency to unregulated techniques, the equivalency of their effect to those that could arise naturally or from conventional breeding, and the inability to detect these changes.
- According to advice from our Technical Advisory Group, unguided and guided repair gene-editing techniques have equivalent levels of risk to each other and to conventional breeding techniques.

Key Questions

We propose to, at a minimum, expand on the current Australian gene-editing exemptions and go with an Australian+ approach (highlighted above). We will investigate going further, as under the English system.

Do you agree to, as a minimum, adopt an Australian+ approach with the potential to go further?

It is proposed that the list of non-regulated technologies and organisms under Australia's and New Zealand's legislation be combined under the new legislation.

Do you agree with the combination of these two non-regulated lists?

At the top you can see how Europe is unlikely to permit gene editing in invertebrates and vertebrates.

Then there are the 'non-regulated technologies and organisms'. These are categorised as 'non-regulated' because they are viewed to be minimal or low risk, or as resulting in a product that the government claims is indistinguishable from organisms arising from conventional reproduction.

Who exactly has decided which factors make it 'scientifically indistinguishable' – this involves setting values. Good science and good information is not something that is cast down from high. That's dogma.

There has been no public release of formal policy documents to help the public understand just how thoroughly risk and benefit have been examined to identify what is 'scientifically indistinguishable'.

The green box below provides a snapshot of which GMOs won't be regulated, and so are therefore presumed to minimal or low risk, or indistinguishable from naturally bred organisms.

Currently, like Europe, we have process-based risk assessment, so everything is screened for risk. That would stop. The comparative approach (indistinguishable) concept (where if no novel protein or novel DNA was produced it is considered 'indistinguishable', no matter the genome rearrangements).

Overview of the proposed Gene Technology regulatory regime

- The legislation is intended to enable New Zealand to safely benefit from gene technologies by managing risks to the health and safety of people and risks to the environment.
- It will achieve this by managing the risks that organisms modified using gene technology pose, proportionate to their risks to the health and safety of people and the environment.

NON-REGULATED TECHNOLOGIES AND ORGANISMS

GENE EDITING TECHNIQUES

➤ Techniques producing results indistinguishable from those achievable using traditional processes or natural mutations would be exempt. Example applications include:

- STERILE WILDING PINES
- GRASS ENDOPHYTES
- GABA TOMATOES
- NON-BROWNING MUSHROOMS
- DISEASE RESISTANT MAIZE
- DISEASE RESISTANT POTATOES

EXEMPT TECHNOLOGIES AND ORGANISMS

➤ Technologies and organisms commonly regarded as not creating or being a GMO would be exempt, including:

- NULL SEGREGANTS
- RNA INTERFERENCE
- REPLICATION DEFICIENT VIRAL VECTORS
- EPIGENETICS
- MUTAGENESIS
- PROTOPLAST FUSION

GENE TECHNOLOGY REGULATOR

- The regulator will be a single decision-maker, supported in their functions by an office, a technical advisory committee, and a Māori advisory committee.
- Their responsibilities will include assessing and authorising activities, developing regulations, providing advice on technical matters to Ministers and other agencies, and providing information and guidance to the public and regulated parties.

KEY FEATURES OF THE REGULATORY REGIME

- Risk proportionate and evidence-based
- Internationally aligned
- Leverages overseas expertise
- Retains public participation
- Streamlined, efficient and transparent processes
- Allows greater use of gene editing
- Focuses on the management of risk

RISK MATRIX FRAMEWORK

The regulator would assign activities to non-notifiable and notifiable risk tiers, the requirements of which will be graduated based on risk. Categories would be tailored for contained activities, activities involving intentional environmental release, and clinical trials and medical applications.



ASSESSMENTS AND APPROVALS

Licensed activities would require assessment and approval by the regulator. The pre-assessed activity pathway would not require a Risk Assessment and Risk Management Plan and only full assessments would require public consultation.



STREAMLINED ASSESSMENT PROCESSES

- Overlapping processes with other domestic regulators will be streamlined through information sharing, cooperation, and delegation, where appropriate.
- This will apply where gene technologies considered by the regulator are also new organisms, medicines, agricultural compounds, and veterinary medicines.

