Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
1	In your view, are these objectives the most effective for developing policy changes to improve the regulatory settings for genetically modified organisms? If not, what should the objectives be, and why?	75/19/6	General agreement with the objectives, however there are some comments that suggest that they are too loose or too tight.	"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." 9(2)(ba)(i)	**Too loose** "Maintain the status quo. GM technology has been around a long time and still hasn't delivered on the great promises that have 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." **Too tight** "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."

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2	What features and overall approach would you like to see in a New Zealand regulatory framework for genetically modified organisms?		• Decreased compliance burden (paperwork) • Change the definition of new organism • 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. • inclusion of economic prosperity and the protection of New Zealand's trade and reputation among considerations • Easier to access and use genetic modification. • Reduce complexity to regulate • More permissive to use and implement GMO	"The risk of a GMO should be assessed based on risk to the following six domains: • The environment. • Human health and safety. • The economy. • The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga, and the principles of the Treaty of Waitangi. • Society and community. • New Zealand's international obligations. This ties into the continued separation of genetically modified organism and new organism in concepts. A genetically modified organism may be considered a new organism, as the risk assessment framework is effectively 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 flower colour)." The regulations need to allow for rapid assessment of organisms for addition to the appropriate risk tier; that is, they	Future regulations should not solely focus on the technique used to create a new organism but should also consider aspects of the product, including: • Novelty of the change (is there an equivalent already in the environment). • Distinctiveness of changes that could be made using other methods (e.g., SDN1, DNA only from a related species). • Evaluation of whether the organism contains added or foreign genetic material (e.g., null segregants). "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.

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				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).	
Proposal 1: Introduce a risk-tiering framework for laboratory research					
3	Do you agree with the proposed change: to establish a risk-tiering framework modelled on the risktiering framework under Australian regulations?	71/12/17	General support of a risk tiering framework but concern that the Australian framework is too prescriptive and may not be future proof. Suggestions for either a comprehensive list, broader definitions or an online tool that "approves" the organisms. Suggestions to make further changes to the HSNO Act to implement other aspects of the Australian system, such as a single regulatory body in Australia and a feasible route from the laboratory to field trials and beyond. Some concern for what "low risk" may mean in practice.	9(2)(ba)(i) "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." "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	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. The risk tier system should be specified by the HSNO Act but maintained outside of the Act as a regulation or standard. The Risk tiers 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

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				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."	Standard that can be updated by the EPA without recourse to parliament. 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.
4	Do you agree with the issues outlined? Would you add any issues to the list? Why?	77/17/6	• Desire to ensure the rules match the risk. • Consider Taonga species – which means not necessarily aligning with Australia in all cases. • Concern that giving compliance of risk tier 1 to the researchers and/or lab facility managers which will add to the administration burden and management risk, which may prevent these activities from happening. • Allow technical experts the opportunity to discuss the risk of these organisms and activities. • Consider how non GM NOs may be affected	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. 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.	"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."

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					"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."
5	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?		Explicitly including gene editing into the text. **Risk Teir 1 in PC1** 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. This would prevent citizen science and education opportunities. 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.	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. 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.	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 with an automated approval process for risk tier 1 through a system such as the calculator/decision making tool like the Hazardous Substances Calculator would be beneficial to quickly gain feedback for any organisms/processes that are not included in the online tool. 9(2)(ba)(i)
Proposal 1.1: Biosafety committees					

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
6	Do you agree with the proposed establishment of accredited biosafety committees and an Environmental Protection Authority biosafety committee?	54/23/23	Concerns included the following: • What will be the process, structure and makeup of ABSC? • Questions about location and regional decision making • Auditing of ABSC is appropriate • Questions surround of conflict of interest and independence • Is this only a transfer of bureaucracy from EPA to institutes – require guidance and support • Concern about how to best incorporate Tangata Whenua perspectives, especially around taonga species and regional decision making • The access of small organisations to an ABSC, given there may not be resources from the bigger institutes. • The ABSC are staffed by researchers, who now have a different compliance role – this doesn't save time or resources	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 institution's research excluding other institution's projects. Accountability, lack of oversight and final decisions of risk tiers would play a big role in the decision. Furthermore, we would like to reiterate the importance of iwi consultation in this scenario. Different iwi in different part of the country might be required for the consultation, making it more difficult 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. 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	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. 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. 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.

