Please note that Te Whare Wānanga o Waikato, The University of Waikato, one of the submitters on the public consultation, is incorrectly recorded in this document as “Te Wānanga o Aotearoa, The University of Waikato”. Te Wānanga o Aotearoa is the name of a different tertiary education institution and did not make a submission on this consultation.

Submitter	Proposal/area of consultation	Tag	Quote
ABSANZ	Objectives	Objectives	We believe the objectives set out will enable a risk based approach to be undertaken but there will need to be some changes to the HSNO Act and other Acts associated with new organisms to enable this to occur.
ABSANZ	Proposal 1 - Risk-tiering framework	Technical feedback	Question 4. Many of our members are already working in the Australian system. One comment about this system is that the current Australian regulations are not easily adapted to new technologies so this is something that will need to be considered.
ABSANZ	Proposal 1 - Risk-tiering framework	Technical feedback	Question 2. ABSANZ would like to see risk groups of host organisms to be genetically modiï¬ed included in the framework with a list of host organisms/cell lines that can be modiï¬ed or imported without a huge administrative burden for researchers.
ABSANZ	Features and approach for regulatory framework	Features and approach for regulatory framework	Question 1. A better deï¬nition of a new organism is required in the Act to enable researchers to work with organisms such as genetically modiï¬ed cell lines, that cannot survive outside a laboratory setting, without having a huge compliance burden in terms of paperwork imposed upon them. Several standards will also require revision as currently a number of cell lines derived from unwanted organisms have unnecessary paperwork associated with them. The HSNO Act deï¬nes genetically modiï¬ed organisms as one category of new organisms so deï¬nitions will need to be changed.
ABSANZ	Proposal 3 - Record-keeping requirements	No	Question 12. For low-risk modiï¬cations the ability to link to a HSNO Act approval should not be a requirement as even if these organisms escaped containment there is no risk to human health or the environment. Most researchers keep their own records and pure cultures for their own research so the issue of cross contamination is probably minor.
ABSANZ	Proposal 3 - Record-keeping requirements	Yes	Question 11. Any changes that reduce the administrative burden for researchers are encouraged.
ABSANZ	Proposal 1 - Risk-tiering framework	Yes	ABSANZ is in favour of introducing a risk-tiered framework for laboratory research. This should reduce the administrative burden on researchers.
ABSANZ	Proposal 1 - Risk-tiering framework	Technical feedback	As we have members in both Australia and NZ who work under diï-€erent systems currently this would also improve research collaborations between the two countries.
ABSANZ	Proposal 3 - Record-keeping requirements	Yes	Question 15. A reduction in external veriï¬cation of internal audits for both PC1 and PC2 to 12 months is supported and should be based on the outcome of previous audits. More frequent audits can occur where previous audits deem this necessary. MPI should retain the ability to audit unannounced at any time. A number of MPI/EPA containment standards would need to be amended to allow this to occur. Parts of large transitional and containment facilities could be exempt based on past audits. Consideration should be given to facilities that have imported biological risk goods as well as genetically modiï¬ed organisms being exempted based on prior audits.
ABSANZ	Proposal 3 - Record-keeping requirements	Technical feedback	Question 15. A reduction in external veriï¬cation of internal audits for both PC1 and PC2 to 12 months is supported and should be based on the outcome of previous audits. More frequent audits can occur where previous audits deem this necessary. MPI should retain the ability to audit unannounced at any time. A number of MPI/EPA containment standards would need to be amended to allow this to occur. Parts of large transitional and containment facilities could be exempt based on past audits. Consideration should be given to facilities that have imported biological risk goods as well as genetically modiï¬ed organisms being exempted based on prior audits.
ABSANZ	Proposal 5 - Movement between facilities	Yes	Question 18. We support movement of low risk organisms being managed by the Operators of the facilities. This will reduce costs for institutions and time for MPI staï-€. As long as packaging is correct for the organisms being transferred there are no issues of concern.
ABSANZ	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Question 21. Agree
ABSANZ	Proposal 7 - Regulatory status of biotechnologies	Yes	Question 24. We support the proposed change as new technologies are emerging with greater frequency. How can more changes be future proofed?
ABSANZ	Proposal 9 - Standards for containment facilities	Outcome-based	Question 32. Outcome based controls are favored allowing institutions to develop their own systems based on international best practice. However, for some smaller facilities it may be better to have prescriptive controls. Many of our Australian members are already using ISO35001:2019.
ABSANZ	Proposal 10 - Reviews of regulatory settings	Yes	Question 36. Reviews every ï¬ve years are a good approach as this will allow new technologies to be incorporated into the system as required. There should also be an option to review inside that time frame if a new technology occurs.
ABSANZ	Proposal 10 - Reviews of regulatory settings	Yes	Question 36. Reviews every ï¬ve years are a good approach as this will allow new technologies to be incorporated into the system as required. There should also be an option to review inside that time frame if a new technology occurs.
ABSANZ	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Question 42. As long as a risk based approach is followed there should be no issues
AgResearch	Objectives	Objectives	The Objectives are reasonable but could be broader, for example, including utilising genetic technologies to resolve issues and provide opportunities related to food security, climate change, and environmental impacts.
AgResearch	Features and approach for regulatory framework	Features and approach for regulatory framework	From the consultation document - "Researchers surveyed by the Ministry noted that many low-risk organisms present essentially zero risk to the environment, or to the health and safety of people and communities" - clearly indicates that researchers are already considering an outcome-based assessment of risks and subsequent impacts. The methodology used to introduce the genetic change is not a consideration unless the action of using the methodology is an inherent risk to the environment or health and safety.
AgResearch	Features and approach for regulatory framework	Features and approach for regulatory framework	The risk of a GMO should be assessed based on risk to the following six domains: â€¢ The environment. â€¢ Human health and safety. â€¢ The economy. â€¢ The relationship of MÄori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued ï¬,ora and fauna and other taonga, and the principles of the Treaty of Waitangi. â€¢ Society and community. â€¢ New Zealandâ€™s international obligations.
AgResearch	Features and approach for regulatory framework	Features and approach for regulatory framework	This ties into the continued separation of genetically modiï¬ed organism and new organism in concepts. A genetically modiï¬ed organism may be considered a new organism, as the risk assessment framework is eï¬€ectively the same in terms of how the characteristics could potentially impact the six domains. Having a single way of thinking of risk, chance, outcome, and impact associated with organisms, and biological products (recognised as not part of this consultation), would develop clarity and lead to a more robust biosecurity system for the future. Although, the potential range of variations in characteristics, and subsequent impacts, could be extremely variable (e.g., the release of a new non-native parasitic wasp species vs. the release of a transgenic petunia with an altered ï¬,ower colour).

AgResearch	Useful quotes	Useful quotes	Many of the comments related to the speed of operation of the current system can be attributed to the resourcing provided to the EPA New Organisms Team. This appears to be a relatively small team dealing with complex yet critical issues. Changes in regulations needs to occur in parallel with adequate resourcing of the regulatory organisation.
AgResearch	Proposal 1.1 - Biosafety Committees	Yes	Smaller organisations may not be in a position to establish an ABSC, so the EPA will still be required to make decisions on risk tiering in some circumstances. We welcome the option for some larger institutions to apply for accreditation of their existing biosafety committees. However, we recognise that not all the organisations have resources or might wish to apply for an ABSC (Accredited Biosafety Commitee). Therefore, we agree with the proposal to have the option to apply to the accredited EPA biosafety committee. It is also recognised that ABSC might only want to approve their own institutionâ€™s research excluding other institutionsâ€™ projects. Accountability, lack of oversight andï¬nal deï¬nitions of risk tiers would play a big role in the ï¬nal decision. Furthermore, we would like to reiterate the importance of iwi consultation in this scenario. Diï¬€erent iwi in dii¬€erent part of the country might be required for the consultation, making it more diï¬ƒcult for ABSCs to assess other institutions research across all of Aotearoa New Zealand. It is important that ABSC structures and settings will account for appropriate iwi consultation. Smaller organisations may not be in a position to establish an ABSC, so the EPA will still be required to make decisions on risk tiering in some circumstances. Many of the comments related to the speed of operation of the current system can be attributed to the resourcing provided to the EPA New Organisms Team. This appears to be a relatively small team dealing with complex yet critical issues. Changes in regulations needs to occur in parallel with adequate resourcing of the regulatory organisation. How an organisation (i.e., ABSC) might go about fulï¬lling their role in a timely and exacting manner is a critical component not deï¬ned in this consultation document. This includes whether they are involved in reviewing the allocation of diï¬€erent host/vector systems to the appropriate Tier. The structure of an ABSC is also critical, given that a major part of this consultation document focuses on risks associated with modiï¬ed organisms escaping from containment. Would a lay person or an iwi representative have the background skills to make an eï¬€ective assessment and add signiï¬cant value to the process? Or should the ABSC be made up of experts in the ï¬eld of the technology being used, and experts in the ï¬eld of potential impact if the organism escaped from containment? There would be many unknown risks, but good knowledge and experience would help to mitigate the shear range of possibilities. The consideration of species as taonga may be rohe-dependent. Has how an ABSC deals with this been considered? For an institute with multiple campuses, has the potential need for multiple streams of engagement to undertake the same work in dii¬€erent locations been considered? Engaging with multiple parties across Aotearoa New Zealand could elicit signï¬cant and/or prohibitive costs for small projects. There can be signiï¬cant ramiï¬cations if there is an incorrect assessment of some risks. Auditing of ABSC decision-making procedures should be undertaken at regular intervals. This could simply be in the form of reviewing standardised reports on the evidence provided to an ABSC, input from the committee's members, and justiï¬€cation for the decision.
AgResearch	Proposal 3 - Record-keeping requirements	Yes	Simplifying the record keeping will allow greater efforts on research without increasing the risk of genetically modified organisms escaping from containment. The current systems are error-prone and time-consuming, while only nominally reducing the risk of escape. Research requires high-quality record keeping, including being able to accurately recognise each separate piece of work underway. Simple standard notations such as a name, date, and unique identiï¬er typically allows the researcher to identify the host and modiï¬cation of each genetically modiï¬ed organism or culture - from one of 1000 bacterial colonies on a plate, to one of 2000 plants in a glasshouse. Often the need for compliant-level labelling duplicates the laboratory records and fails to reduce the chance of escape. Over-labelling to be compliant possibly leads to more errors than a labelling system that suits a researcher's mode of operation. Simplifying the record keeping will allow greater eï¬€orts on research without increased risk to the six domains. At Tier 1 and Tier 2thiscouldbe done at the 'whole lab' level. For example, a sign on the door provides notiï¬cation of organisms being used at Tier 1, and speciï¬cally lists those being used at Tier 2 and their relevant "Approval" (i.e., ABSC or EPA designation). Tier 3 should use more deï¬nitive labelling. If the Approval can be written on the outside of a box containing 81 1.5 mL vial, then why wouldn't it be suitable to have the Approval on the door of a lab. The "box" and the complexity of its contents is often open to the interpretation of the auditor. The current directives around the use of inappropriate labelling regimes leads to training focusing on the "how", rather than the "why". Through gaining a better understanding of the why, researchers can develop personalised systems that are more relevant to their situation than that dictated from experience with limited situations. Applicable across all of the proposals - Monitoring of compliance with legislation and regulations would have to be standardised across regulators, auditors, and laboratories.
AgResearch	Proposal 3 - Record-keeping requirements	Technical feedback	Simplifying the record keeping will allow greater eï¬€orts on research without increased risk to the six domains. At Tier 1 and Tier 2thiscouldbe done at the 'whole lab' level. For example, a sign on the door provides notiï¬cation of organisms being used at Tier 1, and speciï¬cally lists those being used at Tier 2 and their relevant "Approval" (i.e., ABSC or EPA designation). Tier 3 should use more deï¬nitive labelling. If the Approval can be written on the outside of a box containing 81 1.5 mL vial, then why wouldn't it be suitable to have the Approval on the door of a lab. The "box" and the complexity of its contents is often open to the interpretation of the auditor.
AgResearch	Proposal 2 - Assessments for medicines	Technical feedback	Amendments should be able to include changes of vector or techniques as long as an amendment does not increase the risk of work described in Purpose in the original Application. The s67A amendment process should be changed to include new host organisms as long as the new host organism has a similar risk proï¬le to the host organisms that are already listed within an Approval, enabling Approvals to be more readily future-proofed. Research communities would beneï¬t in not having to submit a full Application for a minor amendment to an existing Approval. There would be no additional risk to the environment or to the health and safety of people and communities under this proposal. In addition, EPAâ€™s interpretation of what is minor in eï¬€ect under the s67A amendment process has become more restrictive in that the s67A approval process can only be used for â€œCorrecting typographical or drafting errorsâ€ in an Application. Even the EPAâ€™s website states that â€œan amendment allows changes to a new organism approval after it has been given â€“ but only if the change is minor in effectâ€. We propose that the EPA restores its previous interpretation of what is considered a minor in eï¬€ect amendment. Amendments could then include changes of vector or techniques not speciï¬ed in the original application. A requirement would be that the amendment does not increase the risk of work described in the original Application.
AgResearch	Proposal 2 - Assessments for medicines	Yes	Amendments should be able to include changes of vector or techniques as long as an amendment does not increase the risk of work described in Purpose in the original Application. The s67A amendment process should be changed to include new host organisms as long as the new host organism has a similar risk proï¬le to the host organisms that are already listed within an Approval, enabling Approvals to be more readily future-proofed. Research communities would beneï¬t in not having to submit a full Application for a minor amendment to an existing Approval. There would be no additional risk to the environment or to the health and safety of people and communities under this proposal. In addition, EPAâ€™s interpretation of what is minor in eï¬€ect under the s67A amendment process has become more restrictive in that the s67A approval process can only be used for â€œCorrecting typographical or drafting errorsâ€ in an Application. Even the EPAâ€™s website states that â€œan amendment allows changes to a new organism approval after it has been given â€“ but only if the change is minor in effectâ€. We propose that the EPA restores its previous interpretation of what is considered a minor in eï¬€ect amendment. Amendments could then include changes of vector or techniques not speciï¬ed in the original application. A requirement would be that the amendment does not increase the risk of work described in the original Application.

AgResearch	Proposal 4 - Internal audit frequency	Technical feedback	While the audits do take time, and can be quite stressful because of the unknown range of expectation (another issue), they do oï-€er the chance for people to review practices and make improvements if necessary.
AgResearch	Proposal 4 - Internal audit frequency	Other policy options	The risk profile of the work conducted within the PC2 facility should determine whether the facility receives six-monthly or yearly audits.
AgResearch	Proposal 4 - Internal audit frequency	Other policy options	PC1/PC2 facilities that have good track records/regulator trust should be able to have the external veriï-cation to be pushed to yearly. While Risk Tier 1 is considered low risk, it is not 'no' risk. Therefore, laboratories working solely with Risk Tier 1 organisms should still be audited, more to ensure that a general laissez faire approach to operations is not being applied, rather than reviewing every speciï-€ point of compliance.
AgResearch	Proposal 4 - Internal audit frequency	Other policy options	In addition, as the breadth of risk of work undertaken for Physical Containment level 2 (PC2) is wide, the risk proï-le of the workconductedwithinthePC2facility should determine whether the facility receives six-monthly or yearly audits.
AgResearch	Proposal 4 - Internal audit frequency	Unsure	The risk profile of the work conducted within the PC2 facility should determine whether the facility receives six-monthly or yearly audits. If "Internal audits require time from facility staff and researchers" - then the question would be that if everything is being done correctly in the ï-rst place then what is requiring the extra time for the average scientist? However, it should be noted that it can take considerable time for the internal auditors depending on the size and complexity of the Facility. While the audits do take time, and can be quite stressful because of the unknown range of expectation (another issue), they do oï-€er the chance for people to review practices and make improvements if necessary. PC1/PC2 facilities that have good track records/regulator trust should be able to have the external veriï-cation to be pushed to yearly. While Risk Tier 1 is considered low risk, it is not 'no' risk. Therefore, laboratories working solely with Risk Tier 1 organisms should still be audited, more to ensure that a general laissez faire approach to operations is not being applied, rather than reviewing every speciï-€ point of compliance. In addition, as the breadth of risk of work undertaken for Physical Containment level 2 (PC2) is wide, the risk proï-le of the workconductedwithinthePC2facility should determine whether the facility receives six-monthly or yearly audits.
AgResearch	Proposal 5 - Movement between facilities	Yes	Better definition/assessment of when an organism is considered 'non-viable 'would make transfer of samples for analyses easier. Based on the information provided we support the proposal to adjust the requirements for the movement of new organisms to be proportionate to risk. Our organisation routinely isolates low risk microorganisms from plants and livestock that are not listed on the EPA Present in New Zealand list. A major beneï-t would be the ability to transfer these Aotearoa New Zealand isolates to other collaborative laboratories with minimal administrative procedure. There would be some cost and time reduction by not having to frequently apply for authorities from MPI to transfer between laboratories, but laboratory users would continue to maintain experimental records required for their projects. The Laboratory Manager will need to ensure a clear labelling system of identifying low or high-risk material. The Delegated Facility Operator (DFO) would need to amend operating procedures and train laboratory users to ensure they understand the regulations. Internal process and registers could therefore be retained and the DFO would continue to conduct internal audits to conï-rm the systems are working. Many species of microorganisms were present in New Zealand prior to 29 July 1998, although these species were not described or just not included within the EPA Present in New Zealand list. The process for 'de-newing' New Organism (non-GMO) microorganisms that are already established within New Zealand should be streamlined, cheaper and easier for risk group 1 and risk group 2 microorganism as these organisms are already deï¬ned as low risk. If a researcher provides evidence that a low-risk New Organism microorganism is globally ubiquitous, found throughout New Zealand, and highly likely to have been present prior to 29 July 1998, then the EPA should automatically update the NZ present microbe list. One organisation should not bear the cost of time and money of going through the de- newing process as inclusion on the list also beneï¬ts other organisations. Better deï¬nition/assessment around when the genetically modiï¬ed organism(s) can be considered as 'non-viable' would make transfer of samples to non-pc laboratories for analyses easier. The term 'unbreakable primary container' is not applicable. Again, using existing regulatory guidelines from other jurisdictions as templates would assist in developing Aotearoa New Zealand's regulations in this area and help to ensure that the correct language is used.
AgResearch	Proposal 5 - Movement between facilities	Technical feedback	Better deï¬nition/assessment around when the genetically modiï¬ed organism(s) can be considered as 'non-viable' would make transfer of samples to non-pc laboratories for analyses easier.
AgResearch	Proposal 5 - Movement between facilities	Technical feedback	The term 'unbreakable primary container' is not applicable. Again, using existing regulatory guidelines from other jurisdictions as templates would assist in developing Aotearoa New Zealand's regulations in this area and help to ensure that the correct language is used.
AgResearch	Proposal 5 - Movement between facilities	Other policy options	Many species of microorganisms were present in New Zealand prior to 29 July 1998, although these species were not described or just not included within the EPA Present in New Zealand list. The process for 'de-newing' New Organism (non-GMO) microorganisms that are already established within New Zealand should be streamlined, cheaper and easier for risk group 1 and risk group 2 microorganism as these organisms are already deï¬ned as low risk. If a researcher provides evidence that a low-risk New Organism microorganism is globally ubiquitous, found throughout New Zealand, and highly likely to have been present prior to 29 July 1998, then the EPA should automatically update the NZ present microbe list. One organisation should not bear the cost of time and money of going through the de- newing process as inclusion on the list also beneï¬ts other organisations.
AgResearch	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Genetically modified plants maintained in a vegetative state in artificial media in sealed containers should be exempt from requiring statutory approval.

AgResearch	Proposal 6 - Requirements for eukaryotic somatic cells	Technical feedback	Two points appear too restrictive: "The donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi". This restricts any work on gene function and discovery where the source is a pathogen â€“ regardless of the risk tier of the resulting organism. Thus, you could transfer highly characterised gene that is considered 'safe' in the new host but because it came from a pathogen the new cell line would have to be managed as if it was a higher risk tier. This largely restricts work on understanding pathogenicity, which is a very important area of research. It also restricts work where the genes under question have no role in pathogenicity, simply based on the source organism. In addition, the limitation is not in line with a risk-based assessment of the genetically modiï¬ed organism, but is based on the characteristics of the genetic donor. "The plant cells or tissues cannot spontaneously generate a whole plant and cannot be regenerated into a whole plant". Item 10 in the Hosts and vectors table (pg 48) the Hosts column should include plantlets in artiï¬cial non-aggregate media (i.e., in agar or liquid media; not in vermiculite or soil plugs) in sealed containers, where the plants are maintained in a vegetative state, and where the plantlet or any material associated with it (e.g., leaves, petioles, tubers) cannot propagate without targeted human intervention.
AgResearch	Proposal 7 - Regulatory status of biotechnologies	Other policy options	future-proof legislation for the application of genetically modified organisms. The major characteristic with the purpose of the consultative document is the limitation that it is "not looking to change the rules related to field trials and releases of GMOs into the environment". However, the Objective: We want to ensure that the regulatory framework in Aotearoa New Zealand for genetically modiï¬ed organismsâ€¦ is not only up to date but also future-proof[ed], to anticipate and ï¬‚exibly accommodate future technological developments to the best extent possible. Using appropriate risk deï¬nitions and assessment methodologies the regulatory framework has the opportunity to future-proof legislation for the application â€“ not just for use in research â€“ of genetically modiï¬ed organisms and new technological developments, originating from existing laboratory methodology. Viable policy should include: â€¢ Null segregants â€“ explicitly considered as non-genetically modiï¬ed organisms. â€¢ Gene edited organisms. â€¢ Genetically modiï¬ed organisms. Agreement with the following points could be part of an accredited biosafety committee (ABSC; organisational or government equivalent [e.g., EPA]) assessment in deï¬ning if an organism is a null segregant or contains an SDN-1 mutation: Host Where the organism, before or after the targeted genetic change: â€¢ Is not normally able to infect, colonise, or establish in humans. â€¢ Is not able to (or contain infectious agents normally able to) cause disease in humans, animals, plants, or fungi. and Genetic change Where any interventional genetic change to the organism (e.g., gene edit), including any change to the parental line(s) (e.g., genetic modiï¬cation), has been characterised. and
AgResearch	Proposal 7 - Regulatory status of biotechnologies	Unsure	future-proof legislation for the application of genetically modified organisms. The major characteristic with the purpose of the consultative document is the limitation that it is "not looking to change the rules related to field trials and releases of GMOs into the environment". However, the Objective: We want to ensure that the regulatory framework in Aotearoa New Zealand for genetically modiï¬ed organismsâ€¦ is not only up to date but also future-proof[ed], to anticipate and ï¬‚exibly accommodate future technological developments to the best extent possible. Using appropriate risk deï¬nitions and assessment methodologies the regulatory framework has the opportunity to future-proof legislation for the application â€“ not just for use in research â€“ of genetically modiï¬ed organisms and new technological developments, originating from existing laboratory methodology. Viable policy should include: â€¢ Null segregants â€“ explicitly considered as non-genetically modiï¬ed organisms. â€¢ Gene edited organisms. â€¢ Genetically modiï¬ed organisms. Agreement with the following points could be part of an accredited biosafety committee (ABSC; organisational or government equivalent [e.g., EPA]) assessment in deï¬ning if an organism is a null segregant or contains an SDN-1 mutation: Host Where the organism, before or after the targeted genetic change: â€¢ Is not normally able to infect, colonise, or establish in humans. â€¢ Is not able to (or contain infectious agents normally able to) cause disease in humans, animals, plants, or fungi. and Genetic change Where any interventional genetic change to the organism (e.g., gene edit), including any change to the parental line(s) (e.g., genetic modiï¬cation), has been characterised. and
AgResearch	Proposal 8 - Low-risk fermentation	Other policy options	The limit on vessel size for fermentation is arbitrary. Regulations covering the use of large culture volumes are currently limiting the development of new enterprises in Aotearoa New Zealand. The limit on vessel size is arbitrary. For Risk Tier 1 and 2 organisms a means of containing the full volume (e.g., bund, holding tank) for subsequent treatment or destruction should be suï¬ƒcient.
AgResearch	Proposal 9 - Standards for containment facilities	Hybrid	An organisation should be able to decide whether outcome or prescriptive controls would suit their situation. A hybrid system the utilises both outcome-based or prescriptive controls, and which also allows for the use of GMD approvals across organisations would be the preferred option. An organisation of any size would be able to assess existing Approvals (if relevant to their purpose) and decide whether outcome or prescriptive controls would suit their situation and decide accordingly. There may be an initial spike in applications, but as coverage of diï¬€erent situations expands then the need for new applications/approvals would decrease. Also, there may be costs associated in initially obtaining an Approval, which is subsequently used by multiple organisations. How those costs may be recouped or evenly distributed will have to be considered.

AgResearch	Proposal 9 - Standards for containment facilities	Hybrid	Equivalent standards for both containment facilities and transitional facilities would be preferred.
AgResearch	Proposal 10 - Reviews of regulatory settings	Yes	Agree that the legislation should be reviewed every 5 years.
AgResearch	Proposal 10 - Reviews of regulatory settings	Other policy options	Due to the rapidity of developments in genetic technologies a five-year review cycle to update any list is far too slow. Agree that the legislation should be reviewed every 5 years. However, due to the rapidity of developments in genetic technologies, if specïï-c host species are going to be named in legislation, then a ï¬ve -year review cycle to update the list is far too slow. Ideally a Risk Tier should be descriptive rather than prescriptive, allowing organisations to make decisions on level of containment required for each host/vector system. The alternative is that a list of acceptable host/vector systems is held by the EPA and updated every three months.
AgResearch	Proposal 10 - Reviews of regulatory settings	Technical feedback	Ideally a Risk Tier should be descriptive rather than prescriptive, allowing organisations to make decisions on level of containment required for each host/vector system. The alternative is that a list of acceptable host/vector systems is held by the EPA and updated every three months.
9(2)(a)	Objectives	Objectives	Yes
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1.1 - Biosafety Committees	Yes	Yes
	Proposal 2 - Assessments for medicines	Yes	Yes
	Proposal 2 - Assessments for medicines	Yes	Yes
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 3 - Record-keeping requirements	Unsure	Unsure
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 5 - Movement between facilities	Yes	Yes
	Proposal 5 - Movement between facilities	Yes	Yes
	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes

9(2)(a)

Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 9 - Standards for containment facilities	Outcome-based	Shifting to outcome-based standards
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 9 - Standards for containment facilities	No	No
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes

9(2)(a)

Proposal 10 - Reviews of regulatory settings	Yes	Yes
Objectives	Objectives	Yes
Features and approach for regulatory framework	Features and approach for regulatory framework	Tiered regulation based on potential risk, and greater freedoms to modify the genome in low risk scenarios without extensive oversight.
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1.1 - Biosafety Committees	Yes	Yes
Proposal 2 - Assessments for medicines	Yes	Yes
Proposal 2 - Assessments for medicines	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	No	No

9(2)(a)

Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Eukaryotic somatic cells are very low risk, and should not be subject to the same requirements as research that utilizes whole organisms
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	In a research laboratory setting, 10 litres is a lot. But I suspect manufacturing requires a lot more.
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 9 - Standards for containment facilities	No	No
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Scientific technologies changes incredibly rapidly and if this regulatory oversight is going to remain in place, then it must be kept continuously up-to-date.
Proposal 10 - Reviews of regulatory settings	Yes	Yes

9(2)(a)	Proposal 10 - Reviews of regulatory settings	Yes	As above - science changes quickly.
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	Yes - "Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells". The concept that cell lines are considered organisms seems outdated and does not align with reality.
	Feedback on process/consultation	Feedback on process/consultation	Changes to these regulations is incredibly important to the future of science in New Zealand.
9(2)(a) - Victoria University of Wellington	Features and approach for regulatory framework	Features and approach for regulatory framework	A drop or complete removal of regulatory and administrative burden when working with low-risk organisms, as partially proposed in the 10 objectives.Clear and simple import and export regulations for biological items that do not contain living organisms.
9(2)(a) - Victoria University of Wellington	Proposal 1 - Risk-tiering framework	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 1 - Risk-tiering framework	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 1.1 - Biosafety Committees	Unsure	Unsure
9(2)(a) - Victoria University of Wellington	Proposal 1.1 - Biosafety Committees	Technical feedback	While the establishment of ABSCs sounds like a good way to reduce EPA involvement and burden, it may be prone to frequent review in areas/organisations with high staff turn-over. The time commitments of the committee members might also become significant if located in a large organisation.
9(2)(a) - Victoria University of Wellington	Proposal 2 - Assessments for medicines	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 2 - Assessments for medicines	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 3 - Record-keeping requirements	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 3 - Record-keeping requirements	No	No
9(2)(a) - Victoria University of Wellington	Proposal 3 - Record-keeping requirements	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 4 - Internal audit frequency	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 4 - Internal audit frequency	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 5 - Movement between facilities	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 5 - Movement between facilities	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
9(2)(a) - Victoria University of Wellington	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	I don't work with somatic cells.

9(2)(a) - Victoria University of Wellington	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 7 - Regulatory status of biotechnologies	Unsure	Unsure
9(2)(a) - Victoria University of Wellington	Proposal 7 - Regulatory status of biotechnologies	Unsure	This statement is too broad. DNA is introduced into laboratory organisms on a daily basis to do exactly that: change the organisms genetic set-up. How will this be effected? These changes are aimed at introduction of RNA/DNA and epigenetic changes on humans mainly, but it is not clear to me what this will entail for other organisms, e.g. bacteria.
9(2)(a) - Victoria University of Wellington	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 7 - Regulatory status of biotechnologies	Other policy options	Don't limit the introduction of DNA into laboratory organisms. (classical Transformation, Transfection, Transduction)Make these points specific to vaccines or use in humans.
9(2)(a) - Victoria University of Wellington	Proposal 8 - Low-risk fermentation	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 8 - Low-risk fermentation	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 8 - Low-risk fermentation	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
9(2)(a) - Victoria University of Wellington	Proposal 9 - Standards for containment facilities	Hybrid	More freedom to deal with old buildings and/or challenging building sites.
9(2)(a) - Victoria University of Wellington	Proposal 9 - Standards for containment facilities	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 9 - Standards for containment facilities	No	No
9(2)(a) - Victoria University of Wellington	Proposal 10 - Reviews of regulatory settings	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 10 - Reviews of regulatory settings	Yes	Keeping the legislation up to date with the latest technological development would be very desirable.
9(2)(a) - Victoria University of Wellington	Proposal 10 - Reviews of regulatory settings	Yes	Yes
9(2)(a) - Victoria University of Wellington	Proposal 10 - Reviews of regulatory settings	Yes	A good compromise between technological advancement and legislational time frames
9(2)(a) Victoria University of Wellington	Proposal 10 - Reviews of regulatory settings	Yes	Yes
9(2)(a) - Victoria University of Wellington	Alternative options	Alternative options	Making Risk group 1 and 2 exempt from EPA assessment would be beneficial.
9(2)(a) - Victoria University of Wellington	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Make work with all low risk group microorganisms exempt dealings.

Auckland GE-Free Coalition	Out-of-scope policy ideas	Out-of-scope policy ideas	1. Liability to encourage compliance and moderate appetite for risk - â€™socialised riskâ€™ that creates a public subsidy for developments that are commercially oriented, rather than holding users liable and requiring they have insurance to mitigate risk and fund remediation.
Auckland GE-Free Coalition	Out-of-scope policy ideas	Out-of-scope policy ideas	- lack of high level ethical oversight since the abolition of the Bioethics Council, leaving a lower-level of oversight for animal welfare by institutional committees that have failed in the past to uphold community expectations. See the AgResearch animal experiments - industry continuing with projects to use animals as bioreactors, against the recommendations of the Royal Commission on Genetic Modification. 7.5 of the Royal Commission on Genetic Modification, â€œThat, wherever possible, non-food animals, or animals less likely to find their way into the food chain, be used as bioreactors rather than animals that are a common source of food.â€ The intent of this recommendation is to ensure that GM animals and animal products do not unintentionally enter the human food chain. But the Government decided no further action was required as the current legislative and regulatory requirements would already prevent bioreactors entering the food chain unintentionally. In Aug 2003 to Aug 2004: The Bioethics Council conducted a detailed investigation into the ethical issues surrounding human genes in other organisms, and concluded that the Government should adopt this recommendation (Bioethics Council, 2004a; 2004b; NFO, 2004). However this was not implemented, and the review of regulations now is a time to address the â€¯Business as Usualâ€™ for animals as bioreactors with implicit approval in the consultation document proposal. The consultation document identifies the need for higher security containment for animals with the ability to escapeâ€™i.e.referring to those animals that have the ability to escape their cages/containers. â€œ a documented system of accounting must be in place for: â˜ new organisms in containment facilities operated at PC3 â˜ animals with the ability to escape, for all containment facilities.â€ But this should not be going on at all with â€¯food animalsâ€™ according to the RCGM and Bioethics Council. The new rules should ensure the protections envisaged by both these bodies are respected. As well breaches of containment in New Zealand, mistakes have happened more than once overseas where GE experimental animals have accidentally entered the food chain. This must be prevented by the regulations. (https://www.iatp.org/news/genetically-modified-pigs-made-into-chicken-feed)
Auckland GE-Free Coalition	Feedback on process/consultation	Feedback on process/consultation	The proposals have been developed to respond to industry concerns that current regulations are too hard to be workable. It is important to consider their concerns but also to weigh up the community concerns for effective regulations that are not compromised by industry self interest which could undermine the â€¯social licenseâ€™ to operate. The protections provided under the HSNO Act are considered important by wider civil society and fit for purpose. Whilst some aspects of the proposals seem reasonable on first reading, the detail is yet to be worked out in conjunction with industry. This process to progress the proposals is vulnerable to industry interests being allowed to define and dominate the regulatory approach and requirements. There is a conflict of interest between devolved self-regulation by users of biotechnology and community expectations of independent oversight and strict regulation to ensure containment and prevent escape or shedding. This conflict must be managed and lessons learned from previous failures in compliance by industry.
Auckland GE-Free Coalition	Proposal 1 - Risk-tiering framework	Other policy options	3. Recognise the blurred boundaries of technologies and do not weaken definitions of containment The consultation document does not seek to change rules on release of GMOs outside laboratory settings for field trials and release into the environment. But the scope of what defines a 'laboratory' is not clear and the consultation document must not be used to loosen definitions so that sites are no longer fully contained because they are deemed lower risk. Definition of a lab must include the highest level containment facilities for GE cows, sheep and other animals engineered to be bio-reactors to produce pharmaceuticals. The highest level of containment is also needed for micro-organisms, bacteria and viruses. The line between inside and outside can become blurry, but must be prescriptive. 'Containment' becomes a relative term across different uses of biotechnology. It is possible that transmission 'outside' the lab could occur from a patient undergoing therapy and shedding or from the introduction of a novel vaccine.
Auckland GE-Free Coalition	Proposal 2 - Assessments for medicines	Other policy options	4. Regulation of GE in biomedicine needs to manage new pathways of risk from combinations of emerging technologies and their wider use There is a convergence of Genetic Engineering, Nanotechnology, Synthetic Biology and AI that brings new and more complex risks that need to be recognised and managed. There is increased use of nano-particles to penetrate cell membranes and to provide longevity for novel therapeutic proteins that could make containment less effective. But there is nothing in the consultation document to show these emerging risks are being considered. The scale of risk will expand as new players enter the industry, perhaps less proficient or less professional than the universities and established research centres. The proposals for more self-regulation and reduced reporting but with a lack of monitoring, will create new vulnerabilities.

Auckland GE-Free Coalition	Out-of-scope policy ideas	Out-of-scope policy ideas	Regulations must require laboratories be notified to Councils to ensure effective planning controls for risk of floods, fire and earthquakes. Oversight must be independent of the industry-user to ensure risky experiments are not located near communities or in areas of primary production where biosecurity threats from accidental contamination would be most serious. New Zealand legislation must address this concern and learn from the experience and concerns raised internationally Friends of the Earth, International Center for Technology Assessment, Center for Genetics and Society, and Alliance for Humane Biotechnology have launched a campaign to bring transparency and civil oversight to the siting and operations of biolabs. The project seeks to secure biosafety and ethically responsible research. (http://www.humanebiotech.org/new-page-30) A letter addressed to the City Council of Berkeley is relevant to local government in New Zealand and warns: â€œcivic leaders are not taking necessary precautions in siting biolabs. Biolabs are facilities that can house research on pre-existing as well as novel pathogens and research on genetically engineered plants and animals, even potentially humans. This kind of research is increasingly raising concerns for residents, particularly for public health and the environmental risks of potential lab leaks.â€ â€œWe are especially concerned that these facilities are being established or expanded in densely populated areas and, importantly, where flooding, sea level rise, and earthquakes are real and perennial threats.â€ Regional councils including Hawkes Bay and councils from Cape Reinga to Auckland have precautionary policies on GMOs in their plans. Changes to the RMA may impact this and the MFE must include the needs of regional councils within any proposed changes. (https://www.aucklandcouncil.govt.nz/plans-projects-policies-reports-bylaws/our-plans-strategies/unitary-plan/history-unitary-plan/docs349geneticallymodifiedorganisms/Appendix-3.49.16.pdf) The proposed new rules must include planning notifications so that Local and Regional councils and Civil Defence know where bio-medical research facilities are located.
Auckland GE-Free Coalition	Feedback on process/consultation	Feedback on process/consultation	6. Failure of industry and regulators to acknowledge and address complex safety issues. The risk-appetite of industry may be driven by professional and commercial interests and undermine effective regulation where the user is not independent of the regulating body. Past and recent failures of containment show that mistakes can happen, and has created a trust issue amongst the public who have seen industry promises of caution and responsibility betrayed in the past. (https://biosafetynow.org/lab-accidents-and-mishaps/) The consultation document omits any mention of moderating risk-taking amongst research organisations and biotechnology companies by holding them strictly liable. This is a fundamental weakness in the proposals for self- assessment and regulation and will undermine public confidence unless independent regulation is mandatory at all levels of risk. The 2007 United Kingdom foot-and-mouth outbreak occurred when the discharge of infectious effluent from a laboratory in Surrey led to foot and mouth (FMD) infections at four nearby farms. (https://en.wikipedia.org/wiki/2007_United_Kingdo m_foot-and-mouth_outbreak) Sometimes there is scientific disagreement about what has gone wrong or what to do about it. (https://oversight.house.gov/release/hearing-wrap-up-suppression-of-the-lab-leak-hypothesis-was-not-based-in-science/) Sometimes the failure is for the simplest of reasons, such as the size of mesh being too large to prevent escape of smaller seeds or eggs out of the lab. There is also human error. (https://www.scoop.co.nz/stories/PA0106/S00267/escape-of-ge-salmon-eggs-highly-likely.htm?from-mobile=bottom-link-01)
Auckland GE-Free Coalition	Feedback on process/consultation	Feedback on process/consultation	7. Risks from Converging interests There is a clear issue of conflict of interest when organisations are seeking to profit from an innovation and choose to minimise the scope and recognition of risk. The non-consideration of complex risk â€“ turning a blind eye, is even built in to the approach taken by regulators, and by government agencies promoting innovation and new technology at all cost. For example regulators ignore synergistic effects from agro-chemicals and pretend it doesn't matter. (https://psgr.org.nz/component/jdownloads/send/1-root/106-23-propaganda'when%20does%20science%20become%20propaganda') Investors in new medicines and therapies may have a greater appetite for risk than an independent assessor, and may ignore issues that could slow the path of their product to commercialisation.
Auckland GE-Free Coalition	Proposal 7 - Regulatory status of biotechnologies	No	Industry views to support exemptions of RNA as a GMO technology are not based on evidence that shows the need for regulation and that safety cannot be assumed. It is incorrect to say that the introduction of ribonucleic acid (RNA) using Clustered Regularly Interspaced Short Palindromic Repeat (CRISPR) should be exempted from regulation as would not alter the genome of the host cells. The consultation document itself refers to technology that does not integrate into DNA when there is evidence that this can indeed happen against the belief of some scientists. See: https://www.mdpi.com/1467-3045/44/3/73#B25-cimb-44-00073 Intracellular Reverse Transcription of Pï¬zer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. In this study we present evidence that COVID-19 mRNA vaccine BNT162b2 is able to enter the human liver cell line Huh7 in vitro. BNT162b2 mRNA is reverse transcribed intracellularly into DNA as fast as 6 h after BNT162b2 exposure. A possible mechanism for reverse transcription is through endogenous reverse transcriptase LINE-1, and the nucleus protein distribution of LINE-1 is elevated by BNT162b2.
Auckland GE-Free Coalition	Proposal 1.1 - Biosafety Committees	No	8. The proposals embed rather than address potential conflicts of interest within committees tasked with regulating themselves A fatal flaw in the consultation proposals is relying on the users of the technology to define what to consider as low, medium and high risk, and then to apply the right restrictions on themselves.
Auckland GE-Free Coalition	Feedback on process/consultation	Feedback on process/consultation	The details are to be worked out if changes get approved by cabinet, but the consolation document already reveals disputed scientific views. This demands mandatory precaution rather than a relaxed attitude based on incomplete knowledge or active ignorance of existing data that may conflict with industry wishes. This view that industry have â€˜settled any safety issues for GMOs is patently false and encourages scientists to stop considering emerging evidence or apply critical thinking.

