Environmental Protection Authority
Te Mana Rauhī Taiao

New Zealand Government

MEMORANDUM

Application	APP204024
Applicant	Hopkirk Research Institute, AgResearch Ltd, Palmerston North
To	HSNO Decision making Committee
Purpose of the Memorandum	Information to support the consideration of application APP204024
Date of Advice	29 September 2020

Purpose

1. This memo provides information to support your consideration of Application APP204024 and provide you with guidance around proposed controls. This memo is intended to be read in conjunction with the draft Decision.

2. The decision path for this application can be found in Appendix One of this memo.

The application

3. The application from the Hopkirk Research Institute (the applicant) seeks approval to develop in containment the bacterium, *Mycoplasma bovis* (*M. bovis*) to develop diagnostic tests. To do this they require the ability to propagate New Zealand-sourced strains of *M. bovis* in their enhanced containment facility. As *M. bovis* has been classified as an Incidentally Imported New Organism (IINO)[1], an approval from the EPA is required to develop[2] them.

4. The application was formally received on 10 September 2020. It was decided that the application did not warrant public notification as it did not meet the threshold of 'significant' public interest.

---

[1] As defined in section 2(1) of the HSNO Act, incidentally imported new organism means a new organism that is imported in or on goods, but is not

a) an essential or constituent part of those goods

b) imported in or on the goods with the intention of concealing the presence of the new organism

c) a genetically modified organism

[2] As set out in the Interpretation section (2(1)) of the HSNO Act, develop – in relation to an incidentally imported new organism – means the deliberate isolation, aggregation, multiplication or other use of the organism.

Comments from external agencies

5. The applicant has previously obtained a section 52 permission from MPI under the Biosecurity Act 1993, and a Chief Technical Officer (CTO) approval (see Appendix 1 of the application) to move *M. bovis* samples to their containment facility for diagnostic testing. This is due to the status of *M. bovis* as IINO, an Unwanted Organism and regulated pest (see Appendix 1 of the application).

6. In accordance with section 58(1)a of the HSNO Act, the Department of Conservation (DOC), and the Ministry of Primary Industries (MPI) were provided with the draft application at the pre-application stage (with the applicant's permission) and also following formal receipt of the final application.

7. DOC commented at the pre-application draft stage that they had no objections to the application.

8. MPI's comments, during the pre-application stage, related to the requirement for a s53 approval under the Biosecurity Act 1993 that the applicant would also need and this is now mentioned by the applicant in section 9. Other comments relating to the clarity of language and containment of the microorganism were addressed by the applicant in the final application. Other containment concerns raised by MPI will be specific to their biosecurity requirements and the Biosecurity Act s53 permission that they intend to issue to the applicant. Following a final review after formal receipt of the application, MPI noted that taking into account the nature of the proposed activities in the application and risks associated with these, MPI considers that the proposed containment will manage the risks.

The organism

9. The applicant wishes to conduct research with the new organism, *M. bovis*, that has been isolated from the New Zealand environment. This will include the "deliberate isolation, aggregation, multiplication or other use of the organism" for the development of diagnostic tests to aid in the detection of infected cattle.

10. Mycoplasmas are some of the smallest known bacteria and are characterised by their lack of cell wall, low genomic guanosine + cytosine content (23%-40%) and small genome size (0.58-1.4 Mbp). Although there are a number of *Mycoplasma* species that infect cattle, *M. bovis* is associated with pneumonia and mastitis in cattle and is an important economic burden for the livestock industry (Parker et al. 2018, Bürki et al. 2015a).

11. The species *M. bovis* (Mollicutes: Mycoplasmatales: Mycoplasmataceae) is an obligate pathogen and therefore relies on a mammalian (mainly bovine) host to survive and complete its life-cycle, hence the incidentally imported nature of the new organism. The organism is generally closely associated with the host cells (mucosal surfaces of the respiratory and urogenital tract for instance) and there is also an intracellular aspect to the organism's lifecycle (Bürki et al, 2015b).

12. The applicant intends to undertake *in vitro* research in their enhanced containment facility using the IINO. Primarily this will involve the use of bacterial and cell culture methods to infect cell cultures with *M. bovis*. The applicant will be undertaking experimental work involving the storage, growth and maintenance of *M. bovis* cultures as well as co-culture of the bacteria *in vitro* with cell lines. This is to better understand whether evidence for the presence of the bacterium can be detected by examining the extracellular material (exosomes[3] for instance) released by infected cells into the cell culture media. The applicant has proposed a level of enhanced containment for

[3] A type of extracellular vesicle produced by a cell and released into the extracellular fluid

this experimental work with viable material. Further analysis of non-viable material will be undertaken at a lower level of containment.

