Parliamentary Commissioner for the Environment
Te Kaitiaki Taiao a Te Whare Pāremata

Submission on the Gene Technology Bill

To the Health Committee

17 February 2025

Submitter details

This submission is from the Parliamentary Commissioner for the Environment, Simon Upton.

I wish to appear before the Health Committee to present my submission.

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Parliamentary Commissioner for the Environment

The Parliamentary Commissioner for the Environment was established under the Environment Act 1986. As an independent Officer of Parliament, the Commissioner has broad powers to investigate environmental concerns and is wholly independent of the government of the day. The current Parliamentary Commissioner for the Environment is Simon Upton.

Key points

- The term 'regulated organism' is confusing and creates complexity across legislation that regulates organisms. For clarity and transparency this should be changed to 'genetically modified organisms'.
- For the independence of the gene technology regulator to be credible, the ability for the Minister to impose general policy directions should be removed, matters on which the Regulator cannot be directed should be specified, regulation-making powers should be amended, and the Regulator should be accountable to the board of the Environmental Protection Authority (the employer).
- New Zealand's unique environmental context is an important consideration when assessing risks and determining risk management for licence applications with potential environmental release. This is the minimum risk assessment criteria that should be set out in the Bill.
- Where GMOs have been released into the environment, and the relevant licence is subsequently revoked, those organisms will then be a biosecurity risk. The Committee should consider the interaction between release of GMO and the biosecurity system where the licence has been varied or revoked.

- The appointment criteria for the Māori Advisory Committee should be expanded to ensure that Māori interests are more appropriately represented. The functions of that committee should also be expanded, so that any licence application or proposal that relates to an activity involving, or that is likely to impact, indigenous species is referred for its advice.
- Public consultation should not be excluded for activities that an overseas authority has already authorised, and the information basis on which that authorisation was made is readily accessible to the Regulator.
- In addition to those persons identified in Schedule 3, any person who has an interest in the decision that is greater than that of the general public should also be able to request a review of the Regulator's decision.
- There are a range of differences between New Zealand's proposed regime and other international regime. Whether those differences could cause trade implications should be investigated further.
- The Committee should consider the exercise of compliance and enforcement powers by the EPA, in addition to MPI, and whether provisions to address civil liability should be added to the Bill.

Introduction

Thank you for the opportunity to provide feedback on the Gene Technology Bill. The development and regulation of gene technology and genetically modified organisms (GMOs) raise environmental, social and cultural challenges, some of which are specific to New Zealand. For New Zealand to realise the benefits of gene technology, the regulatory framework must be designed to secure public, industry, and trade confidence, as well as being recognisably responsible and transparent to foreign partners and overseas consumers. Gaining and maintaining that confidence will be achieved with a system that appropriately identifies and manages risks. Overall, I support the Gene Technology Bill, but there are several key areas where it requires improvement for the framework to be fit for purpose. These include clarity in the terminology that is used by the Bill, the independent function of the gene technology regulator (the Regulator), the importance of considering New Zealand's unique environment, and expanding the right of review to include those who will bear the risks.

To assist the Committee's understanding of how the Bill compares with the regulatory frameworks of other jurisdictions, including some major trading partners, a table of comparison accompanies this submission.

Terminology

The intention of the Bill is to establish a new regulatory regime for gene technology and GMOs, improving access to new technologies and providing risk-proportionate regulation.[1] Despite the general policy statement acknowledging that 'regulated organisms' are often referred to as GMOs, the Bill has adopted the imprecise and non-scientific term 'regulated organism'.

Organisms are regulated by a variety of statutes, not all of which relate to genetically altered organisms.[2] This will create confusion and complexity when working with an organism that may be regulated under other legislation. By not using the plain words that are well accepted and recognised internationally, there is almost a sense that something is being concealed. We should not be hesitant to use the term GMO. Being up front about that is a step towards acknowledging that the debate has moved on and will assist with public, industry, and scientific confidence that the regulatory framework will deliver on its objectives.