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				in different locations been considered? Engaging with multiple parties across Aotearoa New Zealand could elicit significant and/or prohibitive costs for small projects. 9(2)(ba)(i) [redacted]	
7	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?		• Ability for ABSC to assign NO to risk tiering • Only audit higher level risk category • Mandate ABSC for larger organism • Winding back regulatory creep would be the best approach • Make approvals facility/researcher based	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. 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). Maintaining approval through the EPA but reducing the application requirements for	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.

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				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).	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.
Proposal 2: Reduce the assessment and approval requirements for medicines that are, or contain, new organisms					
8	Do you agree with the proposed changes: to streamline assessments under section 38I of the Hazardous Substances and New Organisms Act 1996, to introduce an alternative assessment pathway for medicines unlikely to result in viable new organisms from being released into the environment, and to enable rapid assessment of medical devices?	66/8/26	• Additional clarity around when the application would be declined. • Agree is appropriate – faster is beneficial • Will still require assessment by MedSafe and SCOTT • Process should be aligned with Australia • Concern that there could be unintended consequences (by scientific community) • Concern that there has not been enough thought in the proposed changes – is there strong scientific evidence to agree with the change? • Should be extended to NO, not just GMOs	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 effort. The situation significantly more complicated for live veterinary vaccines. Significant 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	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. 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 profile to the host organisms that are already listed within an Approval, enabling Approvals to be more readily

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				assessment of risk is likely to be neither simple nor rapid….In summary, EDS considers that, collectively, these proposals require much more focused thought and analysis. Detailed discussion with Australian regulatory authorities could be helpful. Formulating a joint New Zealand / Australian approach to these rather complicated issues is des" 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 scientific content in the Impact Assessment contained in the Appendix confirms our view 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.	future-proofed. Research communities would benefit 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, EPAs interpretation of what is minor in effect under the s67A amendment process has become more restrictive in that the s67A approval process can only be used for Correcting typographical or drafting errors in an Application. Even the EPA's website states that amendment allows changes to a new organism approval after it has been given but only if the change is minor in effect. We propose that the EPA restores its previous interpretation of what is considered a minor in effect amendment. Amendments could then include changes of vector or techniques not specified in the original application. A requirement would be that the amendment does not increase the risk of work described in the original Application." 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

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					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. As 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.
9	Do you agree with the issues outlined? Would you add any issues to the list? Why?	71/11/18	Mostly agreed – mostly queries about timeframes and process	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.	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. 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.
10	Are there other policy changes that, in your view,		Mostly a general desire to increase/decrease regulation	Policies should permit development of xenotransplantation to meet the chronic	If the proposed rapid assessment pathway is adopted, we suggest that:-Consideration of

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	would provide more benefits or better meet the objectives than the proposed changes above?			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 that a)as large animals they are not likely to escape from a DPF facility b)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. 9(2)(ba)(i)	viability should be included alongside whether, through shedding or excretion, the new organism is likely to make its way into the environment. 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.
Proposal 3: Replace current record-keeping requirements					
11	Do you agree with the proposal to replace the current record-keeping requirements with a new labelling and accounting requirement?	74/19/7	Excessive support as the current system is considered extremely burdensome. Some comments include:	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	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

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
			• Research requires detailed note taking anyway, and that standard lab record keeping could be used. • Labelling should be based on the risk category – perhaps “per lab” basis for lower risk system • Suggestion for a central record • Concern that reduced requirements will lead to reduced standard of records.	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. 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.	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. 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. Simplifying the record keeping will allow greater efforts 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 notification of organisms being used at Tier 1, and specifically lists those being used at Tier 2 and their relevant ""Approval"" (i.e., ABSC or EPA designation). Tier 3 should use more definitive labelling. If the Approval can be written on the outside of a box containing 81 1.5