13. It should be noted that internationally, *M bovis* would be considered a risk group 2 pathogen and the levels of containment described by the applicant would be adequate for the containment of the IINO along with the operational controls described for dealing with the handling of the IINO and biological waste in section 4 of the application. *Mycoplasma bovis* does not, under normal circumstances, infect or cause disease in humans, and is therefore unlikely to pose a serious risk to laboratory personnel or the wider community.

14. Due to its historical absence from the New Zealand environment, *M. bovis* has become a problematic microorganism for our beef and dairy cattle. The bacterium is not lethal but results in a number of non-lethal conditions pertaining to animal welfare and productivity and is managed accordingly. As *M. bovis* is an unwanted organism under the Biosecurity Act, the discovery of infected dairy herds in July 2017 triggered a nationwide biosecurity response by MPI, with the bacterium currently the target of a phased eradication program[4].

15. As an obligate pathogen, *M. bovis* "spreads from animal to animal through close contact. Between farms, it spreads through the movement of animals that are infected but may not be showing symptoms. It is also potentially spread on contaminated equipment and the feeding of untreated milk to calves. It is not windborne" (NZ Dairy, 2020). Therefore the potential for herd to herd transmission is subject to a number of potential on-farm practices that are currently being managed under the phased eradication program.

16. The applicant has noted that their facilities meet the minimum requirements for enhanced PC3 containment under *AS/NZ 2243.3:2002 Standard for Safety in laboratories.* The applicant's enhanced containment facilities will need to be inspected and approved by MPI for the handling and containment of *M. bovis* following the approval of both this application to the EPA as well as a s53 approval from MPI required for the development of this IINO. The use of an outcome-based control structure for this application if approved, will also mean that the operation of the containment facility can be adapted to meet the containment requirements and operational procedures deemed necessary by MPI under the Biosecurity Act and allow the applicant to meet the requirements necessary for a CTO permission.

The draft Decision

17. We evaluated this application as being relatively low-risk and straightforward, therefore elected to prepare a draft Decision and this memo to support your consideration, in place of a full Staff Assessment Report

18. The draft Decision is just that, a draft. Alterations, inclusions and/or deletions to the content may well be appropriate or necessary following your consideration of the application.

Proposed controls

19. Section 45(2) of the HSNO Act specifies that an approval must include controls that provide for the matters specified in Schedule 3, and may include controls that provide for any other matters that give effect to the purpose of the Act.

20. The proposed controls are set out in Appendix 1 of the draft Decision. The proposed controls are primarily outcome-focused, specifying outcomes that must be achieved, rather than prescribing a

[4] https://www.biosecurity.govt.nz/protection-and-response/mycoplasma-bovis/what-is-mpi-doing/eradication-decision/

set method by which the outcome must be achieved. This enables the approval user to update their containment measures (design, construction, and management of the facility) to reflect best practice and any new information about the biology of the organism being contained.

21. Appendix Two of this memo sets out the proposed controls against the matters specified in Part 2 of Schedule 3 (*Matters to be addressed by containment controls for new organisms excluding genetically modified organisms*).

22. In addition to those controls in Appendix Two that address the matters in Schedule 3, we propose that **controls 3 and 4** be imposed. **Control 3** requires that the approval user document the technical and operational policies and procedures that they will implement to meet the controls and the quality control measures they will use to ensure those policies and procedures are effective in achieving the outcomes set out in the controls (ie, containment of *M. bovis*). **Control 4** requires that the containment facility where *M. bovis* is held is to be operated in compliance with the documentation specified in **control 3**.

Risks and Benefits

23. We consider that the risks associated with developing *M. bovis* in containment are not significant. The applicant already has demonstrated considerable experience in the environmental isolation and safe handling of the bacterium in their containment facility. The potential benefit of developing a novel diagnostic assay to help better detect and manage infected herds is readily apparent.

Conclusion

24. There are no issues we would like to bring to the attention of the Committee.

25. We recommend that this application meets the requirements of section 45, and therefore can be approved, subject to the controls set out in Appendix 1 of the draft Decision.

[redacted] Date

Senior Advisor, New Organisms Group
Hazardous Substances and New Organisms

References

Bürki S, Frey J, Pilo P 2015a. Virulence, persistence and dissemination of Mycoplasma bovis. Vet Microbiol 179(1-2): 15-22.