Recommendation: To be clearer and more transparent, the term 'regulated organisms' should be replaced with 'genetically modified organisms' (GMOs) for consistency with usage in the international scientific community and in other jurisdictions.

Independence

The objective of the regulator is "to develop and maintain an independent, efficient, and transparent system to regulate the use of gene technologies…",[3] and in performing its functions and duties and exercising its powers, the Regulator "must act independently of the Environmental Protection Authority (EPA) and the Minister".[4] However, the Minister is able to directly influence the Regulator through "general policy directions".[5] Those directions could include:[6]

- providing direction on risk tolerance
- providing guidance on how the scope of environmental and human health risks should be interpreted
- setting binding operational expectations
- requiring the regulator to make greater use of discretionary powers.

By way of contrast, the Minister is restricted in the scope of directions that may be given to the EPA under the Crown Entities Act, which cannot relate to the exercise of any power, duty, or function of the Authority.[7] Similarly, the Australian regime provides a narrow power for the Ministerial Council (combining Federal and State Ministers) to issue policy principles.[8] As I understand it, only one has ever been issued.

1 MBIE Departmental Disclosure Statement, Gene Technology Bill, 6 December 2024, p 3.
2 For example, the Biosecurity Act 1993 and the Hazardous Substances and New Organisms Act 1996.
3 Cl 109.
4 Cl 111(1)(a).
5 Cl 111(1)(b).
6 Regulatory Impact Statement: Reform of Gene Technology Regulation, 31 July 2021, para 461.
7 Hazardous Substances and New Organisms Act 1996, s 17.
8 Gene Technology Act 2000, ss 21-23. The Ministerial Council consists of one member of the federal government, and one member from each State and Territory governments.

The independence of the Regulator is a critical aspect of gene technology regulatory regimes, securing public and industry confidence alike in the system. A lack of separation from ministerial involvement is likely, as officials have warned, to add unpredictability to the regulatory process and to undermine any basis for claiming that the Regulator is truly independent.[9] A more permissive government might incentivise liberal use of GMOs, a more risk-averse government might take a more restrictive approach. The potential politicisation of the regulatory system would not be good for either economic certainty or scientific integrity.

Public trust in the regime is particularly important given the social and cultural sensitivities around GMOs. The New Zealand public has a history of being apprehensive about gene technologies, and although research has indicated that public perceptions are changing, it appears that there is still a large split in opinion on gene technologies.[10] Having confidence in a truly independent science-based regime will be one that is key to its success. Ministerial influence would likely degrade public trust and confidence in the regime, raising public concern that the regulatory system is politically driven, or susceptible to industry lobbying, and risks a loss of social licence. Equally, it may undermine public confidence that the regime can be trusted as truly science based.

Enabling the Minister to set the Regulator's risk tolerance would undermine the ability of the Regulator to appropriately consider factors affecting human safety and the environment. Once a GMO is approved and released into the environment, it is likely to become uncontrollable. If a Minister lowers the risk tolerance and it is later found that the organism creates more negative impacts than anticipated, it is likely to be too late to prevent harm. Where the potential consequences are irreversible, it is hard to see what value political judgement can add. What is needed is a hard-headed judgment about the level of risk which is being run and that should be based on technical and scientific expertise.

The Regulator is required to prepare a risk assessment for all activities that must submit a licence application.[11] The Bill does not prescribe any matters that the Regulator must take into account in those risk assessments, or the conditions that might be imposed to manage risks. It relies on those being picked up from the Cartagena Protocol and anything that the Minister chooses to add by exercising the power to make regulations.[12] As a result, it will be the Minister who prescribes the final shape of risk assessment criteria and conditions for risk management. Parliament should be wary of making risk assessment and risk management something that can be swiftly and simply changed by regulations. These matters would be better left in the hands of the Regulator who should apply a technical and scientific lens to the risks and uncertainties that arise in any particular case. Any guidance on this matter should be in primary legislation. My recommendation regarding environmental release, and consideration of New Zealand's unique context, should be explicitly required in risk assessments and any conditions for risk management.