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
					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.
12	Do you think labelling requirements should also include that new organisms should be able to be linked to the relevant HSNO Act approval? If not, why?	37/30/33	Reasonably split opinion. Reasons for were lacking (asides from generic comments about traceability) in the comments, but reasons against were: • Size of labels and complexity of number introduces errors • Lower risk for lower tier organisms and therefore should be exempt (but yes for higher risk) • There should be a system that links the sample to the HSNO number, it just may not need to be on the container – perhaps a computer. • Would it apply to packaged medicines? Traceability is important	This is impractical for small containers and something that should be accessible from a central record. It's doable but seems impractical. 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. 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.	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. 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 ABSC'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.
13	Do you agree with the issues outlined? Would you add any issues to the list? Why?	76/11/14	Most comments agreed with the issues outlined. I've put in the most critical comments in "good points – non- technical" and comments that agree or think the proposal could go further in the "good points – technical"	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	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

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				just like to complain. And I can know, because I am one of them. I'm 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. 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.	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. 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.
14	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?		Remove labelling from lower risk tier organisms and spend the time on training. Emphasise the differences – especially in HSNO controls/ Implement a central database – will allow for less paper in PC1/2 facilities.	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. I'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	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. 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

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				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. 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.	administrative/mechanical controls) and/or where an organism is a higher risk to the environment/community.
Proposal 4: Adjust internal audit frequency to be proportionate to risk					
15	Do you agree with the proposed change: to reduce the internal audit frequency requirement for containment facilities operating at Physical Containment level 1 (PC1)?	63/14/22	Mostly agreed – those who do the audits were more likely to want to keep a higher level of audits. Suggestions for less audits for continued compliance and a risk based approach based on the activity and size of the lab. Also suggestion that audits should reduce for PC2 facilities. **Quality of audits** Some desire for the audits to be of laboratory space and for audits to be of a high quality. Desire also to ensure that follow up of issues. Otherwise, no point to audit.	"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." While the audits do take time, and can be quite stressful because of the unknown range of expectation (another issue), they do offer the chance for people to review practices and make improvements if necessary.	"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."

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
16	Do you agree with the issues outlined? Would you add any issues to the list? Why?	77/20/3	Most agreed Some comments that audits shouldn't be focussed on paperwork and more on the systems used. Some comments about the physical laboratory space should only need auditing at the time of building.	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, 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?	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 to 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. PC containment facilities 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 facilities™ 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 Act'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.

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
17	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?		• Frequency of audits for PC1/PC2 should be risk based. • There should be more audits for those who fail previous audits • Reduction in paperwork and administrative load • Alignment with other systems	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. 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.	PC1/PC2 facilities that have good track records/regulator trust should be able to have the external verification 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 specific point of compliance. In addition, as the breadth of risk of work undertaken for Physical Containment level 2 (PC2) is wide, the risk profile of the work conducted within the PC2 facility should determine whether the facility receives six-monthly or yearly audits.
Proposal 5: Adjust the requirements for the movement of new organisms to be proportionate to risk					
18	Do you agree with the proposed change: to remove movement authorisation requirements for laboratories, and containment facilities operating at PC1, provided specific conditions are met?	73/19/8	Strong sentiment in agreement – especially around paying the invoices to MPI and the paperwork required. The use of “unbreakable” was not appreciated.	“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 deemed 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	“Yes and No. Risk tier 1 organisms have no need for regulation during transfer, as they still, even outside of a laboratory, 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 unbreakable

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				present microbe list. One organisation should not bear the cost of time and money of going through the denewing process as inclusion on the list also benefits other organisations.	has been challenged numerous times. I strongly suggest a more sensible way of defining the requirement of container's robustness is found. For example, the USDA-APHIS uses this definition: Shipment 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 transportation."
19	Do you agree with the issues outlined? Would you add any issues to the list? Why?	69/29/2		"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." (later suggested that the requirement to label it a GMO should be removed) "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."	
20	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed option above?		Movement should be based on the risk tiering – the higher the tier, the stricter the movement		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