Bürki S, Gaschen V, Stoffel MH, Stojiljkovic A, Frey J, Kuehni-Boghenbor K, Pilo P 2015b. Invasion and persistence of Mycoplasma bovis in embryonic calf turbinate cells. Vet Res 46(1): 53.

Parker AM, Sheehy PA, Hazelton MS, Bosward KL, House JK 2018. A review of mycoplasma diagnostics in cattle. J Vet Intern Med 32(3): 1241-1252.

NZ Dairy. 2020. What you need to know about the Mycoplasma bovis infection. Retrieved from https://www.dairynz.co.nz/animal/cow-health/mycoplasma-bovis/

Appendix One: Decision path for applications to develop or field test any NO (non GMO) in containment (application made under section 40 of the Act and determined under section 45 of the Act)

Context

This decision path describes the decision-making process for applications to develop or field test any new organism that is not a GMO in containment. These applications are made under section 40 of the HSNO Act, and determined under section 45 of the Act. Applications to develop a new organism in containment require consideration of section 43 (including sections 41 and 37), and applications to field test a new organism require consideration of section 44 (section 37 plus the ability of the organism to escape from containment). Section 37 refers to the ability of the organism to form an undesirable self-sustaining population and ease of eradication.

Introduction

The purpose of the decision path is to provide the HSNO decision maker[5] with guidance so that all relevant matters in the HSNO Act and the Methodology have been addressed. It does not attempt to direct the weighting that the HSNO decision maker may decide to make on individual aspects of an application. In this document 'section' refers to sections of the HSNO Act, and 'clause' refers to clauses of the EPA Methodology.

The decision path has two parts:

- Flowchart (a logic diagram showing the process prescribed in the Methodology and the HSNO Act to be followed in making a decision), and

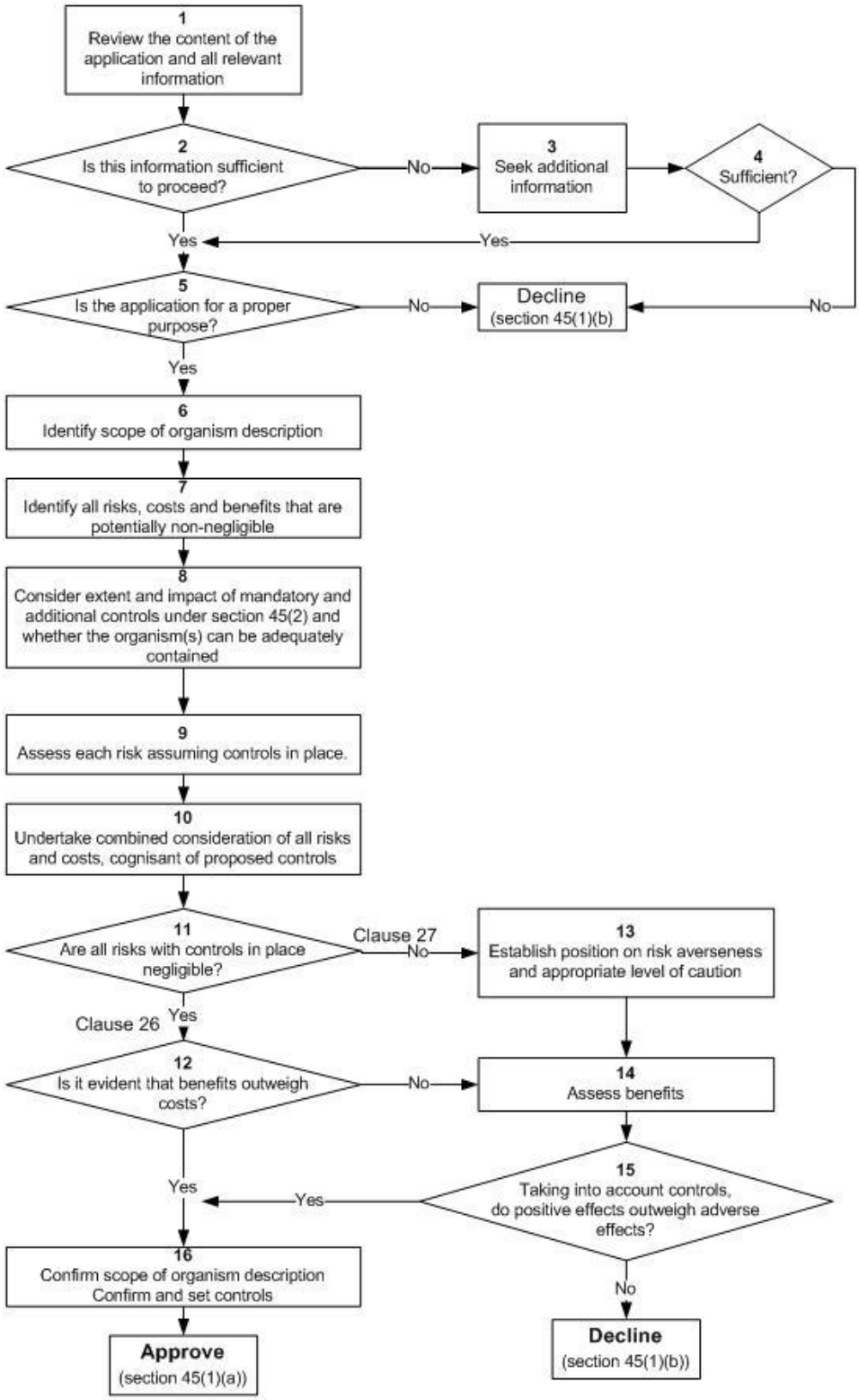
- Explanatory notes (discussion of each step of the process).