Additionally, the Regulator is an employee of the EPA but, in contrast to the Australian regime, is accountable to the Minister. When put together, I consider that the unfettered regulation-making powers in respect of risk assessment and conditions for managing risks, and the accountability arrangements of the Regulator significantly undermine confidence that the

9 Regulatory Impact Statement: Reform of Gene Technology Regulation, 31 July 2024, para 473.

10 Survey done by agricultural research and advisory firm Primary Purpose found 34% of respondents were supportive, 31% opposed, 34% unsure. https://static1.squarespace.com/static/5991327b9f74563f03253a11/t/66832f576083fc1c428cadeb/1719873382191/Public+percpetions+of+genetic+technologies+report+June+2024.pdf.

11 Cl 26, noting there are several exceptions specified by cls 47, 48 and 52.

12 Cl 161.

Regulator is genuinely independent. Yet that independence is one of the best ways public confidence in the greater use of these techniques can be underwritten.

On the face of it, the Bill seems designed to give the Minister the maximum possible capacity to influence the Regulator without actually taking responsibility for any specific decision.

Recommendation:

- To align with the functions of the EPA, and increase the credibility of the Regulator's independence, the Regulator should be accountable to the board of the EPA.
- To insulate the decisions of the Regulator from influence, the Committee should consider amendments that:
    - Explicitly state the matters on which the Regulator may not be directed, similar to section 30 of the Gene Technology Act 2000 (Australia).[13]
    - Remove the ability for the Minister to impose general policy directions in clause 111(1)(b).
    - Remove the regulation-making powers in clause 161(b) and (c).

New Zealand's unique context

New Zealand has a unique environment. Our flora and fauna have evolved in near isolation from the rest of the world, resulting in a high level of endemism. The country spans over 13 degrees of latitude from Cape Reinga's subtropical environments to Rakiura's temperate climate. Along with large mountain chains and our sub-Antarctic islands, New Zealand is home to complex, distinct climatic and hydrological zones. Managing risks to the environment requires specific consideration of this unique environment. The biotic and abiotic differences across New Zealand must be a priority consideration in any gene technology risk assessment and risk management where environmental release is contemplated. As the Bill is currently drafted, it is unclear whether New Zealand's unique biotic and abiotic environments are required to be considered by the Regulator, especially when undertaking joint assessments with overseas regulators. These factors have the potential to alter the risk profile of gene technologies that may not be present overseas.

The Regulator will be able to rely on international expertise, by referencing recognised overseas authorities. Though this approach will allow the Regulator to access overseas risk information and expertise, it is not a panacea. As far as I am aware, few countries have a recognised overseas authority provision in their regulatory framework and no other jurisdiction solely considers overseas risk assessments and risk management proposals or conditions in their gene technology regulation.[14] This is likely due to there being little or no similarity in the scope of functions for regulators, or in the different risk assessment approaches that are applied. That is not, however, a reason for international collaboration to be removed from the Bill. A small country like New Zealand should seek to benefit from the resources and insights that overseas regulators can bring to bear. But if we are going to go down this road, it is essential that New Zealand's unique biotic and abiotic environment are specifically considered alongside any evidence that leverages the expertise of overseas authorities. To put it bluntly, a small continental state might be relaxed about relying on the judgments of overseas regulators.

13 Whether a GMO licence is issued or refused in relation to a particular application, or the conditions to which a particular GMO licence is subject.

14 In Paraguay, some gene technology techniques may be excluded from regulation/pre-market assessment if there is prior approval in other countries with established regulatory processes. In Israel a pre-market safety assessment is not required if two OECD countries have already approved a GM food (only applicable to food).

But a small, remote, and biologically ancient state like New Zealand cannot assume that the judgments of overseas regulators will suffice to encompass the risks of our unique environment.