LEVERAGING THE EXPERTISE OF OVERSEAS REGULATORS

- Joint review provisions will enable the regulator to undertake joint assessments with other overseas regulators. Following the joint assessment, the regulator would make their own independent decision.
- Automatic authorisation of human medicines under the gene technology legislation would apply to medicines approved by at least two overseas gene technology regulators recognised by the New Zealand gene technology regulator.
- Expedited assessments would apply to activities approved by overseas gene technology regulators previously recognised by the New Zealand gene technology regulator.

[Proactive Release of Advice, page 56.](#)

But MBIE has decided to follow Australia. When it comes to gene editing, we are told that:

‘Techniques producing results indistinguishable from those achievable using traditional processes or natural mutations would be exempt’

What comes under that? Sterile wilding pines, grass endophytes, GABA tomatoes, non-browning mushrooms, disease resistant maize and disease resistant potatoes.

When it comes to ‘exempt technologies and organisms’:

‘Technologies and organisms commonly regarded as not creating or being a GMO would be exempt’

What is included here? Null segregants, RNA interference, replication-deficient viral vectors, epigenetics, mutagenesis and protoplast fusion.

We’re left wondering how the hell they decided on deregulating all of that. It’s also interesting to note that many of those categories are the subject of biotech development in our Crown Research Institutes.

We can get an idea from an [NZEPA decision document](#) on null segregants which brushes off the [potential for null segregants to create risk](#). Remember, Europe’s legislation at this stage exclusively concerns plants, Collins has expanded the deregulation far beyond plants, to all invertebrates and vertebrates.

We’re given examples of what will be non-regulated and exempted. The European Commission is having a debate about the extent of how complex modifications can be, and how they might be categorised into more or less modifications. (See for example [sections 14-20 here](#)).

MPs might not be aware that MBIE and Collins are carrying out the current campaign [in parallel](#) with a deregulatory push by our food safety regulator – Food Safety Australia New Zealand (FSANZ).

The two-pronged implications are massive. If FSANZ proposal works, [perhaps up to 94% of foods](#) that are currently considered GMOs would *not* be regulated as a GMO. They would be out of scope and would *avoid pre-market risk assessment*. This would then be New Zealand policy (unless we explicitly differed).

As a consumer, you wouldn’t be able to tell the difference.

There’s an ethical question here: if consumers from [Australia](#), [China](#), [France](#), [the USA](#), [Japan](#), [Russia](#) and [Vietnam](#) prefer to purchase non-GMO, and indeed, pay a premium for non-GMO food – should they be permitted to know that their food has been gene edited –

whether or not a novel protein or novel DNA was produced? While governments are keen to financially prop up GMOs, the example of a [failing Canadian GMO salmon producer](#) suggests that consumers aren't particularly interested in GMO foods. The answer should not be to deregulate GMOs to avoid pre-market risk assessment, tracing and labelling.

The deregulation push seems to be profoundly anti-democratic.

FSANZ's '[proposal 1055](#)' campaign is focusing on the 'comparative approach concept'. FSANZ are proposing that Australia and New Zealand's legislation change to state that if a new GMO doesn't end up having novel DNA in it or a novel protein it's not different enough and doesn't have to be regulated as a GMO (discussed [here](#) and [here](#)).

Like MBIE, FSANZ hasn't undertaken any process-based risk assessment. FSANZ aren't carrying out impartial, methods-based reviews of the scientific literature to underpin their assertions in a transparent and scientifically rigorous manner.

Physicians and Scientists for Global Responsibility New Zealand (PSGR) [documented](#) that not only have FSANZ stepped away from impartial reviews and risk assessment, they *never* engage with scientific information that criticises or contradicts their perspective. FSANZ simply report on the publicly-supplied information but fail to judge that information's merit, or relevance to policy. This occurred during FSANZ's consultations in [2018](#) and [2022](#). FSANZ defuse public (including expert) claims by noting them, but fail to engage with them.

There's a third anti-democratic 'pusher' in the mix. It looks like the big biotech boost is also being Trojan-horsed through secret trade agreements as well. Trade agreements increasingly have less to do with trading wheat for lemons, but instead focus on access agreements for technologies and services.