Of necessity the words in the boxes in the flowchart are brief, and key words are used to summarise the activity required. The explanatory notes provide a comprehensive description of each of the numbered items in the flowchart, and describe the processes that should be followed to achieve the described outcome.

[5] The HSNO decision maker refers to either the EPA Board or any committee or persons delegated from the Board.

Flow Chart: Decision path for applications to develop or field test any NO (non GMO) in containment (application made under section 40 of the Act and determined under section 45 of the Act)

For proper interpretation of the decision path it is important to work through the flowchart in conjunction with the explanatory notes.



Explanatory Notes

An application may be for a single new organism, or for a variety or range of new organisms where the boundaries of the extent of modifications envisaged are well defined. In both of these cases organisms having similar risk profiles should be grouped into categories. Each category should be considered separately via the path below.

Item 1:	**Review the content of the application and all relevant information** Review the application, the E&R Report (or draft decision and EPA staff advice), and information received from experts and that provided in submissions (where relevant) in terms of section 40(2) of the Act and clauses 8, 15, 16 and 20 of the Methodology.
Item 2:	**Is this information sufficient to proceed?** Review the information and determine whether or not there is sufficient information available to make a decision. The Methodology (clause 8) states that the information used by the HSNO decision maker in evaluating applications shall be that which is appropriate and relevant to the application. While the HSNO decision maker will consider all relevant information, its principal interest is in information which is significant to the proper consideration of the application; ie information which is "necessary and sufficient" for decision-making.
Item 3:	**(if no) Seek additional information** If there is not sufficient information then additional information may need to be sought from the applicant, the EPA staff or other parties/experts under section 58 of the Act (clause 23 of the Methodology).
Item 4:	**Sufficient?** When additional information has been sought, has this been provided, and is there now sufficient information available to make a decision? If the HSNO decision maker is not satisfied that it has sufficient information for consideration, then the application must be declined under section 45(1)(b). Under section 40(4) of the Act the applicant may choose to withdraw the application at any time.
Item 5:	**(If 'yes' from item 2 or from item 4) Is the application for a proper purpose?** Section 39(1) of the Act specifies the purposes for which the HSNO decision maker may approve the importation of a new organism. If the application is not for one of the purposes listed under section 39(1) then it must be declined.
Item 6:	**Identify scope of organism description** Clearly identify the scope of the organism description. Particular attention should be paid to whether the application is for a single new organism or a variety of new organisms as referenced in the Introduction to these notes. Exclusions may be used to sets bounds on the scope of the organism description where a range or variety of new organisms is being considered.
Item 7:	**Identify all risks, costs and benefits that are potentially non-negligible[6]**

[6] Relevant effects are **marginal effects**, or the changes that will occur as a result of the organism(s) being available. Financial costs associated with preparing and submitting an application are not marginal effects and are not effects of the organism(s) and are therefore not taken into account in weighing up adverse and positive effects. These latter types of costs are sometimes called 'sunk' costs since they are incurred whether or not the application is successful.