B+LNZ	Objectives	Objectives	Beef + Lamb New Zealand (B+LNZ) is satisfied that the objectives proposed are appropriate for laboratory research and therapeutics for human medicine.
B+LNZ	Features and approach for regulatory framework	Features and approach for regulatory framework	B+LNZ wishes to highlight that additional objectives and considerations are required where any future release or cultivation of GMOs is considered In particular, B+LNZ strongly favours inclusion of economic prosperity and the protection of New Zealandâ€™s trade and reputation among considerations that must be taken into account when deciding upon permitting the release or cultivation of GMOs.
B+LNZ	Proposal 1 - Risk-tiering framework	Yes	B+LNZ agrees with implementing a regulatory regime that adopts a risk- based approach and minimises regulatory impost on researchers. If it has not already done so, B+LNZ recommends that the EPA also looks beyond Australia to assess the benefits and constraints associated with other frameworks internationally before reaching conclusions on the most desirable settings for New Zealand.
B+LNZ	Proposal 1 - Risk-tiering framework	Yes	B+LNZ understands the intent of the proposals and is not aware of any issues that are relevant and not included.
B+LNZ	Proposal 1 - Risk-tiering framework	Other policy options	B+LNZ commissions but does not undertake laboratory research and expects that individuals and entities directly affected by these proposals have been engaged to provide input to the EPA on alternative policy options during the formulation of those presented. B+LNZ is insufficiently familiar with the operating environment to comment on the proposed establishment of accredited biosafety committees and an Environmental Protection Authority biosafety committee to support the risk-tiering framework (questions 6 and 7).
B+LNZ	Proposal 2 - Assessments for medicines	Unsure	B+LNZ has no position on regulating approvals for biomedical therapies. It is our understanding that these proposals relate exclusively to human, and not to veterinary, medicines. GM and adjacent technology also hold great potential for veterinary medicine and the livestock production industries.
B+LNZ	Proposal 3 - Record-keeping requirements	Yes	B+LNZ agrees in principle with this proposal and supports fully secure, unique identification and whole of life tracking to apply to any genetically modified bovines or small ruminants. B+LNZ is insufficiently familiar with the operational details to make further comments on this proposal.
B+LNZ	Proposal 4 - Internal audit frequency	Yes	B+LNZ supports this proposal to reduce the administrative burden on researchers.
B+LNZ	Proposal 4 - Internal audit frequency	Other policy options	B+LNZ suggests that audit failures identified by external inspections should be accompanied by more frequent external inspection at the expense of the institution in question. Alignment with IANZ and NATA laboratory audit processes should be considered to minimise duplication of effort for researcher and institutions.
B+LNZ	Proposal 5 - Movement between facilities	Yes	B+LNZ supports this proposal with appropriate safeguards and sanctions for non-compliance.
B+LNZ	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	B+LNZ supports the intent of this proposal. Noting that somatic eukaryotic cells are incapable of a free-living existence and are unable to survive outside of a laboratory, B+LNZ questions whether the prohibition on the donor nucleic acid being from any form of pathogen is unduly restrictive. The condition that â€œThe donor nucleic acid must not code for a toxin with an LD50 of less than 100 micrograms per kilogramâ€ appears to duplicate the condition that donor nucleic acid must not be derived from a pathogen and requires further definition noting that LD50 values require framing in the context of a target species.
B+LNZ	Proposal 7 - Regulatory status of biotechnologies	Unsure	B+LNZâ€™s support for this proposal is conditional on any therapeutic or performance enhancing products or technologies that are applicable to food producing animals being designated as veterinary medicines or agricompounds under the ACVM Act 1997. This is so that risks to food safety and trade can be properly assessed under section 20 of ACVM Act 1997, prior to the use of these in New Zealand. Regarding technologies yet to emerge and to future-proof the HSNO Act, B+LNZ proposes that the EPA, analogous with its ability to initiate reassessments of hazardous substances, be empowered to initiate a Statutory Determination to clarify the regulatory status of a technology. B+LNZ also believes there may be simple and inexpensive solutions to increasing the transparency of existing determinations and that these should be explored by the EPA.
B+LNZ	Proposal 7 - Regulatory status of biotechnologies	Technical feedback	B+LNZâ€™s support for this proposal is conditional on any therapeutic or performance enhancing products or technologies that are applicable to food producing animals being designated as veterinary medicines or agricompounds under the ACVM Act 1997. This is so that risks to food safety and trade can be properly assessed under section 20 of ACVM Act 1997, prior to the use of these in New Zealand. Regarding technologies yet to emerge and to future-proof the HSNO Act, B+LNZ proposes that the EPA, analogous with its ability to initiate reassessments of hazardous substances, be empowered to initiate a Statutory Determination to clarify the regulatory status of a technology. B+LNZ also believes there may be simple and inexpensive solutions to increasing the transparency of existing determinations and that these should be explored by the EPA.
B+LNZ	Proposal 8 - Low-risk fermentation	Yes	B+LNZ supports this proposal as it aligns with Proposal 1 and may reduce the administrative burden on the research community.
B+LNZ	Proposal 8 - Low-risk fermentation	Unsure	B+LNZ believes that the research community is best placed to advise on appropriate thresholds and how these may impact their operations. The EPA should publish the rationale for originally deciding upon the 10-litre limit, which would then allow for a more transparent assessment of its appropriateness in light of subsequent advances in technology and operating practice.
B+LNZ	Proposal 8 - Low-risk fermentation	Technical feedback	The EPA should publish the rationale for originally deciding upon the 10-litre limit, which would then allow for a more transparent assessment of its appropriateness in light of subsequent advances in technology and operating practice.
B+LNZ	Proposal 9 - Standards for containment facilities	Outcome-based	B+LNZ supports outcome-based standards as these better allow for innovation when compared with prescriptive measures. However, in this case option 3 â€“ the hybrid approach - appears to offer the benefits of outcome-based standards with ease of application for smaller entities, and for this reason is preferred.
B+LNZ	Proposal 10 - Reviews of regulatory settings	Yes	B+LNZ agrees with requiring MfE to review the regulatory settings for GMOs periodically, as this will ensure priority is afforded to this particularly important area among competing policy priorities. B+LNZ notes that a review of settings may also be initiated at any time in the future if considered necessary, as is currently the case.
B+LNZ	Proposal 10 - Reviews of regulatory settings	Yes	B+LNZ does not support the requirement for reviews being shorter than the five-year period proposed for reasons of cost and stability of the regulatory regime.

Biological safety and compliance team, University of Canterbury	Objectives	Objectives	Submission on the Ministry for the Environmentâ€™s consultation document: Improving our GMO regulations for laboratory and biomedical research: Consultation document.
Biological safety and compliance team, University of Canterbury	Objectives	Objectives	Q1: Yes, broadly, the objectives are sound but could be expanded to include mÄtauranga, food security, climate change and other environmental outcomes. In our opinion, the objective of any change to the regulatory framework requirements cannot focus solely on the statement made in Part 2 Section 4 of the HSNO Act as it must also ensure that it encompasses Part 2 Section 5 Principles relevant to the purpose of Act, Section 6 Matters relevant to purpose of Act and section 8 Treaty of Waitangi. These sections include the protection of biodiversity â€œthe sustainability of all native and valued introduced ï¬,ora and fauna, the intrinsic value of ecosystemsâ€, economic trade treaty requirements â€œthe economic and related beneï¬ts and costs of using a particular hazardous substance or new organismsâ€, and Treaty matters â€œrelationship of MÄori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued ï¬,ora and fauna, and other taongaâ€ respectively.
Environmental Defence Society	Objectives	Objectives	Objectives (questions 1, 2) 4.Recent advances in technology now enable DNA to be modiï¬ed in a much more targeted and controlled manner. The genomic modiï¬cations in the recipient organism can also now be analysed with considerable precision and the overall changes to the organism evaluated prior to release from containment. It is therefore timely for Aotearoa New Zealandâ€™s very restrictive regulations to be brought into better alignment with the actual risks involved. 5.EDS therefore supports and endorses the overall objectives detailed in the Consultation Document. The current regulations are seriously out of date and are no longer ï¬t for purpose. They need updating to reï¬,ect the major advances in knowledge that have occurred in the ï¬eld of genetic modiï¬cation since the time the current legislation was ï¬st enacted and to bring them in line with international best practice, particularly with regulations applying in Australia. Such an alignment is compelling given the close scientiï¬c, commercial and industrial ties between our two countries and the growing trans-Tasman traï¬fc in food and agricultural products.
Environmental Defence Society	Proposal 1 - Risk-tiering framework	Proposal 1 - Risk-tiering framework	Proposal 1: Introduce a risk-tiering framework for laboratory research (questions 3, 4, 5) 6.EDS is supportive of the proposal to reduce the administrative requirements associated with low- risk research by establishing a risk-tiering framework modelled on Australian regulations. EDS also supports the adoption of the Australian system which speciï¬es that any unapproved release of GMOs into the environment should be prohibited. 7.We agree that the EPA should undertake additional consultation on the details of each risk tier, including which organisms, modiï¬cations, vectors and exclusionary criteria would be included under each risk tier.
Environmental Defence Society	Proposal 1 - Risk-tiering framework	Yes	EDS is supportive of the proposal to reduce the administrative requirements associated with low- risk research by establishing a risk-tiering framework modelled on Australian regulations. EDS
Environmental Defence Society	Proposal 1 - Risk-tiering framework	Agree with proposal	EDS also supports the adoption of the Australian system which speciï¬es that any unapproved release of GMOs into the environment should be prohibited.
Environmental Defence Society	Proposal 1 - Risk-tiering framework	Agree with proposal	We agree that the EPA should undertake additional consultation on the details of each risk tier, including which organisms, modiï¬cations, vectors and exclusionary criteria would be included under each risk tier.
Environmental Defence Society	Proposal 1.1 - Biosafety Committees	Proposal 1.1 - Biosafety Committees	Proposal 1.1: Transferring decision making to Institutional Biosafety Commi[ees (questions 6, 7) 8.EDS is supportive of transferring initial approval of an application from the EPA to Institutional Biosafety Committees. Such a transfer would encourage researchers to be compliant and would also bring the consideration of applications before local panels where expertise is arguably better than that available under the current centralised system. Beneï¬ts would also accrue in the form of reduced cost. 9.The proposed arrangement has parallels with those for animal experimentation which are matters also controlled by Institutional Committees under the recently reviewed Animal Welfare Act 2018. Those institutions which are either too small or lacking in expertise can access approved Institutional Committees under that Act.
Environmental Defence Society	Proposal 1.1 - Biosafety Committees	Agree with proposal	8.EDS is supportive of transferring initial approval of an application from the EPA to Institutional Biosafety Committees. Such a transfer would encourage researchers to be compliant and would also bring the consideration of applications before local panels where expertise is arguably better than that available under the current centralised system. Beneï¬ts would also accrue in the form of reduced cost.
Environmental Defence Society	Proposal 1.1 - Biosafety Committees	Unsure	9.The proposed arrangement has parallels with those for animal experimentation which are matters also controlled by Institutional Committees under the recently reviewed Animal Welfare Act 2018. Those institutions which are either too small or lacking in expertise can access approved Institutional Committees under that Act.

Environmental Defence Society	Proposal 1.1 - Biosafety Committees	Other policy options	The proposed arrangement has parallels with those for animal experimentation which are matters also controlled by Institutional Committees under the recently reviewed Animal Welfare Act 2018. Those institutions which are either too small or lacking in expertise can access approved Institutional Committees under that Act.
Environmental Defence Society	Proposal 2 - Assessments for medicines	Proposal 2 - Assessments for medicines	10.EDS submits that the release of medical and/or veterinary medicines that contain live organisms into the general environment is a matter of greater complexity than the Consultation Document appears to consider. The minimal scientiï¬c content in the Impact Assessment contained in the Appendix conï¬rms our view. The ï¬rst proposed change is the removal of the current ï¬rst stage of section 38I assessments, involving the evaluation of whether a new organism meets the criteria of a (low-risk) â€˜qualifying organismâ€™. 11.EDS has concerns about this proposition. We consider that it requires more robust scientiï¬c evaluation and perhaps a more detailed discussion with regulatory counterparts in Australia. 12.There appears to be an assumption inherent in this proposal that the assessment of risks involved in the release of viable organisms into the environment can be made in a rapid manner. Live human vaccines, for example, provide an instructive example. For those which have already been approved by the FDA, extensive initial evaluation work will already have been undertaken, followed by extensive human clinical trials. But all vaccines are not of US or European origin and safety standards vary. To determine whether a live viral vaccine sourced from elsewhere is indeed of low risk would require considerable investment of time and eï¬€ort. 13.The situation is signiï¬cantly more complicated for live veterinary vaccines. Signiï¬cant numbers of animal / human viruses and bacteria are capable of initiating zoonotic infections (replicating in both animals and humans). Coronaviruses are an example of this phenomenon. Where there is this type of potential for zoonotic transmission/ infection, the assessment of risk is likely to be neither simple nor rapid. The second proposed change is to introduce an alternative assessment pathway for medicines that are unlikely to result in viable new organisms making their way into the environment. Under this rapid assessment pathway, application information requirements would concentrate on whether, through shedding or excretion, the new organism is likely to make its way into the environment. 14.Similar concerns to those expressed above also apply to this proposition. The use of disabled viral vectors to deliver payloads to human subjects is now relatively widespread at the research level. How might one rapidly evaluate the risk of potential horizontal transmission to the animal kingdom? Given that there is a considerable range of microorganisms that are potentially zoonotic, how might such an assessment be made rapidly? Information from the US Communicable Disease Centre would probably be reliable, but there are many other potential international sources for human medicines where appropriate regulatory standards may not necessarily be considered appropriate.
Environmental Defence Society	Proposal 2 - Assessments for medicines	Unsure	10.EDS submits that the release of medical and/or veterinary medicines that contain live organisms into the general environment is a matter of greater complexity than the Consultation Document appears to consider. The minimal scientiï¬c content in the Impact Assessment contained in the Appendix conï¬rms our view.
Environmental Defence Society	Proposal 3 - Record-keeping requirements	Proposal 3 - Record-keeping requirements	Proposal 3: Replace current record-keeping requirements (questions 11, 12, 13, 14) 17.EDS is supportive of the proposed changes. These changes should simplify and standardise the record keeping system and better align it with the known low risk of procedures carried out in approved laboratories
Environmental Defence Society	Proposal 4 - Internal audit frequency	Proposal 4 - Internal audit frequency	Proposal 4: Adjust internal audit frequency to be proportionate to risk (questions 15, 16, 17) 18.EDS supports these proposals.
Environmental Defence Society	Proposal 5 - Movement between facilities	Proposal 5 - Movement between facilities	Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk (questions 18,19 20) 19.EDS considers that the proposed changes are well thought out and we have no issue with the changes that are proposed.

Environmental Defence Society	Proposal 6 - Requirements for eukaryotic somatic cells	Proposal 6 - Requirements for eukaryotic somatic cells	Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells (questions 21, 22, 23) 20.The Consultation Document states: â€œEukaryotic cells are cells of eukaryotes, which as a category include animals, plants, fungi and many unicellular organisms, and which are distinct from bacteria and archaea.â€ And â€œThe plant cells or tissues cannot spontaneously generate a whole plant and cannot be regenerated into a whole plant.â€ 21.From a strictly scientïï¬c viewpoint, it is generally correct to state that somatic cells of eukaryotic (animal) origin generally cannot be regenerated into whole organisms. But, even for human cells, recent genetic advances have blurred that line. It is now evident that under some circumstances somatic mammalian cells can now be reprogrammed to a haploid state (i.e., equivalent to reproductive cells). 22.For the majority of higher plants, it has been known for many years that somatic cells can readily be regenerated into whole plants by the appropriate manipulation of the in vitro culture conditions. And for fungi, the majority can readily transit to the appropriate sporifying and/or sexual reproductive state. 23.Therefore, while it may be acceptable currently to exempt human eukaryotic vertebrate somatic cells from regulatory controls, it could be unwise to include animal, plant and fungal cells within the group for which regulation is proposed to be relaxed. 24.The New Zealand economy currently remains heavily dependent on the products derived from plants used in agriculture, forestry and horticulture. Given the ability of most cultured diploid plant somatic cells to be regenerated into whole plants, the proposal to exclude plant cells from regulatory controls is highly questionable. Containment within the laboratory environment would be diï¬ƒcult to guarantee should an investigator choose to regenerate viable diploid transgenic plants which will be able to survive outside the laboratory. 25.In our view fungi should be totally excluded from the exempt status envisaged in this proposal given that fungal diseases of plants are particularly diï¬ƒcult to control.
Environmental Defence Society	Proposal 7 - Regulatory status of biotechnologies	Proposal 7 - Regulatory status of biotechnologies	Proposal 7: Clarify the regulatory status of certain biotechnologies (questions 24, 25, 26, 27) 26.The regulatory changes proposed are well craked and are supported.
Environmental Defence Society	Proposal 8 - Low-risk fermentation	Proposal 8 - Low-risk fermentation	Proposal 8: Reduce assessment requirements for low-risk fermentation (questions 28, 29, 30, 31) 27.The proposal speciï¬ed is supported. EDS considers that the proposed 10L maximum, which will not require EPA approval, should be maintained. In our view this volume is probably a reasonable limit / transition point given that it represents a reasonable laboratory scale activity. Above 10L volume, the exercise becomes essentially one constituting Pilot Scale fermentation. That should optimally be undertaken in an appropriately designed specialised fermentation facility.
Environmental Defence Society	Proposal 9 - Standards for containment facilities	Proposal 9 - Standards for containment facilities	Proposal 9: Maintain or adjust the approach to standards for containment facilities (questions 32, 33, 34, 35) 28.There are generally accepted international standards for containment laboratories. EDS has no particular views on the options presented other than to point out that it is obviously preferable for both New Zealand citizens and organisations and their overseas counterparts to have conï¬dence in the integrity of the local containment systems employed. 29.There does not appear to be any justïï¬cation made for New Zealand to design its own particular unique hybrid systems. Indeed, if that were to happen there is the risk that other parties would not recognise them when considering transfers of materials into New Zealand and / or accepting transfers of New Zealand material into their own jurisdictions 30.Containment facilities are expensive both to construct and to maintain. As GMO knowledge progresses, it would appear desirable for existing facilities to be designed in such a manner as to be able to cope with both reduced and increased standards because regulations are likely to require further amendment or reï¬nement. There appears to be a strong case for New Zealand to align its standards with those which apply in Australia.
Environmental Defence Society	Proposal 10 - Reviews of regulatory settings	Proposal 10 - Reviews of regulatory settings	Proposal 10: Require regular reviews of regulatory se`ngs (questions 35, 36, 37, 38, 39) 31.EDS supports the proposed implementation of a 5 year review cycle because the GMO ï¬eld is progressing at a rapid pace. The suggested statutory requirement for a 5 year review of regulatory settings is a reasonable one in these circumstances.
Environmental Defence Society	Proposal 10 - Reviews of regulatory settings	Yes	EDS supports the proposed implementation of a 5 year review cycle because the GMO ï¬eld is progressing at a rapid pace. The suggested statutory requirement for a 5 year review of regulatory settings is a reasonable one in these circumstances.
Environmental Defence Society	Proposal 10 - Reviews of regulatory settings	Agree with frequency	The suggested statutory requirement for a 5 year review of regulatory settings is a reasonable one in these circumstances.
9(2)(a)	Objectives	Objectives	Unsure
	Features and approach for regulatory framework	Features and approach for regulatory framework	Safety first.Direct address of gene editing, which does not necessarily fall under the "in vitro" definition - gene editing is usually "in vivo".

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Proposal 1 - Risk-tiering framework	No	No
Proposal 1 - Risk-tiering framework	No	No
Proposal 1 - Risk-tiering framework	Other policy options	Explicitly including gene editing into the text.
Proposal 1 - Risk-tiering framework	Technical feedback	Explicitly including gene editing into the text.
Proposal 1.1 - Biosafety Committees	Yes	Yes
Proposal 1.1 - Biosafety Committees	Other policy options	No
Proposal 2 - Assessments for medicines	No	No
Proposal 2 - Assessments for medicines	No	No
Proposal 3 - Record-keeping requirements	No	No
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	No	No
Proposal 3 - Record-keeping requirements	No	No
Proposal 1.1 - Biosafety Committees	No	No
Proposal 1 - Risk-tiering framework	Other policy options	Explicitly including gene editing into the text.
Proposal 3 - Record-keeping requirements	Other policy options	No change needed. Current system works.
Proposal 4 - Internal audit frequency	No	No
Proposal 5 - Movement between facilities	No	No
Proposal 5 - Movement between facilities	No	No
Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Proposal 7 - Regulatory status of biotechnologies	No	No

9(2)(a)

Proposal 7 - Regulatory status of biotechnologies	No	No
Proposal 7 - Regulatory status of biotechnologies	Technical feedback	"introduction of DNA into an organism"That would mean that a bacterium carrying a engineered plasmid is no longer a GMO?The wording "independently replicative" here is incorrect. Plasmids are not independently replicative since they rely on host cell machinery.This is written really badly. Hard no.
Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	Any element that is persistent horizontally (to subsequent generation) or can be transferred vertically.Any element that is intended to harm or kill the host organism.Any element that contains an origin of replication, promoter or ribosomal binding site.
Proposal 7 - Regulatory status of biotechnologies	Other policy options	You really need to think about what you want to achieve. It would make more sense to me to get rid of the exceptions for chemical mutagenesis and cell fusions and fold them into the GMO regulation.
Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	If researchers only grudgingly follow the current rules, maybe they should not be trusted to write the new ones?
Proposal 8 - Low-risk fermentation	Unsure	Unsure
Proposal 8 - Low-risk fermentation	No	No
Proposal 8 - Low-risk fermentation	No	No
Proposal 9 - Standards for containment facilities	Status quo	Keeping the status quo approach
Proposal 9 - Standards for containment facilities	No	No
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Costs, benefits or risks	Costs, benefits or risks	You seem to up-play the benefits and down-play the risks.
Te ao Maori	Taonga species	Yes
Te ao Maori	Taonga species	Option 1 and 3 seems to be the in accordance with Te Tiriti.Option 2 is a clear overstepping by the crown. Embarassing to even have it in here.
Useful quotes	Useful quotes	I am not here to give a lecture, but a simple GMO yeast may seem harmless, but once it got out, it may have devastating effects on ecosystems and food production by simply outcompeting and replacing native yeast species. You cannot predict the impact. Period.
Useful quotes	Useful quotes	It is also in human nature that a relaxation of regulations in one area leads to a decrease of vigilance in related areas. Making some GMOs "less bad" than others will lead to an overall lower standard of compliance.
Useful quotes	Useful quotes	I would very much have stricter regulations on something that has the potential of serious unintended consequences.
Objectives	Objectives	Yes

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Features and approach for regulatory framework	Features and approach for regulatory framework	A sensible, scientific, and evidence-based approach to risk-management that is not excessively restrictive, and allows smaller organisations to innovate and compete in the biotech space without undue regulatory requirements.
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1.1 - Biosafety Committees	Yes	Yes
Proposal 2 - Assessments for medicines	Yes	Yes
Proposal 2 - Assessments for medicines	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes

9(2)(a)	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
	Proposal 9 - Standards for containment facilities	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
	Proposal 9 - Standards for containment facilities	No	No
	Proposal 9 - Standards for containment facilities	No	No
Matthew Mayo-Smith	Objectives	Objectives	Yes
Matthew Mayo-Smith	Features and approach for regulatory framework	Features and approach for regulatory framework	1- Reduced regulation for low risk GMOThe current regulations for low risk GMO is overly cautious and does not accurately reflect the danger that the GMO represent to the New Zealand environment.2-Move from methods based risk assessment to outcomes based.Under the current legislation, too much emphasis is placed on how genetic modifications are achieved rather than what the outcome of the desired modifications may be. The methods of genetic modification are just a means to an end and it is not prudent to regulate all "in vitro manipulation" techniques the same when the specific outcomes of different techniques can vary by type, nature and effect. Regulating GMO by the risk of the specific outcomes (i.e transgenic versus small mutations indistinguishable from natural variation) and organism/cell type (i.e somatic/germ line and invasive vs low risk) would be more appropriate.
9(2)(a)	Proposal 1 - Risk-tiering framework	No	Australian politics are traditionally more open to risk and less focussed on preseravtion of the ecosystem or consumer safety.
	Proposal 1 - Risk-tiering framework	No	Risk tiers are arbitrary and a risk upon unintended release cannot efficiently assessed beforehand. It also introduces a political dimension in which lobbyists and special interest groups can pressure the governing body into lowering risk classes for their benefit.A maximum safety approach is needed to protect Aotearoa's unique ecosystem.It is also in human nature that a relaxation of regulations in one area leads to a decrease of vigilance in related areas. Making some GMOs "less bad" than others will lead to an overall lower standard of compliance.
	Proposal 1.1 - Biosafety Committees	No	An independent body for risk assessment is needed, and will require sufficient funding.
	Proposal 2 - Assessments for medicines	No	"unlikely to result in viable new organisms making their way into the environment" is snake oil. If there is any risk, they need to be handled appropriately. This will just lead to dishonesty in applications with risks being downplayed.Every single GMO is a potentially catastrophic risk to the environment because a) once it's out, you never catch it again and b) we have no idea what interactions with other organisms we have to expect.I am not here to give a lecture, but a simple GMO yeast may seem harmless, but once it got out, it may have devastating effects on ecosystems and food production by simply outcompeting and replacing native yeast species. You cannot predict the impact. Period.
	Proposal 2 - Assessments for medicines	No	Seems to be a made-up problem to justify changes. Most applications get rapidly assessed = system is working as intended.
	Proposal 2 - Assessments for medicines	Other policy options	The current system seem to work well.

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Proposal 3 - Record-keeping requirements	No	No reason is given what the problems with the current system are.Why do only animal have the "the ability to escape"? Spores, seeds and just simple mechanical transfer enable all GMOs to escape containment. And once they are out, they are out.A proper and thorough documentation system is the first step to implement the necessary level of compliance. If you reduce the paperwork and requirements, you are inviting sloppy work in other areas.This is not something you can approach with "she'll be fine".
Proposal 3 - Record-keeping requirements	No	As a scientist I can tell you that we HATE paperwork because it is boring.Forcing us to do it is the only way you will get compliance.The problem is not that there is too much paperwork, the problem is a culture in which necessary paperwork is demonized as a waste of time. There is no problem with the current system, scientists just like to complain.And I can know, because I am one of them.
Proposal 4 - Internal audit frequency	No	Again, the only way you get compliance is by enforcing it.This is not an area where you can rely on people doing the right thing.
Proposal 4 - Internal audit frequency	No	Again, the issue is that people are trying to avoid an unpleasant task.So, we will have "low-risk" GMOs with reduced documentation in laboratories that will be less frequently checked. Why don't you just open a window and dump the GMOs straight into the environment?You know what you get from loosening regulations and less frequent checks? Accidents. You get accidents, because people will be less trained, less aware and less worried about what they are doing.
Proposal 4 - Internal audit frequency	Other policy options	Every change you suggest will make things worse.
Proposal 5 - Movement between facilities	No	There are no "harmless" GMOs.Regulations are there to protect. Show me one collaboration that wasn't realized because the paperwork to transfer was too hard?All these proposals sound like you want to enable lazy people to not do their job.
Proposal 5 - Movement between facilities	No	The number of times a simple transfer is handled incorrectly should show you that you rather should think about tightening the rules. I am literally sitting here shaking my head about how much these proposals are obviously written by lobbyists who only have their own interests in mind.
Proposal 5 - Movement between facilities	Other policy options	No.
Proposal 6 - Requirements for eukaryotic somatic cells	No	As a fellow eukaryotic organism, I would very much have stricter regulations on something that has the potential of serious unintended consequences. Again, there is no inherently "harmless" GMO.
Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Proposal 6 - Requirements for eukaryotic somatic cells	No	The common frustration is that there are rules that get in the way. Doing away with the rules is not helping. Because they get in the way for a reason.I am not repeating myself why this change is bad.
Proposal 7 - Regulatory status of biotechnologies	No	"introduction of DNA into an organism"That would mean that a bacterium carrying a engineered plasmid is no longer a GMO?The wording "independently replicative" here is incorrect. Plasmids are not independently replicative since they rely on host cell machinery.This is written really badly. Hard no.
Proposal 7 - Regulatory status of biotechnologies	No	No
Proposal 7 - Regulatory status of biotechnologies	No	Making exceptions just opens the door for exploitation.
Proposal 8 - Low-risk fermentation	No	10 litres is a lot of cells.
Proposal 8 - Low-risk fermentation	No	"Although fermentation applications can be rapidly assessed (or included in other applications), the time required from researchers and organisations to complete these applications would likely take time and funding away from research and development."As do lunch breaks. Should we get rid of those too?This is another example of "scientist doesn't like anything that is not exciting".
Proposal 9 - Standards for containment facilities	Status quo	Keeping the status quo approach
Proposal 9 - Standards for containment facilities	Status quo	Clear rules avoid exploitation.
Proposal 9 - Standards for containment facilities	No	Everything reads like "woe is me, I have to follow rules".
Proposal 9 - Standards for containment facilities	Yes	Yes

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Proposal 9 - Standards for containment facilities	Yes	No.We have a smoothly running system.
Proposal 10 - Reviews of regulatory settings	Yes	Fast moving field with plenty of new technology coming through all the time.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	The outcome of such a review should not be assumed to be a reduction of rules.
Te ao Maori	Taonga species	I prefer option 1, but with a clear pathway how to get approval, ideally brokered through EPA.
Te ao Maori	Use of genetic material	Yes
Te ao Maori	Use of genetic material	Te Tiriti is pretty clear about this.
Te ao Maori	Te ao Maori	I would welcome a MÄori body associated with EPA to provide clear authority in these questions.
Te ao Maori	Te ao Maori	Clearly falls into self-governance and stewardship of MÄori and should be treated as such.
Te ao Maori	Informed consent	Yes
Te ao Maori	Informed consent	This is not my place to make suggestions.
Te ao Maori	Informed consent	There should be a clear hierarchy of which body can block another when it comes to gifting material.
Te ao Maori	Te ao Maori	I hope it will improve and solidify their legal standing on these issues.
Feedback on process/consultation	Feedback on process/consultation	Not impressed.Reducing regulations is the wrong way to make things safer and to improve compliance.Very strong taste of lobbyist infuence to ease regulations for the sake of convenience and likely profits.Does not read like it has been written to protect the interests of the general public.
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Objectives	Objectives	Yes
Features and approach for regulatory framework	Features and approach for regulatory framework	I would like to see lower regulatory burden on low risk GMOs that are only kept in containment. I would specifically like to see it become easier to create and culture GMO bacteria and plants in containment for the purpose of producing valuable products such as enzymes.
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Yes	Yes

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Proposal 1 - Risk-tiering framework	Yes	I agree in principle however, the devil is in the details - specifically what organisms and types of changes will be included in which risk tier. It seems that governing agencies trend towards being more and more risk-averse which results in increasing restrictions and rules about how to perform research. Some of these rules are now becoming ridiculous. For example, the movement of kiwifruit leaf tissue as a risk good (potentially carrying PSA-V) which is then used for destructive testing (DNA extraction) - we have really strict rules surrounding this but the risk is absolutely zero. We would have to be rubbing our samples onto kiwifruit vines for there to be any risk at all and yet there are all these requirements. At the same time, any random person could climb a fence and walk into a kiwifruit orchard, take infected live cuttings and move them anywhere in the country without anyone knowing about it or restricting it. The risk currently does not justify the regulations. So my appeal is to make the regulations actually proportional with the risk without being risk averse in the extreme.
Proposal 2 - Assessments for medicines	Yes	Yes
Proposal 2 - Assessments for medicines	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	I generally agree but I also think that organisations should maintain central records of new organisms, perhaps with reduced details than are currently required.
Proposal 3 - Record-keeping requirements	Unsure	Unsure
Proposal 3 - Record-keeping requirements	Unsure	This is impractical for small containers and something that should be accessible from a central record. It's doable but seems impractical.
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Movement authorisations are unnecessarily time consuming and I don't think that they actually contribute to reducing any risks.
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	An important update to account for new technology.
Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	I agree with the suggested criteria.
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Other policy options	I think that we should reduce the regulation of organisms that cannot survive without supplementation of specific nutrients, such as E.coli that require such nutrients to survive. This would be helpful to make it easier to produce products such as enzymes while the risk to the environment would be very low to zero if the organism were to escape containment, simply due to the fragile nature of the organism itself. Such organisms should remain in containment and still be decontaminated by autoclaving or chemical treatment, for example, but require less permissions to create them.
Proposal 8 - Low-risk fermentation	Yes	Yes

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	Proposal 8 - Low-risk fermentation	Yes	This would be very helpful and have potentially great financial benefits.
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 8 - Low-risk fermentation	Yes	While 10 litres is a good size for small to medium fermentations and is a size manageable by people (ie easy to carry), there is no real logic in restricting it to that size. I would say that something like 100 litres (or perhaps even 1000 litres) would be more appropriate. A spill of 100 litres is not much more difficult to manage than a spill of 10 litres.
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 8 - Low-risk fermentation	Yes	This would be very helpful and have potentially great financial benefits.
	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
	Proposal 9 - Standards for containment facilities	Hybrid	Best of both worlds. A prescriptive approach is simple and that is useful in many situations, while it is useful to have an outcome-based approach for specific situations.
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 9 - Standards for containment facilities	Hybrid	Best of both worlds. A prescriptive approach is simple and that is useful in many situations, while it is useful to have an outcome-based approach for specific situations.
	Proposal 9 - Standards for containment facilities	Yes	Yes
	Proposal 9 - Standards for containment facilities	Yes	Yes
	Proposal 9 - Standards for containment facilities	Yes	Yes
	Proposal 9 - Standards for containment facilities	Cost vs benefits	I expect a hybrid approach to be low or no cost.A shift to a purely outcome-based approach would likely bring more cost with uncertain (or no) benefits.
	eatures and approach for regulatory framework	Features and approach for regulatory framework	My specific wish is to make it easier to create transgenic bacteria (E.coli) which can produce valuable enzymes used in molecular biology. This includes being able create these GMOs and culture them in medium scale fermentations. For a high throughput DNA testing laboratory, I estimate that the cost savings of this could approach $100000 per year so it has very substantial potential in reducing the costs of genetic testing. Current regulations which require specific approvals and PC2 laboratories to carry out this low risk activity are too restrictive and they absolutely make it difficult to impractical to do this and benefit from it.
	Proposal 1.1 - Biosafety Committees	Unsure	Unsure
	Proposal 1.1 - Biosafety Committees	Unsure	I'm not really convinced that this will reduce bureaucracy. Having worked at a CRI, it is possible for these biosafety committees to become expensive (CRIs are so expensive with the massive overheads that they impose on their researchers) and arbitrarily restrictive depending on the personalities of the people involved. I can see how hey could be useful as well but I'm really not sure about this idea.

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	Blanket support for proposals	Blanket support for proposals	I support the 10 proposals as written in the snapshot document.GMO technology, risk assessment, and processes around the world have improved significantly since the current legislation was written.GMO, including CRISPR/CAS-9 is an important technology and if Aotearoa/NZ is going to be at all competitive on the world stage including in agriculture and animal husbandry we need to enable research using these technologies.That being said, I appreciate and fully support the risk-based process written in to this consultation document.
Julie Jones - BioValeo	Objectives	Objectives	Yes
Julie Jones - BioValeo	Features and approach for regulatory framework	Features and approach for regulatory framework	Timely and proportionate regulation.Timely is important for the medical research field as patients' lives depend on it, and we will not be able to attract studies if we cannot open a trial in a timely manner.
Julie Jones - BioValeo	Proposal 1 - Risk-tiering framework	Yes	Yes
Julie Jones - BioValeo	Proposal 1 - Risk-tiering framework	Yes	Agree that Australia and New Zealand should align.

Julie Jones - BioValeo	Proposal 1 - Risk-tiering framework	Yes	Yes
Julie Jones - BioValeo	Proposal 1.1 - Biosafety Committees	Unsure	Unsure
Julie Jones - BioValeo	Proposal 2 - Assessments for medicines	Yes	Yes
Julie Jones - BioValeo	Proposal 2 - Assessments for medicines	Yes	The above-proposed points are the minimum that should occur. Even those requirements are likely more than is really necessary for medical GMOs such as CAR T cell therapy.It is critical that timelines are also implemented. We need to know how long a review will take in order to remain internationally competitive. SCOTT/GTAC review is 45 days but is usually done much sooner. HDEC is 35 days. The review of a medical product should not exceed 45 days so that the regulatory approval timelines for a study or provision of treatment can be maintained for GMO as well as non-GMO medical treatments.
Julie Jones - BioValeo	Proposal 2 - Assessments for medicines	Yes	Yes
Julie Jones - BioValeo	Proposal 2 - Assessments for medicines	Yes	The time it takes to get an application ready for formal acceptance is too long and too burdensome. It is a significant issue. The amount of information requested seems unnecessary for medical therapies where the cells are not viable outside of containment or the human body.
Julie Jones - BioValeo	Proposal 3 - Record-keeping requirements	Yes	Yes
Julie Jones - BioValeo	Proposal 3 - Record-keeping requirements	Unsure	Unsure
Julie Jones - BioValeo	Proposal 3 - Record-keeping requirements	Unsure	Would this also apply to packaged medicines? such as CAR T therapies ready for infusion?
Julie Jones - BioValeo	Proposal 4 - Internal audit frequency	Yes	Yes
Julie Jones - BioValeo	Proposal 4 - Internal audit frequency	Yes	Yes
Julie Jones - BioValeo	Proposal 5 - Movement between facilities	Yes	Yes
Julie Jones - BioValeo	Proposal 5 - Movement between facilities	Yes	Yes
Julie Jones - BioValeo	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Julie Jones - BioValeo	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	good idea
Julie Jones - BioValeo	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Julie Jones - BioValeo	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Agree, these cells pose essentially zero risk as they cannot survive in the environment for any significant length of time.
Julie Jones - BioValeo	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Julie Jones - BioValeo	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	Nothing to add at present.It would be good to pull the consultation results together, then run a workshop (digital or in person). It is easier to identify the outliers when a diverse group discusses the issue and raises different questions.
Julie Jones - BioValeo	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes

Julie Jones - BioValeo	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Julie Jones - BioValeo	Proposal 9 - Standards for containment facilities	Hybrid	It allows greater flexibility but also a degree of clarity for those who don't have extensive experience in the area
Julie Jones - BioValeo	Proposal 9 - Standards for containment facilities	No	No
Julie Jones - BioValeo	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Julie Jones - BioValeo	Proposal 10 - Reviews of regulatory settings	Yes	It should always be fit for purpose. Technology is moving quickly, regulations need to align with changes that occur in the future. We do not yet know what the future holds, therefore we should be willing to adapt as required.
Julie Jones - BioValeo	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Julie Jones - BioValeo	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Julie Jones - BioValeo	Feedback on process/consultation	Feedback on process/consultation	It is fantastic that this legislation is being considered for review.
Julie Jones - BioValeo	Proposal 2 - Assessments for medicines	Technical feedback	The above-proposed points are the minimum that should occur. Even those requirements are likely more than is really necessary for medical GMOs such as CAR T cell therapy.It is critical that timelines are also implemented. We need to know how long a review will take in order to remain internationally competitive. SCOTT/GTAC review is 45 days but is usually done much sooner. HDEC is 35 days. The review of a medical product should not exceed 45 days so that the regulatory approval timelines for a study or provision of treatment can be maintained for GMO as well as non-GMO medical treatments.
School of Biological Sciences, University of Auckland	Objectives	Objectives	Yes
School of Biological Sciences, University of Auckland	Objectives	Objectives	We agree with the stated objectives, but think they should be extended as follows:-Add â€œAllows for straightforward and efficient use of GMOs while proportionately managing the risksâ€¦â€ to the start of the first objective. We think it is important to explicitly recognise that there is a benefit to reducing the administrative burden for researchers who use GMOs (see next bullet point).-Mention in the second bullet point the numerous benefits â€“ not just to health outcomes â€“ of GMO regulations that are more fit-for-purpose: for instance, research into climate change, pest management, and agriculture all contribute to improving the human condition both directly and indirectly (through growing NZâ€™s economy). We suggest replacing â€œbetter health outcomesâ€ with â€œeconomic, social and environmental benefitsâ€.
School of Biological Sciences, University of Auckland	Features and approach for regulatory framework	Features and approach for regulatory framework	We think the NZ regulatory framework should have the following key features:-Degree of regulation is in keeping with level of risk.-Follow international best practice and look to align with other jurisdictions (not just Australia) for ease of international collaboration and access to markets.-Reduction in administrative burden for researchers and research support staff (so their time can instead be spent on doing research).-Outcome-based rather than process-based regulation that recognises the decades-long HOSU of GMOs both within and outside of the laboratory and allows for rapid response to new technologies.While the proposed regulatory changes would represent an important first step in this direction, in our opinion, they do not go nearly far enough. We need to be able to use a range of tools, including GM to address vital issues such as climate change resilience for crop plants, increased food production for increasing population globally, conservation and healthcare applications, and we need regulations that facilitate rather than prevent this.Additionally, with respect to the objectives from Q1, the proposed changes would not satisfy the following aspects:Proportional management of risk:-The organisms listed in Risk Tier 1 have a long history of safe use (HOSU) with little to no regulation across most of the world. We are unsure whether the proposed changes will adequately account for this due to confusion over what the required facilities for Risk Tier 1 organisms would be (see our response to Q3 and to Proposal 1 more broadly).-The risks associated with GMO plants, in particular, have not been properly considered and are greatly over-estimated (elaborated in our response to Appendix 3).Future-proof, able to anticipate and flexibly accommodate future technological developments:-The regulations need to allow for rapid assessment of organisms for addition to the appropriate risk tier; that is, they should reflect and respond to technological advancements and applications, not stifle them. We suggest something like a national (yet nimble) body that would assess organisms at regular intervals (minimum frequency being annual).
School of Biological Sciences, University of Auckland	Proposal 1 - Risk-tiering framework	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 1 - Risk-tiering framework	Yes	We are very supportive of this proposal in that it would be a positive change from the status quo, but we think it doesnâ€™t go far enough. There has been no proven human or animal health issues or environmental harm from the laboratory use of genetically modified organisms, which have been used safely for > 30 years. While the Australian risk-tiering framework would be an improvement on the current situation, the Australian regulations are very prescriptive. We recommend modelling our risk assessment on the international best practice of institutions/organisations such as NIH (USA), USDA (USA), EPA (USA), Health Canada (Canada), CIAF (Canada), MAFF (Japan), MHLW (Japan), OGTR (Australia) and HSE (UK).If risk tiers are to be used, then the system needs to have a rapid and potentially fluid classification strategy that allows for movement down or up a tier as new information becomes available, and for the fast assessment and addition of new strains of an organism already in a risk tier. As noted earlier, we recommend establishing a national body to do this at specified, regular intervals (at least annually).Lastly, we note that it is a little unclear what exactly would be required of a facility that hosts Risk Tier 1 research. It is stated that it â€œwould not need to be a containment facility approved by MPIâ€, but also that â€œany unapproved release of GMOs into the environment would be prohibited.â€ As stated on the EPA website (https://www.epa.govt.nz/industry-areas/new-organisms/applying-for-approval/containment/), â€œContainment facilities are designed and operated to prevent the release of the organism â€“ or its heritable material â€“ into the wider environment.â€This would seem to imply that the requirement for no (unapproved) release into the environment in and of itself requires a containment facility.
School of Biological Sciences, University of Auckland	Proposal 1 - Risk-tiering framework	Yes	Yes

Nicky Vernom	Proposal 1 - Risk-tiering framework	Yes	Yes
Nicky Vernom	Objectives	Objectives	Yes
Nicky Vernom	Proposal 1 - Risk-tiering framework	Yes	Yes
Nicky Vernom	Proposal 1 - Risk-tiering framework	Yes	Yes
Nicky Vernom	Proposal 1.1 - Biosafety Committees	Yes	Yes
Nicky Vernom	Proposal 2 - Assessments for medicines	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 1 - Risk-tiering framework	Other policy options	We suggest greater consideration of practical aspects and consequences of the proposed regulations: as outlined above, it would appear from the description of the proposed changes that facilities for undertaking Risk Tier 1 research are still likely to require some sort of laboratory and/or containment standard to be maintained. This needs to be clarified, and we note that we are very supportive of moving away from requiring containment facilities for Risk Tier 1 research, but if the desire is to still have some sort of laboratory standard in place, it may be that the alternative option suggested in Appendix 1, where exempt dealings still occur within PC1, may be just as straightforward as implementing and regulating some other laboratory standard.However, this would have downsides, particularly in the education space. For instance, in North America, schools can use E. coli in the classroom without any form of containment, meaning secondary students have the opportunity to learn how to correctly and safely use genetic technologies, which would be of great educational benefit given the likely centrality of these methods to the future of biology, and CRISPR gene editing kits can be purchased from Amazon to use at home. NZ may not want to be quite so de-regulated but it is worth considering the fact that other countries see little/no risk in these activities and organisms. We therefore suggest also looking at other countries (US, Canada, UK, Europe) where a tiering-like system is in place before determining the final version of the revised regulations.An alternative and ultimately simpler approach would be to use this opportunity to take a fresh approach to GMO regulation, by separating the regulation of GMOs from the new organisms aspect of the HSNO act (and the many other Acts that reference genetic modification). This would allow a simpler set of regulations to be developed that are better able to reflect the often very small (and sometimes undetectable) changes made when genetically modifying an organism to contain a single new trait compared to the much larger-scale change and potential impact of, for example, introducing a completely new organism to New Zealand and its release into the environment for the purpose of biocontrol.
Nicky Vernom	Proposal 3 - Record-keeping requirements	Yes	Yes
Nicky Vernom	Proposal 4 - Internal audit frequency	Yes	Yes
Nicky Vernom	Proposal 4 - Internal audit frequency	Yes	Yes
Nicky Vernom	Proposal 5 - Movement between facilities	Yes	Yes
Nicky Vernom	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Nicky Vernom	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 3 - Record-keeping requirements	Other policy options	Our strongly preferred policy option is to not have GMO labelling other than for organisms in the highest risk tier. Good training of personnel and specific containment procedures (for organisms in Risk Tier 2 and above) are a much better precaution than labelling each tube, agar plate etc as being GM.
Nicky Vernom	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Nicky Vernom	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 4 - Internal audit frequency	Unsure	Unsure

School of Biological Sciences, University of Auckland	Proposal 1.1 - Biosafety Committees	Yes	Yes
Nicky Vernom	Proposal 8 - Low-risk fermentation	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 1.1 - Biosafety Committees	Yes	We agree that the establishment of institutional EPA-approved ABSCs is an appropriate way to assess research proposals. We also approve of the move to allow smaller organisations access to the ABSC of another organisation in cases where e.g. there is an established agreement to do so between the two organisations so long as the burden does not become too onerous. As such, we support the formation of an EPA ABSC to provide an alternative option. Lastly, we note that an accredited biosafety officer (ideally with a deputy) rather than an entire committee is likely to be sufficient in most places â€“ it is not clear what benefit there is from having a committee given that, as noted in the proposal, the new regulations would be more explicit and so decisions will simply be a matter of checking whether the proposed research fits the appropriate definition.
School of Biological Sciences, University of Auckland	Proposal 1.1 - Biosafety Committees	Other policy options	We suggest that an organisation with more than some minimum number of researchers/research projects requiring ABSC approval could be required to form their own ABSC (or have their own ABS officer).
School of Biological Sciences, University of Auckland	Proposal 2 - Assessments for medicines	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 2 - Assessments for medicines	Yes	We would be supportive of the proposed fast approval process if it really does take the proposed 10 days. However, this does not include the time required to prepare documentation, which could easily take months, a time-scale that is not in proportion to the very low risk for systems such as CAR-T and ex vivo gene editing of patient cells to correct disease-causing mutations. In fact, for these scenarios, we again do not think the proposed changes go far enough, as they still restrict ex vivo gene editing applications more than in vivo applications, which are in general riskier.However, we note that caution still needs to be exercised for systems such as live virus-based human or veterinary vaccines, which need to be carefully evaluated with regard to zoonotic disease (a pathogen that can jump from non-human or in reverse).We note here that our suggestion to separate out the approval of GMOs from the approval of new organisms under the HSNO act would also enable more straightforward and risk-appropriate assessment of new medicines and medical devices.We also note that this proposal may not be required â€“ see our response to Proposal 6, as well as the following from the introduction to Proposal 1: â€œAs noted under risk tier 1, medicines that meet the criteria of that risk tier would also be exempt from requiring EPA approval for their release. For example, should human cells be included under risk tier 1, personalised cancer treatments using human cells (such as CAR T-cell therapies) would be exempt from requiring EPA approval.â€
School of Biological Sciences, University of Auckland	Proposal 2 - Assessments for medicines	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 2 - Assessments for medicines	Yes	We agree with the issues outlined, and would add the issue of the discrepancy between in vivo and ex vivo applications.
School of Biological Sciences, University of Auckland	Proposal 2 - Assessments for medicines	Other policy options	If the proposed rapid assessment pathway is adopted, we suggest that:-Consideration of viability should be included alongside â€œwhether, through shedding or excretion, the new organism is likely to make its way into the environment.â€, in the proposed rapid assessment pathway. For instance, gene-edited skin cells (a promising treatment for epidermolysis bullosa) will be constantly shed by patients, but are completely unviable (not least because they are only shed once dead).-The policy should also cover the regulation of in vivo gene editing of animals.-Reasonable requests for assessment should be able to be made at no charge to the applicant, as the cost of assessment is a barrier to approving new medicines and medical devices, and thus to helping patients.However, our preferred option is that there should be no additional regulatory burdens for the use of non-infectious, non-replicative, non-transmissible (i.e., not germ line) material used in medicine and/or clinical trials. The standard regulations that apply to all clinical approvals (clinical use or in a clinical trial) should be sufficient.
Nicky Vernom	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Nicky Vernom	Proposal 8 - Low-risk fermentation	Yes	Yes
Nicky Vernom	Proposal 9 - Standards for containment facilities	No	No
Nicky Vernom	Proposal 9 - Standards for containment facilities	Yes	Yes
Nicky Vernom	Proposal 5 - Movement between facilities	Yes	Yes
Nicky Vernom	Proposal 5 - Movement between facilities	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 3 - Record-keeping requirements	Unsure	Unsure
School of Biological Sciences, University of Auckland	Proposal 3 - Record-keeping requirements	Unsure	While we are in an organisation with an Institutional Low-Risk Approval, we are still very strongly in favour (in fact we could not be more in favour!) of a system that reduces (or ideally, removes) the extreme level of detail and tracking currently required for GMOs. However, we are not convinced that the proposed new labelling system will alleviate the problem of unnecessary levels of labelling. Labelling every organism/vessel for Risk Tier 1-3 new organisms (or GMO status) simply replaces one onerous record-keeping system with another and is antithetical to the acknowledgement that lab-based GM is low-risk. We appreciate the concern about cross-contamination but think this is an issue for the researcher to worry about, and for which standard lab record keeping is more than sufficient, not something that should be regulated.