The public believe 'we have to keep up' and that our 'laws are out of date' but I believe they have been grossly misled about the facts of the matter.

(The Attorney-General [persists in communicating](#) that there has been a ban, when in fact, [twenty field tests](#) of GM plants, animals and microorganisms have been approved in New Zealand. Many [haven't gone well](#).)

POOR REGULATORY IMPACT ASSESSMENT

MBIE appear to be the only agency to have submitted a [Regulatory Impact Statement](#). MBIE are much more concerned about over-regulation than under-regulation. The public and members of Parliament should be seeing impact statements from the Ministry of Primary Industries that honestly address the impact on the organic sector, farmer concerns, and the extent to which organisations rely on New Zealand's GMO-free status with respect to the evidence on consumer preference.

We should definitely be seeing impact statements from Biosecurity New Zealand – that demonstrates that officials have evaluated and understand the magnitude of the policy shift. From the speed of release of GMOs into the environment with scaled up technologies; to the likelihood, as a [European study](#) pointed out, that most gene edited GMO foods would not be declared GMO and would avoid pre-market assessment.

It's not just new gene editing techniques such as CRISPR-Cas which have [amplified development speed](#) and [shortened the bench-to-market](#) timeline. Scientists are increasingly using artificial intelligence (AI) to identify development opportunities in whatever genome scientists want to work with – from mammals, to fish to insects and microbes. Nothing is off the table.

There's no impact analysis of the risk to the environment from deregulation. Even though the tech development speed is off the charts, bench-to-market timelines are compacted, and A.I. makes it all go faster.

I struggle to believe that biosecurity knows what is going on. I presume that [Biosecurity New Zealand](#), who try to 'protect our native flora and fauna, whenua, freshwater and marine environments, as well as our cultures, lifestyles, livelihoods, and health' have only the slightest idea of the consequences of the joint effect of FSANZ and MBIE's deregulatory campaigns.

The Regulatory Impact Statement notes that biosecurity practices will be improved ([16/131](#)):

'improving the range of risk management tools available may improve protection and reduce risk of a biosecurity incursion of a GMO'

– but there is no language around unintended or off-target impacts from non-regulated organisms. Biosecurity people, who won't know that Europe is only deregulating plants, and not everything from microorganisms, to insects to birds, fish and mammals – won't be able to grasp how much will be undisclosed.

Treaty debate is in full-roar – but I personally want to understand how the [Treaty of Waitangi principle](#) of active protection applies when an indigenous flora or fauna is gene edited. If gene editing fulfils MBIE and Collins' (secret scientific) criteria of being 'indistinguishable' despite genome rearrangements, will this impinge upon the mauri of that flora and fauna, or the rangatiratanga of a tribe or hapū over their taonga?

There is no New Zealand-based, independent review of currently released GMOs into the environment and the impact on environmental and human health. Currently released GMOs [do not](#) significantly create environmental benefits.

MBIE seem to think that instead of economic benefit they only need to ‘greenwash’ their documents to promise health and environmental outcomes. Ironically, the overwhelming preponderance of GMOs currently released into the environment are for technologies which are insecticidal toxins, of dubious allergenicity, which are herbicide tolerant. They have ‘multiple stacked traits’, meaning that the herbicide tolerance allows for multiple herbicides treatments (banned in Europe) including 2,4-D and glufosinate. GMO soy and corn account for [46% of all pesticides](#) used in the U.S. Not very environmental.

There’s no discussion on risk from [outdoor gene editing](#), nor the issue of what might happen to waste from fake ‘cultured’ or ‘cultivated’ meat that is emitted to the environment. [Gene silencing](#) is not discussed.

While Professor Jack Heinemann has probably studied [New Zealand’s GMO rules and regulations](#) more than any other scientist, he’s not in MBIE’s advisory group (have any of the people in the technical advisory group undertaken risk-based research regarding new gene edited GMOs?).

NO ECONOMIC ANALYSES – RISK OR BENEFIT FROM OUTDOOR RELEASES?