	Costs and benefits are defined in the Methodology as the value of particular effects (clause 2). However, in most cases these 'values' are not certain and have a likelihood attached to them. Thus costs and risks are generally linked and may be addressed together. If not, they will be addressed separately. Examples of costs that might not be obviously linked to risks are direct financial costs that cannot be considered as 'sunk' costs (see footnote 1). Where such costs arise and they have a market economic effect they will be assessed in the same way as risks, but their likelihood of occurrence will be more certain (see also item 12). Identification is a two step process that scopes the range of possible effects (risks, costs and benefits).	
	Step 1:	Identify all risks and costs (adverse effects) and benefits (beneficial effects) associated with the approval of the organism(s), and based on the range of areas of impact described in clauses 9 and 10 of the Methodology and sections 5 and 6 of the Act[7]. Relevant costs and benefits are those that relate to New Zealand and those that would arise as a consequence of approving the application (clause 14). Consider short term and long term effects. Identify situations where risks and costs occur in one area of impact or affect one sector and benefits accrue to another area or sector; that is, situations where risks and costs do not have corresponding benefits.
	Step 2:	Document those risks, costs and benefits that can be readily concluded to be negligible[8], having regard to the characteristics of the organism and the circumstances of the application, and eliminate them from further consideration. Note that where there are costs that are not associated with risks some of them may be eliminated at this scoping stage on the basis that the financial cost represented is very small and there is no overall effect on the market economy.
Item 8:	**Consider extent and impact of mandatory and additional controls under sections 45(2) and whether the organism(s) can be adequately contained** Section 45(2) requires the application of controls for all applicable matters specified in the 3rd Schedule (Part II). The HSNO decision maker may consider other controls to give effect to the purpose of the Act. The impact of these controls also needs to be considered. Section 45(1)(a)(iii) requires the HSNO decision maker to be satisfied that the organism can be "adequately contained". The concept of adequate containment includes the satisfactory biological and/or physical containment of the organism and also the ability of the applicant to apply and maintain all the controls satisfactorily.	
Item 9:	**Assess each risk assuming controls in place** The assessment of potentially non-negligible risks and costs should be carried out in accordance with clauses 12, 13, 15, 22, 24, 25, and 29 to 32 of the Methodology. Most of these risks and costs will relate to matters in sections 5 and 6 of the Act. In undertaking this assessment the HSNO decision maker must take into account the principles of the Treaty of Waitangi (section 8, and clause 9(c)(iv)).	

[7] Effects on the natural environment, effects on human health and safety, effects on Māori culture and traditions, effects on society and community, effects on the market economy.
[8] Negligible effects are defined in the Annotated Methodology as "Risks which are of such little significance in terms of their likelihood and effect that they do not require active management and/or after the application of risk management can be justified by very small levels of benefits".

The assessment is carried out with the controls in place. It should consider the following three matters that have particular relevance for this type of application.

1. The ability of the organism to escape from containment (section 44)

Although strictly speaking, this requirement applies only to field test applications and not to development applications (see section 45(1)(a)(ii)), it is prudent and good practice to consider it anyway. This element must be considered in an integrated way in the assessment process because the ability to escape depends on the containment controls set.

2. Self-sustaining population (section 37).

Section 37 of the Act requires the consideration to have regard to the ability of the organism to establish an undesirable self-sustaining population and the ease of eradication if it were to establish such a population. Undesirable means (in effect) able to create significant risks.

3. Additional matters

Other matters to be considered in the assessment are:

- the extent to which the risk will be mitigated by the setting of containment and other controls, including the mandatory controls in the Act; and
- the extent to which the risk will be mitigated by the ability to eradicate the organism if it becomes established.

Assess each potentially non-negligible risk and cost estimating the magnitude of the effect if it should occur and the likelihood of it occurring considering also the level of risk if containment or other controls fail, as well as the probability of such a failure. In estimating the magnitude of the adverse effect take into account the extent to which the risk might be mitigated by how or whether it might be possible to eradicate the organism if a significant adverse effect eventuated (section 37). When estimating the likelihood of the effect occurring, consider the full pathway, that is, all the possible steps that must occur before the final identified effect is realised. Estimating the likelihood requires combining (multiplying) all of the individual likelihoods for each link in the chain of events.

Where there are non-negligible financial costs that are not associated with risks then the probability of occurrence (likelihood) may be close to 1. Relevant information provided in submissions should be taken into account.

The distribution of risks and costs should be considered, including geographical distribution and distribution over groups in the community, as well as distribution over time. This information should be retained with the assessed level of risk/cost.

Approach to risk and approach to uncertainty

Consider the HSNO decision maker's approach to risk (clause 33 of the Methodology) or how risk averse the HSNO decision maker should be in giving weight to the residual risk, where residual risk is the risk remaining after the imposition of controls.