School of Biological Sciences, University of Auckland	Proposal 3 - Record-keeping requirements	Unsure	Unsure
School of Biological Sciences, University of Auckland	Proposal 3 - Record-keeping requirements	Unsure	We do not think HSNO Act approval labelling is needed for Risk Tier 1 research due to the acknowledged extremely low risk to the environment of this research, which essentially fulfils the purpose of the HSNO Act. For research falling under higher risk tiers, the need for containment (which prevents against accidental release to the environment) fulfils the purpose of the Act (to prevent accidental release of GMOs into the environment). Some level of linkage back to the ABSCâ€™s confirmation of the risk tier of a piece of research will be necessary, but, as noted above, this should be done at the least detailed level possible.
School of Biological Sciences, University of Auckland	Proposal 3 - Record-keeping requirements	Yes	Yes
Nicky Vernom	Proposal 3 - Record-keeping requirements	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 4 - Internal audit frequency	Unsure	We are not united in our response to this proposal. While we are all in favour of reducing the external audit frequency to 12-monthly, and researchers were also strongly in favour of reducing the internal audit frequency to 12-monthly (noting that this does not prevent an institution from doing more frequent audits if they so desire), technical staff responsible for the audits felt that 12 months is too long between internal audits, and think the frequency of these should remain 6-monthly.
School of Biological Sciences, University of Auckland	Proposal 4 - Internal audit frequency	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 4 - Internal audit frequency	Other policy options	What would be the audit frequency if Proposal 1 (Risk Tiering of Exempt Dealings, outside of PC1 laboratory) was enacted?
School of Biological Sciences, University of Auckland	Proposal 5 - Movement between facilities	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 5 - Movement between facilities	Yes	We strongly agree with this proposal, and would go further and suggest that all movement between and out of containment should be solely based on the risk tier.
School of Biological Sciences, University of Auckland	Proposal 5 - Movement between facilities	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 5 - Movement between facilities	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	The proposed change here is summarised as â€œinclude eukaryotic somatic cells under risk tier 1 of the proposed risk-tiering framework.â€ Examination of the Australian Risk Tiering system outlined in Appendix 3 would suggest that eukaryotic somatic cells are already under Risk Tier 1 (see Item 4 of Part 1 â€“ Exempt Dealings and rows 7-10 of the Hosts and Vectors table in Part 2). More generally, the Australian risk tiering system appears to categorise modification of any cell line (because there is zero risk of the modified cells perpetuating themselves outside of the laboratory) or modification of somatic cells of any living organism (because the change cannot be propagated through generations) as low-risk. Both of these interpretations suggest that this proposal (and likely also Proposal 2) are not required.We are assuming, therefore, that this proposal is actually to do with the fact that under current NZ legislation, eukaryotic somatic cells are defined as â€˜organismsâ€™ under section 2(1) of the HSNO act, and so may actually be about deregulating cell lines that would otherwise come into NZ as â€˜new organismsâ€™ so that they are no longer restricted organisms. In this case, the alternative to Proposal 6 provided in the Appendix 1 (to exclude certain eukaryotic somatic cell types from the definition of â€˜organismâ€™ under section 2(1) of the HSNO Act â€“ we would prefer the last option, to exclude all eukaryotic cells) seems better suited to address the actual problem.However, we would be strongly supportive of either approach â€“ whichever is seen as the most efficient way to expedite research that involves GM of eukaryotic somatic cells. We note that there will still be ethical approvals in place that would e.g. prevent editing of primary human cells without consent (unless that cell is commercially derived).
School of Biological Sciences, University of Auckland	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 7 - Regulatory status of biotechnologies	Other policy options	We would strongly advocate for following Australia here, which in 2019 opted to exclude organisms gene edited with site directed nuclease edits via non-homologous end-joining from GMO regulation. We would also strongly support a policy in which progeny of transgenic organisms that no longer have the transgenes present are not regulated as GMOs. More broadly, introduction of non infectious/non-replicative (e.g. transitory, not permanent) material that does not alter endogenous DNA/genome could be defined as not a GMO. This allows future-proofing for new strategies.
Nicky Vernom	Proposal 10 - Reviews of regulatory settings	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 8 - Low-risk fermentation	Yes	Yes

Nicky Vernom	Proposal 10 - Reviews of regulatory settings	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 8 - Low-risk fermentation	Yes	Yes
Nicky Vernom	Proposal 10 - Reviews of regulatory settings	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 8 - Low-risk fermentation	Yes	It isnâ€™t clear why the 25 L volume used in Australian risk tiering shouldnâ€™t be used in NZ too. In fact, it is unclear why volume is relevant; the regulations under revision only pertain to laboratory-based research and restrict any release into the environment, regardless of volume. The vessel volume would need to be enormous for there to be any realistic chance of accidental environment release (e.g., from vessel failure).
School of Biological Sciences, University of Auckland	Proposal 8 - Low-risk fermentation	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
School of Biological Sciences, University of Auckland	Proposal 9 - Standards for containment facilities	Hybrid	The hybrid approach would reduce need for change to existing facilities and allow for broader scope for new facilities for different organisms. We note that prescriptive standards are usually very expensive.We also note that if more flexible regulations are adopted, as we are advocating for, then facilities will need to able to be adjusted to match reduced or increased standards as regulations change (this is absolutely not a reason to not have flexible regulations, just something to bear in mind). We advise consultation with Australia on the impact on facilities as they work through changes to their regulations.
Nicky Vernom	Proposal 2 - Assessments for medicines	Yes	Yes
Nicky Vernom	Proposal 3 - Record-keeping requirements	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 9 - Standards for containment facilities	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 9 - Standards for containment facilities	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 9 - Standards for containment facilities	Cost vs benefits	Definitely not - we are very supportive of an outcome-based standard (but have chosen to support a hybrid approach overall due to practical considerations).
School of Biological Sciences, University of Auckland	Proposal 10 - Reviews of regulatory settings	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 10 - Reviews of regulatory settings	Yes	While new processes can take a while to bed in, technology is moving quickly and itâ€™s important that regulations and legislation keep pace. Currently, science is moving far faster than regulations. From this perspective, five years might not be sufficiently often and a shorter time period might sometimes be required, i.e., the â€œat least" part of "at least every five yearsâ€ is important. We note that the Australian Gene Technology scheme has had changes made to it every 5 years or so.We would like to take the opportunity here to reiterate the importance of there being a mechanism for specific organisms to be moved between tiers in something closer to real time, as outlined in our responses to Q1, 3 and 39.
School of Biological Sciences, University of Auckland	Proposal 10 - Reviews of regulatory settings	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 10 - Reviews of regulatory settings	Yes	Yes
School of Biological Sciences, University of Auckland	Proposal 10 - Reviews of regulatory settings	Other policy options	We suggest that the tier lists (if a tier-based system is adopted) would be much better managed/ maintained by the EPA outside of the regulations or Act of Parliament. Dynamic lists are very difficult to manage inside an Act. This would mean that any movement of organisms between risk tier levels could be done quickly, without substantial hold-up to research or, on the flip side, allowing release into the environment before an organism can be appropriately regulated. This could be done in a similar way to current determinations around technologies, albeit ideally a lot faster and more frequently.
School of Biological Sciences, University of Auckland	Alternative options	Alternative options	Some of these have been addressed earlier:Proposal 1 (Q5): Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?As noted in our response to Q5, if a non-containment facility still requires some sort of laboratory standard to be maintained, then the alternative option suggested in Appendix 1, where exempt dealings still occur within PC1, may be just as straightforward as implementing and regulating some other â€œnon-containment but also non-releaseâ€ laboratory standard.Proposal 5: We are supportive of the alternative option outlined in Appendix 1 as well as the option suggested under Proposal 5.Proposal 6: We are supportive of the alternative option outlined in Appendix 1 as well as the option suggested under Proposal 6, so long as the option to exclude all eukaryotic cells from the definition of an organism was adopted.Proposal 8 (Q29): We are supportive of matching the maximum volume to at least that used in the Australian risk tiering system (25 L).
School of Biological Sciences, University of Auckland	Costs, benefits or risks	Costs, benefits or risks	It is telling that many of the proposals have few or no identified risks (and minimal implementation costs), but all have benefits: this reveals how unfit-for-purpose our current regulations are. We foresee an additional benefit of Proposal 2: this change would also speed up the time for developing new medications and so mean they become available to patients earlier.

School of Biological Sciences, University of Auckland	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	We do not think the Australian risk-tiering framework is adequate for dealing with GM plants. For researchers working with GM plants, while the proposed changes to the GMO regulations are steps in the right direction, they will not make much of a difference to time, personnel, admin and facility costs. There is no scientific evidence or historical basis for the purported dangers of GMO plants, which have been grown and eaten for almost 40 years (we note that NZ imports food products containing GMO crops yet makes it extremely difficult to do such research taking place in NZ, meaning that NZ is not benefiting financially from the GM/GE revolution). We therefore look forward to further changes that encourage (rather than hinder) innovation to readily develop and test GM plants that assist in the response to the climate crisis, food security, therapeutics.For example, if the decision is to use something like the Australian risk-tiering framework, we think plants should be treated more like microorganisms, with assessment by species rather than putting them all into Tiers 2/3. At the very least, the model laboratory plants, including Arabidopsis, Medicago truncatula, Nicotiana benthamiana, Nicotiana tabacum, should be named under either Part 1 or in the Part 2 Hosts and Vectors list, as many of the statements in the proposal referring to low risk organisms would also apply to these plants.More broadly, we think the risk of plants (GMO in particular) regenerating, escaping and harming people and the environment have been overestimated, which is reflected in both current legislation and the proposed changes. The majority of plants cannot cause disease in humans (in fact there is no recorded case of a plant infecting a human and causing disease), are non-toxic and non-allergenic (and even those that are typically only have this effect upon ingestion), and are unable to escape PC1 containment without significant human intervention (including dispersal of seeds or pollen, which, in any case, are seldom produced in axenic laboratory culture).Overall, we think that the current and proposed regulation of laboratory-based GM of plants is not proportional to the risk in the majority of cases, and would encourage further consideration of how this might be handled; at the very least, if the Australian risk-tiering system is adopted, plants should be included at the level of individual plant species, not automatically all placed in Risk Tier 3.
School of Biological Sciences, University of Auckland	Feedback on process/consultation	Feedback on process/consultation	We are extremely glad to see that changes to New Zealandâ€™s highly restrictive regulations for GMO research have been proposed. As researchers, we have struggled with the stringent and often pointless levels of regulation, which have severely impeded research while having little to do with risk mitigation (particularly given all GMO research took place in containment facilities, which by definition prevent any release to the environment and thus mitigate the associated risks far better than any labelling or tracking system).As indicated in our responses to the questions, we are in general very supportive of the proposed changes; our only complain is typically that they donâ€™t go far enough! However, the proposed changes will still represent an important first step, and we recognise that it is important to move at a pace that ensures social license as well as allowing for the effect of each change to be measured. Having said that, we note that there is ample evidence from other jurisdictions that most GMOs are very low risk to human health and the environment, and are in fact key to both improved medicines and adapting to climate change.
9(2)(a)	Objectives	Objectives	Yes
	Features and approach for regulatory framework	Features and approach for regulatory framework	Somebody needs to define the word 'risk' as I continuously hear that a GMO potentially possess a higher risk, but the extent of this 'risk' is probably rather minor and not well defined.The words virulence and pathogenicity need to be clearly defined and differentiated - just because a GMO might be more virulent, does not necessarily reflect a higher risk. Who is gonna measure virulence and based on what standard? What is the comparison of something more virulent? How can someone determine if a GMO has more risk when released into the environment - the chance that a more virulent strain will survive in the environment is probably the same as the parent strain - even a longer survival is probably not worth a higher risk - again who would validate such issues? Same for human health - a more virulent strain will probably not make a human more sick than the parent strain. Evidence from clinical studies have shown that there are thousands of different isolates with different virulence and it does not pose any higher risk working with those strains. Pathogenicity is more clear as one organisms classified as e.g. RG1 should not be modified to make it RG2 or higher (this would fall under bioterrorism).Many other countries around the world do not associate virulence with higher risk as it actually does not change the fact that the organism is still classified in the same risk group (RG). So the regulatory framework should remove the association between virulence and risk and rather focus on pathogenicity.The fact that one can import any super highly virulent strain from overseas (e.g., expressing a virulence gene on a plasmid in a host organism), but at the same time is not allowed to transform this plasmid into the same host in New Zealand is counter-intuitive and hinders good science. I propose to remove virulence from the regulatory framework to give researchers more freedom, which would in line with regulations from almost any other developed country around the world.
	Proposal 1 - Risk-tiering framework	Unsure	Unsure
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1.1 - Biosafety Committees	Yes	Yes
	Proposal 1 - Risk-tiering framework	Unsure	hy is this based on Australia and not the rest of the world? Why do we exclude countries like Canada or UK or even USA that have a long history of risk management and approvals.
	Proposal 1 - Risk-tiering framework	Unsure	Wh
	Proposal 5 - Movement between facilities	Yes	Yes
	Proposal 5 - Movement between facilities	Yes	Yes
	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	A comparison to policies from other countries than Australia would have been appreciated.
9(2)(a)	Features and approach for regulatory framework	Features and approach for regulatory framework	1)I stress the importance of robust regulation even for ethical and humane GE/GMO medical research in the laboratory...as you are aware of problems with lab leaks in the past, including from our NZ CRI Plant and Food Research2) I stress the importance of oversight from local councils/ authorities, including my local Auckland Council that has precautionary and prohibitive GE/GMO provisions, policies and rules in the operative Auckland Unitary Plan.3)I fully support the most substantive submission by Physicians & Scientists for Global Responsibility Charitable Trust (NZ), GE Free NZ and GE Free Tai Tokerau.4)4)I understand that the Royal Commission into Genetic Modification report (RCGM 2001 report) noted that requirements for lab experimentation needed tightening up and that this was never done.
Malaghan Institute of Medical Research	Objectives	Objectives	Yes

Malaghan Institute of Medical Research	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Genetic engineering of eukaryotic somatic cell lines or primary cells in culture is essential work for our research in cancerology and immunology. Researchers at Malaghan Institute are welcoming the proposed change as these eukaryotic cultured cells are unable to form an organism and cannot escape their containment. Work with those cells poses very low risk to the health and safety of lab workers, general public and the environment.
Malaghan Institute of Medical Research	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Malaghan Institute of Medical Research	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Malaghan Institute of Medical Research	Features and approach for regulatory framework	Features and approach for regulatory framework	The current NZ regulatory framework for working and generating GMOs in containment is posing several challenges to researcher of the Malaghan Institute due to the precautionary approach of NZ law (notably for introducing/modifying DNA of somatic eukaryotic cell lines) and the case by case basis of GMO approval delivered by EPA. To reduce the administrative burden and the challenges that this NZ regulation additionally imposed on NZ scientific community, the researchers at the Malaghan Institute would like to see a regulatory framework for low-risk genetic modification (especially on eukaryotic cell lines) that could cover the work of every laboratory/university/companies in NZ if they met specific requirement. Instead of the case by case EPA approval system, NZ could introduce a risk management model with several type of certification that will cover certain type of work with GMO depending on the risk (model risk tiering) and the type of physical containment of the facilities. We believe that this approach will reduce the administrative burden for EPA and MPI as well as for researchers and their companies/institutes/universities.
Malaghan Institute of Medical Research	Proposal 1 - Risk-tiering framework	Yes	Yes
Malaghan Institute of Medical Research	Proposal 1 - Risk-tiering framework	Yes	Researchers at Malaghan Institute are welcoming the proposed change in the GMO regulatory environment that goes toward reducing the administrative efforts for working and generating GMOs in containment while keeping strong protections for the health and safety of facilities workers, the general public and the environment of NZ. Aligning the regulatory framework with Australia will also facilitate collaborations efforts between NZ and Australian researcher communities and the work of companies/laboratories that would like to establish branch and/or subsidiaries in both countries.
Malaghan Institute of Medical Research	Proposal 1 - Risk-tiering framework	Yes	Yes
Malaghan Institute of Medical Research	Proposal 1.1 - Biosafety Committees	Unsure	Unsure
Malaghan Institute of Medical Research	Proposal 1.1 - Biosafety Committees	Unsure	In our view, Accredited Biosafety Committees and EPA biosafety committee will certainly provide several benefits for NZ researchers to work and generate GMOs in containment with more flexibilities and faster approval time. However, we are worried that ABSC system will transfer some administrative accreditation work from EPA and MPI to companies/universities/institutes and researchers to unforeseen level especially during the establishment of such ABSC. To reduce this burden, EPA and MPI should provide online portals and applications that will help and guide the work of ABSC.
Malaghan Institute of Medical Research	Proposal 1.1 - Biosafety Committees	Other policy options	As alternative model to ABSC system, EPA and MPI could provide general accreditation to laboratories to generate GMOs in containment with a risk tier system depending on the type of physical containment of their facilities. Once the facilities have received certifications from EPA, companies and institutes should still register their project to work/generate GMOs to EPA. Every project will be limited in time and will be cancelled if the facilities would/could not adhere to rules and regulations of containment facilities. For transparency, the register for accreditation and project for low risk GMO project will be accessible to the general public. This system will both reduce the administrative work of MPI, EPA and researchers while not sacrificing on the health and safety requirements.
Malaghan Institute of Medical Research	Proposal 2 - Assessments for medicines	Yes	Yes
Malaghan Institute of Medical Research	Proposal 2 - Assessments for medicines	Yes	The Malaghan Institute supports the proposed changes to the Hazardous Substances and New Organisms Act 1996 (HSNO Act). These changes are intended to streamline the assessment process for certain types of substances and organisms, while still protecting the environment.The first change, to streamline assessments under Section 38I of the HSNO Act, would allow for a more efficient assessment of substances that are already well-known and understood. This would reduce the regulatory burden on businesses and researchers, while still ensuring that the risks to the environment are adequately assessed.The second change, to introduce an alternative assessment pathway for medicines unlikely to result in viable new organisms being released into the environment, would make it easier for companies to bring new medicines to market.The third change, to enable rapid assessment of medical devices, would also make it easier for companies to bring new medical devices to market. This is important because medical devices can improve the quality of life for many people and save lives.Overall, the Malaghan Institute believe that the proposed changes to the HSNO Act are positive and will help to protect the environment while also making it easier for businesses and researchers to bring new products on the market and help the people of New Zealand get faster access to innovative medicines and medical devices.
Malaghan Institute of Medical Research	Proposal 2 - Assessments for medicines	Yes	Yes
Malaghan Institute of Medical Research	Proposal 3 - Record-keeping requirements	Yes	Yes
Malaghan Institute of Medical Research	Proposal 3 - Record-keeping requirements	Yes	Researchers at Malaghan Institute strongly support the change to replace the record keeping requirement for low risk GMOs as it will reduce the administrative work for the researchers and biosafety officers.
Malaghan Institute of Medical Research	Proposal 3 - Record-keeping requirements	Yes	Yes
Malaghan Institute of Medical Research	Proposal 3 - Record-keeping requirements	Yes	Yes

Malaghan Institute of Medical Research	Proposal 3 - Record-keeping requirements	Other policy options	No, the proposal to replace current record-keeping requirements will greatly benefit New Zealand by simplifying the rules.
Malaghan Institute of Medical Research	Proposal 4 - Internal audit frequency	Yes	Yes
Malaghan Institute of Medical Research	Proposal 4 - Internal audit frequency	Yes	Researchers at Malaghan Institute agreed that adjusting the frequencies of internal audit to 12 month minimun for Physical Containment level 1 facilities will reduce positively the administrative work.
Malaghan Institute of Medical Research	Proposal 4 - Internal audit frequency	Yes	Yes
Malaghan Institute of Medical Research	Proposal 5 - Movement between facilities	Yes	Yes
Malaghan Institute of Medical Research	Proposal 5 - Movement between facilities	Yes	The proposed change is welcomed as low risk GMO or non GMO cells meeting the criteria for the risk tier 1 could be shipped without MPI movement authorisation without changing the risk. We agreed that this will reduce the administrative burden and foster the collaboration between laboratory in Aotearoa.
Malaghan Institute of Medical Research	Proposal 5 - Movement between facilities	Yes	Yes
Malaghan Institute of Medical Research	Proposal 5 - Movement between facilities	Other policy options	We do not think there is any potential policy providing better benefit.
Malaghan Institute of Medical Research	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Malaghan Institute of Medical Research	Proposal 7 - Regulatory status of biotechnologies	Yes	The current regulation for the use of biotechnologies like mRNA vaccine has hindered innovation and the the development of required products and technologies in NZ. Researchers at Malaghan Institute welcome those changes that will provide clarity for researchers and companies for the development of biotechnologies such as RNA and DNA vaccines, cancer therapies, leading to improvements in human health, biotechnology capability and conservation.
Malaghan Institute of Medical Research	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	All those exclusionary criteria for introducing RNA and DNA into an organism are essential safeguards as RNA or DNA should not give rise to an infectious agent nor being able to edit the genome of the cells by integration or encoding genome editing reagents.One exclusionary criteria that could be added is that the RNA, DNA or epigenetic modifiers should not have oncogenic properties (e.g. encode an oncogene) as it has been shown that transient expression of an oncogene is enough to trigger cancerogenesis (For instance, https://doi.org/10.1038/ncomms4904).
Malaghan Institute of Medical Research	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Malaghan Institute of Medical Research	Proposal 7 - Regulatory status of biotechnologies	Other policy options	No, we think that clarifying the regulatory status of RNA, DNA and epigenetic modifiers that cannot edit the genome or give rise to an infectious agent will provide the right change to increase biotechnological development in Aotearoa.
Malaghan Institute of Medical Research	Proposal 7 - Regulatory status of biotechnologies	Other policy options	We could not think of any other biotechnologies that needs to have their status clarified under the current regulations. Biotechnologies are constantly evolving, and new applications and products are being developed all the time. The status of biotechnologies should be reviewed at regular interval to reflect the current knowledge.
Malaghan Institute of Medical Research	Proposal 8 - Low-risk fermentation	Yes	Yes
Malaghan Institute of Medical Research	Proposal 8 - Low-risk fermentation	Yes	It would harmonise the basic research areas working with the identified low risk projects with production and translation of products.
Malaghan Institute of Medical Research	Proposal 8 - Low-risk fermentation	Unsure	Unsure
Malaghan Institute of Medical Research	Proposal 8 - Low-risk fermentation	Unsure	Not technically competent to provide opinion on change in risk
Malaghan Institute of Medical Research	Proposal 8 - Low-risk fermentation	Yes	Yes
Malaghan Institute of Medical Research	Proposal 8 - Low-risk fermentation	Yes	Would harmonise the science discovery involving low risk products and projects with translation to scale up manufacturing, ensuring the success and translation of projects to impact without any associated increases in risk.

Malaghan Institute of Medical Research	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Malaghan Institute of Medical Research	Proposal 9 - Standards for containment facilities	Hybrid	The Malaghan Institute favours to shift to a hybrid approach as it is more flexible for all types of organisations. Smaller institutes and companies that might lack expertise, manpower, time and/or money could apply default measures to run a containment facilities that hold new organisms while larger companies and organisations like university could switch to outcome-based standards option.
Malaghan Institute of Medical Research	Proposal 9 - Standards for containment facilities	Yes	Yes
Malaghan Institute of Medical Research	Proposal 9 - Standards for containment facilities	Yes	Yes
Malaghan Institute of Medical Research	Proposal 9 - Standards for containment facilities	Cost vs benefits	The Malaghan Institute considers that the hybrid approach will not outweigh the benefits as it has the advantages to let organisations choosing their approach depending on its size. However, we are concerned that outcome-based approach might be too costly for smaller biotech startups and organisations at it requires expertise, time and manpower than the prescriptive standards. Shifting to outcome-based will certainly results to a higher entry price and higher cost to run a containment facility which might de-incentivize investments in the biotechnological sectors.
Malaghan Institute of Medical Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Malaghan Institute of Medical Research	Proposal 10 - Reviews of regulatory settings	Yes	The technologies to introduce genetic materials into cells and organisms and to generate GMOs are currently evolving at fast pace. Researchers at Malaghan Institute think that it is essential that the rules and regulations around GMOs will be required to be regularly reviewed.
Malaghan Institute of Medical Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Malaghan Institute of Medical Research	Proposal 10 - Reviews of regulatory settings	Yes	An interval of five years between each reviewing process seems appropriate.
Malaghan Institute of Medical Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Malaghan Institute of Medical Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Malaghan Institute of Medical Research	Alternative options	Alternative options	We are in favour of the Proposal 1.1: Biosafety committees with the alternative options of getting accreditation from EPA as it will reduce the cost and administrative burden for the different institutes, companies and universities.The alternative option for the Proposal 4 of reducing the frequency of internal audits to a frequency matching that in Australia as it will further reduce the administrative costs while still maintaining the health and safety standards. The statement in the report "evidence from Australiaâ€™s Office of the Gene Technology Regulator does not suggest that lower internal audit frequency would lead to significant non-compliances" shows that this will be safe to further reduce the frequency of the internal audit.Those two alternative options might also facilitate the establishment of branch from Australian biotechnological companies in NZ as the regulation will be further aligned to those from Australia.
Malaghan Institute of Medical Research	Costs, benefits or risks	Costs, benefits or risks	One of the risk in Proposal 7 Clarify the regulatory status of certain biotechnologies about inadvertently deregulation of biotechnologies that are not intended to be deregulated will be mitigated by Proposal 10: Require regular reviews of regulatory settings. To mitigate further this risk, the interval for such reviews could be setup every two to three years instead of 5 years at least at the beginning.
Malaghan Institute of Medical Research	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	For the 2.1 Kinds of dealings suitable for at least physical containment level 2, in the point k and m for replication defective retroviral vectors able to transduce human cells:- the donor nucleic acids does not confer an oncogenic modification or immunomodulatory effect in humans.In our view the word "immunomodulatory" is subject to interpretation as this wording could exclude the making of Chimeric Antigen Receptor T cell (CAR-T) therapies for auto-immune diseases. CAR-T cells therapies against auto immune diseases have inherent immunomodulatory effects that dampen the over-activation of the immune system to treat those kind of illnesses. We suggest that the word "immunomodulatory" could be replaced by "severe immunosuppression" that will give more clarity.
Malaghan Institute of Medical Research	Feedback on process/consultation	Feedback on process/consultation	As a New Zealand-based independent biomedical research institute, the Malaghan Institute of Medical Research would like to thank the effort EPA is making in seeking to align our GMO regulatory framework with international best practice and appropriate level of risk for laboratory and biomedical research. We are convinced that the proposed changes highlighted in this consultation will have tremendous positive impact on the whole biotechnological R&D sectors in Aotearoa New Zealand and lead to significant improvements in human, animal and environmental health in Aotearoa New Zealand.
Matthew Mayo-Smith	Proposal 1 - Risk-tiering framework	Yes	Yes
Matthew Mayo-Smith	Proposal 1 - Risk-tiering framework	Yes	This is a sensible approach to classifying the risk of laboratory contained GMO to New Zealand
Matthew Mayo-Smith	Proposal 1 - Risk-tiering framework	Yes	Yes
Matthew Mayo-Smith	Proposal 1.1 - Biosafety Committees	Yes	Yes
Matthew Mayo-Smith	Proposal 2 - Assessments for medicines	Yes	Yes

Matthew Mayo-Smith	Proposal 2 - Assessments for medicines	Yes	Yes
Matthew Mayo-Smith	Proposal 3 - Record-keeping requirements	Yes	Yes
Matthew Mayo-Smith	Proposal 3 - Record-keeping requirements	Yes	Yes
Matthew Mayo-Smith	Proposal 3 - Record-keeping requirements	Yes	Yes
Matthew Mayo-Smith	Proposal 4 - Internal audit frequency	Yes	Yes
Matthew Mayo-Smith	Proposal 4 - Internal audit frequency	Yes	Yes
Matthew Mayo-Smith	Proposal 5 - Movement between facilities	Yes	Yes
Matthew Mayo-Smith	Proposal 5 - Movement between facilities	Yes	Yes
Matthew Mayo-Smith	Proposal 5 - Movement between facilities	Yes	Yes
Matthew Mayo-Smith	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Matthew Mayo-Smith	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Matthew Mayo-Smith	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Matthew Mayo-Smith	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Matthew Mayo-Smith	Proposal 8 - Low-risk fermentation	Yes	Yes
Matthew Mayo-Smith	Proposal 8 - Low-risk fermentation	Yes	Yes
Matthew Mayo-Smith	Proposal 8 - Low-risk fermentation	Yes	Yes
Matthew Mayo-Smith	Proposal 9 - Standards for containment facilities	Outcome-based	Shifting to outcome-based standards
Matthew Mayo-Smith	Proposal 9 - Standards for containment facilities	Outcome-based	Focusing on the outcomes would enable more accurate risk assessment than under the current status quo.
Matthew Mayo-Smith	Proposal 9 - Standards for containment facilities	Yes	Yes
Matthew Mayo-Smith	Proposal 9 - Standards for containment facilities	No	No

Matthew Mayo-Smith	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Matthew Mayo-Smith	Proposal 10 - Reviews of regulatory settings	No	No
Matthew Mayo-Smith	Proposal 10 - Reviews of regulatory settings	No	No
Matthew Mayo-Smith	Proposal 10 - Reviews of regulatory settings	No	No
Matthew Mayo-Smith	Proposal 10 - Reviews of regulatory settings	No	I believe it should be more frequent than five years (2-3 instead). The introduction of new techniques (i.e CRISPR Cas9 gene editing, and derivative techniques) is rapidly accelerating and a review period of 5 years may be too long to respond to new advances.
Matthew Mayo-Smith	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Matthew Mayo-Smith	Costs, benefits or risks	Costs, benefits or risks	No
Matthew Mayo-Smith	Te ao Maori	Use of genetic material	Yes
Matthew Mayo-Smith	Te ao Maori	Taonga species	Number 2. Genetic modification of a taonga species does not necessarily represent an represent an increased risk to the New Zealand environment when appropriately contained. Therefore, prior approval from the EPA seems unnecessary and the consultation of iwi through an ABSC would likely be sufficient.
Matthew Mayo-Smith	Te ao Maori	Use of genetic material	Yes
Matthew Mayo-Smith	Useful quotes	Useful quotes	My general experience with the current regulations of GMO in laboratory settings is that the perceived risk of most GMOs to New Zealand by the MPI and EPA is overemphasized, unnecessary and burdensome.The current regulations are out of date in terms of how genetic modification technologies and approaches have developed, and are ill equipped to respond to future developments. And the focus on whether an organism is genetically modified, rather than what the risk a particular GMO may pose to the New Zealand environment is not the most appropriate method of risk assessment.I strongly support these proposed changes.
Biodynamics New Zealand	Objectives	Objectives	No
Biodynamics New Zealand	Proposal 1 - Risk-tiering framework	No	No
Biodynamics New Zealand	Proposal 1 - Risk-tiering framework	No	The term â€œLow Riskâ€ is subjective.Many examples over time have shown that many substances that were perceived as â€œlow riskâ€ or even â€œsafeâ€ have later changed when better science evolves over time.The agricultural industry is only too familiar with new science delivering â€œimprovedâ€ technology which later proves either less productive or unsafe. Glyphosate is an example, 2,4D and DDT are others. The risk from some of these chemicals werenâ€™t known until decades or generations later when their mode of action proved most detrimental.Science is always evolving and often shows that nature has many solutions to our problems. The further we move away from nature, the riskier the outcomes. There is little further from nature than manipulation of genetic material. It is the fundamental core of nature and one that has evolved over history, unaffected by human ego to control and manipulate it.
Biodynamics New Zealand	Proposal 1 - Risk-tiering framework	No	No
Biodynamics New Zealand	Proposal 1 - Risk-tiering framework	No	As mentioned above, what we deem to be low risk today, is likely to change tomorrow. As science evolves, so does our understanding of unintended consequences of our actions.History has shown us this, time and time again.
Biodynamics New Zealand	Proposal 1 - Risk-tiering framework	Other policy options	Maintain the status quo. GM is not the answer.
Biodynamics New Zealand	Proposal 1.1 - Biosafety Committees	No	No
Biodynamics New Zealand	Proposal 1.1 - Biosafety Committees	No	The option to enable some research to be granted permission that allows GM use to carry on, perhaps with less containment than is currently required, is in opposition to a lot of science that is being generated in the organic and Regenerative agriculture space.The use of GM technology is fundamentally against the beliefs of Biodynamics New Zealand.Itâ€™s use threatens the right of choice for consumers, farmers and tangata whenua once these GMOâ€™s are in our environment.