Overseas regulators will not be looking at the impact a genetic alteration might have directly or indirectly on New Zealand's indigenous species. Given how many of those species are unique and valued by New Zealanders, it is important that there is a specific assessment of what impact a proposed genetic modification might have directly on the species or the ecosystem New Zealand species rely on. The risk is particularly high if we are allowing genetic modification of microorganisms that might cause diseases that could affect indigenous species or where a GMO can outcompete an indigenous organism in its ecological niche.

The Regulator should also give consideration to any risks that modifications undertaken in New Zealand may pose to other jurisdictions. We have pest species, such as possums, that are greatly valued in their home environments. For example, if New Zealand developed an anti-possum genetic modification that is then accidently, or deliberately, introduced to Australia, it may not be welcomed by our neighbour. Our GMO scheme needs to be seen to be acting responsibly in respect to any risks we may pose to other countries as well as to ourselves.

Recommendation: The Bill should require that any application for the release of a GMO into the environment be subjected to a rigorous assessment of its potential impact on New Zealand's indigenous biota and ecosystems, and its potential to create risks overseas.

GMO release and biosecurity

The Bill provides powers for the Regulator to vary or revoke an approval for a GMO.[15] These clauses are important in cases where after approval new information reveals that the risks of the organism or activity are higher than originally assessed or if there is unforeseen harm caused by the GMO.

What is not clear is how organisms, particularly those that have already been released into the environment, are to be treated if their approval has been revoked. Those organisms would now essentially become biosecurity risks. It would be appropriate, at least as an initial default, for them to be treated as 'unwanted organisms' and the associated powers in the Biosecurity Act 1993 should be used to control them.

Recommendation: The Bill should be clear about the biosecurity status of organisms whose approval has been revoked. The Committee should also seek further advice from officials about how GMO regulation and the biosecurity system will interact.

15 15 Cl 49 covers variations or revocation of activities approved by the Regulator as non-notifiable or notifiable. Cls 39-46 cover variations and revocation of licences issued by the Regulator.

Consultation and participation

Subject to the recommended changes that follow, I support the inclusion of clauses that require consultation with the Māori Advisory Committee, and the public, and provide the ability to apply for a review of the Regulator's decision.

Māori Advisory Committee

Not only is New Zealand's natural environment unique, so too are its culture and political expectations. While this is in some way acknowledged by clause 4, and by the establishment of a Māori Advisory Committee, the appointment and functions of that committee merit further clarification

Appointment criteria

The Māori Advisory Committee is appointed by the Minister, in consultation with the Regulator, the Minister for Māori Development, and any other Minister considered appropriate. This excludes Māori from selecting members of a statutory body, which provides advice on their behalf, and on matters which may have significant effects on Māori interests. This concern is mitigated in other Acts with clear legislative requirements regarding the functions of the advisory body, or detailed criteria for appointment. The Plant Variety Rights Act 2022 establishes the Māori Plant Varieties Committee, and specifies that a person must not be appointed by the Commissioner of Plant Variety Rights unless they have:

- had regard to that person's knowledge of mātauranga Māori, tikanga Māori, te ao Māori, and taonga species
- considered whether the proposed member has the mana, standing in the community, skills knowledge, or experience to participate effectively in the committee and to contribute to carrying out the functions of the committee.[16]

Functions

The scope of the advisory committee's advice that must be sought by the Regulator, in relation to indigenous species, is limited to circumstances where the proposed activity relates to a regulated organism that uses indigenous species as a host organism. This is too narrow. Activities which may use genetic material of an indigenous species, where the species is not used as a host organism, may also give rise to environmental risks which may have adverse effects on kaitiaki relationships. Modifications to species or organisms that then might outcompete indigenous species in their ecosystems also need to be considered.

Recommendations:

- The appointment criteria for committee membership should be amended to include considerations, similar to those of the Plant Variety Rights Act, on which the Bill's Māori Advisory Committee was loosely based.[17]
- Section 126(1) of the Bill should be amended so that any licence application or proposal that relates to an activity involving, or that is likely to impact on, indigenous species is referred to the Māori Advisory Committee. Corresponding amendments will also be required for clauses 21(1)(a), and 122 to ensure alignment for any activity, or regulated organism, involving indigenous species.