What about the financial return on investment from New Zealand’s twenty+ years of biotech development? This would be a good way to find out if deregulation into the environment is worth the financial risk to non-biotech sectors. I’ve asked the Crown Research Institutes who get most of the research funding. I can’t find any papers analysing the return on investment from Crown investment in biotech. I have asked ([here](#) and [here](#) and [here](#)).

No economic analysis has been done. The Economic Policy Committee (EPC) instead marvel at hypothetical ‘enormous benefits to New Zealand’ ([p103/150](#)), involving hopefully ‘potential economic benefits’ and ‘potential solutions’. The EPC acknowledge the size of the biotechnology market but fail to address impact on New Zealand export product.

Advances in outdoor (environmental) releases are touted as in agricultural feed grasses able to reduce animal emissions and better heat and drought resistant crops – but as I’ve found out, financial benefits remain unproven, and there is no pathway, particularly in the dietary grasses, to assess the long-term, intergenerational impact on the health and fertility of livestock. We all know that the health of the digestive tract and gut microbiome are central to health and fertility. But this is another issue that is ‘out of scope’.

All too often, the seeds and patents become owned by billion-dollar firms. This is the Monopoly game, where in the long run, offshore institutions simply scoop up locally owned discoveries (patents).

Judith Collins’ claims are largely speculative – this ‘modernisation’ will ‘improve health outcomes, adapt to climate change, deliver massive economic gains’.

But Collins is refusing to engage with any downside.

MBIE has not taken into account the [growth and potential](#) of the [low-polluting](#) organics sector.

A couple of weeks ago New Zealand’s organic sector organisation, Organics Aotearoa New Zealand (OANZ) met with officials and Ministers involved in the deregulation campaign, which involve the agriculture, food safety, and environment portfolios. The OANZ meetings [yielded five main findings](#)

- Rushed and Flawed Process
- Radical Regulatory Shifts
- Misunderstood Science
- Lack of Economic Analysis
- Ignored Agroecological Solutions

OANZ concluded that, as [Brendan Hoare stated](#), the:

‘reform proposals are likely to shift New Zealand from having a high level of precaution to leapfrogging all other global regulatory frameworks to become an outlier with potentially fewer protections than countries with established GMO producers.’

Alarming, officials and Ministers didn’t appear to understand how the policy and science fitted together:

'We get that this is a complex issue, with science that takes time to get your head around, but what we found was little co-ordination between the affected Ministries, a low level of scientific literacy and a poor understanding amongst Ministers as to the implications of the proposed changes.'

MBIE officials acknowledged in the meetings with the organic sector that they would likely face *more compliance costs* in future to prove their non-GMO status, which is a condition of organic agriculture and food. It's extraordinary.

An [NZIER report](#) commissioned by OANZ has [stated that](#):

'NZIER agrees with Caradus (2023a) that a discussion of gene technology in New Zealand should include all the economic actors affected and quantitative analysis to understand the impacts.'

The quantitative analysis we have been able to conduct with limited time and resources suggests that environmental release of GMOs in New Zealand could reduce exports from the primary sector by up to \$10 billion to \$20 billion annually. However, few studies have investigated this exact question and they lead to a range of conclusions, including a conclusion of no impact at all. The uncertainty around these estimates is a reason to investigate the potential economic consequences further before regulatory changes are adopted.'

Following the release of this report, the government responded with Prime Minister Luxon stating that he [disagreed completely](#). Biotechnology industry organisation head Dr William Rolleston [dismissed the report also](#), citing the price premium for GMO eggplants, which have a [ethically-questionable research and development history](#), and which the public would prefer not to eat, with [respondents in a recent trial](#) preferring a native, or local eggplant. Rolleston also claimed GMO canola received a price premium (without a link to 2024 data) – I'm not sure if Rolleston is [correct in 2024](#).

WILL COURT DECISIONS STYMY OFFICIAL ENTHUSIASM?

The NZEPAs current conservative position (as with the more cautious European position) to strictly regulate outdoor releases is predominantly a consequence of court judgements. The [NZEPA acknowledged](#) that earlier attempts to deregulate were stymied by court decisions:

'The EPA's ability to create a more permissive regulatory regime for advancements in gene technology has been impacted by court cases.'