Biodynamics New Zealand	Proposal 1.1 - Biosafety Committees	No	Maintain the status quo.New Zealand is in a unique situation, where a geographically isolated island nation exists, with a reputation already strongly aligned with a â˜green ethos and brandâ€™ and produces high quality products which are exported to the world. There is a level of trust to our brand which is invaluable.Further exploration and increased use of GM technology only threatens to unravel these decades of brand and reputation building.
Biodynamics New Zealand	Proposal 2 - Assessments for medicines	No	No
Biodynamics New Zealand	Proposal 2 - Assessments for medicines	No	Maintain the status quo. What is deemed "low risk" today, is likely to change in the future when science can provide more answers. Also, some flow on effects of GM technology today may not be known for generations to come.
Biodynamics New Zealand	Proposal 2 - Assessments for medicines	No	No
Biodynamics New Zealand	Proposal 2 - Assessments for medicines	No	Maintain the status quo. What is deemed "low risk" today, is likely to change in the future when science can provide more answers. Some flow on effects of GM technology today may not be known for generations to come.We don't know, what we don't know
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	No	Maintain the status quo.The current record keeping requirements should be robust and thorough. Safeguards must be in place to negate the risk of lab escape of foreign genetic material. Our natural environment is our most important taonga and must be protected at all costs.The risks of escape of foreign genetic material will have unknown repercussions on our natural environment, let alone people.
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	No	No
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	Yes	Yes
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	Yes	Traceability of such high risk work is of the utmost importance.The HSNO act is there to protect the environment and the people of NZ.
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	No	No
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	No	Maintain the status quo.The current record keeping requirements should be robust and thorough. Safeguards must be in place to negate the risk of lab escape of foreign genetic material. Our natura environment is our most important taonga and must be protected at all costs.The risks of escape of foreign genetic material will have unknown repercussions on our natural environment, let alone people.If the current rules and regulations are considered excessive, perhaps too much of this work is being carried out. Becoming lackadaisical about records and traceability reflects a growing relaxing in the real risk and dangers that this work involves.
Biodynamics New Zealand	Proposal 3 - Record-keeping requirements	Other policy options	Maintain the status quo.There are other countries that may choose to work in this arena. NZ should not be a part of this flawed approach to find "technological solutions".
Biodynamics New Zealand	Proposal 4 - Internal audit frequency	Unsure	Auditing requirements should be robust and thorough. Safeguards must be in place to negate the risk of lab escape of foreign genetic material. Our natural environment is our most important taonga and must be protected at all costs.The risks of escape of foreign genetic material will have unknown repercussions on our natural environment, let alone people.If the current rules and regulations are considered excessive, perhaps too much of this work is being carried out. Becoming lackadaisical about auditing reflects a growing relaxing in the real risk and dangers that this work involves.
Biodynamics New Zealand	Proposal 4 - Internal audit frequency	Unsure	Unsure
Biodynamics New Zealand	Proposal 4 - Internal audit frequency	No	No
Biodynamics New Zealand	Proposal 4 - Internal audit frequency	No	Auditing requirements should be robust and thorough. Safeguards must be in place to negate the risk of lab escape of foreign genetic material. Our natural environment is our most important taonga and must be protected at all costs.The risks of escape of foreign genetic material will have unknown repercussions on our natural environment, let alone people.If the current rules and regulations are considered excessive, perhaps too much of this work is being carried out. Becoming lackadaisical about auditing reflects a growing relaxing in the real risk and dangers that this work involves.
Biodynamics New Zealand	Proposal 4 - Internal audit frequency	Other policy options	Maintain the status quo
Biodynamics New Zealand	Proposal 5 - Movement between facilities	No	No
Biodynamics New Zealand	Proposal 5 - Movement between facilities	No	No
Biodynamics New Zealand	Proposal 5 - Movement between facilities	No	transport of such GMO's is a high risk step for any item, let alone an item that could be detrimental to the NZ environment, its flora and fauna and its people. Removing barriers to allow greater ease of movement of GMO's only makes such movements become more common and hence increasing the risk of an incident involving the accidental release of such GMO'

Biodynamics New Zealand	Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Biodynamics New Zealand	Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Biodynamics New Zealand	Proposal 6 - Requirements for eukaryotic somatic cells	No	ny form of GM technology which codes for the generation of novel proteins in our environment has an impact which, as it stands, is unknown in terms of environmental impact. If the generation of such novel GMO's and proteins increases, so too does the risk of an unintended and negative effect on the environment, its flora and fauna and the people of NZ.
Biodynamics New Zealand	Proposal 6 - Requirements for eukaryotic somatic cells	No	Any form of GM technology which codes for the generation of novel proteins in our environment has an impact which, as it stands, is unknown in terms of environmental impact. If the generation of such novel GMO's and proteins increases, so too does the risk of an unintended and negative effect on the environment, its flora and fauna and the people of NZ.
Biodynamics New Zealand	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	Any loosening of the laws and regulation of GM technology only increases the frequency at which these organisms are created, further risking our taonga.
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	No	No
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	No	This is a dangerous realm of technology. Just because we can, does not mean we should participate in it. Slowly we erode the moral and ethical tenets which keep our people and our environment safe. It is a line which should not be crossed, and the more it is crossed, the more normal it becomes and the more risk we place upon ourselves.If nature wanted DNA and RNA to be changed, it would allow it to happen naturally, without human intervention. If this continues at an ever increasing pace winch science and governments allow, then the greater risk we place on ourselves if the science proves detrimental in the future.
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	No.Natures solutions are always the best. Human intervention with GM technology is ethically wrong.Perhaps we are now looking for solutions to problems which are likely to have been created by human domination over nature. Our loss of nutritional food by modern intensive agricultural methods are not solving the worlds food problems, in fact our continued domination over nature is creating more chronic illnesses than humanity has seen before.
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	No	No
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	No	Again, our desire to "harness" the cell and its processes will not result in a better outcome for us. It's a world which should not be interfered with.
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	Other policy options	e must maintain robust protections in place to preserve our natural environment, our flora and fauna, our waterways and our people. Humans domination over this only threatens our taonga.
Biodynamics New Zealand	Proposal 7 - Regulatory status of biotechnologies	Other policy options	We must maintain robust protections in place to preserve our natural environment, our flora and fauna, our waterways and our people.
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	No
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	The perception that an organism is "low risk" is based on the science of today. The categorisation of risk changes with time. We cannot be certain that what is considered "low risk" today will meet that same definition in the future.It would be unwise to relax the administration, rules and regulations around such work.
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	The greater the scale, the greater the risk
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	No
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	No
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	This is not an area of technology which is favourable to nature. It serves only to benefit humans, which is a egocentric view.The creation of novel DNA and RNA vaccines for use on humans and indeed on domestivcated animals which are bred and reared for human consumption is not an area of technology NZ should be investing in. The science behind the longterm flow on effects of such manipulation at the cellular level cannot be fully understood for generations.It would be foolish to rush into this irreversible area of science.
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	Other policy options	This is not an area of science which NZ should be partaking in.
Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	Status quo	Keeping the status quo approach

Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	Status quo	Maintaining stringent controls at points of risk is of the utmost importance. The creation of GMO's is not an area of research which NZ should be participating in. Our island nation is unique in terms of its flora and fauna and any threat to this taonga should not be taken lightly.
Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	Unsure	Unsure
Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	Unsure	Maintaining stringent controls at points of risk is of the utmost importance. The creation of GMO's is not an area of research which NZ should be participating in. Our island nation is unique in terms of its flora and fauna and any threat to this taonga should not be taken lightly.The organisation should not be able to choose the controls which best suit them. The work is putting NZ's flora and fauna at risk and stringent controls must be in place if this work is to be carried out.
Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	No	No
Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	No	Maintaining stringent controls at points of risk is of the utmost importance. The creation of GMO's is not an area of research which NZ should be participating in. Our island nation is unique in terms of its flora and fauna and any threat to this taonga should not be taken lightly.The organisation should not be able to choose the controls which best suit them. The work is putting NZ's flora and fauna at risk and stringent controls must be in place if this work is to be carried out.
Kam Salt	Objectives	Objectives	Yes
Kam Salt	Objectives	Objectives	I think a risk tier framework is a great approach, but I think only applying it to GMO and not new organisms is too process oriented, should be more broad to capture future techniques and older techniques, being consistent with relevant risk.
Kam Salt	Proposal 1 - Risk-tiering framework	Yes	Yes
Kam Salt	Proposal 1 - Risk-tiering framework	Yes	Good to encourage more investment into this technology.
Kam Salt	Proposal 1 - Risk-tiering framework	No	No
Kam Salt	Proposal 1 - Risk-tiering framework	No	No
Kam Salt	Proposal 1 - Risk-tiering framework	No	Our regulatory system also presents a false risk to consumers, I think that needs to be acknowledged in issues. Many consumers are skeptical and perceive false health risks of GMO products, with a large cause of that due to strict regulation and anti-GMO marketing exaggerating and misrepresenting the relative risks of these products.Not acknowledging that in your issues may leave respondents confused if they believe there is a risk of consuming GMO products.
Kam Salt	Proposal 1 - Risk-tiering framework	Other policy options	Acknowledge more of the research (and scientific consensus) on the relative safety of GE food compared to current common methods.
Kam Salt	Proposal 1.1 - Biosafety Committees	Unsure	Unsure
Kam Salt	Proposal 1.1 - Biosafety Committees	Unsure	Would like to see specific seats saved for Tangata Whenua perspectives, given cultural beliefs about GE and our obligations to Te Tiriti.
Kam Salt	Proposal 2 - Assessments for medicines	Yes	Yes
Kam Salt	Proposal 2 - Assessments for medicines	Yes	Seems logical, if it doesn't pose the same risk, why regulate it as if it did.
Kam Salt	Proposal 2 - Assessments for medicines	Unsure	No
Kam Salt	Features and approach for regulatory framework	Features and approach for regulatory framework	Consistent regardless of buzzword or methodology used. Objectively assessing the new product, regardless of creation, and assigning a risk category based on induced changes and understood risk benefit.A regulatory framework should also encourage community and consumer benefit, ensuring that genetic engineering techniques are used for the benefit of Aotearoa, not just cost cutting.
Kam Salt	Proposal 1.1 - Biosafety Committees	Other policy options	Add in an assessment of intending outcome and who benefits of a new product. For medical research that would be patients of X disease, for agriculture that might be the consumer to have access to greater nutrition.
Kam Salt	Proposal 2 - Assessments for medicines	Yes	Yes

Kam Salt	Proposal 2 - Assessments for medicines	Other policy options	No
Kam Salt	Proposal 3 - Record-keeping requirements	Yes	Yes
Kam Salt	Proposal 3 - Record-keeping requirements	Yes	Yes
Kam Salt	Proposal 3 - Record-keeping requirements	Unsure	Unsure
Kam Salt	Proposal 3 - Record-keeping requirements	Unsure	Im unsure if this proposal is trying to increase labelling or decrease.I think even if it's time consuming, labelling should be strict, as to prevent cross contamination of different cultures with different regulatory risks.
Kam Salt	Proposal 4 - Internal audit frequency	Yes	Yes
Kam Salt	Proposal 4 - Internal audit frequency	Yes	Yes
Kam Salt	Proposal 5 - Movement between facilities	Yes	Yes
Kam Salt	Proposal 5 - Movement between facilities	Yes	Yes
Kam Salt	Proposal 5 - Movement between facilities	Yes	Yes
Kam Salt	Proposal 5 - Movement between facilities	Yes	Yes
Kam Salt	Proposal 5 - Movement between facilities	Yes	Yes
Kam Salt	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Kam Salt	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Cannot proliferate in the environment, so seems good, as mentioned in your context, some Eukaryotes outside of animalia, fungi, and plants can exist as single celled organisms, and they probably should be considered as higher risk if they can self proliferate in the environment
Kam Salt	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	No	No
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	No	I do not think narrowing the definition of GMO is a good regulatory strategy, instead we should expand GMO to include most modification techniques (such as older ones like mutagenisis), distiguish some as GE, and regulate based on being a new organisms, not being a GMO.
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	Epigenetic modifications is questionable, since we are still quiet unsure on this field and how impactful they are. Seems like opening a can of regulatory worms to start classifying epigenetic changes as a new organism. Environmental effects change it all the time, why would we say technological changes to the epigenome pose more risk?
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	Unsure	Unsure
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	Other policy options	Expand the scope of GMO, and stop regulating based on process but on product
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	Other policy options	Mutagenisis techniques should be considered under the same regulatory umbrella

Kam Salt	Proposal 8 - Low-risk fermentation	Yes	Yes
Kam Salt	Proposal 8 - Low-risk fermentation	Yes	Good industry to promote and invest in.
Kam Salt	Proposal 8 - Low-risk fermentation	Yes	Yes
Kam Salt	Proposal 8 - Low-risk fermentation	Yes	Stability and contents of the vessel matters more than size.
Kam Salt	Proposal 8 - Low-risk fermentation	Unsure	Unsure
Kam Salt	Proposal 8 - Low-risk fermentation	Unsure	Not enough knowledge of this area
Kam Salt	Proposal 9 - Standards for containment facilities	Outcome-based	Shifting to outcome-based standards
Kam Salt	Proposal 9 - Standards for containment facilities	Outcome-based	Not enough knowledge of this area to give a confident answer
Kam Salt	Proposal 9 - Standards for containment facilities	Unsure	Unsure
Kam Salt	Proposal 9 - Standards for containment facilities	Unsure	Not enough knowledge of this area
Kam Salt	Proposal 9 - Standards for containment facilities	Unsure	Not enough knowledge of this area
Kam Salt	Proposal 9 - Standards for containment facilities	No	No
Kam Salt	Proposal 9 - Standards for containment facilities	Other policy options	Not enough knowledge of this area
Kam Salt	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Kam Salt	Proposal 10 - Reviews of regulatory settings	Yes	We have not been incoperating latest evidence into our regulation, a review that encourages that would be good.
Kam Salt	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Kam Salt	Proposal 10 - Reviews of regulatory settings	Other policy options	Shift regulations to less process specific wording, but new organisms (product oriented), so newer techniques can be captured without rewriting regulation.
Kam Salt	Answer contradicts previous answer	Answer contradicts previous answer	No
Kam Salt	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Kam Salt	Proposal 7 - Regulatory status of biotechnologies	No	I do not think narrowing the definition of GMO is a good regulatory strategy, instead we should expand GMO to include most modification techniques (such as older ones like mutagenisis), distiguish some as GE, and regulate based on being a new organisms, not being a GMO.
Kam Salt	Proposal 10 - Reviews of regulatory settings	Unsure	Unsure

Kam Salt	Proposal 10 - Reviews of regulatory settings	Unsure	Hard to say what specific timeline is best, too frequent might reduce willpower to actually review, too little might mean we miss out of latest research and more detailed dives.

9(2)(ba)(i)

9(2)(ba)(i)

Bat Janssen	Objectives	Objectives	No
Bat Janssen	Objectives	Objectives	Both the first and third bullet points are OK. But the second bullet point is too specific. By specifically mentioning only health, biomedical research, therapies and medicines it suggests that other GMC research is not part of the objectives. My worry is that a lawyer could argue that these changes should not apply to non-medical research.This leaves two options, first try and list all the possible valuable research outcomes that are intended to be benefited by these changes, or second, list no specific type of research at all.I would strongly favour the second since it is far more flexible and proof against future research goals.I would suggest replacing bullet point 2 with something likeâ€œcontributes to better outcomes for New Zealanders through better research outcomes and innovationâ€

Bat Janssen	Features and approach for regulatory framework	Features and approach for regulatory framework	I believe it is important to have a system which focuses on the risks associated with the outcome of the modification and not on source material or method of modification or place where the modification occurred. Because the regulation will be subject to scrutiny and challenge it needs to be consistent throughout all the changes so that the intent of the regulations is absolutely clear and obvious to courts and authorities that might be tasked with ruling on specific issues.Given our experience with a legislation that was focused on technology I would favour an approach that was agnostic with respect to technology and instead focused on the outcome rather than the method used to achieve that outcome. Thus it should be the resulting organism that should be assessed for risk to safety, environment or culture and not the method or technology used to develop that organism.That does not mean methods should not be considered for safety (physical, cultural and environmental) but rather that the safety questions around methods used should be part of normal lab operations and independent of GMO regulations.While I am not sure how to achieve it, I believe the regulation needs to avoid regulatory creep where what was initially intended to make work with GMOs easier becomes progressively more restrictive over time as people change interpretation of the regulations. This is particularly vulnerable to the organisations and individuals charged with auditing acting to increase the importance of their job by making the regulations more restrictive.I think these regulations need to consider the overall goal of GMO field trials and eventual commercial release of GMOs in order to allow the research to have beneficial impact on society. In particular these regulations must maintain a rigorous focus on the risk of the resulting organism and not the methods used to develop the organism nor the containment conditions in which the organism was developed. While the changes outlined here cannot alter the HSNO act itself they should consider that fundamental principles established in these regulations should provide a template and guide for subsequent replacement of the HSNO act.
Bat Janssen	Proposal 1 - Risk-tiering framework	Yes	Yes
Bat Janssen	Proposal 1 - Risk-tiering framework	Yes	YesButThe details are important see Q42Given the tier structure in Appendix 3 this change would greatly simplify lab operation and record keeping without increasing risks to safety, culture anc environment.It is worth noting that such a structure is largely how most labs in the world operate without any evidence of harm or any evidence of â€œescapeâ€ from the lab and as such it would be expected that changing to such a system would not result in harm in New Zealand.Assuming a tier structure roughly in line with the Australian tiers this change would dramatically reduce the time taken to track and record low risk GMOs. An additional benefit is the cost to import low risk GMOs for use in research (eg competent cells) would be greatly reduced and the importation process much simplified.Another big advantage of this system is it reduces the number of minor non-compliance breaches associated with the complicated record keeping required for low-risk GMOs. This would allow effort to be focused on areas of genuine risk.
Bat Janssen	Proposal 1 - Risk-tiering framework	Yes	Yes
Bat Janssen	Proposal 1 - Risk-tiering framework	Agree with issues	While the Australian regulations appear to be largely clear and well considered there is (understandably) no consideration of the special nature of Taonga species. While the safety and environmental risks may be the same as in Australia the cultural risks are significantly different.
Bat Janssen	Proposal 1 - Risk-tiering framework	Other policy options	No
Bat Janssen	Proposal 1.1 - Biosafety Committees	Yes	Yes
Bat Janssen	Proposal 1.1 - Biosafety Committees	Other policy options	It is stated that ABSCs are intended to be different and simpler to operate.â€œThis is because the criteria under the risk tiers will be more explicit than interpretive. For instance, organisms included under that risk tier will be explicitly listed, rather than using interpretive criteriaâ€¦â€However, a danger of defining explicit organisms in risk tiers is that as technology changes new organisms may become more useful and unless the risk tiers are regularly updated then ABSCs may be unable to approve newer technologies.This feature undermines the desire to make the regulations future proof.One possible solution is that if an ABSC is asked to assess a new organism not explicitly included in the risk tiers that some ABSCs be given the power to recommend assignment of new organisms into the risk tiers allowing other ABSCs to approve them. The advantage is that the ABSC approached with a new organism is likely to be associated with an institute where expertise on that organism is most likely to already exist making an informed judgement easier.Obviously such a system would need to be subject to oversight.A danger of ABSCs is that they have a tendency to become more restrictive in their assessments over time. This tendency would act over time to undermine the objective of proportionately managing risk.
Bat Janssen	Proposal 2 - Assessments for medicines	Yes	Yes
Bat Janssen	Proposal 2 - Assessments for medicines	Yes	Yes
Bat Janssen	Proposal 2 - Assessments for medicines	Other policy options	No
Bat Janssen	Proposal 3 - Record-keeping requirements	Yes	Yes
Bat Janssen	Proposal 1 - Risk-tiering framework	Agree with issues	While the Australian regulations appear to be largely clear and well considered there is (understandably) no consideration of the special nature of Taonga species. While the safety and environmental risks may be the same as in Australia the cultural risks are significantly different.
Bat Janssen	Proposal 1.1 - Biosafety Committees	Proposal 1.1 - Biosafety Committees	However I would note that different ABSCs will have different expertise according to the organisation with which they are associated and some ABSCs may have limited expertise. While some ABSCs may simply apply the risk tier structure I believe that some ABSCs should be able to assess organisms not already within the risk tier structure and provide expert assessment of the appropriate risk tier that would then be applied universally (with appropriate oversight).Additionally, some, but probably not all, ABSCs will require representation from relevant iwi where taonga species are being considered or may be affected. I am not certain (and definitely not qualified to judge) how broadly or narrowly consideration of taonga species needs to be assessed. In some cases a nationwide decision of cultural risk will be necessary but there may be cases where local considerations are more relevant.
Bat Janssen	Proposal 2 - Assessments for medicines	Yes	Yes

Bat Janssen	Proposal 2 - Assessments for medicines	Agree with issues	The statementâ€the EPA would still retain the right to decline an application under section 38I, should it determine that a rapid assessment would be insufficient for a particular application.â€lacks any definition of what might constitute â€œinsufficientâ€. It would be helpful is examples of insufficient were given.
Bat Janssen	Proposal 3 - Record-keeping requirements	Proposal 3 - Record-keeping requirements	I would note that research requires record keeping anyway. Knowing the history and characteristics of samples is a normal part of research.As such the existing record keeping requirements both duplicate scientific record and require largely irrelevant information to be recorded.Our experience with the systems is they are error prone and time consuming without any additional benefit. They also consume a huge amount of auditing time that could and should be better spent.
Bat Janssen	Proposal 3 - Record-keeping requirements	No	No
Bat Janssen	Proposal 3 - Record-keeping requirements	No	From our experience including the HSNO approval numbers on labels only serves to create the possibility of errors with no improvement in risk management. It is of far greater value to have the researchers read and understand the relevant controls for management of risks than to have them mechanically apply a number to a label.
Bat Janssen	Proposal 3 - Record-keeping requirements	Other policy options	NoIâ€™d comment though that under the current regime most (all) of the training is focused on ensuring the records have all the numbers and boxes correct and very little training on the actual handling of GMOs in a manner appropriate to their risk. In my opinion this emphasis on spreadsheets and numbers increases the risk of harm and exists for the ease of auditing and not for the reduction of risk.
Bat Janssen	Proposal 4 - Internal audit frequency	Yes	Yes
Bat Janssen	Proposal 4 - Internal audit frequency	Yes	Yes
Bat Janssen	Proposal 4 - Internal audit frequency	Proposal 4 - Internal audit frequency	At present most of the time spent on internal audits and MPI inspections is focused on checking spreadsheets and registers. With the changes to risk tiers most of those registers will be gone. This means much more time is available to actually inspect the physical labs. As a result audits and inspections should both be quicker and more likely to address genuine hazards. I would argue that, as a consequence, audits and inspections could be reduced in frequency.I particular I see no benefit from 6 monthly internal audits for PC2 and I believe a 24 month inspection cycle would also achieve the same results as a 12 monthly cycle for both PC1 and PC2 facilities.
Bat Janssen	Proposal 4 - Internal audit frequency	Other policy options	Yes. Reduce audit and inspection frequencies further and keep them focused on physical containment.
Bat Janssen	Proposal 5 - Movement between facilities	No	No
Bat Janssen	Proposal 5 - Movement between facilities	Proposal 5 - Movement between facilities	Yes and NoYes the change is goodNo you cannot specify â€œunbreakableâ€. That word can never be achieved and is far too easily challenged by lawyers. Simply delete the word unbreakable.There are several definitions of suitable containers for transport of GMOs developed by other countries
Bat Janssen	Proposal 5 - Movement between facilities	No	No
Bat Janssen	Proposal 5 - Movement between facilities	No	The conditions for transfer are inconsistent with the new model of risk tiers.The conditions for transfer should refer only to the risk associated with the organism and not refer to where the organism was developed or how the organism was developed.In particular, the requirements for PC level, confirmation by facility managers and recording of the movement are all inconsistent with the rest of these new regulations and merely replicated existing paperwork that has been all but eliminated in the rest of the regulations. The maintenance of a transfer register does not reduce the risk but merely maintains an existing bureaucracy.These three bullet points should be deletedâ€¢ The containment facility the organisms are being sent to is operated at a PC level equal to or greater than PC1.â€¢ The facility operator of the sending facility confirms the movement meets these requirements.â€¢ Both the sending and receiving facilities record the movement in a register.The third bullet point should be replaced by something likeâ€¢ The facility the organisms are being sent to is operated at a PC level appropriate to the risk tier of the transferred organisms.
Bat Janssen	Proposal 5 - Movement between facilities	Other policy options	This section should be rewritten from the perspective of managing movement of organisms in a manner consistent with the risk tier of those organisms. Where organisms are of a risk tier that requires management in labs of PC1 or below transfers should merely require sealed containment and labelling. Organisms with a higher risk tier may require more substantial containment.Record keeping should be consistent with the record keeping required for the risk tier of the organism.I would note that the complexity of the existing system for transfers results in regular failures by suppliers of routine laboratory organisms. The exercise of opening inspecting and recording packages of low risk organisms is very time consuming and it is common for distributors and overseas suppliers to fail to include necessary documentation resulting in wasted time and effort for everyone involved without any change in the risk of harm to environment, staff or culture.
Bat Janssen	Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Bat Janssen	Proposal 6 - Requirements for eukaryotic somatic cells	No	There are two bullet points which I believe are far too restrictiveFirstâ€œThe donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi.â€This bullet point restricts any work on gene function and discovery where the source is a pathogen of any kind â€“ regardless of the risk tier of the resulting organism. Thus, you could transfer a gene for a well-understood completely safe protein but because it came from a pathogen the new cell line would have to be managed as if it was a higher risk tier.This largely restricts work on understanding pathogenicity which is a very important area of research. It also restricts work where the genes under question have no role in pathogenicity, simply based on the source organism. Finally, it is inconsistent with the other changes in the document where it is the risk of the change that should be assessed not simply its source or method.In short, where the modification could be expected to result in pathogenicity then those cell lines should be included in a different risk tier but not simply that the donor DNA came from a pathogenic organism.Secondâ€œThe plant cells or tissues cannot spontaneously generate a whole plant and cannot be regenerated into a whole plant.â€It is a feature of plants that all cells can be regenerated into a whole plant â€“ albeit usually with significant effort. This bullet effectively excludes all plant cell cultures from tier 1 regardless of the actual risk from those cells or the plants into which they might potentially (unlikely) regenerate.Again, this bullet focuses on the method and source rather than the outcome. A culture of GM tomato cells may regenerate into a GM tomato but if that tomato poses no risk to safety, environment or culture the cell line should be regulated according to the actual risk of escape and potential harm â€“ in most cases negligible.

Bat Janssen	Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Bat Janssen	Proposal 6 - Requirements for eukaryotic somatic cells	No	The issues raised overstate the risk of actual harm and the potential for escape from the lab. The issues raised focus on methods and source material and not on outcome of the modification â€“ this is inconsistent with the fundamental changes proposed.As noted previously if the changes are internally inconsistent they will be vulnerable to challenge.
Bat Janssen	Proposal 6 - Requirements for eukaryotic somatic cells	No	The issues raised overstate the risk of actual harm and the potential for escape from the lab. The issues raised focus on methods and source material and not on outcome of the modification â€“ this is inconsistent with the fundamental changes proposed.As noted previously if the changes are internally inconsistent they will be vulnerable to challenge.
Bat Janssen	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	No
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	No	No
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	No	The change does improve a bad piece of law but does not address the fundamental problem with trying to regulate by method instead of outcome.Furthermore, the exclusions given require the proof of a negative which is almost impossible in biology.For example it is impossible to be 100% certain that RNA â€œcannot result in an alteration of the organismâ€™s genomic sequenceâ€A better phrasing might be â€œis not expected to be able to alter the organismâ€™s genomic sequenceâ€Similarly the next line could be â€œIs not expected to give rise to an infectious agentâ€Similar language would be better for point 2 and 3 in this section.
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	No	The change does improve a bad piece of law but does not address the fundamental problem with trying to regulate by method instead of outcome.Furthermore, the exclusions given require the proof of a negative which is almost impossible in biology.For example it is impossible to be 100% certain that RNA â€œcannot result in an alteration of the organismâ€™s genomic sequenceâ€A better phrasing might be â€œis not expected to be able to alter the organismâ€™s genomic sequenceâ€Similarly the next line could be â€œIs not expected to give rise to an infectious agentâ€Similar language would be better for point 2 and 3 in this section.
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	No
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	Other policy options	No. The fundamental problem with defining and adding new technologies is that it legitimizes a flawed and harmful piece of legislation.Every time a new exception is added it creates more confusior and more opportunity for litigation. We donâ€™t legislate against specific technologies in computing or engineering and we should not for biology.Furthermore, such an approach is always going to become outdated and irrelevant with new technology.Essentially, we must remove this bad piece of law and replace it with legislation that regulates risk from outcomes and not from methodology. Changing the regulations around lab use of GMOs is a small step in the right direction and the more consistent this set of changes is the more likely it is that this approach will be applied to release of GMOs from the lab for field trial and eventually for release to benefit society.
Bat Janssen	Proposal 8 - Low-risk fermentation	Yes	Yes
Bat Janssen	Proposal 8 - Low-risk fermentation	Yes	Yes
Bat Janssen	Proposal 8 - Low-risk fermentation	Increase to vessel size	There is no reason for a volume limit at all. If the GMO is low risk, then it is low risk at any volume
Bat Janssen	Proposal 8 - Low-risk fermentation	Yes	Yes
Bat Janssen	Proposal 8 - Low-risk fermentation	Other policy options	No
Bat Janssen	Proposal 8 - Low-risk fermentation	Other policy options	No
Bat Janssen	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Bat Janssen	Proposal 9 - Standards for containment facilities	Hybrid	Of the three options I prefer a hybrid approachFor many operators the existing prescriptive approach will be simpler to institute and require simpler assessment.However, particularly for larger organisations with in-house expertise it may be feasible to adopt an outcome-based standard that reduces cost and maintenance without compromising risk to safety, environment or culture.BUT it requires both internal and external assessors to allow for flexibility. Unfortunately, because of the nature of their job it is all too common for assessors to get blamed for breaches and as such they become highly conservative. I suspect that this is likely to make any shift to outcome-based standards difficult to maintain.

Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	No	The change does improve a bad piece of law but does not address the fundamental problem with trying to regulate by method instead of outcome.Furthermore, the exclusions given require the proof of a negative which is almost impossible in biology.For example it is impossible to be 100% certain that RNA â€œcannot result in an alteration of the organismâ€™s genomic sequenceâ€A better phrasing might be â€œis not expected to be able to alter the organismâ€™s genomic sequenceâ€Similarly the next line could be â€œIs not expected to give rise to an infectious agentâ€Similar language would be better for point 2 and 3 in this section.
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	Other policy options	No. The fundamental problem with defining and adding new technologies is that it legitimizes a flawed and harmful piece of legislation.Every time a new exception is added it creates more confusior and more opportunity for litigation. We donâ€™t legislate against specific technologies in computing or engineering and we should not for biology.Furthermore, such an approach is always going to become outdated and irrelevant with new technology.Essentially, we must remove this bad piece of law and replace it with legislation that regulates risk from outcomes and not from methodology. Changing the regulations around lab use of GMOs is a small step in the right direction and the more consistent this set of changes is the more likely it is that this approach will be applied to release of GMOs from the lab for field trial and eventually for release to benefit society.
Bat Janssen	Proposal 8 - Low-risk fermentation	Other policy options	No
Bat Janssen	Proposal 9 - Standards for containment facilities	Hybrid	Of the three options I prefer a hybrid approachFor many operators the existing prescriptive approach will be simpler to institute and require simpler assessment.However, particularly for larger organisations with in-house expertise it may be feasible to adopt an outcome-based standard that reduces cost and maintenance without compromising risk to safety, environment or culture.BUT it requires both internal and external assessors to allow for flexibility. Unfortunately, because of the nature of their job it is all too common for assessors to get blamed for breaches and as such they become highly conservative. I suspect that this is likely to make any shift to outcome-based standards difficult to maintain.
Bat Janssen	Proposal 9 - Standards for containment facilities	Yes	Yes
Bat Janssen	Proposal 9 - Standards for containment facilities	No	No
Bat Janssen	Proposal 9 - Standards for containment facilities	No	No
Bat Janssen	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Bat Janssen	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Bat Janssen	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Bat Janssen	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Bat Janssen	Proposal 10 - Reviews of regulatory settings	Agree with issues	I think there needs to be a flexibility in the system to respond to really rapid changes in technology.It should be possible for an ABSC to instigate a review.The example of the development of gene editing technology is a case where even a five year delay in assessment would have been too long. A flexible system would allow for new technologies to be addressed rapidly especially where they have the potential to dramatically alter either the scale of change and/or the risk from organisms developed with that new technology.
Bat Janssen	Proposal 10 - Reviews of regulatory settings	Other policy options	Fundamentally the entire legislation needs to adopt regulation based on outcomes not based on technology as does the current legislation. We legislate other fields based on risks from the outcomes not on the technology used to achieve that outcome and that should be true for biology as well.If we regulated pornography based on the method of printing then internet pornography would be unregulated or if pornography legislation was modeled on the HSNO act then we would not allow the internet in New Zealand!Regularly updating a fundamentally flawed piece of legislation is at least better than doing nothing but still does not solve the problem.
Bat Janssen	Alternative options	Alternative options	Proposal 4 I think the alternative option is better.For reasons stated previously, with reduced spreadsheets and GMO registers the job of auditing internally and externally is much easier and can focus on physical risks. That should make less frequent audits more efficient and more thorough.Proposal 5 the alternative is no better because it focuses on existing PC levels and not the actual risk associated with the GMO. It also retains the pointless registers at both ends of any transfer and makes use of the unenforceable word â€œunbreakableâ€.
Bat Janssen	Costs, benefits or risks	Costs, benefits or risks	No

Bat Janssen	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Yes.There are several odd inclusions/exclusions that should be discussed and probably altered. I also found the use of the word â€œdealingsâ€ confusing, but Iâ€™m not a lawyer.Overall the logic for assigning risk tiers is sensible and understandable (with the exceptions noted below)If an organism is unlikely to escape and has no selective advantage, then PC1 or PC0 should be sufficient for containment.If the transferred genes/DNA confer a selective advantage or is expected to produce toxins or harmful compounds, then PC2 applies.I think for New Zealand a special category for Taonga species is reasonable. It may not require a change in PC level but may require additional consideration by ABSCs.I think for New Zealand, specific inclusion of species important to our agricultural sector might make enforcement simpler.Some inclusions are really specific. That makes knowing which GMO fits where easy but it will require regular updating by an expert panel, most likely an ABSC associated with the organisation most likely to have expertise.Risk tier 1Part 1Item2 Why is C. elegans specifically highlighted as exempt when other similar organisms might offer the same low risk? Is the intention to build a New Zealand list?Item 3A these are really specific, perhaps too specific to be flexible?Item 4 why 25 L? Why not 50L or 100L? Iâ€™m not sure volume makes any difference to risk, if the organism is safe then it should be exempt at any volume.Item 4 (2) (ii) says the donor DNA must be â€œcharacterisedâ€ without being specific about what that might entail. Is sequencing sufficient? I would have thought so but if not then a specific aim of the characterization would helpPart 2 item 10I think this means that while still in tissue culture then Agrobacterium-mediated transformation of plant material is considered risk tier 1 and would not require a PC lab. This is great and entirely appropriate.Plant material in tissue culture should all fit into this category as without significant intervention survival of material is dependent on supportive media and controlled growth conditions. Scenarios where such material might somehow escape and survive are largely fanciful. Only if the resultant organism is expected to pose additional risk (eg the transfer of pathogen genes) should PC2 containment be required.Risk tiers 2 and 3Schedule 3Part 1 GMOs suitable for PC1This section lists several organisms as suitable for PC1 unless they have â€œan advantageâ€. I presume this means they are not expected to have a selective advantage which would allow them to persist in the environment. This makes good sense since without an advantage it is likely that any modification would disappear from the population should a GM organism escape containment. That fact makes the risk of harm from escape much lower.However, it is not clear how the list of organisms was developed. Why is a mouse or rat included in PC1 but not a goat or sheep or cow?Furthermore, why are plants not included since they are significantly less likely to escape containment in the first place and much easier to track.I believe this section needs to be expanded to include several other lab mode organisms eg zebrafish, drosophila etc and include domesticated animals and agriculturally important species.I also strongly believe that GM plants should fit into this category.That is, most GMO plant material should by default be considered suitable for PC1. There is a very low risk of plant material â€œescapingâ€ from PC1. Furthermore most GMO plant material is low risk to the environment and low risk to safety. Except as noted in part 2 where the resultant organism is expected to contain harmful characteristics.Part 2 defines GMOs that should be in PC2Again, this section specifically excludes GM C. elegans, mice, rats, rabbits and guinea pigs which can be studied in PC1.Everything else appears to be limited to PC2 or PC3.I cannot see any rational for allowing only those five species to be studied in PC1 but not also allow several other model organisms to also be studied in PC1. I also believe the case could easily be made for inclusion of several domestic animals and agriculturally important animals to be studied under PC1.In particular GM plants are highly unlikely to run, swim or fly away from the lab (lacking as they do, limbs).Joking aside there are some cases where pollen might be able to travel some distance but, in most cases, PC1 is sufficient to contain GM plants even for species that produce wind-borne pollen. It is worth noting that even for species where wind pollination is the dominant mode pollination in a greenhouse pollination is difficult to achieve without manual intervention, demonstrating that pollen "escape" is unlikely. And again the risks from any such escape are low.It is worth noting that in most other countries GM plant material is contained in PC1 laboratories and greenhouses without any instances of escape causing harm.
Bat Janssen	Te ao Maori	Taonga species	Unsure
Bat Janssen	Te ao Maori	Taonga species	Unsure
Bat Janssen	Proposal 9 - Standards for containment facilities	No	No
Bat Janssen	Te ao Maori	Use of genetic material	Unsure
Bat Janssen	Te ao Maori	Use of genetic material	Again I don't feel competent to comment.From what I do understand I think there is likely to be a difference in risk tieringHowever I would say operating from a risk structure rather than a method or source structure seems likely to be best
Bat Janssen	Proposal 3 - Record-keeping requirements	Yes	Yes
Bat Janssen	Proposal 7 - Regulatory status of biotechnologies	No	The change does improve a bad piece of law but does not address the fundamental problem with trying to regulate by method instead of outcome.Furthermore, the exclusions given require the proof of a negative which is almost impossible in biology.For example it is impossible to be 100% certain that RNA â€œcannot result in an alteration of the organismâ€™s genomic sequenceâ€A better phrasing might be â€œis not expected to be able to alter the organismâ€™s genomic sequenceâ€Similarly the next line could be â€œIs not expected to give rise to an infectious agentâ€Similar language would be better for point 2 and 3 in this section.
Bat Janssen	Te ao Maori	Taonga species	Unsure
Bat Janssen	Proposal 9 - Standards for containment facilities	Cost vs benefits	I don't run a facility. I am merely a user.That said I can see that for most facilities having a simple prescriptive set of rules is easier to enact.However, I can also see that for some facilities with either a narrow focus or significant scale then adopting a bespoke set of standard could well reduce costs without increasing risks.I would note though that BOTH containment and transitional regulations need to be kept in step with each other. there is no point in modifying one without also modifying the other.
Bat Janssen	Proposal 9 - Standards for containment facilities	Other policy options	In general, the PC system is widely used and well understood and while it is prescriptive in nature it does provide safe working environments. Combined with a better risk tier system, which more appropriately places organisms in risk categories based on outcomes, I think the benefits of maintaining the current PC prescriptive system outweigh any costs.However, there are potentially very specific applications where the nature of the work being done, or the scale of the work being done, warrants the effort of adopting an outcome-based standard.I think Iâ€™m saying I prefer a hybrid approach but mostly based around the prescriptive â€œPCâ€ standards.
Bat Janssen	Te ao Maori	Taonga species	I am not competent to comment or judge these issuesI just know we do need to consider them
Bat Janssen	Te ao Maori	Informed consent	Unsure
Bat Janssen	Feedback on process/consultation	Feedback on process/consultation	Largely I feel the risk tier approach is a good way of addressing concerns about the technology present and future.I think the regulations need to be very consistent in their approach to avoid legal challenge and confusion by ABSCs and those enforcing regulationsI think one danger of this approach is the catastrophising of possible escape.Another problem is people acting to maintain their job rather than to promote research that is of benefit to New Zealand. This leads to regulatory creep that could undermine the aims of this document and the research itself.One key point is that the HSNO Act itself needs to be rewritten - preferably separating New Organsims from GMOs and leaving health and safety of labs distinct as well.

Adrian Bibby	Objectives	Objectives	Yes
Adrian Bibby	Features and approach for regulatory framework	Features and approach for regulatory framework	NZs system needs to be verifiable and adaptable enough that it can be applied in niche cases, while still providing a clear set of guidelines and requirements for more routine research and teaching cases.
Adrian Bibby	Proposal 1 - Risk-tiering framework	Yes	Yes
Adrian Bibby	Proposal 1 - Risk-tiering framework	Yes	A close alignment with the Australian framework makes the training of subject matter experts easier with increased opportunities for resources through professional bodies like the ABSANZ.
Adrian Bibby	Proposal 1 - Risk-tiering framework	Yes	Yes
Adrian Bibby	Proposal 1 - Risk-tiering framework	Other policy options	Whilst I agree with the proposed adoption of a risk tiers, I believe that it would still be beneficial to maintain a requirement for laboratories working at the lowest level to still be registered as part of a larger Containment Facility. This would allow for oversight by subject matter experts and ensure that activities taking place at this level are appropriate. The lowest teir of labs under this proposal don't necessarily need to operate to a physical containment level or containment standard, but it allows for potential risks to remain the responsibility of the organization and allows the organization to impose self-governing rules on the low-risk labs as required, Without oversight I am concerned that laboratory activities will change over time and unforeseen biosecurity risks may result.I would support the alternative tier of containment laboratories given in appendix 1, provided that the other proposals around changing to tracking of GMOs are also adopted.
Adrian Bibby	Proposal 1.1 - Biosafety Committees	Yes	Yes
Adrian Bibby	Proposal 1.1 - Biosafety Committees	Yes	A biosafety committee provides an effective means to ensure that organisations and appropriately considering the hazards and risks of their research and the controls that are in place to maintain containment. The key issues that may arise that should be addressed in the regulations are:1) any statutory membership of such a committee... e.g. it should include the facility Operator or a subject matter expert. Should the committee include community representation?2) How will the committee ensure it has the necessary knowledge to conduct the assessments3) Will the government provide for training of biosafety experts?4) How will the responsibilities be delineated between Operator oversight and the biosafety committee given approvals by the committee may impact on the operations of laboratories and requirements for auditing.
Adrian Bibby	Proposal 1.1 - Biosafety Committees	Other policy options	To reduce costs and time overheads, it may be beneficial to limit the auditing of biosecurity committee decisions to proposals working with risk category 2 organisms or higher. Auditing of low level decisions could be incorporated into a facility's regular external verification audits, with MPI having the power to require assessments to be reviewed by the EPA if there are concerns.
Adrian Bibby	Proposal 2 - Assessments for medicines	Yes	Yes
Adrian Bibby	Proposal 2 - Assessments for medicines	Yes	I support this change - new technologies, such as engineering immune cells to treat cancers lag behind the rest of a world.
Adrian Bibby	Proposal 2 - Assessments for medicines	Yes	Yes
Adrian Bibby	Proposal 3 - Record-keeping requirements	Yes	Yes
Adrian Bibby	Proposal 3 - Record-keeping requirements	Proposal 3 - Record-keeping requirements	This proposal has the potential to a massive time saver for researchers and auditors alike, however, I believe the labelling should instead be based on the Risk Category level of the organism being held. While PC2 labs can hold risk category 2 organism, the vast majority of the organism worked with on a day to day basis are risk category 1. Rather than tracking all of the thousands of colonies that are created and then disposed a week or two later, instead focus on the ones that have the potential to cause harm to the community or environment.
Adrian Bibby	Proposal 3 - Record-keeping requirements	Unsure	I agree that it should be possible to be able to link a culture dish to the set of controls governing its use, it would be better to require that a Facility has a demonstratable means of linking GMOs with those controls, rather than setting specific requirements for what is written on each dish/tube/plate.
Adrian Bibby	Proposal 3 - Record-keeping requirements	Yes	Yes
Adrian Bibby	Proposal 3 - Record-keeping requirements	Other policy options	With very few exceptions, most HSNO approvals have identical controls which are all incorporated into the operating Code of the Facility... the key requirement should be for it to be possible to identify where an unusual control exists (e.g. restrictions on certain antibiotics, or additional administrative/mechanical controls) and/or where an organism is a higher risk to the environment/community.
Adrian Bibby	Proposal 4 - Internal audit frequency	Yes	Yes
Adrian Bibby	Proposal 4 - Internal audit frequency	Proposal 4 - Internal audit frequency	The frequency of internal audits should be set by the Operator in relation to the risk profile of a laboratory. A lab that handles GMOs for 2 weeks a year by knowledgeable staff shouldn't need to be audited with the same frequency as a lab with 50 researchers processing thousands of strains a week. Set it on the Operator to set the frequency in the Operating Code as part of an outcomes focused control.

Adrian Bibby	Proposal 4 - Internal audit frequency	Agree with issues	This statement understates the issue... external inspections of containment facilities are conducted every six months with no exceptions, even where satisfactory compliance has been demonstrated for years, There are huge costs associated with each audit (MPI fees, and the time of the facility staff). For some facilities the audits take an entire day and involve travel to multiple sites for inspections carrying out low risk GMO work.
Adrian Bibby	Proposal 5 - Movement between facilities	Unsure	Unsure
Adrian Bibby	Proposal 5 - Movement between facilities	Proposal 5 - Movement between facilities	Transfer authorities serve an important purpose for notifying the receiving facility of legal obligations that exist for any particular item and ensuring that the operators of both facilities are aware of the movements taking place. By removing the verification checks by MPI I would be concerned that regular transfers would be taking place without Operator oversight. Perhaps a means of self-registering movements by the Operators without needing an MPI official to sign the forms would be appropriate. I would also welcome making transfer authorities for PC1 level default to a permit to allow movements without tracking individual movements (simply making all parties aware of the HSNO/MPI permit conditions that apply to the proposed movements).
Adrian Bibby	Proposal 5 - Movement between facilities	No	No
Adrian Bibby	Proposal 5 - Movement between facilities	No	The biggest issue isn't the time it takes to complete the transfer paperwork, but rather the >$25.57 cost per signed form and the inevitable headache of dealing with dozens of invoices from the ministry to multiple billable organisations. If these costs were absorbed into the facility fee, then most of the headaches involved in the transfer process would go away.
Adrian Bibby	Proposal 5 - Movement between facilities	Other policy options	Consider streamlining the MPI approval process by moving things to an online system that can be accessed by the Operators/approved delegates to enter data of proposed movements... this will allow for continued verification, while reducing the time commitment to MPI staff to manually enter everything themselves (with those costs passed back to the facilities).
Adrian Bibby	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Adrian Bibby	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	I agree that eukaryotic somatic cells do not represent a risk and would support them being included as tier 1 organisms, however, the biggest risk with mammalian cell culture is from the media often used with the cells which often contain antibiotics, and serums with the risk of viruses and prions. If mammalian cells are included as tier 1 organisms it would be appropriate to define minimum levels of post treatment to render the cells and media non-viable.
Adrian Bibby	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Adrian Bibby	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	A generic HSNO approval that can be utilised by any research organisation meeting the controls of the approval might be the simplest means of addressing the issues outlined.
Adrian Bibby	Proposal 7 - Regulatory status of biotechnologies	Unsure	Unsure
Adrian Bibby	Proposal 7 - Regulatory status of biotechnologies	Unsure	The change as written has the potential to cause confusion for work with bacteria and fungi where epigenetic modifications are considered to be GMO, and introduction of DNA and RNA is a common genetic manipulation. If this change goes ahead, very clear guidance will be required. Perhaps consideration could be given to limiting the biotechnologies to somatic eukaryotic cells.
Adrian Bibby	Proposal 3 - Record-keeping requirements	Unsure	Unsure
Adrian Bibby	Proposal 4 - Internal audit frequency	Yes	Yes
Adrian Bibby	Proposal 7 - Regulatory status of biotechnologies	Unsure	The change as written has the potential to cause confusion for work with bacteria and fungi where epigenetic modifications are considered to be GMO, and introduction of DNA and RNA is a common genetic manipulation. If this change goes ahead, very clear guidance will be required. Perhaps consideration could be given to limiting the biotechnologies to somatic eukaryotic cells.
Adrian Bibby	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Adrian Bibby	Proposal 7 - Regulatory status of biotechnologies	Other policy options	Production of modified cells to be reintroduced into a patient.Differentiation of patient cells to produce new cells for implantation
Adrian Bibby	Proposal 8 - Low-risk fermentation	Unsure	Unsure
Adrian Bibby	Proposal 8 - Low-risk fermentation	Unsure	Assessment by a Biosecurity Committee is appropriate for controlling the additional risks of large scale fermentation, however, I would favour that large scale fermentation of a risk category 1 organism should be conducted at PC2 containment level (tier 2 in this proposal) because of the additional risks that a large spill creates. PC2 containment controls for these additional risks by removing floor drains.