16 Plant Variety Rights Act 2022, s 57.
17 Regulatory Impact Statement: Reform of Gene Technology Regulation, 31 July 2021, para 121.

Public consultation

When assessing a licence application, the Bill requires the Regulator to release the draft risk assessment and management plans for public consultation.[18] An exception to this requirement is if an overseas authority has already authorised the activity, and the information basis on which that authorisation was made is readily accessible to the Regulator.[19] This inappropriately narrows public access to information, and the ability to consider and comment on activities of medium-high or uncertain risk. In circumstances where the application concerns an eventual environmental release, and the risks associated with release will largely be borne by the public, it is even more important that there is an opportunity to provide written submissions. As noted below, there will be situations where a GMO might affect other sectors' interests or broader public interests.

Recommendation: Clause 28(2)(b) should be removed from the Bill.

Review of the Regulator's decision

Only those listed in Schedule 3 of the Bill may apply for a review of a decision made by the Regulator.[20] This limits the ability to request a review to the applicant and/or licence holder. In other words, the only people able to request a review of the regulator's decision are those who would benefit from the technology, not those who might bear any risks that it poses. If the opportunity to review decisions is only given to those who benefit, over time the decisions of the Regulator will increasingly favour users.

For GMOs, the benefits will primarily accrue to private companies and individuals – those using the technology. However, the risks will fall generally on the public at large, the environment, or other economic sectors.

Take, for example, an application for genetic modification to a microorganism that members of the scientific community think may present risks to both native and exotic ducks. Members of the scientific community, conservationists, and duck hunters should all be able to have a say and request a review of any decision that will present a risk to their interests.

GMO decisions may also affect the trade and economic interests of other sectors. Consider, for example, an approval for a genetically altered wasp to control agricultural insect pests. If that same wasp might somehow affect bee populations, putting at risk the vital pollination services those bees provide to the horticulture industry, that sector's productivity might be impaired. In that case, the horticulture industry should have a right to seek a review of the decision if it thinks the Regulator has not adequately considered the risk posed to it.

Similarly, if the Regulator has made a decision on a microorganism that will affect the viticulture industry, and the viticulture industry believe that that genetically modified microorganism poses a high risk to trade with the EU, or other markets, it should be allowed to request a review, if it considers that the Regulator has inadequately considered the risks to its interests.

18 Cl 25(1)(b).
19 Cl 28(2)(b).
20 Schedule 3 and Part 5, subpart 1 of Gene Technology Bill.

Recommendation: Given that the regulator is ultimately managing risk to the public, if persons that represent aspects of the public interest (e.g. commercial or environmental groups) think the risks have not been appropriately considered, those persons should also be able to seek a review of the Regulator's decision.

Alignment with international jurisdictions

As demonstrated by the table in Appendix 1, different jurisdictions regulate GMOs in different ways. I am not in a position to make a judgement on which of these is the best way forward. However, I wish to draw the Committee's attention to some key differences.

- New Zealand, like Australia, is proposing that exemptions to the Act can apply to plants, animals and microorganisms. I note that the European Union and China are proposing that exemptions are limited to plants, which is similar to Canada. The United States and England only allow exemptions for plants and animals.[21]
- To be eligible for exemption from regulation, the United States limits the number of modifications and their distribution in plants.[22] The European Union is proposing similar limits.[23] The New Zealand Bill has no limitations of this kind unless they are to be specified in regulations.
- Countries allow various types of modifications to be exempt from regulation. For example, New Zealand is going to allow both unguided repair (SDN-1) and guided repair (SDN-2) modifications[24] to be able to be made exempt, whereas Australia only allows SDN-1 modifications to be exempt from regulation.[25] Other jurisdictions exempt a greater number of techniques.
- Australia considered, and consulted on, a model that was based on a risk matrix approach, but concluded that it was too complex, and insufficiently future proof. As a result, Australia's proposed new risk framework will not define activities by categories such as laboratory and industrial, environmental release, and medical use as this Bill does.