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					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.
Proposal 6: Reduce regulatory requirements for the use of eukaryotic somatic cells					
21	Do you agree with the proposed change: to include certain eukaryotic somatic cells under risk tier 1 of the risk-tiering framework outlined in Proposal 1?	65/15/20	• General agreement • Some concern that somatic cells can be reprogrammed and turned into organisms, while others not this is unlikely to occur. • Some concern that the wording is not appropriate and needs to be addressed further. One example given in “good points - technical”	Some somatic cells can be reprogrammed to haploid state – suggest that it could be unwise to include animal, plant and fungal cells. It would be difficult to identify whether a researcher has regenerated viable diploid transgenic organisms. 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	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: “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” and “if the donor nucleic acid includes a viral sequence, it cannot give rise to infectious agents when introduced into any potential host species.” appear contradictory since the first prohibits the second. It would be better stated: “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, unless the donor nucleic acid includes is a viral sequence, which cannot give rise to infectious agents when introduced into any potential host species.” The condition that “The donor nucleic acid must not code for a toxin with an LD50 of less than 100

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
				hard just trying to keep them alive in the lab. The current EPA review approval process is a barrier to entry for overseas companies wanting to commercialise these treatments in New Zealand. 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.	micrograms per kilogram" 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. 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.
22	Do you agree with the issues outlined? Would you add any issues to the list? Why?	62/29/10	General agreement – some concern about scope and/or leaving plants in/out/	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.	"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

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					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 modified 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 artificial 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." Donor nucleic acid must not be derived from organisms implicated in or with a history of causing disease - 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.

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					"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 genes or other genetic material that contribute to disease. "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 spontaneously 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 spontaneously regenerate. Perhaps some consideration of the wording here without significant human intervention and some description as to what this involves, and also a reasonable expectation the plant cells in tissue culture do not form plants.
23	Are there other policy options that, in your view, would provide more benefits or better meet the objectives		Mostly similar to above	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	Yes. Condition 5 would be better expressed as: "The plant cells or tissues cannot spontaneously generate a whole plant and must not be regenerated into a whole plant." The reason for

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
	than the proposed change above?			believe that consideration should be given to whether eukaryotic somatic cells that cannot survive outside culture conditions (without considerable human input) are organisms.	the change in condition 5 is that the word "cannot" s 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.
Proposal 7: Clarify the regulatory status of certain biotechnologies					
24	Do you agree with the proposed change: to clarify the regulatory status of the introduction of ribonucleic acid (RNA) into an organism, the introduction of deoxyribonucleic acid (DNA), and epigenetic modifications under the HSNO Act?	61/28/11	General agreement but clarification of scope required	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. 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 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	"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." "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."

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
				fact that under current NZ legislation, eukaryotic somatic cells are defined as "organisms" under section 2(1) of the HSNO act, and so may actually be about deregulating cell lines that would otherwise come into NZ as "new organisms" 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 "organism" under section 2(1) of the HSNO Act 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 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).	
25	Are there any exclusionary criteria that, in your view, should or should not be associated with any of these three biotechnologies?				Two other processes should also be considered for clarification and/or exclusion. The first are "null-segregant" 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

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					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.
26	Do you agree with the issues outlined? Would you add any issues to the list? Why?	72/19/8	Consideration needs to be given about how to regulate Epigenetics that can give rise to inheritable changes.	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 changes. Under the proposal for epigenetic modifications, we feel that there should be more thought around what epigenetic modifications would be exempt from GMO regulations. “Epigenetic modifications” is an extremely broad category - what types of modifications, in what specific contexts, or with what sort of impacts, would be regulated or exempt?	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).
27	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above? In your view, should the status of any other biotechnologies be clarified under regulations?		Lots of ideas: • Don’t forget other regulatory regimes – such as ACVM Act – and the safeguards they bring. Must be a way to ensure new technologies can be put into the HSNO Act. • It would make more sense to me to get rid of the exceptions for chemical mutagenesis and cell	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?	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