Adrian Bibby	Proposal 8 - Low-risk fermentation	No	No
Adrian Bibby	Proposal 8 - Low-risk fermentation	Yes	Yes
Adrian Bibby	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Adrian Bibby	Proposal 9 - Standards for containment facilities	No	No
Adrian Bibby	Proposal 9 - Standards for containment facilities	Yes	Yes
Adrian Bibby	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Adrian Bibby	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Adrian Bibby	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Adrian Bibby	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Adrian Bibby	Proposal 9 - Standards for containment facilities	Cost vs benefits	None. As a consequence of more recent EPA approvals being outcome based, our organisation completely revised its Quality Management Plan in 2018, as such only minor changes would be required to adapt to an outcome focused containment standard.
Adrian Bibby	Proposal 9 - Standards for containment facilities	Other policy options	Perhaps a new containment standard that allows for operation of laboratory facilities to outcome focused controls could exist in parallel with the existing regulations. So rather than forcing all facilities to operate to proscriptive controls, they would have the option to register to one or more of the existing proscriptive standards, or instead register to the outcome focused standard and define their own operating rules in their Code that meet a minimum set of conditions for signoff by MPI.
Adrian Bibby	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Adrian Bibby	Proposal 10 - Reviews of regulatory settings	Other policy options	Alternate proposal 1 (setting risk tier 1 as PC1) seems safter than releasing all regulatory control on the lowest risk genetic manipulations taking place in NZ, although I currently favour an approach that would allow for these manipulations to be done wihtout the current rules and restrictions of a PC1/2/3 lab, but still require registration and Operator oversight (i.e. perhaps the definition of a new class of low risk containment - PCnull).
Adrian Bibby	Costs, benefits or risks	Costs, benefits or risks	No
Adrian Bibby	Proposal 9 - Standards for containment facilities	Options	Once in place, outcome-based standards are not onerous on the Facility, but they are time consuming to enact. Prescriptive standards for construction are often helpful when working with architects, but outcome-based standards are easier for day-to-day operation of a facility.The 35001 standard is a good outcome focused standard, although AS/NZS2243 is also a good standard to follow to meet most common containment needs if NZ didn't lock itself into using the 2002 version.
Adrian Bibby	Alternative options	Alternative options	Alternate proposal 1 (setting risk tier 1 as PC1) seems safter than releasing all regulatory control on the lowest risk genetic manipulations taking place in NZ, although I currently favour an approach that would allow for these manipulations to be done wihtout the current rules and restrictions of a PC1/2/3 lab, but still require registration and Operator oversight (i.e. perhaps the definition of a new class of low risk containment - PCnull).
Peter Dearden	Objectives	Objectives	Yes
Peter Dearden	Features and approach for regulatory framework	Features and approach for regulatory framework	A risk/benefit approach rather than a method-of-making approach. i.e. assessment o the benefits and risks of the organism used, rather than blanket risk/not risk based on wether it is GM or not.
Peter Dearden	Proposal 1 - Risk-tiering framework	Yes	Yes
Peter Dearden	Answer contradicts previous answer	Answer contradicts previous answer	no

Peter Dearden	Proposal 1 - Risk-tiering framework	Other policy options	no
Peter Dearden	Proposal 1 - Risk-tiering framework	Yes	Yes
Peter Dearden	Proposal 1 - Risk-tiering framework	Other policy options	no
Peter Dearden	Proposal 1.1 - Biosafety Committees	Yes	Yes
Peter Dearden	Proposal 1.1 - Biosafety Committees	Other policy options	no
Peter Dearden	Proposal 2 - Assessments for medicines	Yes	Yes
Peter Dearden	Proposal 2 - Assessments for medicines	Yes	Yes
Peter Dearden	Proposal 2 - Assessments for medicines	Other policy options	This approach needs to be taken with all potential GM releases
Peter Dearden	Proposal 3 - Record-keeping requirements	Yes	Yes
Peter Dearden	Proposal 3 - Record-keeping requirements	Yes	Yes
Peter Dearden	Proposal 3 - Record-keeping requirements	Yes	Yes
Peter Dearden	Proposal 3 - Record-keeping requirements	Other policy options	no
Peter Dearden	Proposal 4 - Internal audit frequency	Yes	Yes
Peter Dearden	Proposal 4 - Internal audit frequency	Yes	Yes
Peter Dearden	Proposal 4 - Internal audit frequency	Agree with issues	This is currently a massive cost
Peter Dearden	Proposal 4 - Internal audit frequency	Other policy options	no
Peter Dearden	Proposal 5 - Movement between facilities	Yes	Yes
Peter Dearden	Proposal 5 - Movement between facilities	Yes	Yes
Peter Dearden	Proposal 5 - Movement between facilities	Other policy options	no
Peter Dearden	Proposal 5 - Movement between facilities	Other policy options	no

Peter Dearden	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Peter Dearden	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Peter Dearden	Proposal 5 - Movement between facilities	Other policy options	no
Peter Dearden	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Peter Dearden	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	no
Peter Dearden	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Peter Dearden	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Peter Dearden	Proposal 7 - Regulatory status of biotechnologies	Other policy options	no
Peter Dearden	Proposal 7 - Regulatory status of biotechnologies	Other policy options	no
Peter Dearden	Proposal 8 - Low-risk fermentation	Yes	Yes
Peter Dearden	Proposal 8 - Low-risk fermentation	Yes	Yes
Peter Dearden	Proposal 8 - Low-risk fermentation	Yes	Yes
Peter Dearden	Proposal 8 - Low-risk fermentation	Other policy options	no
Peter Dearden	Proposal 9 - Standards for containment facilities	Outcome-based	Shifting to outcome-based standards
Peter Dearden	Proposal 9 - Standards for containment facilities	Outcome-based	Outcomes-based approaches will effectively manage risks better and make better links between actually biological activity and containment
Peter Dearden	Proposal 9 - Standards for containment facilities	Yes	Yes
Peter Dearden	Proposal 9 - Standards for containment facilities	Yes	Yes
Peter Dearden	Proposal 9 - Standards for containment facilities	Cost vs benefits	no the costs will not outweigh the benefits
Peter Dearden	Proposal 9 - Standards for containment facilities	Other policy options	no
Peter Dearden	Proposal 10 - Reviews of regulatory settings	Yes	Yes

Peter Dearden	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Peter Dearden	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Peter Dearden	Proposal 10 - Reviews of regulatory settings	Other policy options	no
Peter Dearden	Alternative options	Alternative options	no
Peter Dearden	Costs, benefits or risks	Costs, benefits or risks	no
Peter Dearden	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	no
Peter Dearden	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	no- I think this is a sensible change
Peter Dearden	Proposal 9 - Standards for containment facilities	Yes	Yes
Peter Dearden	Proposal 10 - Reviews of regulatory settings	Yes	Yes
9(2)(a)	Proposal 10 - Reviews of regulatory settings	Yes	This is vital- this needs to be updated regularly- it should happen now.
	Objectives	Objectives	No
	Objectives	Objectives	Simplify the second objective to read:Contributes to better outcomes for New Zealanders through better biological research and innovation, and through greater access to biotechnology processes and products.Another option (not a great option) would be to extend the objectives to the list of four below:Contributes to better food security outcomes through better microbial, plant and animal research outcomes and innovation, and through greater access to novel food processes and products.Contributes to better climate change adaptation outcomes through better microbial, plant and animal research outcomes and innovation, and through greater access to climate resilient processes and products.Contributes to better environmental health outcomes through better microbial, plant and animal research outcomes and innovation, and through greater access to sustainable agriculture processes and products.Contributes to better human health outcomes for New Zealanders through better biomedical research outcomes and innovation, and through greater access to therapies and medicines.
	Features and approach for regulatory framework	Features and approach for regulatory framework	HSNO Act gives quite reasonable voice to these protection goals, if only if the broadest terms in Part 2 â€“ Purpose of the Act. It is easy to see how a hazardous substance (e.g., methyl bromide) or a new organism (e.g., fall army worm) might produce harm directly contradicting the purpose, principles or matters of the Act. On the other hand, RG1 microorganisms and cell cultures have been used for research and teaching without harm to human health or the environment in many countries (e.g., USA, UK, Australia, Canada and the EU) for many years without the strict controls in the HSNO Act. In addition, it is difficult to see how some GM versions of otherwise common plants might produce any harm (e.g., African sunset petunia). Indeed, when those petunias were found in NZ MPI stated that â€œThere is negligible biosecurity risk from these seeds and no risk to people or the environment.â€ Nonetheless the plants were declared illegal and destroyed, and additional controls on imported petunias were emplaced.Reading the latest annual report (2022) produced by the EPA under â€œWhat we doâ€ page 24 there is a section titled â€œManage rules for new organismsâ€ and under this â€œDecide if new organisms can be imported â€“ from viruses and bacteria to plants and animals.â€ There is no mention of genetic modification or that this might be occurring in NZ. This highlights the difficulty in defining genetically modified organisms as â€œnew organismsâ€ making it difficult to set protection goals and to regulate in a way that meets these goals. Additionally, I note that the only defined measure of success for the â€œnew organismsâ€ goals is â€œNo approved organisms have had unanticipated negative side effects, for example, have become pests or weedsâ€ (page 86) a measure which is either uselessly vague or outright unapplicable to most genetically modified organisms in research and biomedicine in NZ.Reading the latest â€˜statement of intentâ€™ (2022-2026) produced by the EPA I again did not find in the opening pages any clear expression of what the protection goals were. On page 16 there is a diagram that appears to state defined measurable outcomes over 3-, 30-, and 300-year timeframes. However, there is no mention of â€˜new organismsâ€™ or genetically modified organisms in these goals. On page 25 â€˜new organismsâ€™ are finally acknowledged. I am heartened to see that the benefits to people and the environment of new organisms are being directly considered. However, I also note that considering parasitic wasp biocontrol programs and laboratory experiments with genetically modified cell cultures using the same rules is unlikely to deliver effectively to the protection goals.2. The complete separation of genetically modified (GM) organisms from the HSNO Act, making GM organisms a separate legal entity from â€˜new organismsâ€™. A potential fallback position would be to separate â€˜new organismsâ€™ from GM organisms within the HSNO act. A new purpose written Act (or section of the HSNO Act) with forward looking procedures for rapid review and updating should be written. This document should clearly state what the environmental protection goals are and how this legislation will effectively allow New Zealand to reach those goals, preventing or mitigating foreseeable pathways to harm, while benefiting from biotechnology processes and products in the specific context of GM organisms.All other Acts mentioning genetic modification should be required to reflect the processes and procedures of this new Act/Section. This new Act/Section would establish a new integrated single regulator of gene technology (see next point).At a minimum this would allow a more sensible approach to the often very minor changes made in the process of genetically modifying an organism to contain a single new trait as opposed to the introduction of a wholly new organism to the New Zealand environment. For example, consider the introduction of a parasitic wasp for biocontrol or the invasion of a new disease, by comparison with a genetically modified petunia with orange flowers.3. An integrated single regulator. All laboratory research work on genetically modified organisms would be overseen by a single body. I note that currently MfE (EPA), MPI (Biosecurity NZ) and MBIE (Standards NZ) have intertwined roles when it comes to allowing which research in which laboratory. When the time comes there should be very clear lines of regulatory hand off for use in agriculture (plants), agriculture (animals), food, medicine, or industrial fermentation. Some of these might be retained within the core regulator where an existing separate regulator is not established. Clearly, food would continue to be regulated by FSANZ and medicines by MedSafe.The linkages between the regulators would be managed through something like the â€œCoordinated framework for regulation of biotechnologyâ€ in the USA.4. Removal of explicit and prescriptive regulation of very low risk research. Organisms such as those included in the Australian Risk tier 1 now have a long history of safe use with no particular regulation across most of the world. The definition of â€˜very low riskâ€™ organisms and research will need significant thought beyond

9(2)(a)

Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Proposal 1 - Risk-tiering framework	1. A risk tier framework is an excellent idea.However, I note that the Australian system is highly prescriptive in its approach. This will inevitably lead to delays where an organismâ€™s name doesnâ€™t fit with the list and must be added for research to begin. A rapid (with enforced time frames) review of the organisms in each tier must be a fundamental part of the regulations; adding an organism to the tier system, or lowering or raising organisms between tiers, as new information becomes available should be standard practice. As ABSCs are likely to be the subject experts regarding organisms within their field of specialty they should have the right to instigate such reviews as and when they see fit.Risk assessments for adding organisms to the tier system should consider, the risk to the laboratory staff as the first priority, followed by risk assessment for the ability to escape containment (without human aid) and establishment in the environment (without human aid), finally considering harm to wider human health and the environment should they escape.Other regulatory systems of note with useful risk tiering already established (beyond Australia) are those of the USA, Canada and the United Kingdom. An effort to consider these systems in conjunction with the Australian system would be a good approach.Other considerations aside, avoiding the very prescriptive approach of the Australian system any NZ system would maintain a strong advantage for rapid innovation in the processes and products of biotechnology. If whole classes of organism could be captured by simple characteristics the process of updating the Risk tiers would be greatly accelerated.2. The inclusion of Risk Tier 1 as proposed in Table 1 is an excellent idea in line with much of the worldâ€™s regulations.Risk group 1 (RG1) organisms and those organisms in cell or tissue culture (included in this option in Risk tier 1) can be understood as those organisms that can be controlled by their inability to grow and establish without significant human intervention. This is sometimes referred to as biological containment (USA-NIH guidelines page 15 and Appendix I). Using the biology of the organism as the controlling parameter so that reduced physical containment is required.For example, in Canada RG1 (risk group 1) organisms are considered of such low risk to human health and the environment that primary school aged children can do experiments with these organisms at school. Also, in the USA any RG1 microbe, any tissue cultured cell and any plant within a laboratory and maintained in axenic culture is exempt from regulation (USA-NIH guidelines, Appendix C, page 50). As detailed above, this Risk tier (along with the others) should also be rapidly and routinely updated to include new organisms as new data on their risk characteristics becomes available.3. The risk tier system should be specified by the HSNO Act but maintained outside of the Act as a regulation or standard.The Risk tiersâ€™ inclusions, exclusions and listed organisms should be routinely and rapidly updated as requested by ABSCs and/or the EPA as information is developed to change the risk status of any organism. This is likely best executed if the Risk tiers are written as a Standard that can be updated by the EPA without recourse to parliament.
Proposal 1.1 - Biosafety Committees	Other policy options	Removing the need for a Containment laboratory to also be a Transitional facility seems a sensible reduction in complexity.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	I agree that the legislation needs regular review, with enforced timeframes.
Proposal 10 - Reviews of regulatory settings	No	No
Proposal 10 - Reviews of regulatory settings	No	While the wider state of the legislation could be reviewed on a five year cycle the inclusion of organisms in Risk tiers should be considered at least every year, but this review process should also be rapidly adaptive in the face of applications from ABSCs for changes to the Risk tier status of particular organisms.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Agree with issues	I agree that insisting that all research, even very low risk research, must be undertaken with explicit and prescriptive approval from EPA and within MPI approved and audited Physical containment (PC) laboratories is a direct handbrake on innovation and the uptake to biotechnology by NZ and does nothing to improve the safety of human health or the environment.1. How exactly will unapproved â€˜laboratoriesâ€™ suitable for Risk tier 1 research be defined?What process or standard will define what a â€˜laboratoryâ€™ is? Would â€˜laboratoriesâ€™ have to be registered? Should I register my kitchen? I routinely use RG1 organisms (Saccharomyces cerevisiae, Lactobacillus bulgaricus and) Streptococcus thermophilus) in it. Would school classrooms need to be registered? I suggest that registering these â€˜laboratoriesâ€™ would be counterproductive.A school classroom will and should meet the requirements for Risk tier 1! In Canada primary schools can carry out experiments on Risk Group 1 (RG1) organisms (included in Risk tier 1) using guidelines published by the Public Health Agency of Canada as part of the International Federation of Biosecurity Associations. In the USA science fair projects frequently involve genetic modification of RG1 organisms (just buy the kit from Amazon.com).Will other auditing of â€˜laboratoriesâ€™ for the purposes of hazardous chemicals and workplace safety still be required even if the Physical containment criteria are removed? What exemptions for private residences might be required?Would an â€˜unapprovedâ€™ laboratory still be required to follow some form of biocontainment facility standard? What form would this take? Who would set this standard? Would this become auditable? It seems that it is possible this could descend into a new cycle of over regulation, which should be avoided.An additional point here is the management of waste streams from research with Risk tier 1 organisms (GMO or not). How does the disposal of waste interact with this requirement. Again, using the Canadian example above RG1 organisms are considered safe for disposal by normal municipal waste management without prior sterilisation (although bleach is recommended).2. This document doesnâ€™t include mention any impact on, or even reference to, MÄori culture. While there is a secondary document, I would also like to include in my response here that considering MÄori culture and the taonga species of Aotearoa New Zealand should be fundamental to the application of this regulation.3. This sentence from page 13 of the consultation document is concerning. A key requirement of all risk tiers would be that any "unapproved release" of GMOs into the environment would be prohibited.â€ For clarity the wording should be something like "unapproved deliberate release for the purpose of establishment within the environment". Disposal of waste to landfill should not be captured by this requirement. Remembering that the goal is to prevent harm to human health and the environment, neither of which are endangered by burying waste in land fill any more than normal waste.
Proposal 1 - Risk-tiering framework	Other policy options	A much tidier approach would be to simply start from scratch removing all genetic modification research and use from the HSNO Act (and as much as possible the many other Acts that reference genetic modification) and developing a simpler set of regulations with an appropriate risk assessment structure modelled on the best practice of NIH (USA), USDA (USA), EPA (USA), Health Canada (Canada), CIAF (Canada), MAFF (Japan), MHLW (Japan), OGTR (Australia) and HSE (UK).This should acknowledge that there has been no proven human or animal health issues or environmental harm from the laboratory use of genetically modified organisms and that there is now a history of safe use (HOSU) which extends for more than 30 years.
Proposal 1.1 - Biosafety Committees	Yes	Yes

9(2)(a)	Proposal 2 - Assessments for medicines	Unsure	Unsure
	Proposal 2 - Assessments for medicines	Unsure	No comment
	Proposal 1.1 - Biosafety Committees	Other policy options	No comment
	Proposal 2 - Assessments for medicines	Unsure	Unsure
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 1.1 - Biosafety Committees	Yes	The idea of ABSCs is valid and increases the bandwidth of the approval process. However, as noted in the consultation document the old IBSCs became very difficult to maintain with complexity and regulatory creep driving most into dissolution. However, as Risk tier 1 research does not need to be reviewed by these committees it is possible they would be more sustainable.Certain ABSCs will have more time and resources, likely those at the larger science institutions. As these committees will consist of subject matter experts one of their major functions should be to assess organisms for inclusion into the Risk tier system, or to lower or raise the risk tier of an organism. This process should be considered a routine part of their function and be enabled by the Act and supported by MfE and/or the EPA. Once an ABSC has made a recommendation for a risk tier change the EPA ABSC should be required to assess the recommendation and to make any changes to the regulation/standard within short and legislated timeframes.I am not convinced that the auditing of major ABSCs by the EPA is necessary. I see little use in second guessing experts in risk assessment and biological safety by an external regulator, that have already been through an accreditation process enforced by the same regulator. Particularly as any organism that does not fall into the risk tiering system will still require approval by the EPA so that an institutionâ€™s field of research/expertise will be well known to, and monitored by, the regulator. Potentially smaller ABSCs ,should these come about, might need support from the EPA, but auditing should be replaced with mentoring.The EPA will still need to maintain an ABSC. As noted in the consultation document smaller biotechnology companies and startups are unlikely to be able to meet the requirements of the accreditation process, and this is likely to be a slow process. However, timeframes for the determinations of EPAâ€™s ABSC will need to be both rapid and enforced. This group will also need to be able to assess the recommendations of the other ABSCs for changes to inclusion in the Risk tiers.Although not mentioned in this document the ABSC framework is likely to be a suitable place for the input of tÄngata whenua into the process of new approvals and risk determinations.
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 3 - Record-keeping requirements	Yes	Current record keeping practice as required by EPA/MPI is very difficult and time consuming, and inherently prone to failure due to unnecessary complexity. Simplifying the record keeping as suggested will allow greater efforts on research without increase of risk to human health or the environment.I note that if GMOs were a separate class of entity from â€˜new organismsâ€™ this might make record keeping even simpler.
	Proposal 3 - Record-keeping requirements	No	No
	Proposal 3 - Record-keeping requirements	No	That the label on a GMO container should list the specific HSNO approval can be kept to only the very most high-risk organisms (above risk tier 3), that might have reasonable pathways to escape.
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 4 - Internal audit frequency	Yes	The reduction of auditing frequency is a good idea. I would suggest that audit frequencies of once per 12 months for internal audits and once per 24 months for external audits are likely sufficient to deliver the desired human health and environmental outcomes.
	Proposal 4 - Internal audit frequency	Yes	The reduction of auditing frequency is a good idea. I would suggest that audit frequencies of once per 12 months for internal audits and once per 24 months for external audits are likely sufficient to deliver the desired human health and environmental outcomes.
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 4 - Internal audit frequency	Agree with issues	PC containment facilitiesâ€™ physical properties are carefully defined. Auditing of the physical properties of new laboratories should be assessed at the time of design and opening. However, the need for ongoing routine auditing of these laboratories physical integrity is likely of little value. There is still the requirement to notify MPI if there is damage (or deliberate changes are made) to the physical components of these laboratories.PC containment facilitiesâ€™ operating procedures are also carefully defined. I note that much of the auditing done is as a mechanism of quality management for these systems. It is in these systems and their auditing that significant and unnecessary regulatory creep has occurred over the time of the HSNO Actâ€™s enforcement. Efforts to simplify and reduce the operating procedures should be investigated and risk benefit analyses used to determine if these are significantly supporting the desired human health and the environmental outcomes.Risk tier 1 organisms should not be auditable no matter what PC laboratory grade they are contained within.

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Proposal 5 - Movement between facilities	No	No
Proposal 5 - Movement between facilities	Agree with proposal	Yes and No. Risk tier 1 organisms have no need for regulation during transfer, as they still, even outside of a â€˜laboratoryâ€™, have practically zero chance of establishing in the environment or causing harm to human health. Further to this the disposal of Risk tier 1 waste should be via standard municipal waste management (see Canadian PHAC guidelines).Risk Tier 2 and 3 organisms need no particular regulation for laboratory-to-laboratory transfers as the movement of the organism will be carried out to ensure the safe transfer by the inherent need to deliver the organism to the recipient in a fit state for further use in research. Transfer to waste might be considered as a special case requiring some regulation.For organisms that do not fit within the Risk tiers 1-3, regulation during transfer is likely necessary.The term â€˜unbreakableâ€™ has been challenged numerous times. I strongly suggest a more sensible way of defining the requirement of containerâ€™s robustness is found. For example, the USDA-APHIS uses this definition:â€œShipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportationâ€.
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 3 - Record-keeping requirements	Agree with issues	Record keeping is important. All laboratories need to keep adequate records of their research to track and maintain their materials. The changes suggested will not lead to a lack of record keeping but will allow researchers to keep records in a manner that is best suited to the needs of the research without reference to the needs of an external auditor.The benefit of requiring Risk tier 1-3 organisms (GMO or not) to carry a mandated labelled is minimal to none. Standard practice record keeping in any research environment will fulfil this requirement. Potentially this could be a voluntary mechanism in those laboratories where large numbers of high risk and low risk organisms are cultured together.
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 4 - Internal audit frequency	Other policy options	As with these regulations in general the auditing of Transitional and Containment facilities should be done with direct reference to the environmental protection goals. If no direct positive good towards the protection goals can be determined, then there is no value in auditing that particular aspect of the regulations and/or procedures.
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	I agree with the issues as outlined
Proposal 5 - Movement between facilities	Other policy options	A fully outcome-based system would not need such frequent review.
Proposal 5 - Movement between facilities	Other policy options	All movement between facilities and out of containment should be based solely on the Risk tier of the organism involved.Any non-viable products of these organisms should not require any regulation for import, transport or release. This is already the case within the import health standard (IHS) for animal feed derived from the HSNO Act. If the feed being imported is non-viable it does not require any additional approval in the case that it is derived from a GM organism over a non-GMO source.
Proposal 5 - Movement between facilities	Technical feedback	I agree that the current system is complicated and slow and does little to improve the safety of human health or protection of the environment. Reducing the regulations to be risk proportionate is a sensible decision.The current situation is that the type of containment facility defines the risk of the organism and the release from containment of any product derived from organisms held inside that facility. This has led to extremely disproportionate interpretations of the risk profile of both organisms and of biological products derived from those organisms. For example, MPI verifiers have recently suggested highly purified protein and DNA isolated from very low risk organisms requires transfer permits for movement between PC1 facilities (let alone release).It is very important that under the new system the movement between and out of â€˜laboratoriesâ€™ and containment facilities should be based solely of the risk profile (Risk tier) of the organism, not on the status of the laboratory in was developed within and be proportionate to the Risk tier alone. Additionally, non-viable purified products of these (very) low risk organisms should have no need of regulation during transfer or release.Using a method of determining risk of transfer and therefore transfer requirements based of the Risk tier system (not the physical containment standard) is extremely important to maintain the internal consistency of these regulations. The mixing and matching of Risk tiers and Physical containment standards will lead to confused and inappropriate regulatory outcomes.In addition to transfers the issue of importation also arises within the scope of this question. In the same way that GM organisms in Risk tier 1 should be exempt from regulation during transfer they should also be exempt from regulation during importation. Again, the risk to human health and the environment is still essentially nil during this process. This point additionally draws in whether there is a need for laboratories and containment facilities to also be transitional facilities. A careful analysis of the implications for the importation will be needed to maximise the benefits of changes to these regulations. If laboratories are no longer required to be containment facilities but are still required to be transitional facilities many of the efficiency gains might be lost.
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	I agree that under the current system these technologies are poorly defined, and the current rules do nothing to improve the safety of human health or the environment. Clarifying these definitions so that the regulations are risk proportionate is a sensible decision

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Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	The listed exclusionary criteria listed in the proposal are likely to provide a suitable level of risk mitigation.
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Agree with issues	No comment
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	I agree that isolated eukaryotic cells (with genetic modifications as described) pose no threat to human health or the environment so should be included in Risk tier 1.Most DNA from most organisms should not alter the risk tier of the research. There are very few genes capable of causing any harm to people or the environment.
Proposal 6 - Requirements for eukaryotic somatic cells	No	Plants and plant cells and tissues are an unusual case within these rules. Firstly, it is true that plant cells and plants in tissue culture pose essentially zero risk to human health. Secondly, however, it is also true that with appropriate human intervention it is possible to regenerate a complete plant from even a single plant cell. The wording of the rules here will need to very careful to ensure that all plant cells and plant tissue culture are understood to be Risk Tier 1. This is reasonable as only with significant deliberate human intervention would it be possible for the cells or tissues to regenerate a whole plant and for it to then establish within the environment.
Proposal 7 - Regulatory status of biotechnologies	Other policy options	The problem here is that the prescriptive nature of the HSNO regulations will continue to produce weird issues like this. Until such time as the Act is rewritten to be fully outcome based it will run up against these sorts of anomalies.
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	I agree that insisting that all research, even very low risk research, must be undertaken with explicit and prescriptive approval from EPA and within MPI approved and audited Physical containment (PC laboratories is a direct handbrake on innovation and the uptake to biotechnology by NZ and does nothing to improve the safety of human health or the environment.
Proposal 8 - Low-risk fermentation	Unsure	Unsure
Proposal 8 - Low-risk fermentation	Unsure	This limit seems both very low and entirely arbitrary. I note that the Australian Risk tier 1 limit is 25 L, but again this seems quite arbitrary.
Proposal 8 - Low-risk fermentation	Unsure	This limit seems both very low and entirely arbitrary. I note that the Australian Risk tier 1 limit is 25 L, but again this seems quite arbitrary.
Proposal 8 - Low-risk fermentation	Unsure	This limit seems both very low and entirely arbitrary. I note that the Australian Risk tier 1 limit is 25 L, but again this seems quite arbitrary.
Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Proposal 9 - Standards for containment facilities	Hybrid	It seems sensible that a hybrid approach is used. This should be used to allow as much flexibility as possible. Organisations should be able to use the default standards as a base but modify these with outcome based methods where they see fit.
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 9 - Standards for containment facilities	Agree with issues	In a number of cases organisations have chosen to â€¯plus oneâ€™ their laboratory facilities containment rating beyond the minimum required due to small amounts of the work done within potentially requiring the higher containment standard. As with the transfer and release of (very) low risk organisms it should be the Risk tier that determines the treatment of the organisms and any derived products, not the Physical containment rating of the laboratory they are developed within. Laboratory standards should acknowledge organisms and their non-viable products will be regulated based solely on the Risk tier of the organism involved.
Alternative options	Alternative options	Proposal 1: The main document proposal is the better option.Proposal 1.1: Organisational level approval would likely act as a significant barrier to small research organisations.Proposal 4: The options here are similar to the ones a proposed in the main document. I find these would also be suitable.Proposal 5: I find that these options are still unnecessarily restrictive and over regulated. See my comments in the main document.Proposal 6: Defining isolated and tissue cultured eukaryotic cells as â€œnot an organismâ€ is useful mechanism for reducing regulatory burden. As no multicellular eukaryote can regenerate into a free-living organism without significant human intervention if the goal is the prevention of an organism becoming established in the environment, then this definition would likely still adequately deliver to the protection goal. Two things should be considered. First there would need to be an exclusion of yeast (a single celled eukaryote) and an explicit inclusion of plants despite their greater potential to regenerate into a whole organism (although only with significant deliberate human intervention).Proposal 8: No comment beyond what is in the main document.
Costs, benefits or risks	Costs, benefits or risks	Proposal 1: The benefit of allowing school age children to interact directly with biotechnology is unmeasurable. This will enable the next generation of citizens and biotechnologists to interact in informed and constructive ways.Proposal 9: Maintaining Containment laboratories that are also Transitional facilities seems like a waste of time. Finding a mechanism that allows all containment facilities to also automatically be transitional facilities is likely to provide significant efficiencies with no increased risk to human health or the environment.

9(2)(a)	eedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	protection of MÄori culture and taonga.We need a legal and regulatory framework that enables an informed discussion of an organismâ€™s risk profile and how it might impact on the protection goals rather than have us focus on, sometimes contradictory, scientific naming and whether these are an approved organism of predetermined risk.Of particular note is the treatment of plants within the existing and proposed Risk tier system. These organisms seem to have acquired an almost mythological ability to regenerate, escape and cause harm to people and the environment. There is no scientific or historical basis for this. The NIH guidelines for laboratory research in the USA exempt from regulation all plants grown in axenic tissue culture. This has been in effect for several decades without damage to human health or the environment. Taken individually the criteria for assessing plantâ€™s risks to human health and the environment might take a form like this:1.Ability to cause disease in humans. There are no recorded cases of plants infecting humans and causing disease. This suggests these organisms are very low risk.2.Toxicology in humans. Only small number of plants are toxic to humans, and this is mostly only when eaten. Very few if any of these types of plants are used in research laboratories. This suggests these organisms are very low risk, certain toxic plants might need additional controls.3.Allergenicity in humans. Most severe allergic reactions to plants require ingestion of the plant material. Many milder allergic reactions to plants come from inhaling pollen. This suggests these organisms are very low risk, certain allergenic plants might need additional controls.4.Ability to escape containment â€“ plants in axenic laboratory culture. Plants are kept in sealed containers with strict protocols to ensure axenic culture. The plants cannot escape these containers and will not survive outside of these containers without significant human intervention. Plants rarely flower in this growth environment â€“pollen and/or seed is therefore very rarely produced. However, even if plants do flower they are still contained, and simple precautions can ensure no pollen or seed escapes the containers. These observations suggest these organisms are very low risk when grown in this manner.5.Ability to escape containment â€“ plants in containment glasshouses. Plants are frequently grown to maturity with flowers, pollen and seeds produced. The pollen of plants has a limited life span and ability to disperse. Most regulatory bodies (e.g. USA, UK and Australia) have defined exclusion zones around contained outdoor field trials to prevent the unintended cross pollination of neighbouring plants. This has proven an effective method of preventing escape even in these outdoor trials. It can be inferred that using PC1 glasshouses would provide significantly increased restriction of pollen dispersal. Combined with exclusion zones this will reduce risk of escape to near zero. Seeds from most plants have limited ability to disperse requiring animals or strong wind to travel more than a few meters from the parent plant. As with pollen, the growth of plants in PC1 containment glasshouses with exclusion zones will reduce the risk of escape to near zero. These observations and mitigating measures suggest these organisms can be treated as low risk organisms requiring PC1 containment. Certain high dispersal potential plants might need additional controls.6.Ability to escape containment â€“ stored seeds. The seeds of different plants have very different characteristics. Size of the seeds and their fertility rates are both important factors when considering their need for storage and containment. Maintaining careful catalogues of stored seeds is necessary for effective and efficient research. In and of itself these needs lead to containment. Nonetheless due to the greater risks of working with seeds it seems likely that most will need to be stored and worked with in PC1 facilities.7.Harm to the environment upon escape. Here it is very important to consider the environmental protection goals. What exactly is considered to be harm to the environment? Certainly, harm would be clear from releasing a highly invasive plant with the potential in disrupt native ecosystems. However, most plants are not invasive or â€˜weedyâ€™ and most of the research carried out on plants will have no impact on their â€˜weedinessâ€™. The US-EPA and USDA regulations for GM plants are quite well developed for regulating â€˜weedyâ€™ plants. Research on plants known to be invasive, to cross with native species, or to have been modified to be resistant to herbicides might require additional controls.In conclusion the regulation of research using genetically modified plants should be proportional to the risk of the particular plant and its growth and dispersal characteristics. Potentially this is by simply placing individual plant species into the risk tier system more carefully than a blanket Risk tier 3 determination. Some plants might be considered Risk tier 1 but my own interpretation is that most plants would fit safely within Risk tier 2.
	Te ao Maori	Taonga species	Unsure
	Te ao Maori	Use of genetic material	Unsure
	Te ao Maori	Informed consent	Unsure
	Proposal 5 - Movement between facilities	Other policy options	All movement between facilities and out of containment should be based solely on the Risk tier of the organism involved.Any non-viable products of these organisms should not require any regulation for import, transport or release. This is already the case within the import health standard (IHS) for animal feed derived from the HSNO Act. If the feed being imported is non-viable it does not require any additional approval in the case that it is derived from a GM organism over a non-GMO source.
	Proposal 7 - Regulatory status of biotechnologies	Technical feedback	Two other processes should also be considered for clarification and/or exclusion. The first are â€˜null-segregantâ€™ organisms. Those organisms that were, at one time, or had parents that were, genetically modified. But now by some process have had the transgenic DNA removed. In NZ these are GMOs despite having no transgenic DNA.The second are gene edited organisms. Fundamentally unable to be distinguished from naturally occurring mutants (in some cases) and also able to reproduce naturally occurring mutations and alleles this process poses an existential crisis to process driven regulation of genetic technologies. In NZ these are GMOs despite being practically unable to be distinguished from naturally occurring mutants.Many jurisdictions (Australia, Canada, UK, USA, with the EU likely later this year) have recognised this problem and updated their regulations to match the current realities of genetic modification, excluding both null-segregants and gene edited (SDN-1 and some SDN-2) organisms from regulation as GMOs.
	Alternative options	Alternative options	Proposal 1: The main document proposal is the better option.Proposal 1.1: Organisational level approval would likely act as a significant barrier to small research organisations.Proposal 4: The options here are similar to the ones a proposed in the main document. I find these would also be suitable.Proposal 5: I find that these options are still unnecessarily restrictive and over regulated. See my comments in the main document.Proposal 6: Defining isolated and tissue cultured eukaryotic cells as â€œnot an organismâ€ is useful mechanism for reducing regulatory burden. As no multicellular eukaryote can regenerate into a free-living organism without significant human intervention if the goal is the prevention of an organism becoming established in the environment, then this definition would likely still adequately deliver to the protection goal. Two things should be considered. First there would need to be an exclusion of yeast (a single celled eukaryote) and an explicit inclusion of plants despite their greater potential to regenerate into a whole organism (although only with significant deliberate human intervention).Proposal 8: No comment beyond what is in the main document.
Manaaki Whenua - Landcare Research	Objectives	Objectives	Yes
Manaaki Whenua - Landcare Research	Objectives	Objectives	These objectives are effective for developing these policy changes. However, clarity needs to be provided for the first objective on what is meant by â€œproportionately managesâ€ and how this would be determined.
Manaaki Whenua - Landcare Research	Proposal 1 - Risk-tiering framework	Unsure	Unsure
Manaaki Whenua - Landcare Research	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	This would make working with these cells a lot easier and would significantly reduce the administration burden.
Manaaki Whenua - Landcare Research	Proposal 1 - Risk-tiering framework	Unsure	Unsure

Manaaki Whenua - Landcare Research	Proposal 1 - Risk-tiering framework	Unsure	Preparing an application for an internal Biosafety committee does not reduce the administration burden or improve the time, resources, or funding commitments for researchers. In fact, it may increase the burden if each biosafety committee needs to come up with its own application process. This was a key objective in the executive summary. Similarly, annual reporting doesnâ€™t reduce the administration burden.The comment â€œStringent measures to ensure nothing inadvertently gets inâ€ (page 12) does not necessarily reduce the likelihood of anything getting out of the facility. Low risk items that do not need to be in containment facilities, i.e. PC1 or higher, are easily poured down the sink and potentially released into the environment without prior treatment.Under the proposed framework there is a shift of the risk management from the EPA/MPI to the individual organisations, especially for low-risk organisms/processes which may lead institutions to be overly cautious and in turn limit the work able to be done. There is also an increased risk for innocent mistakes to be made within this framework, especially at low risk. Additionally, policing of risk tier 1 would now fall to the researchers and/or lab facility managers which will add to the administration burden and management risk for these individuals.By aligning to Australian policies would they then be linked, i.e. when one goes under review both are affected? While this may be beneficial in some instances it is equally likely to be detrimental in others. If the two policies are independent, then there is more room to manage NZ specific issues.There also needs to be a process for newly discovered organisms that have been found in NZ, i.e. are not imported such as bacteria that have been found in soils, and that do not pose a disease risk to humans, plants, animals etc? These organisms should not be classed as new organisms under these proposals. There needs to be an easy way to â€œde-newâ€ organisms that are not GMO?What are the implications for collections (e.g. herbarium collections) of foreign material, i.e. new organisms under this framework
Manaaki Whenua - Landcare Research	Proposal 1 - Risk-tiering framework	Other policy options	Another option would be to base the framework on the low-risk Category A/B and 1/2 already defined in the HSNO act, set out in a matrix format. This should also include details about GMO properties that would not be allowed.An automated â€œapprovalâ€ process for risk tier 1 through a system such as the calculator/decision making tool like the Hazardous Substances Calculator would be beneficial. A tool likeThe EPA providing written confirmation through this sort of system would provide some assurance for lab managers/organisations/researchers. Providing a contact person would enable lab managers/organisations/researchers to quickly gain feedback for any organisms/processes that are not included in the online tool.
Manaaki Whenua - Landcare Research	Proposal 1.1 - Biosafety Committees	No	No
Manaaki Whenua - Landcare Research	Proposal 1.1 - Biosafety Committees	No	This is simply shifting the responsibility for approvals from the EPA to individual organisations. One of the key items listed in the executive summary is to provide benefits to the research community by making more time and funding available for research by reducing the time and resources required for applications, approvals, and day-to-day administrative tasks. Under this proposal researchers will still need to prepare applications and deal with the administrative tasks associated with these approvals only now they will need to submit approvals to a Biosafety committee rather than the EPA.Additionally, if an organisation decides to create their own ABSC there will be an increase in cost and time not only for processing the applications but also for meeting accreditation, auditing, and reporting requirements to maintain that ABSC.
Manaaki Whenua - Landcare Research	Proposal 1.1 - Biosafety Committees	Other policy options	Maintaining approval through the EPA but reducing the application requirements for risk tier 1. Simplified/express application process for risk tier 2.Ability to use already approved HSNO applications without needing to get individual approval if you meet the same controls e.g. able to append your name, facility or organisation to approvals. This would require an easily searchable database of current approvals and applications.Ability to amend currently approved applications (your own and other organisation) for your own work (saves time and money).
Manaaki Whenua - Landcare Research	Features and approach for regulatory framework	Features and approach for regulatory framework	General approach â€“ if organism and modification fall within a defined low risk group then no formal approval process is required, and work can continue. However, low risk work should still be done under containment.Suggested features of a revised policy:-Ability to use already approved HSNO applications without needing to get individual approval if you meet the same controls e.g., able to append your name, lab or organisation to approvals.-For higher risk applications - Ability to amend currently approved applications (your own and other organisations) for your own work (saves time and money).-Easily searchable database of current applications and approvals.-Would be good to have an EPA/MPI led calculator or decision-making tool. This would include a dropdown list of organisms and processes and would provide a dated confirmation or unique reference number stating that the organism and work falls under risk tier X. Ideally, a statement such as â€œno ABSC/EPA approval requiredâ€ or â€œEPA approval required due to x.â€ would also be included. This would provide details directly to the EPA about the work in the facility. Would be ideal if the result gave you the risk tier as well as directions. Flowcharts as guidance for risk tier decision-making would also be useful.-List of organisms falling under each risk tier should be a living document online and updated regularly as needed.-A designated EPA contact person for your facility (similar to an MPI verifier) would be great for first point of contact for queries.-A researcher/user submission form to raise issues or propose potential modifications as they occur would be great, i.e., live feedback option.
Manaaki Whenua - Landcare Research	Proposal 1.1 - Biosafety Committees	Other policy options	Maintaining approval through the EPA but reducing the application requirements for risk tier 1. Simplified/express application process for risk tier 2.Ability to use already approved HSNO applications without needing to get individual approval if you meet the same controls e.g. able to append your name, facility or organisation to approvals. This would require an easily searchable database of current approvals and applications.Ability to amend currently approved applications (your own and other organisation) for your own work (saves time and money).
Manaaki Whenua - Landcare Research	Proposal 2 - Assessments for medicines	Unsure	Unsure
Manaaki Whenua - Landcare Research	Proposal 3 - Record-keeping requirements	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 3 - Record-keeping requirements	Yes	This would reduce administration time.The need for a documented system of accounting should not be just for animals with the ability to escape, it should also be for all organisms with the ability to escape, propagate and cause harm. This includes some PC2 organisms.
Manaaki Whenua - Landcare Research	Proposal 2 - Assessments for medicines	Unsure	We are concerned that the removal of EPA approval at the early stages may mean the wider impacts of the new organism may not be captured. For instance, using an organism as a basis of a vaccine may have unintended consequences. In itself, the new organism may not be harmful but widespread use may interfere with the ability to detect the presence of a related unwanted organism. E.g. non-pathogenic strain used in a vaccine may mask the ability to detect the pathogenic strain.
Manaaki Whenua - Landcare Research	Proposal 3 - Record-keeping requirements	Yes	This would reduce administration time.The need for a documented system of accounting should not be just for animals with the ability to escape, it should also be for all organisms with the ability to escape, propagate and cause harm. This includes some PC2 organisms
Manaaki Whenua - Landcare Research	Proposal 3 - Record-keeping requirements	Unsure	Unsure
Manaaki Whenua - Landcare Research	Proposal 3 - Record-keeping requirements	Unsure	We agree there should be some link between the approval (from ASBC or EPA) and the new organism, i.e., able to trace the label back through documentation to the approval.We do not agree that it should be linked to the risk tier as well, as this should already be done by proxy.
Manaaki Whenua - Landcare Research	Proposal 3 - Record-keeping requirements	Other policy options	It would be beneficial to have a centralised institutional low risk approval that all organisations can piggyback onto.