The risk characteristics set out in clause 33 are:

Exposure to the risk is involuntary:

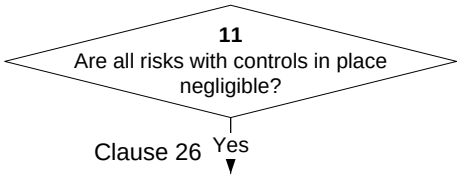
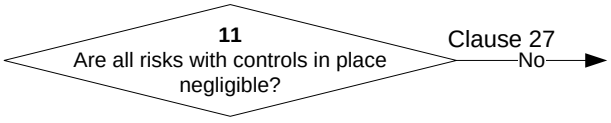
(a) The risk will persist over time:

(b) The risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence:

(c) The potential adverse effects are irreversible:

(d) The risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects.

	Consider each non-negligible risk in terms of the factors listed and decide whether to be risk averse by giving additional weight to that risk. This may be done as part of estimating the magnitude of the effect or where this is not relevant, it may be done separately. Where the HSNO decision maker chooses to be risk averse, and there is uncertainty as well, the approach to risk may be consolidated with the approach to uncertainty by adopting a conservative approach such as the worst feasible case scenario.
	The assessment includes consideration of how cautious the HSNO decision maker will be in the face of uncertainty (section 7 and clauses 29-32). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the adverse effect as a means of identifying the range of uncertainty (clause 32). It is also important to bear in mind the materiality of the uncertainty and how significant the uncertainty is for the decision (clause 29(a)). For each component (magnitude and likelihood) consider the degree of uncertainty associated with the estimation of each component. In some cases it may be clear that the uncertainty could be reduced by gathering further information (undertaking more scientific tests, or extending the literature search). Before requesting or seeking further information it is important to consider how important the uncertainty is in terms of the decision (clause 29(a) – materiality), and to essentially consider the cost-effectiveness of gathering further information. Another approach to addressing uncertainty is to look at a range of scenarios and consider a best feasible-worst feasible scenario range. However, where there is a large degree of uncertainty, this may not be particularly meaningful for calculating the level of risk. In other cases, calculating the level of risk for each end of the range may result in a fairly similar level of risk. Where this does not occur, rather than presenting a wide range in the level of risk it may be better to concentrate on analysing why the uncertainty occurs and whether or not there is any obvious way of resolving it.
	Additional controls Controls additional to those mandated in section 45(2) of the Act (see item 8) may need to be considered in order to mitigate risks to whatever level is considered to be appropriate, and to provide adequate containment.
Item 10:	**Undertake combined consideration of all risks and costs, cognisant of proposed controls** Once the risks and costs have been assessed individually, if appropriate consider all risks and costs together as a 'basket' of risks/costs. This may involve combining groups of risks and costs as indicated in clause 34(a) of the Methodology where this is feasible and appropriate, or using other techniques as indicated in clause 34(b). The purpose of this step is to consider the interactions between different effects and determine whether these may change the level of individual risks.
Item 11:	**Are all risks with controls in place negligible?** At this point the decision path branches. Looking at individual risks in the context of the 'basket' of risks, consider whether all of the residual risks are negligible. Consider also the cumulative effect of the assessed risks. Where all risks are negligible, and the cumulative effect of the risks is considered to be negligible then take the clause 26 option and move to item 12. If one or more of the risks is considered to be non-negligible, or the cumulative sum of the risks is non-negligible, then take the clause 27 option and move to item 13.

Item 12:	 **(from item 11 - if 'yes') Is it evident that benefits outweigh costs?** Risks have already been determined to be negligible (item 11), therefore the decision must be made under clause 26 of the Methodology. In the unusual circumstance where there are non-negligible costs that are not associated with risks they have been assessed in item 9. Costs are made up of two components: internal costs or those that accrue to the applicant, and external costs or those that accrue to the wider community. Consider whether there are any non-negligible external costs that are not associated with risks. If there are no external non-negligible costs then external benefits outweigh external costs. The fact that the application has been submitted is deemed to demonstrate existence of internal or private net benefit, and therefore total benefits outweigh total costs[9]. As indicated above, where risks are deemed to be negligible, and the only identifiable costs resulting from approving an application are shown to accrue to the applicant, then a cost-benefit analysis will not be required. The act of an application being lodged will be deemed by the HSNO decision maker to indicate that the applicant believes the benefits to be greater than the costs. However, if this is not the case and there are external non-negligible costs then all benefits need to be assessed (via item 14).
Item 13:	 **(from item 11 - if 'no') Establish position on risk averseness and appropriate level of caution** Although 'risk averseness' (approach to risk, clause 33) is considered as a part of the assessment of individual risks, it is good practice to consolidate the view on this if several risks are non-negligible. This consolidation also applies to the consideration of the approach to uncertainty (section 7).
Item 14:	**Assess benefits** Assess benefits or positive effects in terms of clause 13 of the Methodology. Since benefits are not certain, they are assessed in the same way as risks. Thus the assessment involves estimating the magnitude of the effect if it should occur and the likelihood of it occurring. This assessment also includes consideration of the HSNO decision maker's approach to uncertainty or how cautious the HSNO decision maker will be in the face of uncertainty (section 7). Where there is uncertainty, it may be necessary to estimate scenarios for lower and upper bounds for the positive effect.