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			fusions and fold them into the GMO regulation. • Reduce the regulation of organisms that cannot survive without supplementation of specific nutrients, such as E.coli that require such nutrients to survive. • The status of biotechnologies should be reviewed at regular interval to reflect the current knowledge. • Concern about whether specifying epigenetic modifications as NO is wise, given the environment can also affect the genetic expression. • Clarify whether a bacterium carrying a engineered plasmid is no longer a GMO. • Production of modified cells to be reintroduced into a patient. Differentiation of patient cells to produce new cells for implantation • Mutagenesis techniques should be considered under the same regulatory umbrella. • Regulate the product, not the process • Null-segregants gene edited organisms (where that modification could have occurred naturally) should also be excluded • Clarifying the regulatory status of siRNA in vivo therapies. • Don't limit the introduction of DNA into laboratory organisms. (classical Transformation, Transfection, Transduction) Make these points	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. 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.	(For instance, https://doi.org/10.1038/ncomms4904). The first are null-segregant 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. 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.

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
			specific to vaccines or use in humans. • 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. • 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. • Some additional consideration should also be given to the impact of epigenetic modifications that may create/increase virulence and toxicity of the organism. • We would suggest clarifying the regulatory status of siRNA in vivo therapies. • Epigenetic modifications is an extremely broad category - what types of modifications, in what specific contexts, or with what sort of impacts, would be regulated or exempt?		
Proposal 8: Reduce assessment requirements for low-risk fermentation					
28	Do you agree with the proposed change: to remove EPA assessment and	80/12/8	Strong desire to align the fermentation requirements to the other criteria, based on there not necessarily be a spill risk.		Assessment by a Biosecurity Committee is appropriate for controlling the additional risks of large scale fermentation, however, I would favour

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
	approval requirements for fermentation of GMOs meeting the criteria of risk tiers 1 to 3?				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.
29	In your view, do you think that the current maximum vessel size not requiring EPA assessment and approval (10 litres) should be increased?	70/9/21	Strong desire to increase vessel size, especially those involved in pilot plants. Many comment that the volume appeared arbitrary.	It isn't clear why the 25 L volume used in Australian risk tiering shouldn'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). 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.	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. Would it affect all types of fermentation?
30	Do you agree with the issues outlined? Would you add any issues to the list? Why?	75/19/6	No significant comments given that wasn't already covered		
31	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?			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	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. 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

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				sufficiently prepared to manage a spill from vessels of this size. (note another submitter said 10L is pilot scale fermentation)	2 organisms a means of containing the full volume (e.g., bund, holding tank) for subsequent treatment or destruction should be sufficient.
Proposal 9: Maintain or adjust the approach to standards for containment facilities					
32	Of the three options presented above, which is your preferred option and why?	16/25/59 Status quo/outcome based/hybrid	The majority of feedback was positive for a hybrid approach. There was a desire to have a prescriptive approach to fall back on, but the ability to make their own rules. Hybrid allows for easy compliance for small operators, with ability for larger operators to do their own thing. Also - interesting idea for prescriptive standards for infrastructure and hybrid for operational purposes.	"A hybrid approach, where prescriptive controls are available but effects-based controls are permitted where justified, provides both certainty and flexibility." "Using international standards will allow for easier transfer of goods overseas. Containments facilities are expensive to construct and maintain so should be consistent." "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. " "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 different 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."	"We advise consultation with Australia on the impact on facilities as they work through changes to their regulations. " "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."

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
33	Do you agree with the issues outlined? Would you add any issues to the list?	73/8/19	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.		"In a number of cases organisations have chosen to "plus one" 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."
34	Do you run a facility that is approved as both a containment facility and a transitional facility? Would the costs of a shift to outcome-based or hybrid standards for new organisms outweigh any benefits to you or those who use your facilities?	15/21 Yes/no	The cost of the status quo would be the least. Otherwise, the least amount of change will cost less. Prescriptive standards will reduce compliance cost of outcome based.	"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." 9(2)(ba)(i) [redacted]	.
35	Are there other policy options that, in your view, would provide more benefits or better meet the objectives			"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	