Manaaki Whenua - Landcare Research	Proposal 4 - Internal audit frequency	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 4 - Internal audit frequency	Yes	This would reduce the administration burden for PC1 facilities.
Manaaki Whenua - Landcare Research	Proposal 5 - Movement between facilities	Yes	Yes
9(2)(ba)(i)	Objectives	Objectives	Yes
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1 - Risk-tiering framework	Other policy options	No
	Proposal 1.1 - Biosafety Committees	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
9(2)(ba)(i)	Proposal 1.1 - Biosafety Committees	Other policy options	No
	Proposal 2 - Assessments for medicines	Yes	Yes
	Proposal 2 - Assessments for medicines	Unsure	Unsure
	Proposal 2 - Assessments for medicines	Unsure	Medical Therapeutic Agent that result in 'new organisms' such as Gene Edited Medical Grade Pigs as sources of organs, tissues and cells as a therapeutic agent
Manaaki Whenua - Landcare Research	Proposal 6 - Requirements for eukaryotic somatic cells	Agree with issues	â€œDonor nucleic acid must not be derived from organisms implicated in or with a history of causing diseaseâ€ â€“ some clarification may be required here, e.g. E. coli would be excluded here. Perhaps gene rather than nucleic acid?Clarification is required about the use of DNA sequences from NZ donor species into the somatic cells. Would this be included in Risk tier 1? More clarity about what would be included in Risk tier 1 is required before a full response can be made.There is currently no guidance under this proposal on the insertion of DNA from native species. Use of DNA from native species should require consultation to avoid breaches of Te Tiriti o Waitangi.
9(2)(ba)(i)	Proposal 2 - Assessments for medicines	Other policy options	Policies should permit development of xenotransplantation to meet the chronic shortage of human donor organs..GENE EDITED PIGS for human xenotransplantation are animals that require to be in a designated pathogen free (DPF) pig facility We wish to clarify thata)as large animals they are not likely to escape from a DPF facilityb)These gene edited animals are essentially healthy animals with healthy organs, tissues and cells for human therapeutics. Healthy medical grade pigs bred as a source of organs, tissues or cells for human transplantation are of low risk and should be distinguished from genetically modified animals which are experimental models of disease.c)These pigs would generate new animals that are healthy animals as sources of organs, tissues and cells for human therapeutics in a containment facility.
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 3 - Record-keeping requirements	Unsure	Unsure
	Proposal 3 - Record-keeping requirements	Unsure	The ACT should take into account the safety of medical grade gene-edited pigs bred in containment for medical therapeutics
	Proposal 3 - Record-keeping requirements	Unsure	Unsure

Manaaki Whenua - Landcare Research	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
9(2)(ba)(i)	Proposal 3 - Record-keeping requirements	Unsure	The ACT should take into account the safety of medical grade gene-edited pigs bred in containment for medical therapeutics
	Proposal 3 - Record-keeping requirements	Unsure	he ACT should take into account the safety of medical grade gene-edited pigs bred in containment for medical therapeutics
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 4 - Internal audit frequency	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 7 - Regulatory status of biotechnologies	Yes	But some clarification as to what is covered here is required. What is the difference between adding DNA to a large organism (e.g. vaccinating humans) and adding it to a cell via transfection - particularly transient transfection (the transfected cell does not pass this modification on to subsequent generations and is not incorporated into the genome).Why are these non-GMO rather than classified as risk tier 1?
9(2)(ba)(i)	Proposal 4 - Internal audit frequency	Other policy options	No
	Proposal 5 - Movement between facilities	Yes	Yes
	Proposal 5 - Movement between facilities	Yes	Yes
	Proposal 5 - Movement between facilities	No	No
	Proposal 5 - Movement between facilities	Other policy options	No
	Proposal 5 - Movement between facilities	Other policy options	No
	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	Should include special consideration for DNA from native species or taonga.
9(2)(ba)(i)	roposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
	roposal 7 - Regulatory status of biotechnologies	Yes	Yes
	roposal 8 - Low-risk fermentation	Proposal 8 - Low-risk fermentation	No
	roposal 7 - Regulatory status of biotechnologies	No	Unsure
	roposal 7 - Regulatory status of biotechnologies	No	. Human gene editing that alters the genome of the patient2. Xenotransplantation of genome edited pig donor organs, tissues or cells that do not alter the genome of human recipient.
	roposal 7 - Regulatory status of biotechnologies	Unsure	1. Clinical Trials of in-vivo gene editing of humans has occurred in New Zealand patients.Gene editing that does correct the genome of individuals, especially in those with rare genetic diseases should be permitted. In some cases gene editing treatment may be the only significant therapeutic option. We have a moral obligation to develop a safe and effective gene editing therapy especially for rare genetic disorders.2. Xenotransplantation of gene edited pig organs, tissues or cells is the transplantation of material from genome edited pig donors but do not affect the genome of the human recipient. The transplantation of a gene edited pig heart in a human recipient has occurred in the USA.
	roposal 7 - Regulatory status of biotechnologies	Other policy options	1. Human gene editing that alters the genome of the patient2. Xenotransplantation of genome edited pig donor organs, tissues or cells that do not alter the genome of human recipient.

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Proposal 7 - Regulatory status of biotechnologies	Other policy options	1. Human gene editing that alters the genome of the patient: This has been delivered to a few New Zealand patients2. Xenotransplantation of genome edited pig donor organs, tissues or cells that do not alter the genome of human recipient.Clinical xenotransplantation of medical grade pig cells has been approved in clinical trials in New Zealand.
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Unsure	Unsure
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Other policy options	No
Proposal 9 - Standards for containment facilities	Options	Not Answered
Proposal 9 - Standards for containment facilities	Options	Currently unsure of best system for setting up the only containment and transitional designated pathogen free medical grade pig facility in New Zealand.
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 9 - Standards for containment facilities	Yes	We intend our facility to be a containment and transitional facility. MPI has so far indicated that our facility is approvable as we do not yet have gene edited animals. We are unsure which option would be least cumbersome or expensive.
Proposal 9 - Standards for containment facilities	Other policy options	No
Proposal 9 - Standards for containment facilities	Other policy options	No
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Unsure	Unsure
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	No	No
Proposal 10 - Reviews of regulatory settings	Other policy options	The Alternative for Proposal 6
Costs, benefits or risks	Costs, benefits or risks	Proposal 7 and the Benefits of1. Human gene editing that alters the genome of the patient2. Xenotransplantation of genome edited pig donor organs, tissues or cells that do not alter the genome of human recipient.
Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	RISK TIER 1 item 3.Animals (such as medical grade pigs) that are not infected with a virus or infectious agents and maintained for xenotransplantation therapy are low risk.

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Austen Ganley	Proposal 1 - Risk-tiering framework	Yes	Yes
Austen Ganley	Proposal 1 - Risk-tiering framework	Yes	I agree, but I think the Australian lists should be amended. See my general comment for details
Austen Ganley	Proposal 1 - Risk-tiering framework	Yes	es
Austen Ganley	Proposal 1.1 - Biosafety Committees	No	No
Austen Ganley	Proposal 3 - Record-keeping requirements	No	No
Austen Ganley	Proposal 3 - Record-keeping requirements	No	Labelling is unnecessary under proposal 1. See my general comment for details
Austen Ganley	Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Austen Ganley	Proposal 6 - Requirements for eukaryotic somatic cells	No	I don't think this makes sense - it seems to misunderstand the point of somatic in the Australian regulations. See my general comment for details
Austen Ganley	Proposal 6 - Requirements for eukaryotic somatic cells	No	No
Austen Ganley	Te ao Maori	Other issues or considerations	Yes, the focus only on health is strange. Economy, environment and society need adding to the Objectives in order to not produce regulatory biases, as these are also areas that the technology is critical for. See my general comment for details
Paula Jameson	Objectives	Objectives	No

Paula Jameson	Objectives	Objectives	While I agree with the objectives in principle, they are simply not broad enough and are unlikely to be effective in improving the regulatory settings for genetically modified organisms in New Zealand.For example, the current objectives do not consider the well-documented challenges facing the primary sector and environment and the importance the primary sector has on the New Zealand economy and the health and well being of New Zealanders.Both the Productivity Commission and Climate Change Commission have documented how review of the regulatory framework for genetic technologies is required for New Zealand as New Zealand risks losing its competitiveness in international markets. New Zealand is unlikely to be able to transition to a sustainable agricultural sector in a changing environment without the use of genetic technologies in the field.Crippling legislation feeds into the fear some members of the public have about these technologies - they must all be really dangerous if they (still) have to be so tightly regulated.
Paula Jameson	Features and approach for regulatory framework	Features and approach for regulatory framework	The regulatory framework must be up to date and also future-proofed, to anticipate and flexibly accommodate future technological developments to the best extent possible.Any new framework must address all current uses of genetic technologies and be sufficiently flexible to accommodate new techniques, which it currently is not. For example, NZ looks to be one of the very last countries to be considering modifying its legislation relating to gene edited organisms. Currently, NZ legislates all gene edited organisms as being genetically modified organisms, a powerfully limiting piece of legislation for this promising technology.The current amendments are merely tinkling around the edges and not addressing the real elephant in the room - genetically modified/gene edited plants and animals in the field.A complete review of the relevant legislation and regulations surrounding genetic technologies and genetically modified organisms, including gene edited organisms is required, towards the establishment of an Australian style OGTR i.e. a dedicated agency.Preferably, future legislation will address the product and not the technology used to produce that product.Future legislation/regulation needs to address transfer to the field, with controls proportionate to the type of genetic change in the plant/fungus/animal.
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Yes	Yes, because as stated this would/should reduce the likelihood of regulatory settings remaining inappropriate and out of date for long periods of time; and encourage horizon-scanning and beneficial regulatory work in anticipation of coming advances in biotechnology.Clearly, the advent of and continuing restrictive legislation on gene editing is a case in point. NZ is well behind our major trading partners in reconsidering the legislation around this technology.
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Yes	Genetic technologies have been developing at a very fast rate. This may slow down (and so a light review may be all that is needed) - or it may speed up, and require a comprehensive review. Five years seems appropriate, although horizon scanning should be continuous.
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Yes	The primary legislation is out of date and needs revision. As do the regulationsAn OGTR might avoid some of the listed issues.
Paula Jameson	Proposal 10 - Reviews of regulatory settings	Other policy options	Both legislation and regulations need to be reviewed - starting now - not in five years time!There is no time left for tinkering around the edges!
Manaaki Whenua - Landcare Research	Proposal 5 - Movement between facilities	Technical feedback	Removing the movement authorisation requirements for risk tier 1 organisms would reduce the administration burden as well as saving time and money.The proposal jumps between risk tier 1 and PC1 which is confusing and not the same thing. This needs to be clarified and preferably linked to the risk tier group rather than PC standard.Rather than restricting movements between facilities based on their operating processes (PC1 vs PC2 etc), movement of organisms between facilities should be based on the risk of the new organism or the GMO as per the initial assessment of the research/process by the EPA or ASBC. i.e. this should be added to the end of a permit/approval like the controls are already.
Manaaki Whenua - Landcare Research	Proposal 5 - Movement between facilities	Technical feedback	Removing the movement authorisation requirements for risk tier 1 organisms would reduce the administration burden as well as saving time and money.The proposal jumps between risk tier 1 and PC1 which is confusing and not the same thing. This needs to be clarified and preferably linked to the risk tier group rather than PC standard.Rather than restricting movements between facilities based on their operating processes (PC1 vs PC2 etc), movement of organisms between facilities should be based on the risk of the new organism or the GMO as per the initial assessment of the research/process by the EPA or ASBC. i.e. this should be added to the end of a permit/approval like the controls are already.
Manaaki Whenua - Landcare Research	Proposal 7 - Regulatory status of biotechnologies	Technical feedback	But some clarification as to what is covered here is required. What is the difference between adding DNA to a large organism (e.g. vaccinating humans) and adding it to a cell via transfection - particularly transient transfection (the transfected cell does not pass this modification on to subsequent generations and is not incorporated into the genome).Why are these non-GMO rather than classified as risk tier 1?
Manaaki Whenua - Landcare Research	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	Additional exclusions for epigenetic modifications should include e.g. â€œcannot give rise to an infectious agent and cannot be independently replicativeâ€. Some additional consideration should also be given to the impact of epigenetic modifications that may create/increase virulence and toxicity of the organism.
Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Options	It is good to have baseline standards to meet but also to have the option for outcome-based decisions for specific situations/organisms because we know the organisms we are working with, and how to best to contain them.
Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Unsure	Unsure
Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Agree with issues	The more â€˜grey areasâ€™ there are with standards, the more likely we are to get corrective actions based on what opinion/experience the verifier has on the day.Providing guidelines for best practice is great for facilities that have limited scope and routine experiments but may be hard for facilities that cover diverse organisms and processes for exploratory research.Incorporating international standards into some facilities may be difficult.The proposal also asks for approaches that may best upskill operators and improve biosafety practices. Providing clear guidelines and materials is useful, especially when paired with a designated contact person as well as online feedback or calculators. Specific, highly focused training workshops or information sessions run by the EPA would also be beneficial for upskilling new operators.

Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Cost vs benefits	We do not foresee the cost outweighing the benefits of a change to a hybrid approach. Some clarification is needed on the validation process and what level of peer-review is acceptable, i.e., would an internal peer review be sufficient, or would the results require an â€œindependent reviewerâ€ or publication in a peer-reviewed journal?
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Agree with proposal	But there is a risk here of recommended changes not being implemented before the next review occurs and this may lead to confusion about which regulations are to be followed.
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Unsure	Unsure
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Agree with frequency	5-10 years would be good, this will likely help keep up to date with new technologies while also giving sufficient time to implement the new changes
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Agree with issues	Consideration needs to be given to changes that would require major capital investment to laboratories or facilities which may not be feasible to be completed within allocated timeframes/review periods.
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Agree with issues	Consideration needs to be given to changes that would require major capital investment to laboratories or facilities which may not be feasible to be completed within allocated timeframes/review periods.
Manaaki Whenua - Landcare Research	Alternative options	Alternative options	Yes, the following alternative options:-Proposal 4: reducing internal audit frequencies to match Australia.-Proposal 5: remove current movement authorisation requirements for GMOs requiring PC2. Clarification on PC2 or risk tier 2 is needed here.-Proposal 6: excluding eukaryotic cells from the definition of â€˜organismâ€™.
Manaaki Whenua - Landcare Research	Proposal 10 - Reviews of regulatory settings	Other policy options	The option of a researcher/user submission form to raise issues or potential modifications for review would be great, i.e., live feedback option. Prefer a live feedback option to full review response submission every 5 years.List of organisms and modifications under each of the risk tiers should be a live document online and updated as needed.
Manaaki Whenua - Landcare Research	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Species specific lists need to be comprehensive, searchable, and updated frequently to incorporate name changes, newly discovered species etc.Are exempt dealings risk tier 1?Tier level should match up to PC level: exempt = no PC, tier 1 = PC1, tier 2 = PC2 etc.Need to be really clear about what risk tier organisms can be in each PC level. The proposal jumps between risk tier and PC quite a bit which is confusing.
Manaaki Whenua - Landcare Research	Proposal 1 - Risk-tiering framework	Yes	A risk-tier framework is a good idea however the Australian framework seems highly prescriptive (down to species level in some instances) which may lead to issues if the organism you want to work on is not included in the list.The explicit listing of organisms precludes the use of newly discovered organisms or processes/techniques and is therefore not future proofing. A broader scope for which organisms are in each tier would be beneficial, i.e. risk tier 1 is organisms that are clearly identifiable and classifiable and not able to cause diseaseâ€¦as per the HSNO act. Specificity is great if it is a fully comprehensive list.Access to a calculator or decision-making tool would help give researchers confidence that their research falls into risk tier 1 and no approval is required. Additionally, the ability to save or print this result will help with record keeping and MPI auditing.
Manaaki Whenua - Landcare Research	Proposal 9 - Standards for containment facilities	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Objectives	Objectives	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 1 - Risk-tiering framework	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 1 - Risk-tiering framework	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 1.1 - Biosafety Committees	No	No

Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 2 - Assessments for medicines	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 3 - Record-keeping requirements	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 3 - Record-keeping requirements	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 3 - Record-keeping requirements	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 4 - Internal audit frequency	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 4 - Internal audit frequency	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 4 - Internal audit frequency	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 5 - Movement between facilities	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 5 - Movement between facilities	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 7 - Regulatory status of biotechnologies	Agree with proposal	Self explanatory
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 8 - Low-risk fermentation	Unsure	Unsure
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 8 - Low-risk fermentation	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 9 - Standards for containment facilities	Status quo	Keeping the status quo approach
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 9 - Standards for containment facilities	Status quo	The current system as responsibilities and requirements are clear and precise
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 9 - Standards for containment facilities	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Answer contradicts previous answer	Answer contradicts previous answer	No

Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 9 - Standards for containment facilities	No	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 10 - Reviews of regulatory settings	Yes	Legislation must keep up with technology which means it must be regularly reviewed
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 10 - Reviews of regulatory settings	Yes	Attempts to match the rate of change that is occurring
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 10 - Reviews of regulatory settings	Other policy options	More detailed consultation that is aimed at audiences outside of the science community would have improved this process so should be considered for the future.
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Taonga species	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Taonga species	The EPA Maori Advisory Group do not speak for all Maori and all Maori would be affected therefore engagement must be NZ wide
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Taonga species	Not something that can be managed by policy as the issue is too big for that
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Use of genetic material	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Use of genetic material	This goes against tikanga for Maori and would need to be an individual's decision to make in regard to human cells or an iwi Maori decision for taonga species, not a governments decision
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Informed consent	No
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Informed consent	Risk tier 1 must not overrule Section 7 of the Human Tissue Act 2008
Ngati Tahu-Ngati Whaoa Runanga Trust	Te ao Maori	Other issues or considerations	This whole section should have been included in the consultation document so Iwi Maori could consider their answers in a timely manner, not added in via this process. It is unlikely that this section will be given the due diligence it deserves and almost seems like a late "add-on" to the original consultation which is unacceptable
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 2 - Assessments for medicines	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 8 - Low-risk fermentation	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 8 - Low-risk fermentation	Yes	Yes
Ngati Tahu-Ngati Whaoa Runanga Trust	Proposal 8 - Low-risk fermentation	Yes	Yes

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Proposal 9 - Standards for containment facilities	No	No
Objectives	Objectives	Yes
Proposal 9 - Standards for containment facilities	Cost vs benefits	we support an outcome-based approach.
Proposal 9 - Standards for containment facilities	Other policy options	none
Features and approach for regulatory framework	Features and approach for regulatory framework	The degree of regulation in New Zealand around GMOS is not fit for purpose is not in line with the risks associated with GMOs. These policies have slowed down groundbreaking research, discovery, and industry in New Zealand.
Proposal 1 - Risk-tiering framework	No	No
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Yes	No other issues
Proposal 1 - Risk-tiering framework	Other policy options	No other policy issues.
Proposal 1.1 - Biosafety Committees	No	No
Proposal 1.1 - Biosafety Committees	No	The development of Institutional EPA-approved accredited biosafety committees that can be used by small companies or organisations is a welcome change. We do wonder however if this will work in practice. There seems to be little benefit for a large institution ABSC to lend its time and resources to evaluate applications from smaller institutions/small companies. There should also be the option to establish and use an EPA ABSC.
Proposal 1.1 - Biosafety Committees	Other policy options	Institutions with a set size or number of applications should be mandated to form their own ABSC.
Proposal 2 - Assessments for medicines	Unsure	Unsure
Proposal 2 - Assessments for medicines	Unsure	We do not have enough knowledge around this topic to comment at this time.
Proposal 2 - Assessments for medicines	Unsure	Unsure
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Features and approach for regulatory framework	Features and approach for regulatory framework	The degree of regulation in New Zealand around GMOS is not fit for purpose is not in line with the risks associated with GMOs. These policies have slowed down groundbreaking research, discovery, and industry in New Zealand.
Proposal 1 - Risk-tiering framework	Proposal 1 - Risk-tiering framework	alligning with Australia would be an improvement
Proposal 1 - Risk-tiering framework	Proposal 1 - Risk-tiering framework	We feel it would be better to align with international best practices, rather than just aligning with Australia. We feel the proposed modelling of risk tiering on Australian standards does not go far enough.
Proposal 2 - Assessments for medicines	Unsure	Unsure

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Proposal 2 - Assessments for medicines	Unsure	We do not have enough knowledge around this topic to comment at this time.
Proposal 2 - Assessments for medicines	Other policy options	We do not have enough knowledge around this topic to comment at this time.
Proposal 3 - Record-keeping requirements	No	We feel the process of labelling and tracking GMOs as it is currently done AND with the proposed changes is simply too excessive and does not do anything to limit the escape of GMOs into the environment. The current process of tracking each GMO is extremely time-consuming, expensive and onerous. The proposed changes here seem to simply move the labelling from the tubes to the container and don't fix the issue.If the GMO is a higher risk, then the lab containment practices should be enough to prevent escape. For low risk tier 1 GMOs, these are low risk as they pose little to no threat to the environment if they escape anyway.
Proposal 3 - Record-keeping requirements	Yes	Labs should be able to show the ASBC (or EPA approval) for the lab and the strains/cultures held there.
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Facilities can always self audit more frequently.
Proposal 3 - Record-keeping requirements	Other policy options	For GMOs that are considered higher risk or for cultures/strains that pose a threat to human/agriculture/environment/etc these should be labelled and tracked. For low risk GMOs (which constitute the vast majority of GMOs), little to no tracking should be required. This is in line with how many other countries around the world operate.
Proposal 4 - Internal audit frequency	Yes	Facilities can always self audit more frequently.
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	no further issues.
Proposal 4 - Internal audit frequency	Other policy options	no further policies.
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	The movement authorisation is overly burdensome and outcomes do not justify the work or time involved when GMOs are considered low risk.
Proposal 5 - Movement between facilities	Yes	Yes
Proposal 5 - Movement between facilities	Yes	Movement of Risk Group 1 organisms and their products (DNA, RNA, and proteins) should be free of regulation, as these by definition, are low risk.
Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	We do not have enough knowledge around this topic to comment at this time.
Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	We do not have enough knowledge around this topic to comment at this time.
Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	We do not have enough knowledge around this topic to comment at this time.
Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	none.

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Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	no other issues.
Proposal 7 - Regulatory status of biotechnologies	Other policy options	none.
Proposal 8 - Low-risk fermentation	No	No
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	See above. The proposed rules should allow risk group one organisms to be grown at scale outside of a PC1 space, as it is not clear how the volume of a culture changes it's risk level.
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Other policy options	Allowing non-containment fermentation of GMOs for a set of "GRAS" organisms, like Saccharomyces and Pichia, similar to what us already applied in beer in wine industry
Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Proposal 9 - Standards for containment facilities	Hybrid	A hybrid approach could reduce any expenditure to update existing facilities. It will also allow for new facilities.
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 9 - Standards for containment facilities	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes, however, with the note that it can be done earlier if a new technology arises that needs immediate review.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes, however, with the note that it can be done earlier if a new technology arises that needs immediate review.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	none.
Proposal 10 - Reviews of regulatory settings	Other policy options	no.
Alternative options	Alternative options	no.
Costs, benefits or risks	Costs, benefits or risks	no.
Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	no.

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Te ao Maori	Taonga species	Unsure
Objectives	Objectives	The second objective should be expanded to not only include better outcomes through use of GMOs in biomedical research, but for the vast array of research and technologies that use GMOs, including diverse research areas such as climate change, agriculture, food technology, and fundamental research.
Proposal 3 - Record-keeping requirements	No	No
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 4 - Internal audit frequency	Yes	Yes
Proposal 5 - Movement between facilities	Other policy options	none.
Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Proposal 7 - Regulatory status of biotechnologies	Yes	We agree with this.
Proposal 7 - Regulatory status of biotechnologies	Other policy options	none.
Proposal 8 - Low-risk fermentation	No	The rules proposed here are not logical. There is no clear reason why different culture *volumes* change the risk level. If an organism is deemed safe, and proper mitigations are taken for containment of spills, there should be no reason why an organism grown in a 10L culture volume is any different, from a risk perspective, when grown at 100 L or 1,000 L. There are several opportunities for New Zealand to grow in the precision fermentation space, however, the costs associated with operating this type of fermentation at scale in a PC1 lab will make it financially untenable for the majority of the companies in this space. We see massive benefits to developing precision fermentation in New Zealand for a range of commercial products, including food, fabrics, and medicines. These technologies are needed to address New Zealand's commitment to reduce our greenhouse gas emissions. The proposed rules should allow risk group one organisms to be grown at scale outside of a PC1 space, as it is not clear how the volume of a culture changes it's risk level.
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	See above. The proposed rules should allow risk group one organisms to be grown at scale outside of a PC1 space, as it is not clear how the volume of a culture changes it's risk level.
Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	no.
Proposal 9 - Standards for containment facilities	Yes	none.
Proposal 8 - Low-risk fermentation	Yes	See above. The proposed rules should allow risk group one organisms to be grown at scale outside of a PC1 space, as it is not clear how the volume of a culture changes it's risk level.

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Objectives	Objectives	No

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Objectives	Objectives	While we agree with these objectives in principle, we believe they are not broad enough and may not be fully effective in addressing the complex challenges associated with GMO regulation. This submission aims to highlight some important considerations that we believe should be integrated into the objectives to create a more comprehensive and effective framework.1.Incompleteness of Current Objectives:The current objectives, while addressing key aspects of GMO regulation, are incomplete. They do not fully consider the significant challenges facing New Zealand's primary sector and environment. The primary sector plays a crucial role in the New Zealand economy and the overall well-being of its citizens. Both the Productivity Commission and the Climate Change Commission have documented the need for a thorough review of the regulatory framework for genetic technologies. This review is essential to ensure New Zealand remains competitive in international markets and can transition to a sustainable agricultural sector in an evolving global environment.Suggested Modification: Expand Objective 2 to include language such as "contributes to better health and environmental outcomes for New Zealanders and New Zealand through increasing research outcomes and innovation, and greater access to biotechnology processes and products."2.Complexity of the Regulatory System:The objectives as currently outlined only address a fraction of the intricate regulatory system governing GMOs. New Zealand's GMO regulatory landscape involves multiple pieces of legislation and is overseen by various agencies. Making small, isolated changes to this system can be time-consuming and challenging. Furthermore, without a comprehensive approach, there is a risk that addressing one issue may inadvertently create new complications.Suggested Modification: Consider including an objective aimed at simplifying the regulatory landscape for GMOs in New Zealand. For instance, this could involve consolidating GMO-related legislation and establishing a dedicated agency, as recommended by the Royal Commission into Genetic Modification in 2000/2001.3.Redefining Genetically Modified Organisms:The objectives do not address the need to redefine what constitutes a genetically modified organism. The current definition of GMOs may no longer be suitable, especially considering the advancements in genetic technologies like site-directed mutagenesis.Suggested Modification: Include an objective to reevaluate and update the definition of genetically modified organisms to ensure it aligns with contemporary scientific understanding and technological advancements.4.Primary Industries Consideration:The objectives do not explicitly address the importance of New Zealand's primary industries in the context of GMO regulation. Given the significant role of these industries in the country's economy and the challenges posed by climate change, it is essential to have an objective that focuses on sustainable production and climate change adaptation within the New Zealand primary industries through research, innovation, and production.Suggested Modification: Add an objective that emphasizes sustainable production and climate change adaptation within New Zealand's primary industries through research, innovation, and production.Incorporating these suggested modifications into the objectives for improving GMO regulatory settings in New Zealand would create a more comprehensive and effective framework that addresses the multifaceted challenges associated with genetic modification while ensuring the well-being of New Zealanders and the country's economic and environmental sustainability.
Features and approach for regulatory framework	Features and approach for regulatory framework	1.Proportional Risk Assessment: The current regulatory framework for genetic modification in New Zealand lacks proportionality in addressing risks. Scientific consensus suggests that genetically modified food carries no greater risk than conventional methods, potentially even less. The environmental impact depends on the specific trait introduced. However, the precautionary principle has often acted as a barrier instead of effectively managing risks. It's crucial to consider the potential benefits of genetic technologies in this process.2.Revised Definition of Genetically Modified Organisms: The existing definition of genetically modified organisms poses issues as it is based on the technique used (in vitro) and the date of first use in New Zealand. This definition serves as an all-encompassing term for various techniques with distinct risk profiles. Consequently, organisms developed differently but containing the same modification may face different regulatory routes, causing inconsistency.3.Future-Proofing: Genetic technologies will likely continue evolving with new techniques emerging. The regulatory approach should be flexible enough to adapt to these advancements while maintaining risk proportionality. Establishing a timetable for regular reviews is advisable.4.Simplified Regulation: Currently, genetic modification regulation in New Zealand is spread across multiple legislations and overseen by various agencies. It would be beneficial to streamline this process by removing genetic modification from the HSNO Act and creating a dedicated regulator, akin to the OGTR.5.International Alignment: New Zealand's genetic modification regulations do not align with those of major trading partners, such as Australia. This misalignment, as highlighted in the 2021 Productivity Commission report, poses risks to our international reputation and trade. It can impede research and our ability to respond to changing circumstances and raises concerns about the import of fresh food when it's classified as genetically modified here but not elsewhere.6.Facilitating Laboratory Research to Field Trials: The HSNO Act allows for applications for field trials and the release of genetically modified organisms, but there have been no recent applications for either. There's a need for a more accessible pathway that maintains risk proportionality.7.Preventing Regulatory Expansion: There has been a notable expansion of regulations under the HSNO Act, leading to increasingly complex and restrictive standard operating procedures (SOPs) within transitional facilities and containment laboratories. Regulators, their enforcement contractors, and accredited biological safety committees should be mandated to simplify containment SOPs in line with a proportional risk response rather than making them more stringent.8.Consider Removal from HSNO Act: It's worth considering the removal of genetic modification from the HSNO Act altogether.9.Comprehensive Regulation: Future regulations should not solely focus on the technique used to create a new organism but should also consider aspects of the product, including:oNovelty of the change (is there an equivalent already in the environment).oDistinctiveness of changes that could be made using other methods (e.g., SDN1, DNA only from a related species).oEvaluation of whether the organism contains added or foreign genetic material (e.g., null segregants).

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Objectives	Objectives	Yes
Features and approach for regulatory framework	Features and approach for regulatory framework	None.
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1 - Risk-tiering framework	Other policy options	None.
Proposal 1.1 - Biosafety Committees	Yes	Yes
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 1.1 - Biosafety Committees	Yes	Yes
Proposal 1.1 - Biosafety Committees	Other policy options	None.
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes

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Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	None.
Proposal 7 - Regulatory status of biotechnologies	Yes	Fully agree with the proposed change. Introduced RNA or DNA is not known to modify the genetic material of an organism and such organisms should not be considered a GMO.
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Other policy options	1.Whereas the proposed one-time regulatory change is a welcome step, EPA can consider setting up a system for continuous engagement with researchers whereby EPA is able to provide relatively quick statutory counsel (<2 week?) on variations of regulations and previous determinations. For example, even when the proposed regulation aims to clarify that organisms with introduced RNA shall not be deemed a GMO, researchers will still have to seek counsel, if not explicitly stated, for example, on the method of RNA transfection, the source of the RNA (natural or artificial) etc to remove any ambiguity, to avoid the risk of inadvertent noncompliance.2.This is related to the first point. To provide better clarity for researchers, EPA can consider documenting and explicitly stating all potential use cases (to the extent possible). Such an attempt has been made in Australian OGTR's document titled â€˜Overview â€“ status of organisms modified using gene editing and other new technologiesâ€™ (please see here- https://www.ogtr.gov.au/sites/default/files/2021-11/overview_-_status_of_gene_editing_and_other_new_technologies.pdf).
Proposal 7 - Regulatory status of biotechnologies	Other policy options	One of the aims of this document is to ensure that the proposed changes to regulations are both up to date and future proof. Recent advances have identified CRISPR associated protein Cas13 that perform targeted degradation of cellular RNA in the presence of specific guide RNA without changing the cell's genetic material. The method involves the injection of Cas13 and artificial guide RNA into cell lines which results in downregulation of mRNA and non-coding RNA levels. Clarification on the use of this technology in the proposed regulation will enable researchers to adopt this and similar RNA-targeting technologies for gene expression studies without having to seek a statutory determination from EPA.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Very good proposal and very important one too.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Yes	Very good proposal and very important one too.
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Other policy options	None.
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	None.
Proposal 7 - Regulatory status of biotechnologies	Agree with issues	None.

9(2)(a)

Objectives	Objectives	No

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Objectives	Objectives	While the objectives are sound and address some of the issues concerning the HSNO Act and the regulation of GMOs, I feel that they are incomplete and are not the most effective objectives for policy changes.The regulatory landscapes for GMOs have not been comprehensively reviewed for the more than 20 years since the Royal Commission. During this time there has been extensive research on the safety of GMOs leading to the scientific consensus that they present no greater risk (and potentially a lower risk) than organisms developed through other techniques and there has been major advancements in genetic techniques resulting in very different risk profiles. This has left New Zealand with a legislative environment that is no longer fit-for-purpose, does not reflect risk proportionally and is putting New Zealand increasingly out-of-step with our major trading partners. Further, the reliance on the precautionary principle risks New Zealand failing to take advantage of technologies and innovation. The objectives recognise this in terms of medicines, but do not address the urgent need for the transition to a sustainable agriculture sector without significant economic losses.I believe the objectives should be widened to allow for a complete review of both the definition and the regulation of genetically modified organisms. It is disappointing that this is not being undertaken as part of this consultation, given the â€œdiagnoses of the policy problemâ€ in the accompanying document â€œInterim regulatory impact statement on optionsâ€ (and the documents cited within), and the limited rational given for the narrow scope of these objectives. This is particularly disappointing as we know we face the urgent and unprecedented challenge of a fair transition to a environmentally and economically sustainable primary sector. Thus, the objectives should be widened to include the use genetic technologies and biotechnology outside research and medical settings in a risk proportionate manner. This could be similar to Objective 2 â€œcontributes to better health outcomes for New Zealandersâ€ but without limiting it to biomedical research and medicines.
Features and approach for regulatory framework	Features and approach for regulatory framework	New Zealand regulatory framework should be risk proportional rather than risk adverse.The regulation should recognise that the use of a genetic technology does not necessarily mean that an organism developed using the technologies posses a higher risk than other organisms. For example, a null segregant (an organism descended from a transgenic organism but not containing any transgene/added genetic material) poses very little risk (the transgene is not released into the environment). Additionally, other techniques result in changes to the genetic material that could happen in alternative ways (site-directed versus random mutagenesis) but the same change is differently regulated.The regulatory environment should enable a risk/benefit analysis rather than be based on an overly risk adverse system. What is the risk of not releasing an organism (e.g., continued used of high levels of nitrogen fertilizer or continued use of insecticidal sprays).The definition of a GMO or even defining a GMO needs to be updated. The use of the term GMO and trying to define a GMO is problematic as there is no sensible scientific definition and there should not be an all-encompassing term for multiple techniques with very different risk profiles. Historically, a GMO was broadly considered a plant containing added or foreign DNA that was added in a laboratory setting (in vitro). However, the definition now covers a range of techniques where there is no added DNA in the final organism and techniques to add DNA to some organisms (e.g. Arabidopsis thaliana or through grafting) can be achieved using plants grown in soil (i.e. not in vitro). The inability to be able to determine how an organism has been developed (if not previously informed as to what the change is) also poses problems for defining a GMO. How can something be effectively regulated if it cannot be detected?Consideration could also be given whether cells that cannot survive outside of laboratory or industrial (fermentation) conditions (i.e., tissue culture cells) should be considered organisms.Any approach should also also a risk proportionate, workable and practical pathway for an organims to move out of a research laboratory. While the current legislation was designed to allow for field trials and release of GMOs, it has effectively acted at a barrier to innovation (which was not the intent). The regulatory environment should enable an effective route for products from the laboratory with consideration given to the risk profile of the organism, based the genetic makeup. For example, a lower bar for an organism generated by site-directed mutagenesis or containing genetic material from a relative (could be crossed), compared to an organism containing DNA from an distantly related organism. This could also be a risk-tier approach, but not restricted to research laboratories.One of the current difficulties with the regulation of genetic modification is that it is covered by multiple pieces of legislation and overseen by multiple agencies. Removing genetic modification from the HSNO Act and setting up a dedicated regulator (such as the OGTR) would be beneficial. It is also important to try to avoid the regulatory creep that has occurred in New Zealand.
Proposal 1 - Risk-tiering framework	Unsure	A risk-tiering regulatory framework does reflect a more risk-proportionate approach to the regulation of organisms developed by genetic technologies. As noted in Part 1, consideration of such an approach should also include field trials and release.
Proposal 1 - Risk-tiering framework	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Proposal 1 - Risk-tiering framework	Other policy options	Given the complexity of the regulatory environment in New Zealand and the risk adverse nature, I hold concerns that the suggested changes may result in very little change. This is particularly so for researchers like myself at an institution that has a broad approval managed by a Institutional Biological Safety Committee.It is also noted that the details for what the tiers would look like has not been determined. While it is good that further consultation would be undertaken, there is potential for this process to be very difficult resulting in an equally complex system with a long time before implementation. Care would also need to be taken to ensure:-No organism (or parts of organisms) face a higher regulatory burden that under the current system-A highly prescriptive approach (as used in Australia) does not result in long delays if an organism is not listed and an application to add the organisms needs to go through an EPA approval system that is similar to the system today.As noted, I would favour a wide review of the entire regulatory landscape of the use of genetic technologies in New Zealand.Another approach that could be considered as an interim step (although I would argue a full review is becoming more critical) is a review of the current situation and eliminating some of the regulatory creep that has occurred in the regulatory system. This could likely achieve some of the aims around reducing the burden of compliance and freeing up time for laboratory research. Since I moved to New Zealand a little over 10 years ago, it appears that the goal posts are often changed which have lead to the higher and higher burden of biological compliance. Some examples- for the small facility that I run we have always needed to provide written training documents, then suddenly there is a recommendation from an MPI audit that we also should document practical/ in room training.- we used to be able to send waste for disposal by Interwaste, but now have to autoclave it all in house.- when we import GMOs we have a check list which includes a box to note the packaging is intact, but now we need to add a photo to show this.- we are continually asked to provide more and more Standard Operating Procedures for actions that have been taken for many year with no problems.These little changes all add up over time.As noted, I am at an institution with a wide low-risk approval, but from speaking to colleges I believe these sorts of incremental steps, especially in the labelling required are more arduous elsewhere (e.g. having to write the HSNO Approval number onto every tube).By reviewing these changes and the regulatory creep that has occurred (which would require input from MPI) and removing those that do not help manage risk, quicker changes to help address some of the issues in research could be achieved.
Proposal 1.1 - Biosafety Committees	Unsure	Unsure
Proposal 2 - Assessments for medicines	Unsure	I agree with the principle that the regulations should be risk proportionate and rapid assessments of medicines would be beneficial, but I am not well acquainted with the current system or this area.
Proposal 1 - Risk-tiering framework	Unsure	Unsure
Proposal 2 - Assessments for medicines	Unsure	Unsure

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Proposal 1.1 - Biosafety Committees	Proposal 1.1 - Biosafety Committees	I am at an institution with an Institutional Biological Safety committee, so for my day-to-day research this is unlikely to have a substantial impact.However, I have noted that a number of institutions have dissolved their IBSCs, and as such these organisations may not wish to establish accredited biosafety committees, and so would rely on the EPA committee. If there were similar delays at the EPA as currently experienced, then this system would offer little benefit.
Proposal 2 - Assessments for medicines	Unsure	Unsure
Proposal 2 - Assessments for medicines	Agree with proposal	I agree with the principle that the regulations should be risk proportionate and rapid assessments of medicines would be beneficial, but I am not well acquainted with the current system or this area.
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	Yes	As noted above, I work at an organisation with the wide approval and these changes would have little impact on my day-to-day research. However, I understand at other organisation record-keeping is complicated and time consuming, but does not help manage risk, so I am supportive of replacing the current requirements.
Proposal 3 - Record-keeping requirements	Unsure	Unsure
Proposal 3 - Record-keeping requirements	Agree with linking to HSNO approval	I think it is important that GMOs can be linked to a HSNO Approval, but that information does not need to be on every tube/pot/container etc. At an institution with a broad approval we can do this by having an electronic register with the approval noted there. I was be supportive of this being the system for all institutes and facilities.
Proposal 3 - Record-keeping requirements	Yes	Yes
Proposal 3 - Record-keeping requirements	Agree with issues	My understanding is that record keeping requirements have become more and more complex over the past 10-20 years, despite the underlying legislation not changing. It is therefore important that the changes also prevent further regulatory creep.
Proposal 3 - Record-keeping requirements	Other policy options	These requirement would also be considered as part of a wider review.
Proposal 4 - Internal audit frequency	Agree with proposal	A agree in principle but I am not sure if this will make much difference. My research is carried out in both a PC2 laboratory (MicroBio) and PC2 plant growth facility. In a year we can get up to:-Two audits from the departmental compliance manager (one each facility)-Four audits from the IBSC (two each facility)I therefore agree that internal audit frequency could be reduced and still effectively manage risk. However, the proposed changes will make virtually no difference as the facilities I work in registered as both transition and containment facilities and are PC2.
Proposal 4 - Internal audit frequency	Unsure	Unsure
Proposal 4 - Internal audit frequency	Agree with issues	Additionally, the focus of the audits should be on ensuring biological containment, but they have become increasingly more and more focused on paper work. This does not seem the best approach to manage risk (being a GMO getting onto the wider environment).It would also be good to review the frequency (and cost) of external audits (I can have up to three a year â€“ two for the lab and one for the plants (although sometimes the MPI auditor has popped their head into the plant facility at the time of the other audit).This also raises a question about the auditing of organisms in risk tier 1 or risk tier 2 that are grown or used inside a PC2 facility. Will they be audited as though they are in risk tier 3?
Proposal 4 - Internal audit frequency	Other policy options	A better change to the internal audit frequency would allow some flexibility based on the institutions to determine the frequency for all facilities (with a requirement of at least every 24 months) based on several factors. These could include the physical containment level, along with the amount of work using genetic modification, and a history of compliance and good management.
Proposal 5 - Movement between facilities	Unsure	Unsure
Proposal 6 - Requirements for eukaryotic somatic cells	Agree with proposal	I agree that certain eukaryotic cells (particularly those that a laboratory dependent and will not survive in the environment without considerable human input) pose a very low risk. Therefore, lowing the regulatory threshold for these cells makes sense.
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 7 - Regulatory status of biotechnologies	Agree with proposal	This really relates back to the definition of a GMO in the HSNO Act being out-of-date and no longer fit-for-purpose. As one of the objectives is to future proof the regulations, then a complete review of the HSNO Act and the definition of a GMO is required. While clarification may be useful, it is treating a symptom not the cause.
Proposal 7 - Regulatory status of biotechnologies	Other policy options	Simply continuing to clarify technologies as they become developed will only lead the further increases in the complexity of the regulatory landscape around genetic technologies, and likely little change in a risk-adverse framework. A better policy option would be to review the entire environment to update it so that techniques such as there do not need clarification.
Proposal 7 - Regulatory status of biotechnologies	Other policy options	Clarification is also required for organisms that do not contain any added/foreign DNA such as:- null segregants (exempt to regulation in many countries, and not detectable).- technologies such as grafting a scion onto a rootstock with a mobile RNA for site directed mutagenesis (it could be argued that there is no in vitro step here so resultant seeds are not GMO).