[9] Technical Guide 'Decision making' section 4.9.3. Where risks are negligible and the costs accrue only to the applicant, no explicit cost benefit analysis is required. In effect, the HSNO decision maker takes the act of making an application as evidence that the benefits outweigh the costs

	An understanding of the distributional implications of a proposal is an important part of any consideration of costs and benefits, and the distribution of benefits should be considered in the same way as for the distribution of risks and costs. The HSNO decision maker will in particular look to identify those situations where the beneficiaries of an application are different from those who bear the costs[10]. This is important not only for reasons related to fairness but also in forming a view of just how robust any claim of an overall net benefit might be. It is much more difficult to sustain a claim of an overall net benefit if those who enjoy the benefits are different to those who will bear the costs. Thus where benefits accrue to one area or sector and risks and costs are borne by another area or sector then the HSNO decision maker may choose to be more risk averse and to place a higher weight on the risks and costs. As for risks and costs, the assessment is carried out with the default controls in place.
Item 15:	**Taking into account controls, do positive effects outweigh adverse effects?** In weighing up positive and adverse effects, consider clause 34 of the Methodology. Where possible combine groups of risks, costs and benefits or use other techniques such as dominant risks and ranking of risks. The weighing up process takes into account controls proposed in items 8 and 9. Where this item is taken in sequence from items 13 and 14 (i.e. risks are not negligible) it constitutes a decision made under clause 27 of the Methodology. Where this item is taken in sequence from items 12 and 14 (i.e. risks are negligible, and there are external non-negligible costs) it constitutes a decision made under clause 26 of the Methodology.
Item 16:	**Confirm scope of organism description** **Confirm and set controls** At this step the scope of the organism description for generic applications should be reviewed. If changes are made to the organism description, items 7-15 above should be repeated for the revised organism description. Then the weighing up process in this item for the revised organism description should also be repeated. The scope of the organism description has been identified in item 6. This step in the decision-making process confirms the scope of the organism description in such a way that the risk boundaries are defined. Controls have been considered at the earlier stages of the process (items 8, 9 and 15). The final step in the decision-making process brings together all the proposed controls, and reviews them for overlaps, gaps and inconsistencies. Once these have been resolved the controls are confirmed.

[10]Clause 13 of the Methodology

Appendix Two: Proposed Controls that address the matters specified in Part 2 of Schedule 3

Schedule 3 (Part 2) Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
1	To limit the likelihood of any accidental release of any organism or any viable genetic material, the controls imposed by an approval shall specify—		
1(a)	Requirements for treatment and decontamination to prevent escape by way of expelled air, discharge of water or liquid waste, removal of solid waste, or breaches in facility boundary:	6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism(s) from escaping.
		7	Persons entering and exiting the containment facility must do so in a way that does adversely affect containment of the approved organism(s).
		14	Unauthorised persons must be excluded from the containment facility.
		17	Any waste (including biological material) that may harbour the approved organism(s), or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to disposal.
		18	Any equipment, that may harbour the approved organism(s) or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to the equipment being used for another purpose or being removed from the containment facility.
1(b)	Equipment and requirements for facility construction to enable the requirements for treatment and decontamination to be readily met:	6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism(s) from escaping.
		17	Any waste (including biological material) that may harbour the approved organism(s), or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to disposal.
		18	Any equipment, that may harbour the approved organism(s) or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to the equipment being used for another purpose or being removed from the containment facility.
1(c)	Requirements to be complied with for the access of persons to the facility:	7	Persons entering and exiting the containment facility must do so in a way that does not adversely affect containment of the approved organism(s).