The key potential risk if New Zealand's GMO regulations differ from other countries is friction with the trade biosecurity regimes of those countries. Differences will exist between different countries' regulatory settings – they do now. But we should be careful to avoid providing trading partners with fresh pretexts for imposing fresh regulatory barriers and restrictions to trade. Such barriers could make trade more difficult, either generally or for specific sectors (for example organics). The greater the difference between regulatory regimes, the greater the potential risk. Greater alignment to international approaches to legislative design may provide some basis for achieving compatibility, enhancing the potential for international collaboration, and potentially reducing barriers to trade.

21 See Appendix 1. For additional examples see https://www.foodstandards.gov.au/sites/default/files/2024-07/P1055%20Supporting%20document%201%20Updated%20compilation%20of%20regulatory%20approaches.pdf

22 For example, up to 12 simultaneous (multiplex) or sequential modifications if each modification individually qualifies the plant for exemption and occurs in a different gene. https://www.govinfo.gov/content/pkg/FR-2024-11-13/pdf/2024-26232.pdf

23 https://food.ec.europa.eu/document/download/5a994ff5-153a-4886-a3cc-794512dce27a_en?filename=gmo_biotech_ngt_proposal_2023-411_annex_en.pdf

24 Site directed nucleases (SDN). An enzyme creates site-specific double-strand breaks (DSBs) in the DNA at a defined sequence. Depending on the approach (SDN-1, 2 or 3) different outcomes are possible. SDN-1: following the DSBs, the DNA undergoes spontaneous repair, introducing random mutations (substitutions, insertions or deletions) at the target site, without the addition of foreign DNA (hence 'unguided' repair). SDN-2: following the DSBs, DNA is repaired with template DNA to generate a predicted modification (hence 'guided' repair). SDN-3: following the DSBs, DNA is repaired with the addition of a large stretch of template DNA (can be entire genes). This template DNA could be from within species (cisgenic), or from a 'foreign' species (transgenic).

25 https://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_reg/gtr2001271/sch1.html

Recommendation: The Committee should seek advice from officials whether any of the differences between regimes would cause significant trade issues, particularly in light of the limited assessment of costs and benefits in the regulatory impact statement. The Committee may also want to question different industry sector groups about risks or benefits of the proposed regime they have identified for trade in their sector.

Compliance and enforcement

The Ministry for Primary Industries (MPI) is proposed to be responsible for compliance, monitoring and enforcement of the regulatory regime. This is logical given that in many respects enforcing GMO regulation is similar to enforcing biosecurity regulation. It would also be consistent with comparable enforcement responsibilities for other regimes, including for the Hazardous Substances and New Organisms (HSNO) Act 1996. However, in contrast to this Bill, the HSNO Act allows the EPA to also undertake enforcement of the Act.[26] Environmental compliance and enforcement are key components to ensuring the risks of GMOs are being appropriately managed.

Recommendation: Given that the EPA's primary role focuses on protecting the environment, in contrast to MPI's, and that the EPA has relevant compliance and enforcement expertise for enforcing the GMO regulations, the Bill should be amended to give the EPA, as the host organisation of the Regulator, powers to enforce the Act in addition to those given to MPI.

Civil liability

While various offences will be established by the Bill, imposing criminal sanctions, it does not appear to address civil liability. This contrasts with the treatment of GMOs under the HSNO Act.[27] Potential liability in damages incentivises industry best practice in undertaking gene technology activities, and would mean that if an issue arose, either by accident or mal intent, those who were responsible could be held accountable. Without such a clause, it is likely that the taxpayer and food producers would be left bearing the brunt of the costs. Civil liability would aid in securing public trust and confidence in the regulatory regime and should be carefully considered and addressed.

Recommendation: The Committee should include civil liability provisions in the Bill.

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26 HSNO Act, s 11.
27 As above, s 124G.