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
	than the three options above?			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."	
Proposal 10: Require regular reviews of regulatory settings					
36	Do you agree with the proposed change: to require the Ministry for the Environment to review the regulatory settings for GMOs at least every five years?	90/10/0	General agreement to review every five years, with some suggestion that technology moves so quickly that five years may not be sufficient. Would prevent adverse effects of not regulating things.	Desire to allow organisms to move risk tier more quickly – perhaps annually.	
37	Do you agree with the proposed frequency of reviews (that is, at least every five years)?	66/24/10	On balance, the majority of feedback said that five years appropriate. No one suggested longer timeframe.	Quicker review times will allow for faster adoption of technology but will create additional regulatory burden for businesses changing to the conditions.	
38	Do you agree with the issues outlined? Would you add any issues to the list? Why?	92/8/0	Issues broadly agreed with		
39	Are there other policy options that, in your view, would provide more benefits or better meet the objectives than the proposed change above?		Some options that would allow for quicker change of rules if needed.	Risk based on outcome vs risk based on method is appropriate. Put the tier list outside of Acts of Parliament – perhaps like EPA notices. Have a specific expert committee take over this review Live feedback options or quicker turnaround time	
Appendix 1: Other options considered					
40	Of the alternative options outlined, are there any that,		Most alternative proposals that were commented on were thought to be	Proposal 6: Defining isolated and tissue cultured eukaryotic cells as "not an	**Internal audits**

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
	in your view, would provide greater benefits or better meet the objectives of this policy work than the proposed changes under each proposal?		reasonable, with an emphasis on the idea that making it easier to focus on risks that occurred rather than compliance was appropriate.	organism" 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). 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.	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. 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 aren't carried out annually, in fact far from it. Most were only visited and inspected once during the ~ 5-year period, the remainder not 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. We do note however that more responsibility is placed on the biosafety committees in Australia than is proposed here Movement of new organisms: the proposal should be extended to PC2 with the requirement

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
					that MPI is notified if the shipment is lost or damaged in transit. Proposal 4 - 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.
Appendix 2: Impacts of each proposal					
41	In your view, have we overlooked any costs, benefits or risks for any of the proposals presented in this document?		General risks raised associated with the loosening of compliance requirements, audit resourcing and the "relaxing" of compliance approach.	"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." "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"	"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." "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."
Appendix 3: The Australian risk-tiering framework					
42	Are there aspects or specific criteria of the Australian risk-tiering framework that in your view should or should not be included in any New Zealand risk-tiering framework?		Strong desire to reduce the risk tiering of plants and plant materials – see separate comments Suggested more animal types to be in PC1 conditions, especially agricultural animals – see separate comments. The inclusions/exclusions should be revisited and makes sure are fit for purpose in NZ.	"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."	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

Questions		% yes/no/unsure	General comments on the views put forward	Good points – non technical	Good points – technical and relating to certain organisms
			Taonga species need to be considered. “It may not require a change in PC level but may require additional consideration by ABSCs”		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. Risk tier 1Part 1Item2 Why is C. elegans specifically highlighted as exempt when other similar organisms might offer the same low risk? Item 4 (2) (ii) says the donor DNA must be “characterised” 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 help.

Appendix 3 comments

Australian risk tiering and GMO plants

We do not think the Australian risk-tiering framework is adequate for dealing with GM plants. 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. 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.

I strongly believe that GM plants should fit into this category (GMOs suitable for PC1) since they are significantly less likely to escape containment in the first place and much easier to track. That is, most GMO plant material should by default be considered suitable for PC1. There is a very low risk of plant material escaping 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. 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.

Part 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.

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 plant'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 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 weedy and most of the research carried out on plants will have no impact on their weediness. The US-EPA and USDA regulations for GM plants are quite well developed for regulating weed 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.

Animals in PC1

Risk tiers 2 and 3Schedule 3Part 1 GMOs suitable for PC1 This section lists several organisms as suitable for PC1 unless they have “selective advantage” 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? I believe this section needs to be expanded to include several other lab model organisms eg zebrafish, drosophila etc and include domesticated animals and agriculturally important species. Part 2 defines GMOs that should be in PC2 Again, 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.

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.
"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.