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Proposal 7 - Regulatory status of biotechnologies	Other policy options	Clarification is also required for organisms that do not contain any added/foreign DNA such as:- null segregants (exempt to regulation in many countries, and not detectable).- technologies such as grafting a scion onto a rootstock with a mobile RNA for site directed mutagenesis (it could be argued that there is no in vitro step here so resultant seeds are not GMO).
Proposal 4 - Internal audit frequency	Unsure	Unsure
Proposal 5 - Movement between facilities	Yes	Unsure
Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	Unsure
Proposal 8 - Low-risk fermentation	Agree with proposal	I am not involved in fermentation, but agree that fermentation using GMOs should be managed in a risk-proportionate manner.
Proposal 10 - Reviews of regulatory settings	Yes	The lack of a review of the settings for GMOs is has been a considerable flaw in the New Zealand system. I agree that a requirement for a regular review is important, especially around limiting the regulatory creep is an manner that is not risk proportionate that has been occurring.
Proposal 10 - Reviews of regulatory settings	Unsure	Unsure
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 10 - Reviews of regulatory settings	Other policy options	As already noted, I believe that the entire regulatory landscape should be reviewed, and as part of that a system of regular review should be incorporated.
Proposal 6 - Requirements for eukaryotic somatic cells	Agree with issues	The document provides â€œThe genetic modification of these cells would likely include the following conditionsâ€. I have a couple of comments on these."The donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi. "This would be overly restrictive. Not every gene or nucleic acid sequence in a disease-causing organism causes disease and many are already widely used. For example, CaMV35S (from the Cauliflower Mosaic Visur) promoter is very commonly used in plant biology, and does not give the cells an ability to cause disease. This restriction should be more focused on â€œgenes or other genetic material that contribute to diseaseâ€."The plant cells or tissues cannot spontaneously generate a whole plant and cannot be regenerated into a whole plant."This could also be problematic as plant cells are often reported to be totipotent (able to regenerate a new organisms). In the current overly risk adverse environment, I fear that this could exclude plant cells being included. The word â€œspontaneouslyâ€ is therefor very important, but I fear there could be challenges to what this means, and I fear that at some stage we may be asked to provide evidence for each plant cell type to show it cannot â€œspontaneouslyâ€ regenerate. Perhaps some consideration of the wording here â€œwithout significant human interventionâ€ and some description as to what this involves, and also a reasonable expectation the plant cells in tissue culture do not form plants.
Proposal 8 - Low-risk fermentation	Unsure	Unsure
Proposal 10 - Reviews of regulatory settings	Yes	Yes
Proposal 5 - Movement between facilities	Unsure	Unsure
Proposal 7 - Regulatory status of biotechnologies	Other policy options	Clarification is also required for organisms that do not contain any added/foreign DNA such as:- null segregants (exempt to regulation in many countries, and not detectable).- technologies such as grafting a scion onto a rootstock with a mobile RNA for site directed mutagenesis (it could be argued that there is no in vitro step here so resultant seeds are not GMO).
Proposal 10 - Reviews of regulatory settings	Agree with proposal	The lack of a review of the settings for GMOs is has been a considerable flaw in the New Zealand system. I agree that a requirement for a regular review is important, especially around limiting the regulatory creep is an manner that is not risk proportionate that has been occurring.
Proposal 10 - Reviews of regulatory settings	Agree with proposal	The lack of a review of the settings for GMOs is has been a considerable flaw in the New Zealand system. I agree that a requirement for a regular review is important, especially around limiting the regulatory creep is an manner that is not risk proportionate that has been occurring.
Proposal 10 - Reviews of regulatory settings	Agree with proposal	The lack of a review of the settings for GMOs is has been a considerable flaw in the New Zealand system. I agree that a requirement for a regular review is important, especially around limiting the regulatory creep is an manner that is not risk proportionate that has been occurring.
Proposal 10 - Reviews of regulatory settings	Yes	The lack of a review of the settings for GMOs is has been a considerable flaw in the New Zealand system. I agree that a requirement for a regular review is important, especially around limiting the regulatory creep is an manner that is not risk proportionate that has been occurring.

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	Objectives	Objectives	These are a beginning. Field trials and release of GMOs as in other countries needs to be considered also.
	Features and approach for regulatory framework	Features and approach for regulatory framework	The HSNO Act needs to be replaced with a new act that is fit to meet the Objectives. Legislation more similar to Australia's would be better.
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1 - Risk-tiering framework	Other policy options	The HZNO Act needs to be replaced.
	Proposal 2 - Assessments for medicines	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Out-of-scope policy ideas	Out-of-scope policy ideas	The HSNO Act is outdated and should be replaced with new legislation similar to Australia's or that proposed by the EU. In particular the scope of what is a GMO should be updated.

9(2)(a)	Objectives	Objectives	Yes
	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
	Proposal 7 - Regulatory status of biotechnologies	Agree with issues	The definition of a GMO needs to be updated
Wellington UniVentures	Objectives	Objectives	No
Wellington UniVentures	Objectives	Objectives	The objectives do not go far enough. An additional objective should be-contributes to better environmental and societal outcomes for New Zealanders through better access to technologies that offer environmental and societal benefits
Wellington UniVentures	Features and approach for regulatory framework	Features and approach for regulatory framework	Complete overhaul/replacement of the Biosecurity Act 1993 with provision for genetic technologies to be considered on a case-by-case basis rather than be subject to a blanket ban.
Wellington UniVentures	Proposal 1 - Risk-tiering framework	Yes	Yes
Wellington UniVentures	Proposal 1 - Risk-tiering framework	Yes	Yes
Wellington UniVentures	Proposal 1.1 - Biosafety Committees	Yes	Yes
Wellington UniVentures	Proposal 3 - Record-keeping requirements	Yes	Yes
Wellington UniVentures	Proposal 3 - Record-keeping requirements	Unsure	Unsure
Wellington UniVentures	Proposal 3 - Record-keeping requirements	Yes	Yes
Wellington UniVentures	Proposal 4 - Internal audit frequency	Yes	Yes
Wellington UniVentures	Proposal 4 - Internal audit frequency	Yes	Yes
Wellington UniVentures	Proposal 5 - Movement between facilities	Yes	Yes
Wellington UniVentures	Proposal 5 - Movement between facilities	Yes	Yes
Wellington UniVentures	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Wellington UniVentures	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Wellington UniVentures	Proposal 8 - Low-risk fermentation	Yes	Yes
Wellington UniVentures	Proposal 8 - Low-risk fermentation	Yes	Yes

9(2)(ba)(i)	Proposal 8 - Low-risk fermentation	Yes	There is an increasing demand for scale-up of fermentation processes prior to transfer of the technology to pilot-scale and large-scale facilities that do not presently exist in New Zealand. Ten litres is not sufficient for establishing scalable conditions. The maximum vessel size should be increased to 50 litres in dedicated fermentation vessels and provided that the facility is sufficiently prepared to manage a spill from vessels of this size.
	Proposal 9 - Standards for containment facilities	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	No	No
	Proposal 10 - Reviews of regulatory settings	No	Agree in principle except that five yearly is insufficient per answer to Q37.
	Proposal 10 - Reviews of regulatory settings	No	No
	Proposal 10 - Reviews of regulatory settings	No	This does not go nearly far enough. Although implementation of the proposed standards will be a step forward, they will still be outdated and review every five years will not be sufficient, either to bring New Zealand up-to-date or to keep pace with technological advancement. We suggest a continuous review cycle with the opportunity to introduce changes at least every two years.
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
9(2)(a)	Feedback on process/consultation	Feedback on process/consultation	We need change! Thank you taking the initiative.The only general comment: A comparison to policies from other countries than Australia would have been appreciated.
Biodynamics New Zealand	Objectives	Objectives	Maintain the status quo.GM technology has been a round a long time and still hasnâ€™t delivered on the great promises that Iâ€™ve been claimed.The risks far outweigh the potential benefits.The development of GM technology unfairly favours the commercial interests of multinational corporations who own the patents from the work.
Biodynamics New Zealand	Objectives	Objectives	Maintain the status quo.GM technology has been a round a long time and still hasnâ€™t delivered on the great promises that Iâ€™ve been claimed.The risks far outweigh the potential benefits.The development of GM technology unfairly favours the commercial interests of multinational corporations who own the patents from the work.
Biodynamics New Zealand	Features and approach for regulatory framework	Features and approach for regulatory framework	Maintain the status quo.GM technology is not the answer.Nature provides all that society requires for healthy living.
Biodynamics New Zealand	Proposal 1 - Risk-tiering framework	No	As mentioned above, what we deem to be low risk today, is likely to change tomorrow. As science evolves, so does our understanding of unintended consequences of our actions.History has shown us this, time and time again.
Biodynamics New Zealand	Proposal 1.1 - Biosafety Committees	No	The option to enable some research to be granted permission that allows GM use to carry on, perhaps with less containment than is currently required, is in opposition to a lot of science that is being generated in the organic and Regenerative agriculture space.The use of GM technology is fundamentally against the beliefs of Biodynamics New Zealand.Itâ€™s use threatens the right of choice for consumers, farmers and tangata whenua once these GMOâ€™s are in our environment.
Biodynamics New Zealand	Proposal 2 - Assessments for medicines	Other policy options	No. Maintain the status quo.
Biodynamics New Zealand	Proposal 5 - Movement between facilities	No	GMO technology is not an area of research that NZ needs to play a part in.The transport of such GMO's is a high risk step for any item, let alone an item that could be detrimental to the NZ environment, its flora and fauna and its people. Removing barriers to allow greater ease of movement of GMO's only makes such movements become more common and hence increasing the risk of an incident involving the accidental release of such GMO's.
Biodynamics New Zealand	Proposal 5 - Movement between facilities	Other policy options	The transportation of GMO's entails the most risk of inadvertent release of such material.No easing of standards or checks of any kind are a good idea in regard to this.
Biodynamics New Zealand	Proposal 8 - Low-risk fermentation	No	No
Biodynamics New Zealand	Proposal 9 - Standards for containment facilities	Other policy options	Maintaining stringent controls at points of risk is of the utmost importance. The creation of GMO's is not an area of research which NZ should be participating in. Our island nation is unique in terms of its flora and fauna and any threat to this taonga should not be taken lightly.The organisation should not be able to choose the controls which best suit them. The work is putting NZ's flora and fauna at risk and stringent controls must be in place if this work is to be carried out.
Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	No	No
Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	No	The topic of GM is not to be taken lightly. NZ should not be partaking in this field of research.NZ made a stance on nuclear technology in the 1980's which we are to be grateful for.It's current stance on GM technology, although not completely GM free, means we can be more confident in our island nation that we are free from the risk of GM technological failures.NZ should be GE free. Any work in this field puts our flora, fauna and people at risk.

Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	No	No
Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	No	NZ should be GE free
Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	No	No
Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	No	I'm sure one could say the same for Nuclear technologies.The risks involved with a failure in this field of work is too great compared to the benefits. Any long term impact of GM technology may not be know for generations when it will be too late to reverse.
Biodynamics New Zealand	Proposal 10 - Reviews of regulatory settings	Other policy options	The risks involved with a failure in this field of work is too great compared to the benefits. Any long term impact of GM technology may not be know for generations when it will be too late to reverse.
Biodynamics New Zealand	Costs, benefits or risks	Costs, benefits or risks	The risks cannot be fully outlined in this document, as they may not be fully understood and explained by the science of today.The risks may be far greater than any current understanding that exists at present.
Biodynamics New Zealand	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Any work in this field goes against nature. Millions of years of evolution have brought us here and to think we can improve on natures work is an egocentric view of domination over nature and is ethically questionable.
Biodynamics New Zealand	Alternative options	Alternative options	Maintain the status quo. Stringent regulatory and safety checks must be in place at all times, for all facilities if this work is to continue.The risks involved with a failure in this field of work is too great compared to the benefits. Any long term impact of GM technology may not be know for generations when it will be too late to reverse.
Biodynamics New Zealand	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Any work in this field goes against nature. Millions of years of evolution have brought us here and to think we can improve on natures work is an egocentric view of domination over nature and is ethically questionable.
Biodynamics New Zealand	Te ao Maori	Taonga species	No
Biodynamics New Zealand	Te ao Maori	Taonga species	We must prohibit the GM of cells and tissues of our taonga species. Any modification will negatively affect their mauri.
Biodynamics New Zealand	Te ao Maori	Taonga species	We must prohibit the GM of cells and tissues of our taonga species. Any modification will negatively affect their mauri.
Biodynamics New Zealand	Te ao Maori	Use of genetic material	No
Biodynamics New Zealand	Te ao Maori	Use of genetic material	We must prohibit the GM of cells and tissues of our tangata whenua and our taonga species. Any modification will negatively affect their mauri.Tangata whenua must always maintain the right to veto research of this kind.
Biodynamics New Zealand	Te ao Maori	Use of genetic material	We must prohibit the GM of cells and tissues of our tangata whenua and our taonga species. Any modification will negatively affect their mauri.Tangata whenua must always maintain the right to veto research of this kind.
Biodynamics New Zealand	Te ao Maori	Use of genetic material	We must prohibit the GM of cells and tissues of our tangata whenua and our taonga species. Any modification will negatively affect their mauri.Tangata whenua must always maintain the right to veto research of this kind.
Biodynamics New Zealand	Te ao Maori	Informed consent	No
Biodynamics New Zealand	Te ao Maori	Informed consent	We must prohibit the GM of cells and tissues of our tangata whenua and our taonga species. Any modification will negatively affect their mauri.Tangata whenua must always maintain the right to veto research of this kind.
Biodynamics New Zealand	Te ao Maori	Informed consent	We must prohibit the GM of cells and tissues of our tangata whenua and our taonga species. Any modification will negatively affect their mauri.Tangata whenua must always maintain the right to veto research of this kind.
Biodynamics New Zealand	Te ao Maori	Other issues or considerations	Other potential implications would be the unknown consequences of genetically modifying DNA of tangata whenua and our taonga in the generations in the future. Flow on effects to future generations cannot be known or predicted with any great certainty.

Biodynamics New Zealand	Feedback on process/consultation	Feedback on process/consultation	Genetic modification is ethically wrong.This kind of technology has no place in Aotearoa.Nature has provided us with food, shelter and medicine for millennia and will continue to do so if we allow it. Any genetic alteration of our flora, fauna and tangata whenua fundamentally threatens that ability for nature to provide.The genetic modification of natural organisms only further separates us from our connection to the land and nature and strengthens the egocentric view of human domination over nature rather than working alongside as part of nature.
Biodynamics New Zealand	Te ao Maori	Use of genetic material	We must prohibit the GM of cells and tissues of our tangata whenua and our taonga species. Any modification will negatively affect their mauri.Tangata whenua must always maintain the right to veto research of this kind.
9(2)(ba)(i)	Features and approach for regulatory framework	Features and approach for regulatory framework	Facilitate policies for improving human health and more options for developing new therapies for human health
	Proposal 6 - Requirements for eukaryotic somatic cells	Unsure	EUKARYOTIC organs, tissues, cells, embryos do not survive outside culture conditions should be considered low riska)for their TRANSPORT, IMPORT, EXPORT OR TRANSFER to another containment laboratoryb)and be DISPOSABLE as for any non-infectious organs, tissues or cells
	Proposal 1.1 - Biosafety Committees	Yes	Yes
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	GENE EDITED PIGS for human xenotransplantation:NON-HUMAN MEDICAL GRADE ANIMAL (PIG) EMBRYOS from a CONTAINMENT FACILITY should also be in the low risk category as they are developed into healthy live animals in another CONTAINMENT FACILITY as sources of healthy organs, tissue, cells as treatment for medical conditions
	Proposal 7 - Regulatory status of biotechnologies	Other policy options	1. Human gene editing that alters the genome of the patient2. Xenotransplantation of genome edited pig donor organs, tissues or cells that do not alter the genome of human recipient.
	Proposal 8 - Low-risk fermentation	Unsure	Unsure
	Proposal 8 - Low-risk fermentation	Yes	Yes
	Proposal 9 - Standards for containment facilities	Cost vs benefits	We intend our facility to be a containment and transitional facility. MPI has so far indicated that our facility is approvable as we do not yet have gene edited animals. We are unsure which option would be least cumbersome or expensive.
	References	References	REFERENCESBartley P. Griffith et al .Genetically Modified Porcine-to-HumanCardiac Xenotransplantation. N Engl J Med 2022;387:35-44.DOI: 10.1056/NEJMoa2201422NZ leads world in trial of futuristic therapy26 August 2022. Health and medicine, Faculty of Medical and Health SciencesAn innovative treatment that repairs a faulty genetic mechanism is being trialled by Kiwis with a rare muscle disease for the first time in the world.Julian D. Gillmore,. CRISPR-Cas9 In Vivo Gene Editing for Transthyretin Amyloidosis. N Engl J Med 2021;385:493-502. DOI: 10.1056/NEJMoa2107454S. Matsumoto a, *, P. Tan b , J. Baker c , K. Durbin b , M. Tomiyaa , K. Azumaa , M. Doi a , and R.B. Elliott b. Clinical Porcine Islet Xenotransplantation Under ComprehensiveRegulation. Otsuka Pharmaceutical Factory, Naruto, Japan; Living Cell Technologies, Auckland, New Zealand; c Centre for Clinical Research and Effective Practice, Middlemore Hospital, Auckland, New Zealand. Transplantation Proceedings, 46, 1992e1995 (2014)
Austen Ganley	Proposal 1 - Risk-tiering framework	Yes	Yes
Paula Jameson	Objectives	Objectives	While I agree with the objectives in principle, they are simply not broad enough and are unlikely to be effective in improving the regulatory settings for genetically modified organisms in New Zealand.For example, the current objectives do not consider the well-documented challenges facing the primary sector and environment and the importance the primary sector has on the New Zealand economy and the health and well being of New Zealanders.Both the Productivity Commission and Climate Change Commission have documented how review of the regulatory framework for genetic technologies is required for New Zealand as New Zealand risks losing its competitiveness in international markets. New Zealand is unlikely to be able to transition to a sustainable agricultural sector in a changing environment without the use of genetic technologies in the field.Crippling legislation feeds into the fear some members of the public have about these technologies - they must all be really dangerous if they (still) have to be so tightly regulated.
9(2)(a)	Objectives	Objectives	No
	Objectives	Objectives	While I agree with the objectives in principle, they are not broad enough and are unlikely to be effective in improving the regulatory settings for the use of genetically modified organisms in New Zealand.The Ministers letter states â€˜Our approach follows international practice. Across the world, other countries are modernising their GMO regulations, so they can more fully benefit from what these technologies offer.â€™However the stated objectives of the proposed review remain very constrained and do not reflect international practice and will limit opportunities for New Zealanders.Importantly:1)It is well documented that the current definition of a genetically modified organism is no longer fit-for-purpose, especially given the development of technologies such as site-directed mutagenesis. This needs to be addressed before revising the regulations.2)The current regulatory system related to genetic modification in New Zealand is complex, involving multiple acts and different agencies. The Royal Commission into Genetic modification 2000/2001 recommended a dedicated agency. The complex regulatory framework needs to be addressed, with a focus on simplification and risk.3)It is time to review application of genetic modification to address the challenges facing the primary sector and environment. The review must address this urgent need.Suggestion to modify the objectives:Widen Objective 2. e.g., â€œcontributes to better health and environmental outcomes for New Zealanders and Aotearoa New Zealand through increasing research outcomes and innovation, and providing greater access to biotechnology processes and productsâ€Add an objective to address the primary industries. e.g, â€œsustainable production and climate change adaptation within the New Zealand primary industries through research, innovation and productionâ€.

9(2)(a)	Features and approach for regulatory framework	Features and approach for regulatory framework	A complete review of the entire regulatory systems for genetic technologies and genetically modified organisms is required.The review should cognisant of international best practice and risk based. Our current regulatory framework is out of step with that of our trading partners and, as the Productivity Commission noted in 2021, poses a risk to our international reputation. Taking a risk based approach would offer many advantages and opportunities for New Zealand. Current systems mean that two identical organisms developed differently (one genetically modified, the other the result of conventional breeding) would face very different regulatory routes. This makes no sense.Reducing complexity and having a forward facing approach would have considerable benefit. Technologies have and will evolve, thus it is important to not regulate the technology, instead a focus on the resultant organism would be more constructive. This should be coupled with a mindset shift that evaluates risk and encourages innovation.
9(2)(a)	Objectives	Objectives	Yes
	Features and approach for regulatory framework	Features and approach for regulatory framework	Something that is far more reflective of the risks involved. I understand and appreciate the concern for the biosecurity of New Zealand, however, understanding that some areas of research involve GMOs that pose no risk would be a better way to handle it. Carrying out large amounts of paperwork for cells that barely survive in the incubator, let alone anywhere else, is really frustrating and it wil make people be less engaged in times when it is really crucial.
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 1 - Risk-tiering framework	Yes	I think the low risk "cells on life support" is very crucial as these are the types of cells that I work with and having the regulations recognise the low risk associated with these would be really helpful moving forward so that everyone who works in the lab and comes into the lab has a better understanding of when risk is actually high vs the life support cells that will die the instant they are slightly at the wrong temperature (they are SO temperamental!!).
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 3 - Record-keeping requirements	Yes	Please can we do this. Our current record keeping is not fit for purpose. Even if the cells are a threat to ecosystems, recording volume vs cell number makes absolutely no sense. I could have 1 million cells in 1ml or 1 million cells in 10ml and all the paper work cares about is 1ml or 10ml. I find the paperwork unnecessary given the cells I work with are not going to grow anywhere else. PC3 should 100% be carefully regulated but as I have no experience with how that system works I can't say anything more meaningful. Knowing where GMOs are is completely fair to ask and having them clearly labelled I am fine with. Doing 5-10 mins paperwork each time I handle cells on life support however, is frankly a waste of my time - especially given the paperwork does not lend itself well to traceability.
	Proposal 3 - Record-keeping requirements	No	No
	Proposal 3 - Record-keeping requirements	No	As long as the new organisms are labelled with what they are and where they are, I think that is sufficient. You definitely should be able to prove you have them legally, but I think just a certificate of proof of your facility and import should be enough vs the HSNO Act aspect.
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 1 - Risk-tiering framework	Yes	Yes
	Proposal 3 - Record-keeping requirements	Yes	Yes
	Proposal 3 - Record-keeping requirements	Yes	I just want to re-emphasise how much I agree with "Record-keeping requirements for low-risk research was one of the issues most frequently cited by researchers surveyed by the Ministry. In the view of researchers, the amount of time and effort required for maintaining these records was excessive, considering the low risk of their research. It is common for GMOs to be created daily in most laboratories. With record-keeping required for each new variant and sample created, the cumulative time and energy required to maintain these records across the many laboratories in New Zealand is likely to be very significant." It describes my view exactly.
	Proposal 4 - Internal audit frequency	Unsure	Unsure
	Proposal 4 - Internal audit frequency	Unsure	I use PC2 and there is no change to what is currently done. I think 12 months is fine. My only comment is whether we have sufficient people to carry out these inspections and then chase up. I am thinking of Pike River (although a very different circumstance) had regular audits, but not the resources to check changes were made. So I would just want to make sure the staffing is sufficient to make sure everything can be done to the correct quality and there is space to check up if any issues have been identified. Telling someone to change their lab and then not confirming or placing pressure for the change to happen, doesn't achieve anything and lengthens the amount of time that harm can happen.
	Proposal 3 - Record-keeping requirements	Other policy options	Most labs have access to computers in some way. So maybe a centralised database that is online would make more sense? I'm unsure, but having lots and lots of paper required in a PC2 lab is honestly not ideal. I prefer to keep paper etc out of the lab and if I have to use a system, I would prefer it is something I can access using my lab tablets, vs providing paper copies.
	Proposal 4 - Internal audit frequency	Unsure	Unsure
	Proposal 4 - Internal audit frequency	Yes	Yes
	Proposal 4 - Internal audit frequency	Other policy options	It is not necessarily the frequency of the audits, but the time spent during the audit trying to go through piles of paperwork. If this could be centralised (or removed in certain circumstances) that would reduce the administrative load that comes with these audits.

9(2)(a)

Proposal 4 - Internal audit frequency	Yes	As I said, the paperwork is not fit for purpose, it is not easy to follow and straightforward for traceability. Therefore the amount of time spent on internal (or even external audits) is definitely higher than it needs to be. Showing you have everything above board should be more straightforward. People tend to want to do the right thing, so you need to make it easy for them to do so.
Proposal 5 - Movement between facilities	Unsure	Unsure
Proposal 5 - Movement between facilities	Unsure	I do not work at PC1, so cannot answer and it won't let me untick my answer.
Proposal 5 - Movement between facilities	No	No
Proposal 4 - Internal audit frequency	Other policy options	It is not necessarily the frequency of the audits, but the time spent during the audit trying to go through piles of paperwork. If this could be centralised (or removed in certain circumstances) that would reduce the administrative load that comes with these audits.
Proposal 5 - Movement between facilities	No	No
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Given the amount of day to day work that involves genetic modification in science, I would expect that the current regulations is massive overkill. 100% if it involves diseases etc, but making things like making E coli fluorescent should not really be an issue that MPI needs to worry about and get involved in.
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Just this "these cells pose essentially zero risk to the environment or people and communities, and are reliant on specific laboratory conditions, making their survival in the environment highly unlikely. In addition, stringent measures taken by researchers to eliminate environmental contamination to these cells means their inadvertent escape from their containers is also highly unlikely" is so relevant These are really frustrating issues that as explained are unnecessary given these cells aren't going to cause harm and we work so hard just trying to keep them alive in the lab.
Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	No just please listen to the researchers on this one.
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 8 - Low-risk fermentation	Yes	Yes
Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
Proposal 9 - Standards for containment facilities	Hybrid	Status quo is overkill for what is needed and there needs to be a more outcome-based approach. However, leaving it up to the facility operators I think is an accident waiting to happen. There is a reason we have safety laws and that is because companies will not necessarily do the safest thing, but the easiest, cheapest thing and the results aren't seen until the damage has been done. I think combining the two approaches to give some flexibility depending on the organism but maintaining oversight is the best way forward out of the options given.
Proposal 9 - Standards for containment facilities	Unsure	Unsure
Proposal 9 - Standards for containment facilities	No	No
Proposal 10 - Reviews of regulatory settings	Yes	Yes

9(2)(a)	Proposal 10 - Reviews of regulatory settings	Yes	It baffles me that a lot of NZ regulations are not set up for regular review. If they aren't reviewed, how are we meant to learn and change. Also as I mentioned in a previous answer, if things are overkill (like the current paperwork and administrative burden for low risk organisms), that just turns people against agencies like MPI, not want to work with them, and not trust when they are told something is risky because they have also been told their low risk work is high risk. So you need regular input that the regulations are sufficient for what is needed, but are also appropriate. If you update the regulations, you also want to have opportunity to check if they are working as required as opposed to just leaving it until someone decides to pick it up.
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 5 - Movement between facilities	No	I have moved plenty of cells around and between labs and it honestly isn't that difficult. Filling out the MTA and getting it signed off has never been an issue and I think it has benefits regarding traceability. If both sides have to sign off, then they will both take responsibility ensuring safe transport. I have imported several cell lines from several NZ universities and the paperwork has never been a barrier.
	Proposal 8 - Low-risk fermentation	Yes	I mean, doing some proper scale up of say genetically modified E coli seems perfectly fine to me and has no requirement for oversight from EPA etc. As long as the organism has been sufficiently assessed for risk, I see no problem with these changes.
	Proposal 8 - Low-risk fermentation	Yes	Low risk GMOs should be able to be grown at scale without adding paperwork and administration that does not add any meaningful information.
	Proposal 10 - Reviews of regulatory settings	Yes	Not too long or too short. You don't want a fast turnaround (say 2 years) because there are other aspects of just life in general that need attention. However, if you leave it too long, then they are going to potentially spend longer out of date and out of touch.
	Proposal 10 - Reviews of regulatory settings	Yes	Yes
	Proposal 10 - Reviews of regulatory settings	Yes	GMOs are changing the face of medicine. To allow NZ to stay at the front of the research, it needs to ensure that the regulations keep pace. By making it incredibly hard to work with GMOs has definitely (from what I've seen) prevented researchers pursuing certain pathways or even careers. We need something that is flexible and fit for purpose with this rapidly changing industry. Being caught on the back foot (like we currently are) means that our research is stinted.
	Proposal 10 - Reviews of regulatory settings	Other policy options	I think from what I have read from the proposals, there has been real engagement with researchers and like the researchers are being listened to. I really hope this collaboration continues so that we can both work together to further research, further medicine, keep everyone safe, and appropriately manage the risks involved.
	Alternative options	Alternative options	Proposal 1 - I don't think it adds any benefit.Proposal 4 - I mean, reducing internal audits for PC2 would be fine. I just think they should be made to do them at least 4 months away from the external audit so that facilities are not focusing on regulations only once a year.Proposal 5 - I definitely think secondary containment should be a requirement.Proposal 6 - I think it actually makes it too complicated. It is safer to stick with standard terminology.Proposal 8 - I have no problem with increasing the size of fermentation as long as the organism has been appropriately quantified for risk.
	Costs, benefits or risks	Costs, benefits or risks	Nothing immediately comes to mind but there are aspects that are not my area. I agree any one off costs should be off set by the time saved in the long run. Benefits are definitely tied to freeing up researcher time and being able to explore more GMO options, especially any therapeutics. The risks are that if you make the regulations too loose, or put all the trust in the researchers, gaps will form. There is also risk associated with audits if there aren't sufficient resources for external auditors to audit and then check back etc. This also leads into the idea that if auditing frequency is decreased, then facilities will probably do their internal and external audit around the same time which will lead to regulations only being in focus for a month or so as opposed to at all times. People will leave it to the last minute and then play catch up in the weeks leading up to their audit.
	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Australia doesn't audit PC1 and I think that we should maintain auditing of PC1.
	Feedback on process/consultation	Feedback on process/consultation	It sounds like proper consultation has been done with researchers and their responses listened to and incorporated. This is really great to see and I hope it continues.
	Proposal 9 - Standards for containment facilities	Unsure	Yes outcomes based is more appropriate, but also people can't be trusted so oversight is needed to ensure the proper containment is utilised.
	Proposal 8 - Low-risk fermentation	Yes	As I said in the previous answer, scaling up is what we do in engineering and requiring oversight to test various aspects at scale, as long as the organism is approved and determined to be low risk, I don't see what value EPA is adding.
	Feedback on process/consultation	Feedback on process/consultation	It sounds like proper consultation has been done with researchers and their responses listened to and incorporated. This is really great to see and I hope it continues.
International Society for Cell & Gene Therapy (ISCT)	Objectives	Objectives	Yes
International Society for Cell & Gene Therapy (ISCT)	Objectives	Objectives	Yes
International Society for Cell & Gene Therapy (ISCT)	Features and approach for regulatory framework	Features and approach for regulatory framework	We have no comments

International Society for Cell & Gene Therapy (ISCT)	Proposal 1 - Risk-tiering framework	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 1 - Risk-tiering framework	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 1 - Risk-tiering framework	Other policy options	Yes. We would suggest to take into account changes being implemented in the Australian system and provide a process for the regulator to be able to make decisions about what is in and out of scope in cases where it is unclear.
International Society for Cell & Gene Therapy (ISCT)	Proposal 1.1 - Biosafety Committees	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 1.1 - Biosafety Committees	Other policy options	We have no comments
International Society for Cell & Gene Therapy (ISCT)	Proposal 2 - Assessments for medicines	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 2 - Assessments for medicines	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 2 - Assessments for medicines	Other policy options	We have no further comments
International Society for Cell & Gene Therapy (ISCT)	Proposal 3 - Record-keeping requirements	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 3 - Record-keeping requirements	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 3 - Record-keeping requirements	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 3 - Record-keeping requirements	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 4 - Internal audit frequency	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 4 - Internal audit frequency	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 5 - Movement between facilities	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 5 - Movement between facilities	Yes	We endorse Proposal 5 and agree to adjust the current movement approval requirements, provided the conditions are met.
International Society for Cell & Gene Therapy (ISCT)	Proposal 5 - Movement between facilities	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No

International Society for Cell & Gene Therapy (ISCT)	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 1 - Risk-tiering framework	Yes	We endorse Proposal 1 as it aligns with GTR (AUS) regulations and will reduce the administrative work required of researchers to gain approval for low-risk research. It is acknowledged that there is a wide range of risks to the environment and to the people based on the transgene, targeted cell, and ex-vivo vs. in-vivo treatment. However, we would suggest to clarify if clinical research is included in proposal 1 or 2
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 2 - Assessments for medicines	Yes	We endorse Proposal 2 as the current EPA review approval process is a barrier to entry for Sponsors developing these products in New Zealand. We particularly appreciate the use of â€˜an alternative assessment pathway for biomedical therapies using new organisms that are unlikely to make their way into the environmentâ€™ because it is in line with Australia's DIR and DNIR pathways, which are based on the ability to shed the GMO.
International Society for Cell & Gene Therapy (ISCT)	Proposal 3 - Record-keeping requirements	Yes	We endorse Proposal 3 and agree with the proposals for replacing the current record-keeping requirements but would suggest providing guidance on suitable labeling (e.g., â€˜GM organism nameâ€™ or, â€˜Organism name-GFPâ€™).
International Society for Cell & Gene Therapy (ISCT)	Proposal 4 - Internal audit frequency	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 4 - Internal audit frequency	Yes	We endorse Proposal 4
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 5 - Movement between facilities	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	We endorse Proposal 6 as it is the main difference between NZ and AUS regulations and would align EPA with OGTR. The current EPA review approval process is a barrier to entry for overseas companies wanting to commercialise these treatments in New Zealand.
International Society for Cell & Gene Therapy (ISCT)	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 4 - Internal audit frequency	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Yes	We endorse Proposal 7.
International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	No, we have no comments

International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 7 - Regulatory status of biotechnologies	Other policy options	We would suggest clarifying the regulatory status of siRNA in vivo therapies.
International Society for Cell & Gene Therapy (ISCT)	Proposal 8 - Low-risk fermentation	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 8 - Low-risk fermentation	Yes	We endorse and agree with Proposal 8 as outlined.
International Society for Cell & Gene Therapy (ISCT)	Proposal 8 - Low-risk fermentation	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 8 - Low-risk fermentation	Yes	We would suggest increasing the maximum vessel size not requiring an EPA assessment and approval (e.g., 25L).
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 8 - Low-risk fermentation	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach
International Society for Cell & Gene Therapy (ISCT)	Proposal 9 - Standards for containment facilities	Hybrid	We support the hybrid approach to standards in Proposal 9.
International Society for Cell & Gene Therapy (ISCT)	Proposal 9 - Standards for containment facilities	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 9 - Standards for containment facilities	No	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 9 - Standards for containment facilities	No	This question is not applicable as we are a non-profit organization and do not have a facility.
International Society for Cell & Gene Therapy (ISCT)	Proposal 10 - Reviews of regulatory settings	Yes	We endorse Proposal 10 â€˜to review regulations at least every 5 yearsâ€™. The HSNO Act was issued in 1996 and never reviewed until 2023, which is an inadequate timeframe based on the speed of technological advances in cell and gene therapies.
International Society for Cell & Gene Therapy (ISCT)	Proposal 10 - Reviews of regulatory settings	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 10 - Reviews of regulatory settings	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Answer contradicts previous answer	Answer contradicts previous answer	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 10 - Reviews of regulatory settings	Other policy options	No

International Society for Cell & Gene Therapy (ISCT)	Alternative options	Alternative options	No, we have no comments.
International Society for Cell & Gene Therapy (ISCT)	Costs, benefits or risks	Costs, benefits or risks	No, we have no comments.
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Taonga species	No
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Taonga species	No, we have no comments
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Use of genetic material	No, we have no comments
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Use of genetic material	No
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Use of genetic material	No, we have no comments
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Use of genetic material	No
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Use of genetic material	No
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Informed consent	No
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Informed consent	No, we have no comments
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Informed consent	We have no comments
International Society for Cell & Gene Therapy (ISCT)	Te ao Maori	Other issues or considerations	We have no comments
International Society for Cell & Gene Therapy (ISCT)	Feedback on process/consultation	Feedback on process/consultation	Thank you for the opportunity to comment on the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organisms (GMOs) used in laboratory settings and for biomedical therapies.Please accept these comments on behalf of the International Society for Cell & Gene Therapy (ISCT) and its Australia and New Zealand Legal and Regulatory Affairs Committee.
International Society for Cell & Gene Therapy (ISCT)	Proposal 8 - Low-risk fermentation	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Proposal 9 - Standards for containment facilities	Other policy options	No
International Society for Cell & Gene Therapy (ISCT)	Proposal 10 - Reviews of regulatory settings	Yes	Yes
International Society for Cell & Gene Therapy (ISCT)	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	No, we have no comments
International Society for Cell & Gene Therapy (ISCT)	Feedback on process/consultation	Feedback on process/consultation	Thank you for the opportunity to comment on the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organisms (GMOs) used in laboratory settings and for biomedical therapies.Please accept these comments on behalf of the International Society for Cell & Gene Therapy (ISCT) and its Australia and New Zealand Legal and Regulatory Affairs Committee.
Te Herenga Waka - BIOL430 Advanced Genetics class	Objectives	Objectives	Yes

Te Herenga Waka - BIOL430 Advanced Genetics class	Features and approach for regulatory framework	Features and approach for regulatory framework	Proportionate management of risk is absolutely key.We would like to see clarity, and more sophistication in the definition of what a Genetically Modified Organism (GMO) is.We would also like to see some definition of what is exactly meant by having an â€¯advantageâ€™ in this document in regard to cells and organisms.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 1 - Risk-tiering framework	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 1 - Risk-tiering framework	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 1.1 - Biosafety Committees	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 1.1 - Biosafety Committees	Yes	There must be a requirement for internal biosafety committees, with an outside body to oversee processes. This would ensure some level of standardisation and reproducibility, which would be important. A regular audit process from MfE or similar would be needed to ensure that the committee is making appropriate decisions
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 2 - Assessments for medicines	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 2 - Assessments for medicines	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 2 - Assessments for medicines	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 2 - Assessments for medicines	Yes	Would need to specify how the different risk systems will be assessed - show the level of actual risk and make sure that proportionate action is taken.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	No	It may be more appropriate to specify more extensive accounting requirements for GMOs than what is being proposed. Keeping track of samples containing HIGH RISK GMOs that are stored long term is important, and therefore, researchers responsible for these should record details â€“ more than just the fact that it is a GMO. This avoids contamination, but also increases efficiency overall. Information such as date of production, and the researcher responsible should be required. This is good lab practice and will be recorded by any good lab, but is worth specifying. This would be checked by the institutional biosafety committee.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	No	Not for low risk tiers - whole institutions operate under a small number of approvals. There need to be records available that can be used to link higher risk tiers, but the very highest risk are out of scope for this review
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	Yes	We agree that inefficiency due to record-keeping requirements is an problem for low-risk research.However, inadequate labelling can also cause inefficiency due to cross-contamination and loss of samples if researchers are not aware of their specific location. This comes down to good lab management. Poor lab management would be okay for low-risk GMO, but is not appropriate for higher risk tiers.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	Other policy options	We think a compromise between proposal 3 and current legislature would be optimal for record-keeping requirements, particularly for higher risk tiers.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 4 - Internal audit frequency	Unsure	Unsure
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 4 - Internal audit frequency	Unsure	Again the key phrase is proportionate to risk - IF the lowest risk tier is not required to be managed in PC1 then there is only institutional or investigator oversight.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 2 - Assessments for medicines	Yes	It would be very beneficial to have faster applications.The alternative assessment needs to assess the actual proportionate risk of GMO medicines and devices. This only needs to assess the GMO risk as the safety of the device/treatment will still be rigorously assessed by groups such as MedSafe and SCOTT

Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	No	It may be more appropriate to specify more extensive accounting requirements for GMOs than what is being proposed. Keeping track of samples containing HIGH RISK GMOs that are stored long term is important, and therefore, researchers responsible for these should record details â€“ more than just the fact that it is a GMO. This avoids contamination, but also increases efficiency overall. Information such as date of production, and the researcher responsible should be required. This is good lab practice and will be recorded by any good lab, but is worth specifying. This would be checked by the institutional biosafety committee.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 3 - Record-keeping requirements	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 4 - Internal audit frequency	No	The Australian framework appears to only audit at PC2 level. Under the proposed framework, we are not clear whether there would be any audit of risk tier 1 or 2. We think it would be appropriate tc have institutional audits of facilities at PC1, assuming that includes risk tier 2.The problem will be if an someone wants to do a GMO experiment at a higher risk level then they may not have an appropriate facility available - say, moving from risk tier 1 to risk tier 2. Or from risk tier 2 to risk tier 3. This will need to be managed by institutional biosafety committee and their stick will not be as big as external auditing.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 5 - Movement between facilities	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 5 - Movement between facilities	No	We do not agree with the proposed amendment due to the terms in the proposal that cannot be fulfilled. The first term in the proposal is â€œThe GMOs to be transported should be wholly contained inside a sealed, unbreakable primary containerâ€. There is no such thing as an unbreakable primary container. Secondary container, yesFor higher risk categories - 2 and 3 - we should have additional safeguards such as: Conducting thorough risk assessments before transportation to identify and address potential risks. Implementing strict protocols for packaging and handling GMOs during transportation, such as double containment and using secure, tamper-resistant packaging. Requiring researchers to undergo training on proper transportation procedures and biosafety measures. Establishing a system for monitoring and auditing the transportation process to ensure compliance with regulations. Designing contingency plans in case of any accidents or breaches during transportation to mitigate potential consequences.For anything categorised as low risk tier 1, good laboratory practice and Internal tracking of resources should be enough if it is carried out properly.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 6 - Requirements for eukaryotic somatic cells	Agree with proposal	For standard cell cultures, this seems to be totally appropriate.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 7 - Regulatory status of biotechnologies	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 7 - Regulatory status of biotechnologies	No	Not fully. See below.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	Epigenetics does not modify the underlying genome, but it can modify HOW a genome is used, the genome activity. It must be considered within this discussion, that there are inheritable epigenetic changes. For the other two proposed modifications - DNA and RNA - it is specifically listed that non-heritable are exempt from regulation. This is not necessarily the case for epigenetic changesUnder the proposal for epigenetic modifications, we feel that there should be more thought around what epigenetic modifications would be exempt from GMO regulations. â€œEpigenetic modificationsâ€ is an extremely broad category - what types of modifications, in what specific contexts, or with what sort of impacts, would be regulated or exempt?
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 8 - Low-risk fermentation	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 8 - Low-risk fermentation	Yes	In risk tier 1 there would be no assessment at all. We are largely okay with this for the small volumes discussed.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 8 - Low-risk fermentation	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 8 - Low-risk fermentation	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 8 - Low-risk fermentation	No	â€œRisks: If adequate controls on fermentation vat design and use are not put in place, there may be an increased risk of spills.â€ - copied straight from the documentAre spills the only concern with fermentation vats? What about non-broth fermentation, ie does this include solid-state fermentation? Do spills still count with solid-state?How about control of aerosolisation?
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Outcome-based	Shifting to outcome-based standards
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Outcome-based	As lab-based scientists, we would prefer an outcomes-based approach. There is significant over-engineering of lab facilities under the current system, particularly for very low-risk activity such as transfection of vertebrate cell lines..If an experiment had the potential to increase in the risk level, then a consideration of whether appropriate lab facilities were available would be important. This depends on where the risk tiers end up.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 1 - Risk-tiering framework	Yes	The idea of a framework seems like a good idea as it will speed up the process of getting approval and save unnecessary paperwork etc. but the current proposal is quite vague - would like to see more specifics like that of the Australian regulation framework

Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 4 - Internal audit frequency	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 5 - Movement between facilities	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Outcome-based	As lab-based scientists, we would prefer an outcomes-based approach. There is significant over-engineering of lab facilities under the current system, particularly for very low-risk activity such as transfection of vertebrate cell lines..If an experiment had the potential to increase in the risk level, then a consideration of whether appropriate lab facilities were available would be important. This depends on where the risk tiers end up.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 8 - Low-risk fermentation	Yes	In Australia, itâ€™s 25 (?) litres according to the information in Appendix 3. Presumably the risk here is about the ability to clean up a spill - when does a volume become too big to spill without approval? 10 L is one household bucket, a larger volume seems appropriate
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	No	Reviews should be conducted more often, and I feel a separate governing body, such as a committee for genetic modification, should be established to conduct these reviews. This group would need real-world expertise in the area of GMO production and handlingAlternatively, if this was to stay with the current team within the Ministry for the environment, more members with familiarity to genetic modification would be required.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	Yes	Yes, one of the main issues is that the current guidelines have become out of date and are inappropriate for current technologies. I think more regular and often reviews would also allow for discussion around emerging technologies that should be addressed.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	Other policy options	A committee established as a governing body to undertake these reviews, as well as address any other GMO issues that may arise, would function better to continually monitor the regulatory settings. Much as we have a health and disability ethics committee, a committee of experts in genetic modification from around Aotearoa could be established to review the regulatory settings, and present their recommendations to the Minister for the Environment. Rather than having this responsibility fall to the Ministry for the Environment, a committee of those already established and continually educated on genetic modification technology would be much better suited towards reviewing technologies and making recommendations.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Outcome-based	As lab-based scientists, we would prefer an outcomes-based approach. There is significant over-engineering of lab facilities under the current system, particularly for very low-risk activity such as transfection of vertebrate cell lines..If an experiment had the potential to increase in the risk level, then a consideration of whether appropriate lab facilities were available would be important. This depends on where the risk tiers end up.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	No	No
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	No	Reviews of the regulatory settings should be conducted at least every two years in order to stay up to date with discoveries being made, and to make sure our legislature addresses any concerns that may arise around new discoveries.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 10 - Reviews of regulatory settings	Other policy options	A committee established as a governing body to undertake these reviews, as well as address any other GMO issues that may arise, would function better to continually monitor the regulatory settings. Much as we have a health and disability ethics committee, a committee of experts in genetic modification from around Aotearoa could be established to review the regulatory settings, and present their recommendations to the Minister for the Environment. Rather than having this responsibility fall to the Ministry for the Environment, a committee of those already established and continually educated on genetic modification technology would be much better suited towards reviewing technologies and making recommendations.
Te Herenga Waka - BIOL430 Advanced Genetics class	Proposal 9 - Standards for containment facilities	Outcome-based	As lab-based scientists, we would prefer an outcomes-based approach. There is significant over-engineering of lab facilities under the current system, particularly for very low-risk activity such as transfection of vertebrate cell lines..If an experiment had the potential to increase in the risk level, then a consideration of whether appropriate lab facilities were available would be important. This depends on where the risk tiers end up.