The [High Court in 2014 in Sustainability Council of New Zealand Trust v The Environmental Protection Authority](#) [2014] NZHC 1067, found that NZEPAs decision to deregulate new breeding techniques did not sit well with a 'legal duty 'to protect the environment, and the health and safety of people and communities''.

The world may not be as 'loose and fast' as MBIE and Collins imagine. Last week a U.S. court overturned [earlier deregulatory actions](#):

'a federal district court ruled today that genetically engineered (GE) organisms must be regulated. The Court's ruling overturns the 2020 rule overhaul by the first Trump administration that had eliminated most government oversight over GE crops, trees, and grasses.'

The European Commission's decision is [currently at a standstill](#) on deregulation, and will be influenced by the [2018 European Court of Justice](#) ruling which decided that under the EU regulation on GMOs, modern techniques and methods of directed alteration of genetic material (genome editing) constitute a genetic modification.

It is exquisitely ironic that it is the Attorney-General that wants to reframe regulatory oversight according to MBIEs ideas and alter the NZEPAs powers to suit MBIE. In the process, Collins may be magically dispensing with inconvenient High Court findings and writing-off hard-won battles in New Zealand's regions, by (in the process) removing regulatory and decision-making power in the regions. Court decisions in Northland and Hawkes Bay have previously confirmed that GMO-free status should be protected.

Worryingly, without any domestically funded research to assess harm, any allegation of trespass from new GE species may face a tough battle in the courts, with judges likely [bending](#) to government policy claims that the GE version is benign (comparatively equivalent).

COLLINS – GETTING HERSELF IN A STICKY UNCONSTITUTIONAL MESS?

Parliament, by voting to pass the currently proposed regulatory framework, would effectively race New Zealand to the bottom of the barrel – but our MPs wouldn't even know. Anyone wanting to develop and release anything – from plants, to microbial organisms, insects and animals, could come here and set up shop.

As we've [discussed at PSGR](#) (note, I'm a trustee), disclosure of policies, regulatory impact statements and 'evidence of 'systematic and evidence-informed policy development' is crucial for evidence-based, democratic governance.

When officials are transparent and accountable, we are more likely to trust that the actions of officials and government agencies are fair, impartial, responsible, and trustworthy.

Scientific authority is also a function of officials and scientists following well established and transparent processes and being open to challenge and contradiction. This is what makes scientific information trustworthy, too. Just ask [Popper](#) and [Kuhn](#).

But Attorney-General Judith Collins [never intended](#) to let the public (lay and expert) challenge or contradict the claims in the Media Pack or just released policy documents. Her communications mislead us by failing to communicate how much more lax New Zealand regulations will potentially be, compared to Europe.



MBIE and Collins have effectively prohibited and censored discussion on the underlying scientific presumptions about risk. They are corraling members of Parliament and society so that the only response can be to a new Bill which would set the priorities and issues of risk for a new regulator, but where all the scientifically-relevant issues are locked in as 'facts'.

This is the trick, this is the game: You won't be able to talk about risk, and how it might apply to the regulator, when you finally get to respond to the GMO legislation, *because that will be 'settled science'*.

MBIE is the economic growth agency. Controlling the scientific evidence relating to the evidence on the safety of GM technologies, including gene editing, and the regulation in the environment, is not an appropriate governance role for MBIE. We're witnessing old-school regulatory capture.

Lawyer Judith Collins has been in government for 20 years. She understands government. As Attorney-General, she recently gave a [guest lecture](#) to Western Sydney University on the 'constitutional and rule of law challenges in the current uncertain global environment.' As Attorney-General she is responsible for ensuring that legislation is fair and just, and that legislation, including secondary legislation is designed to serve New Zealand, and the New Zealand people well.

So, I am rather perplexed to find that Collins is the primary advocate for new legislation that, from what a wide group of observers are concluding, would move New Zealand from being a country with strong, precautionary regulations around genetic modified organisms (GMOs) and the release into the environment of these GMOs.

I believe that the Attorney General is gaming important legal and constitutional process, and that is no place for an Attorney-General.