Appendix 1: Comparison of international regulatory frameworks[28]

Country	Regulatory approach	Terminology	Exemptions for some techniques/ pre-market assessment?	Criteria for exemption	Applies to
New Zealand (proposed)	Hybrid – with risk matrix framework	Regulated organism	Yes	Unguided (SDN-1) and guided repair (SDN-2)	Animals, plants, microorganisms 
Australia (current)	Hybrid – with contained dealings and dealing involving intentional release	GMO[29]	Yes	Unguided repair only (SDN1). Exempt dealings cannot be released into the environment (e.g. cannot involve field trials or commercial releases)	Animals, plants, microorganisms 
Australia (proposed)	Hybrid – risk tier framework. No categorisation of dealings as 'contained' 'involving intentional release' or 'clinical trials and medical applications'	GMO[30]	Yes	Unguided repair (SDN1)	Animals, plants, microorganisms 
European Union (current)	Process based	GMO[31]	No	N/A	GMO assessment framework applies to all organisms or food products
European Union (proposed)	Hybrid	GMO	Yes	Unguided (SDN-1), guided (SDN-2) and genes from within species repair (SDN-3 without foreign DNA); specified maximum number of genetic modifications compared to parent plant (proposed no more than 20 genetic modification)[32]	Plants 

28 Adapted from https://www.mbie.govt.nz/dmsdocument/29940-regulation-of-gene-technologies-policy-decisions-proactive-release-of-advice-proactiverelease-pdf ; https://www.foodstandards.gov.au/sites/default/files/2024-07/P1055%20Supporting%20document%201%20Updated%20compilation%20of%20regulatory%20approaches.pdf ; https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P1055%20SD3%20Regulatory%20approaches%20and%20definitions.pdf

29 https://www.legislation.gov.au/C2004A00762/2016-07-01/text

30 https://consultations.health.gov.au/best-practice-regulation/amendments-to-the-gene-technology-act-200/supporting_documents/Gene%20Technology%20Act%202000%20future%20law%20compilation%20taking%20into%20account%20the%20Gene%20Technology%20Amendment%20Bill%202024.pdf

31 Directive 2001/18/

32 https://food.ec.europa.eu/document/download/5a994ff5-153a-4886-a3cc-794512dce27a_en?filename=gmo_biotech_ngt_proposal_2023-411_annex_en.pdf

Country	Regulatory approach	Terminology	Exemptions for some techniques/ pre-market assessment?	Criteria for exemption	Applies to
England	Hybrid	Precision bred organism[33]	Yes	Unguided (SDN-1), guided (SDN-2) and genes from within species repair (SND-3 without foreign DNA)	Plants, vertebrate animals 
United States	Product based	GMO, bioengineered	Yes	Specific criteria (see[34]); for example, unguided repair (SDN-1), single base pair substitution, introduces gene known to occur in plant's gene pool, up to 12 simultaneous (multiplex) or sequential modifications if each modification individually qualifies the plant for exemption and occurs in a different gene	Plants, animals 
Canada	Product based	Novel foods/ plants with novel traits	Yes[35]	Absence of foreign DNA in final plant product; no new or increase in toxins, allergens, and antinutrients; no compositional changes; no new food use	Plants 
China	Unknown	Gene-edited[36]	Unclear how rules will apply	Techniques classified into risk categories, unsure as to further detail	Plants 
Argentina	Product based	GMO[37]	Yes	Absence of new combination of genetic material in NBT organism/final product free of transgenes	Animals, plants, microorganisms 

33 33 https://www.legislation.gov.uk/ukpga/2023/6/pdfs/ukpga_20230006_en.pdf.
34 https://www.govinfo.gov/content/pkg/FR-2024-11-13/pdf/2024-26232.pdf
35 Exclusion from regulation as "novel foods", not GMOs.
36 From unofficial translation: https://www.fas.usda.gov/data/china-mara-issues-first-ever-gene-editing-guideline.
37 https://www.food.gov.uk/sites/default/files/media/document/comparing-international-approaches-to-food-safety-regulation-of-gm-and-novel-foods_0.pdf