Waipapa Taumata Rau, University of Auckland	Feedback on process/consultation	Feedback on process/consultation	In general, the Ministry for the Environmentâ€™s proposed improvements to genetically modified organism (GMO) regulations for laboratory and biomedical research have been received very positively at Waipapa Taumata Rau, University of Auckland.The intent of the changes â€“ to move closer to an environment where the regulatory settings are proportionate to risk â€“ is expected to reduce the compliance workload for the university significantly and allow for the promotion of low-risk GMO research and collaboration with domestic and international partners without compromising the biosecurity of Aotearoa New Zealand.Responses have been provided in the provided supporting documentation on Objectives, the ten Proposals and supplementary questions in the Appendices, providing additional commentary on further issues for consideration and areas where clarification is sought.The proposed changes represent a very welcome step in a positive direction, but there is a desire for further changes. Technology is moving rapidly in this field and the regulatory environment must retain a level of flexibility to ensure that Aotearoa New Zealand does not fall further behind the rest of the world. Consideration must therefore also be given to legislative amendments to ensure the full benefits of the proposed reforms are achieved.
Life Sciences Network Incorporated	Objectives	Objectives	The LSN agrees with the objectives to proportionately manage risks, contribute to better health outcomes and future-proof the regulatory framework.However, these proposals are aimed at all laboratory research not just medical, therefore the second objective should include â€˜better social, environmental and economic outcomes for Aotearoa New Zealandâ€™.
Life Sciences Network Incorporated	Proposal 1 - Risk-tiering framework	Yes	Yes
Life Sciences Network Incorporated	Features and approach for regulatory framework	Features and approach for regulatory framework	The regulatory framework for GMOs should have the following features:- Effective- Efficient- Proportional to risk- Evidence based and objective- Based on effects rather than on the technologyUnder current regulatory settings two organisms with exactly the same genetic code would be regulated differently if one were produced using genetic technologies and the other bred through conventional techniques (including chemical or radiation mutagenesis).The government should consider a regulatory framework which takes into account the level of competency/track record of any facilities and operators which are subject to the controls. For example, performance-based audit frequency and flexibility to delegate decision making.A risk-based approach should be extended to all regulation of GMOs rather than a permissive system for medicines (which may involve the release of, for example, modified human viruses) and a restrictive system for other applications (for example a petunia modified to be orange in colour or a sterile pine tree).
Life Sciences Network Incorporated	Proposal 1 - Risk-tiering framework	Yes	Yes
Life Sciences Network Incorporated	Proposal 1 - Risk-tiering framework	Yes	Yes, the LSN agrees with the proposal to establish a risk-tiering framework but submits there should be two tiers (exempt and not exempt) rather than three.The LSN notes that the Australian system has two tiers â€“ exempt and notifiable dealings whereas the consultation document proposes three tiers â€“ exempt, PC1 and PC2.The proposal to create three tiers increases complexity for little if any benefit.
Life Sciences Network Incorporated	Proposal 1 - Risk-tiering framework	Yes	The LSN agrees with the issues outlined, in particular:- The time and resource to prepare applications is disproportionate in low-risk cases and takes resources from research- The pre-assessment stage can be lengthy- Case-by-case applications for low-risk is unnecessary- Containment is unnecessary for essentially zero risk organisms in particular â€œlaboratory dependentâ€ organisms- Case-by-case assessment should continue for not low risk- We are out of step with other similar jurisdictions- Risk tier 1 research and release of medicines (Human and veterinary) should be exempt from EPA assessment and approval.The paper notes that certain import approvals can be used by people other than the applicant (provided they meet the conditions of the approval which includes a certified level of containment), however it does not make clear what tier the current import approvals would sit under and therefore whether, for imports, the regulatory burden would be greater (assessment by ABSC where no assessment is currently required) or the same (all current import approvals of this nature fit under tier 1).Thus, the proposed system is potentially more bureaucratic than the current system with respect to import approvals and therefore, since this proposal increases oversight and bureaucracy in the absence of supporting evidence, it does not, in this respect, meet the objectives set out â€œto lower the administrative requirementâ€ and â€œproportionately manage riskâ€.It is not stated explicitly that the ABSC has the power to impose conditions on the approvals (Tier 2&3) but use of the phrase â€œbiosafety committee confirmsâ€ suggests that the ABSC does not have that power. The LSN agrees with this point.We agree that rapid assessment should continue to be available for low-risk research which falls outside the criteria of risk tiers 1-3.The three tiers should be condensed to two as in the Australian model: exempt and not exempt low risk projects.
Life Sciences Network Incorporated	Proposal 1 - Risk-tiering framework	Other policy options	Yes, a two-tier system should be considered rather than a three-tier system â€“ exempt and non-exempt low risk projects (i.e., combine tiers two and tier 3).
Life Sciences Network Incorporated	Proposal 1.1 - Biosafety Committees	Yes	Yes
Life Sciences Network Incorporated	Proposal 1.1 - Biosafety Committees	Yes	The LSN agrees with the establishment of accredited biosafety committees and an Environmental Protection Authority biosafety committee subject to the comments below.The ABSC s job is to confirm:â€¢The research meets the criteria for that risk tierâ€¢The researcher can undertake the research, orâ€¢That the facility is appropriate for the researchIt is unclear in the proposal if, in making the assessment, the facility is appropriate for the research the ABSC is making a desktop assessment that the facility is the containment level required, or that it is to assess the facility (e.g., by audit and inspection) to ensure it is the appropriate facility.The LSN points out that under the tier system, that research which qualifies is automatically assigned to a containment level and the containment facility is inspected and approved by MPI, therefore we assume the exercise is confirmation that the appropriate research is being carried out in the appropriate (and accredited) facility. If not then the ABSC will have to have a different set of skills and will be doubling up on the work carried out by MPI and the institution.
Life Sciences Network Incorporated	Proposal 1.1 - Biosafety Committees	Other policy options	Regular meetings of the EPA BSC may still lead to delays in approvals. The EPA should consider that assessments could be made by staff as per the current rapid assessment process so that the approvals are more on demand then beholden to a fixed meeting schedule.
Life Sciences Network Incorporated	Proposal 2 - Assessments for medicines	Yes	Yes
Life Sciences Network Incorporated	Proposal 2 - Assessments for medicines	Yes	Yes. The LSN agrees that removal of section 38I, while changing an assessment to determine the pathway for approval doe not change the assessment itself. That is a non-low-risk qualifying organism is still going to be assessed, with the regulator having the option to decline the application. While this may reduce some time and bureaucracy, it would not necessarily, in our opinion, reduce the information required to make an assessment.The introduction of an alternative pathway for organisms which are unlikely to result in viable organisms is supported. The LSN recognises that in the case there is uncertainty the regulator has the authority to decline the application in favour of a most detailed assessment. This process should be aligned with Australia to provide consistency in a field where collaboration and integration between the countries is progressing at pace.
Life Sciences Network Incorporated	Proposal 2 - Assessments for medicines	Yes	Yes
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes, however it would be sufficient to label animals with a number (tag +/-microchip) provided that number record identifies the animal as genetically modified.

Life Sciences Network Incorporated	Proposal 1 - Risk-tiering framework	Yes	Yes
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Yes	Yes
Life Sciences Network Incorporated	Proposal 2 - Assessments for medicines	Yes	Yes, in particular:-The time and resources used to assess if an organism is a qualifying organism in order for it to be assessed under s38I is not adding value. All medicines should proceed (at least initially) through the rapid assessment pathway.- The inclusion of medical devices
Life Sciences Network Incorporated	Proposal 2 - Assessments for medicines	Other policy options	No.
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes, except for exempt organisms (Tier 1)
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes, the LSN agrees with the issues outlined.The LSN have no issues to add to the list.
Life Sciences Network Incorporated	Proposal 4 - Internal audit frequency	No	No
Life Sciences Network Incorporated	Proposal 4 - Internal audit frequency	No	No, internal audits for PC1 and PC2 should be initially annual and thereafter performance based at the discretion of the MPI inspector. This should also be the same for external inspections by the MPI inspector.
Life Sciences Network Incorporated	Proposal 4 - Internal audit frequency	Yes	Yes
Life Sciences Network Incorporated	Proposal 4 - Internal audit frequency	Yes	Yes, in particular that the frequency of internal audits is unnecessarily high for most facilities.
Life Sciences Network Incorporated	Proposal 4 - Internal audit frequency	Other policy options	Yes, the audit frequency should be performance based.
Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Yes	Yes
Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Yes	Yes, however the LSN submits that this should also apply to PC2 facilities. The purpose of obtaining permission from MPI for every movement is extremely cumbersome and remains obscure. An added requirement in the case of PC2 movements would be the requirement for operators to notify MPI if a shipment has not reached its destination.
Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Yes	Yes
Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Yes	Yes, in particular that the current requirements are unnecessary and consume valuable time and resources for researchers.An added issue is that the imposition of requirements (when they are not scientifically justified) creates a perception that an organism is dangerous when in fact it may not be. This is used by activists to justify tougher rules in vicious circle.
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Other policy options	No.
Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Yes	Yes, in particular that the current requirements are unnecessary and consume valuable time and resources for researchers.An added issue is that the imposition of requirements (when they are not scientifically justified) creates a perception that an organism is dangerous when in fact it may not be. This is used by activists to justify tougher rules in vicious circle.

Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Other policy options	Yes, containers containing PC1 and PC2 organisms (both GMO and non-GMO cell lines) should only require labelling to indicate they contain live organisms and other health and safety labelling such as â€œmay contain infectious agentsâ€ (where that may be appropriate), would be more instructive. Labelling with â€œGMOâ€ implies a danger which is unlikely to exist for these containment level organisms. Records of movement for GMO and non-GMO organisms (including not new organisms) should be undertaken for all cultures as a matter of good practice.
Life Sciences Network Incorporated	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes, in part. It is noted that the eukaryotic cells in risk tier 1 would be limited to the somatic cells of animals, humans and plants.The statements:â€œThe donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi.â€andâ€œIf the donor nucleic acid includes a viral sequence, it cannot give rise to infectious agents when introduced into any potential host species.â€appear contradictory since the first prohibits the second. It would be better stated:â€œThe donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi, unless the donor nucleic acid includes is a viral sequence, which cannot give rise to infectious agents when introduced into any potential host species.â€
Life Sciences Network Incorporated	Proposal 3 - Record-keeping requirements	Yes	Yes, however it would be sufficient to label animals with a number (tag +/-microchip) provided that number record identifies the animal as genetically modified.
Life Sciences Network Incorporated	Proposal 5 - Movement between facilities	Other policy options	Yes, containers containing PC1 and PC2 organisms (both GMO and non-GMO cell lines) should only require labelling to indicate they contain live organisms and other health and safety labelling such as â€œmay contain infectious agentsâ€ (where that may be appropriate), would be more instructive. Labelling with â€œGMOâ€ implies a danger which is unlikely to exist for these containment level organisms. Records of movement for GMO and non-GMO organisms (including not new organisms) should be undertaken for all cultures as a matter of good practice.
Life Sciences Network Incorporated	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Life Sciences Network Incorporated	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes, in part. It is noted that the eukaryotic cells in risk tier 1 would be limited to the somatic cells of animals, humans and plants.The statements:â€œThe donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi.â€andâ€œIf the donor nucleic acid includes a viral sequence, it cannot give rise to infectious agents when introduced into any potential host species.â€appear contradictory since the first prohibits the second. It would be better stated:â€œThe donor nucleic acid must not be derived from organisms implicated in, or with a history of causing, disease in otherwise healthy human beings, animals, plants or fungi, unless the donor nucleic acid includes is a viral sequence, which cannot give rise to infectious agents when introduced into any potential host species.â€
Life Sciences Network Incorporated	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
Life Sciences Network Incorporated	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	Yes. Condition 5 would be better expressed as:â€¢The plant cells or tissues cannot spontaneously generate a whole plant and must not be regenerated into a whole plant.The reason for the change in condition 5 is that the word â€œcannotâ€ is ambiguous meaning either it is not possible or it should not be done. Many plant cells can, with effort, be generated into a whole plant. The LSN agrees that this should be avoided without appropriate authorisation.
Life Sciences Network Incorporated	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Life Sciences Network Incorporated	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Life Sciences Network Incorporated	Proposal 7 - Regulatory status of biotechnologies	Exclusionary criteria	The LSN agrees with the exclusions already provided.
Life Sciences Network Incorporated	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
Life Sciences Network Incorporated	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes, in part. There is no reason why statutory declarations should be hard to find. These could be listed on the EPA website.The LSN agrees that the definition of GMO is arbitrary and that a GMO (through gene editing) and a non-GMO (through natural mutation) could have the same genetic code but would be regulated differently. A risk-based system would help address this inconsistency.
Life Sciences Network Incorporated	Proposal 7 - Regulatory status of biotechnologies	Other policy options	Yes, null segregants and gene edited organisms (where that modification could have occurred naturally) should also be excluded.New Zealand is an outlier in determining that null segregants are GMO and since these organisms no longer have the modified genes, they are not distinguishable from conventionally bred organisms.
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Yes	Yes. We assume that fermentation in this context includes cell culture as well as fermentation of microorganisms (fungi, bacteria, etc).
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Yes	Yes, for risk Tier 1-3 provided the facility is approved by MPI specifically for that purpose.
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Yes	Yes
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Yes	Yes, in particular that the time taken for assessment at levels 1-3 for a predictable outcome is unwarranted.
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Other policy options	The containment facility standards and controls should be approved by MPI Inspectors on behalf of the EPA, not the EPA. It is therefore a duplication of oversight to also have the ABSC also approve the proposed controls. The LSN submits that containment facilities are specifically approved for large scale fermentation by MPI which would also ensure the level of controls are standardised across research and industry and will avoid mission creep by ABSCs. The proposal to have the ABSC assessing the controls would also require an additional skill set to the ABSC which would be not be justified for risk tier 1-3.
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Hybrid	Shifting to a hybrid approach

Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Yes	Yes
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Yes	Yes, in particular that outcome-based controls are more appropriate but require more technical knowledge. Purely outcome-based approaches also risk duplication of effort as we have seen in the Resource Management Act. Outcome based approaches do however allow greater innovation.An additional issue is that many researchers in New Zealand are from abroad and are familiar with international approaches. They often find New Zealandâ€™s GMO regulations arcane which decreases the likelihood of compliance and reduces staff retention.
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Yes	Yes
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Cost vs benefits	Many organisations under the LSN umbrella run both containment and transitional facilities. The outcome-based approach may add costs if controls which are prescribed for transitional facilities have to be justified for containment facilities. The hybrid approach would not add cost if the default prescriptive controls aligned with the transitional facility controls. Provided transitional facilities do not move to a similar hybrid model innovation in containment facilities will be stifled. The LSN submits that the controls in transitional facilities allow for effects-based controls where containment and transitional facilities are run together.
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes, political paralysis with respect to GMO regulation has resulted in an act which is no longer fit for purpose and erodes our scientific leadership and competitiveness on the world stage. Biotechnology is a fast-moving area; regular reviews would enable the regulatory setting to be regularly updated and adaptable and would reduce the likelihood of onerous unnecessary regulation being promulgated to deal with unknowns twenty years in the future.
Life Sciences Network Incorporated	Proposal 8 - Low-risk fermentation	Yes	Yes
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Hybrid	The hybrid approach is preferred as prescriptive controls avoids duplication of effort in repetitively developing and justifying controls as is seen in the Resource Management Act. Effects based controls allow for innovation with improved effectiveness and efficiency. A hybrid approach, where prescriptive controls are available but effects-based controls are permitted where justified, provides both certainty and flexibility.
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Other policy options	Yes, the controls in transitional facilities allow for effects-based controls where containment and transitional facilities are run together.
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes, every review wonâ€™t lead to regulatory change but will provide a balance between efficiency and adaptability.
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Yes	Yes, biotechnology is changing rapidly and the current regulatory settings are no longer fit for purpose.
Life Sciences Network Incorporated	Proposal 10 - Reviews of regulatory settings	Other policy options	The Act should provide for a change process which is not overly bureaucratic while providing the appropriate levels of safety and public confidence.There is a danger that if an independent party conducts the review the appointments could be politically motivated, therefore the appointment criteria and skill sets of the reviewers should be specified in the Act to insure they are objective and evidence based.
Life Sciences Network Incorporated	Alternative options	Alternative options	The current proposal has a three-tier system. The operative differences between tier 2 and 3 are in the frequency of internal audits and the shipping requirements. The LSN submits that a two-tier system (exempt projects and PC1/PC2 projects) would be more appropriate with audit frequency (internal and external) based on risk and track record.While these proposals seek to address unnecessary control of GMOs in the laboratory and in medicine (including release of medical GMOs into the environment), the controls relating to environmental releases for agricultural and environmental purposes should also reviewed in this process.Audit frequency â€“ the LSN considers that the internal audit frequency should align with Australia, removing the internal audit requirement for PC1 facilities, reducing internal audits for PC2 facilities to 12 monthly. We also contend that the audit schedule should be based on risk and track record. We have reviewed the audit frequency of the OTGR in Australia and note:- In the 26 calendar quarters between Q1 2017 and Q2 2023, (inclusive), the OGTR has inspected 138 types of facilities across 85 entities throughout Australia.- Of that total, 7 facilities (5.07%) were PC1 Facilities, and individual visitation records indicate inspections arenâ€™t carried out annually, in fact far from it.- Deakin Universityâ€™s PC1 Facility was the only institution of seven which had inspections at their PC1 Facility more than once in that ~ 5-year period, (Q4 2019 and Q3 2017).- All others were only visited and inspected once during the ~ 5-year period. Further, weâ€™d speculate there would be a significant number of additional PC1 Facilities in Australia not included in OGTR reporting, because they werenâ€™t inspected over that timeframe whatsoever.- Of the PC2-PC3 Facility inspections, whilst they generally occur more frequently than PC1 inspections, there is no distinguishable reoccurring visitation pattern, which we conclude indicates the OGTR inspects based upon historical risk and compliance track-record, as opposed to a strict regime of visiting facilities once a year or biennially etc.- To illustrate, the following institutions inspected in Q3 2018 (almost 5-years ago), comprising a range of PC1 through PC3 facilities, have not received returning visitations/inspections since:Entity Facility LevelFacility TypeFacility NosAustralian Catholic University PC2 Laboratory 1Centre for Eye Research Australia Ltd PC1 Facility 1 PC2 Laboratory 1Federation University Australia PC1 Facility 1 PC2 Laboratory 1Macfarlane Burnet Institute for Mental Research & Public HealthPC3 Laboratory 1Sugar Research Australia Ltd PC2 Laboratory 2Sunshine Coast Health Institute PC2 Laboratory 3University of Adelaide PC2 Animal Facility2 PC2 Aquatic Facility1 PC2 Laboratory 1 PC2 Plant Facility 1University of Newcastle PC2 Animal Facility3 PC2 Laboratory 7University of Sunshine Coast PC2 Laboratory 1The only Institution visited then and subsequently was:Entity Facility LevelFacility TypeFacility NosDates visitedSequris Pty Ltd PC2 Large Scale 1 Q3, 2018 PC2 Large Scale 3 Q4, 2018It is probable that this case it was a single inspection of the institution running across two quarters.We do note however that more responsibility is placed on the biosafety committees in Australia than is proposed here.Movement of new organisms â€“ the proposal should be extended to PC2 with the requirement that MPI is notified if the shipment is lost or damaged in transit.

Life Sciences Network Incorporated	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Yes, these have been mentioned in the submission and include:- a two tier, not three tier system- internal audits for PC1 not required
Life Sciences Network Incorporated	Feedback on process/consultation	Feedback on process/consultation	debates on science issues, in particular the regulation of genetic modification. The LSN was considered by the Royal Commission on Genetic Modification to have an interest greater than the general public and was thus awarded interested person status.SUBMISSION ON IMPROVING OUR GMO REGULATIONS FOR LABORATORY AND BIOMEDICAL RESEARCH CONSULTATION PAPERINTRODUCTIONThe Life Sciences Network welcomes the opportunity to submit on the consultation document: Improving our GMO regulations for laboratory and biomedical research: Consultation document (Consultation Document).Genetically modified organisms have been in use in medicine for almost forty years (Insulin production 1984) and in the production of food for more than 25 years (Chymosin for cheese manufacture).The first GMO crops were commercialised in the USA in 1996. By 2017 up to 17 million farmers in 24 countries planted 189.8 million hectares of genetically modified crops, an accumulated area since 1996 of 2.3 billion hectares. Uptake by farmers in the top five growing countries is as high as 90-100%. Economic gains from GM crops reached US$186.1 billion from 1996 to 2016.The National Academy of Sciences in the USA concluded in a 2016 report that the use of GM in agriculture has had an overall positive outcome for the environment and despite the consumption of trillions of meals no scientifically credible negative health effect has been observed.Live GMOs are increasingly being used in medicine, in particular the use of viral vectors for gene therapy, live modified microorganisms for immunisation and in cancer therapy.As of August 2023, there have been 9 approvals for the release of genetically modified organisms into the environment in New Zealand including 2 unconditional releases. These releases have been medical and veterinary and have been approved through the rapid assessment pathway for qualifying medicines which allows for no public consultation.The 2001 Royal Commission of Enquiry into Genetic Modification (â€˜RCGMâ€™) concluded that:- we should proceed with caution while preserving opportunities,- â€œan appropriate regulatory and institutional framework for the controlled use of genetic modification- is already provided by the Hazardous Substances and New Organisms Act 1996 (HSNO).â€regulations relating to the development of genetically modified organisms in containment be reviewed and updated, and- medicines that include live genetically modified organisms be approved for use by Medsafe without a requirement for additional approval from the EPA.In response to the RCGM, in 2003 the then government introduced into legislation a new category of Conditional Release (as recommended by the Commission) and put in place prescriptive and onerous rules for field trials (which were not recommended by the Commission).There have been 14 approvals for field trials under the HSNO Act 1996 and only three approvals. There have been no field trial approvals in the last 13 years (since 2010).In the last ten years four councils â€“ Far North District Council, Whangarei District Council, Auckland Council and the Hastings District Council have put in place precautionary and prohibitive rules for the use of GMOs requiring resource consents for field trails and prohibiting the release of GMOs into the environment (except medicines).The act of regulation in itself creates the perception of risk, not only amongst the public but in the minds of laboratory workers and regulators. An unjustified focus on the control of low-risk organisms simply because they are GMOs risks non-GMO cultures being perceived as safer than they may be.Laboratory workers should not be distracted from the real and present dangers from organisms such as meningococcus and typhus by onerous and unnecessary requirements placed on low-risk organisms. The proposals put forward in this paper go a long way in aligning regulation and risk and ultimately will make laboratories safer.Another aspect of overbearing, time consuming and unnecessary regulation which is disproportionate to risk is that it provides greater opportunity for non-compliances which while of no or trivial consequences are used as â€œevidenceâ€ that danger has been created. Aligning the controls with the actual risks will reduce these types of non-compliances.The perception of danger (when there may be none) which unjustified controls create and non-compliances (which may be inconsequential) in an overly bureaucratic system is often usen used as evidence for tighter and more bureaucratic regulation in an ever-tightening circle.Unjustified controls reduce New Zealandâ€™s credibility in the eyes of our international collaborators and distracts scientists from the actual dangers (e.g., a non-GMO human cell line may contain an infectious disease).The Life Sciences Network supports this review of the regulations relating to the use of GMOs in the laboratory and the proposal to reduce the requirements for medicines that are or contain new organisms noting that it is almost a quarter of a century since these recommendations were made by the Royal Commission.In 2019 the Life Sciences Network wrote to the Minister for the
Life Sciences Network Incorporated	Proposal 9 - Standards for containment facilities	Cost vs benefits	Under proposal 9 the risk is misstated. The risk of increased spills is not a consequence of the proposed regulatory changes since the standards are expected to be maintained. The risk of spills and the consequence of spills is likely to be the same.
Life Sciences Network Incorporated	Feedback on Australian risk-tiering framework	Feedback on Australian risk-tiering framework	Yes, these have been mentioned in the submission and include:- a two tier, not three tier system- internal audits for PC1 not required
New Zealand Society of Plant Biologists	Objectives	Objectives	No
New Zealand Society of Plant Biologists	Proposal 8 - Low-risk fermentation	Yes	Yes
New Zealand Society of Plant Biologists	Proposal 8 - Low-risk fermentation	Yes	We support a risk-proportionate approach for all genetic technologies including fermentation.
New Zealand Society of Plant Biologists	Proposal 9 - Standards for containment facilities	Options	These questions are better addressed by individual researchers and research organisations.
New Zealand Society of Plant Biologists	Proposal 10 - Reviews of regulatory settings	Yes	Yes
New Zealand Society of Plant Biologists	Objectives	Objectives	The current objectives are sound, but we believe they are too narrow in scope to be effective in providing in any meaningful change.As has been well documented (Royal Society Te AÃ¢ngi, the Productively Commission, FSANZ, the Prime Ministerâ€™s Science Advisor etc) the regulations around genetic modification are out-of-date and no longer fit-for-purpose. The NZSPB agrees with these views, and believes regulation of genetic technologies should be risk-proportionate. Thus, we would like to see the review widened to include a complete review of the regulation of genetically modified organisms and the definition of a genetically modified organism. This would require field trials and release to be within the scope of the review. In particular, we suggest objectives such as:-ensure the definition of a genetically modified organism reflects the risk of an organism and how different it is to an organism produced using different techniques, and is consistent with those of our major trading partners.-ensure that the regulatory environment for genetically modified organisms and modern genetic technologies is fit-for-purpose and risk proportionate.-contributes to better health and environmental outcomes for New Zealanders through increasing research outcomes and innovation, and greater access to biotechnology processes and products.
New Zealand Society of Plant Biologists	Features and approach for regulatory framework	Features and approach for regulatory framework	We would like to see a regulatory environment that enables risk-proportionate approach that will enable Aotearoa New Zealand to take advantage of modern biotechnology, particularly in plant breeding and production. We believe such an approach can manage risk and provide outcomes that deliver health, environmental and economic benefits to Aotearoa New Zealand in a manner supported by the majority of the population.Key features would include:risk proportionality. Modern genetic technologies enable a wide range of outcomes that present very different risk profiles; from null segregants (no added genetic material in the final product; can be verified by whole genome sequencing), to small targeted changes that cannot be distinguished from other changes (e.g., site-directed mutagenesis), to the transfer of genes between related species, to the addition of foreign genetic material. Many other countries, including our main trading partners, have reviewed (with recommended changes) or changed their legislation to reflect these different risk profiles.workability. This would include-reduced complexity: currently aspects of genetic technologies are covered in different Acts and different agencies are involved in decisions making and enforcement-future-proofing: being able to adapt to new technologies-be enforceable: if a genetic change cannot be detected (unless it has been previously declared) it is very hard to regulate. Therefore there is a risk of putting New Zealand breeders and producers at a competitive disadvantage. i.e. other countries using technologies, and products being imported into New Zealand, while our breeders and producers face time and financial barriers to making a genetically identical plant. Potentially this could include covering genetic technologies in a dedicated genetic technologies Act, and setting up a dedicated regulatory authority.benefit/risk analyses. While we recognise the use of new breeding and genetic technologies will not solve all of the problems facing the primary sector, we believe they could play an important role in developing crops with improved stress tolerance and reduced needs for chemical inputs. The potential benefits should therefore be weighed against any risks.

New Zealand Society of Plant Biologists	Proposal 1 - Risk-tiering framework	Unsure	Unsure
New Zealand Society of Plant Biologists	Proposal 1 - Risk-tiering framework	Unsure	While we believe that this would be a step in the right direction, it would only be a small step. It may provide some benefits in the research environment, but would still limit the implementation o biotechnologies outcomes and innovation. While the system is modelled on the Australian system, we note that there are several differences, such as a single regulatory body in Australia and a feasible route from the laboratory to field trials and beyond.
New Zealand Society of Plant Biologists	Proposal 7 - Regulatory status of biotechnologies	Other policy options	Rather than limiting this review to several technologies, a wider review of the regulatory landscape in New Zealand would provide better clarity.
New Zealand Society of Plant Biologists	Proposal 1 - Risk-tiering framework	Yes	While we believe that this would be a step in the right direction, it would only be a small step. It may provide some benefits in the research environment, but would still limit the implementation of biotechnologies outcomes and innovation. While the system is modelled on the Australian system, we note that there are several differences, such as a single regulatory body in Australia and a feasible route from the laboratory to field trials and beyond.
New Zealand Society of Plant Biologists	Proposal 1 - Risk-tiering framework	Yes	Yes
New Zealand Society of Plant Biologists	Proposal 1 - Risk-tiering framework	Other policy options	As noted in Part 1, we believe that a review of the definition of a genetically modified organism and the regulatory environment around genetic technologies would be a better approach rather than making smaller changes, that on their own may still be difficult to implement.
New Zealand Society of Plant Biologists	Proposal 1.1 - Biosafety Committees	Unsure	Unsure
New Zealand Society of Plant Biologists	Proposal 1.1 - Biosafety Committees	Unsure	These questions are better addressed by individual researchers and research institutes
New Zealand Society of Plant Biologists	Proposal 2 - Assessments for medicines	Unsure	Unsure
New Zealand Society of Plant Biologists	Proposal 2 - Assessments for medicines	Unsure	We support a risk-proportionate approach for all genetic technologies including those used in medicines.
New Zealand Society of Plant Biologists	Proposal 3 - Record-keeping requirements	Unsure	Unsure
New Zealand Society of Plant Biologists	Proposal 5 - Movement between facilities	Yes	Yes
New Zealand Society of Plant Biologists	Proposal 5 - Movement between facilities	Yes	As a society, one of our roles is to facilitate collaboration across the plant sciences in New Zealand. Thus, we would be supportive of moves to make the transfer of new organisms more risk proportionate and reduce the regulatory burden.
New Zealand Society of Plant Biologists	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	Yes
New Zealand Society of Plant Biologists	Proposal 6 - Requirements for eukaryotic somatic cells	Yes	We agree that certain eukaryotic somatic cells represent an almost negligible risk and should be regulated as such.We believe it is important that plant cells in culture are included here. While plant cells can display totipotency, it should be recognised that considerable and deliberate human intervention is required to regenerate an entire plant from plant cells in tissue culture.
New Zealand Society of Plant Biologists	Proposal 6 - Requirements for eukaryotic somatic cells	Other policy options	As described above, the NZSPB believes that a full review of the regulation and definition of genetically modified organisms is required. As part of this, we believe that consideration should be given to whether eukaryotic somatic cells that cannot survive outside culture conditions (without considerable human input) are organisms.
New Zealand Society of Plant Biologists	Proposal 7 - Regulatory status of biotechnologies	Yes	Clarity around the regulatory status of different biotechnologies is very important as New Zealandâ€™s plant scientists develop strategies for the development of improved plant varieties.
New Zealand Society of Plant Biologists	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes

New Zealand Society of Plant Biologists	Feedback on process/consultation	Feedback on process/consultation	Response from the New Zealand Society of Plant Biologists on the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organismsOverviewThe New Zealand Society of Plant Biologists (NZSPB) consists of plant biologists and research students from academic institutions and Crown Research Institutes and industry throughout New Zealand. We study a broad range of plant sciences including ecology, physiology, molecular biology and biotechnology. We are passionate about plant science and are motivated to use our expertise to help New Zealand adopt sustainable farming practices and protect our natural environment, while continuing to produce the high-quality food desired by New Zealand consumers and our export markets. The NZSPB is an incorporated society and a constituent organisation of the Royal Society Te ApÄrangi.The NZSPB welcomes the opportunity to respond to the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organisms (GMOs). We appreciate the recognition that the current legislative environment around genetically modified organisms is no longer risk proportionate and places unnecessary burdens on the New Zealand research community (as described in the Interim regulatory impact statement on options). However, we believe that the proposed changes represent only a small step, and that a full review of the regulation and definition of genetically modified organisms is required if Aotearoa New Zealand is going to innovate to address the current environmental challenges and maintain the health and well being of New Zealanders.
New Zealand Society of Plant Biologists	Proposal 1 - Risk-tiering framework	Yes	We agree that the administrative requirement for research is currently very high and places limitations on New Zealand-based research. We believe this should be extended to include field trials.If a risk-tiering approach was adopted, it would be important to ensure that the requirement for any organism is not increased, in particular, the handling of plant tissues (without reproductive organs).
New Zealand Society of Plant Biologists	Proposal 3 - Record-keeping requirements	Unsure	The labelling and record-keeping practices vary widely across New Zealand depending on the HSNO approvals that different research institutes hold. Reducing the burden of record keeping and making this more coherent across New Zealand would be advantageous to plant biology across New Zealand.
New Zealand Society of Plant Biologists	Proposal 7 - Regulatory status of biotechnologies	Yes	Yes
New Zealand Society of Plant Biologists	Proposal 10 - Reviews of regulatory settings	Agree with proposal	Given that the Royal Commission was over 20 years ago and there has not been a systematic review (despite the recommendations) and the continual development of new technologies with altered risk profiles, we believe regular reviews are essential. Consideration for the timing of the reviews should be given, with some potential for short-term views of practical aspects and less frequent reviews of the entire system with an eye on technologies that have been developed, or are likely since the previous review.
New Zealand Society of Plant Biologists	Feedback on process/consultation	Feedback on process/consultation	Response from the New Zealand Society of Plant Biologists on the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organismsOverviewThe New Zealand Society of Plant Biologists (NZSPB) consists of plant biologists and research students from academic institutions and Crown Research Institutes and industry throughout New Zealand. We study a broad range of plant sciences including ecology, physiology, molecular biology and biotechnology. We are passionate about plant science and are motivated to use our expertise to help New Zealand adopt sustainable farming practices and protect our natural environment, while continuing to produce the high-quality food desired by New Zealand consumers and our export markets. The NZSPB is an incorporated society and a constituent organisation of the Royal Society Te ApÄrangi.The NZSPB welcomes the opportunity to respond to the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organisms (GMOs). We appreciate the recognition that the current legislative environment around genetically modified organisms is no longer risk proportionate and places unnecessary burdens on the New Zealand research community (as described in the Interim regulatory impact statement on options). However, we believe that the proposed changes represent only a small step, and that a full review of the regulation and definition of genetically modified organisms is required if Aotearoa New Zealand is going to innovate to address the current environmental challenges and maintain the health and well being of New Zealanders.
New Zealand Society of Plant Biologists	Proposal 4 - Internal audit frequency	Agree with proposal	We agree that reducing the audit frequency to be proportionate to risk would be beneficial. In particular, we suggest that audits should be focussed on environmental protection goals and should recognise facilities with a good track record of compliance may require less frequent audits.
New Zealand Society of Plant Biologists	Feedback on process/consultation	Feedback on process/consultation	Response from the New Zealand Society of Plant Biologists on the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organismsOverviewThe New Zealand Society of Plant Biologists (NZSPB) consists of plant biologists and research students from academic institutions and Crown Research Institutes and industry throughout New Zealand. We study a broad range of plant sciences including ecology, physiology, molecular biology and biotechnology. We are passionate about plant science and are motivated to use our expertise to help New Zealand adopt sustainable farming practices and protect our natural environment, while continuing to produce the high-quality food desired by New Zealand consumers and our export markets. The NZSPB is an incorporated society and a constituent organisation of the Royal Society Te ApÄrangi.The NZSPB welcomes the opportunity to respond to the proposed changes to Aotearoa New Zealandâ€™s legislation and regulations for genetically modified organisms (GMOs). We appreciate the recognition that the current legislative environment around genetically modified organisms is no longer risk proportionate and places unnecessary burdens on the New Zealand research community (as described in the Interim regulatory impact statement on options). However, we believe that the proposed changes represent only a small step, and that a full review of the regulation and definition of genetically modified organisms is required if Aotearoa New Zealand is going to innovate to address the current environmental challenges and maintain the health and well being of New Zealanders.
Te Wānanga o Aotearoa, The University of Waikato	9(2)(ba)(i)		
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Te Wānanga o Aotearoa, The University of Waikato			
9(2)(a)	Features and approach for regulatory framework	Features and approach for regulatory framework	I feel that medical GM technologies for human health should be considered separately to GM technologies for food, climate change, environment, species recovery etc.
	Objectives	Objectives	Unsure
	Features and approach for regulatory framework	Features and approach for regulatory framework	I feel that medical GM technologies for human health should be considered separately to GM technologies for food, climate change, environment, species recovery etc.
	Feedback on process/consultation	Feedback on process/consultation	My overall feeling is this consultation is primarily focussed on medical treatments based on GM technology, which I am fully in favour of. However, my professional opinion 9(2)(a) with a focus on Primary Industry rather than medicinemeans the majority of our GM research is gene technologies for agriculture and horticulture - of which the majority will be lab-contained and subject to PC2 rather than PC1. I have attached my feedback to the consultation in the attached PDF.
	Features and approach for regulatory framework	Features and approach for regulatory framework	I feel that medical GM technologies for human health should be considered separately to GM technologies for food, climate change, environment, species recovery etc.
Wellington UniVentures	Proposal 9 - Standards for containment facilities	Yes	Yes