Schedule 3 (Part 2) Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
		14	Unauthorised persons must be excluded from the containment facility.
		20	Any person (including contractors, staff, students, visitors, and volunteers) entering the containment facility must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities in relation to containment.
1(d)	Procedures and requirements for transport, identification, and packaging for all biological material to and from the facility and within the facility:	5	The containment facility where the approved organisms will be held must be clearly defined, described, and documented, including the location and boundaries.
		8	The approved organism(s) must be identifiable as a new organism and able to be linked to the relevant HSNO Act approval.
		9	Notification must be given to MPI of any intended movement of approved organisms outside of the facility, or any proposed modification to the containment regime which may affect the integrity of containment of the approved organism(s), before the actions are undertaken
		10	The EPA and MPI must be notified in writing before this HSNO Act approval is used for the first time.
		12	The approved organism(s) must be contained during movement within, to, or from the containment facility.
		13	When being moved outside of a containment facility, within New Zealand, the approved organism must accompanied by documentation stating the: a) identity of the approved organism b) containment requirements c) details of the sender d) details of the receiving facility.
1(e)	Requirements for the disposal of any biological material:	17	Any waste (including biological material) that may harbour the approved organism(s), or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to disposal.
		18	Any equipment, that may harbour the approved organism(s) or heritable material from the approved organism, must be treated to ensure that the approved organism or any heritable material is killed prior to the equipment being used for another purpose or being removed from the containment facility.
1(f)	Requirements for facility construction:	1	The approved organism(s) must be contained.

Schedule 3 (Part 2) Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
		6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism(s) from escaping.
		9	Notification must be given to MPI of any intended movement of approved organisms outside of the facility, or any proposed modification to the containment regime which may affect the integrity of containment of the approved organism(s), before the actions are undertaken.
		24	Any remedial requirements identified under control 23, or by any other means, must be actioned as soon as possible.
1(g)	Requirements to secure the facility and openings, including securing against failure in the event of foreseeable hazards.	6	The containment area(s) must be designed, constructed and maintained to prevent the approved organism(s) from escaping.
		14	Unauthorised persons must be excluded from the containment facility.
		19	The containment facility must be secured and monitored to ensure the exclusion of undesirable organisms that might compromise the containment of the approved organism(s).
		23	To ensure containment is being achieved, containment measures must be: a) inspected, monitored and reviewed as appropriate b) inspected as soon as possible after any event that could compromise the containment regime such as an Act of God (such as flood, earthquake) or any unauthorised attempt to enter the containment facility.
2	To exclude unauthorised people from the facility, the controls imposed by an approval shall specify—		
2(a)	Means of identification of all entrances to the facility:	5	The containment facility where the approved organisms may be held must be clearly defined, described, and documented, including their location and boundaries.
		15	All containment facility entrances must be clearly identified including specifying who has the right of access
		16	The number and location of entrances to the containment facility where the approved organism(s) are held must be identified and documented.
2(b)	The numbers of entrances and access to the facility:	5	The containment facility where the approved organisms may be held must be clearly defined, described, and documented, including their location and boundaries.
		16	The number and location of entrances to the containment facility where the approved organism(s) are held must be identified and documented.

Schedule 3 (Part 2) Matters to be addressed by containment controls for new organisms (excluding GMOs)		Addressed by control:	
2(c)	Security requirements for the entrances and the facility.	14	Unauthorised persons must be excluded from the containment facility.
		15	All containment facility entrances must be clearly identified including specifying who has the right of access.
		16	The number and location of entrances to the containment facility where the approved organism(s) are held must be identified and documented.
3	To control the effects of any accidental release or escape of an organism—		
3(a)	Controls imposed by an approval shall specify an eradication plan for escaped organisms:	21	The containment facility must have a documented contingency plan for each approved organism held in that containment facility.
3(b)	Controls imposed by an approval may specify requirements to limit the likelihood of an escaped organism spreading, surviving, and breeding, including, but not limited to,— (i) Exclusion zones (spatial or temporal): (ii) Location of the facility outside the usual habitat range of the organism.	11	MPI must be notified as soon as possible, and within 24 hours, of any escape and/or breach of containment and the actions taken in response to that incident
		21	The containment facility must have a documented contingency plan for each approved organism held in that containment facility.
		22	The contingency plan must be implemented immediately if there is any reason to believe that an approved organism has escaped or been released from a containment area or the containment facility, or any other breach of containment has occurred.
4	Controls imposed by an approval shall specify inspection and monitoring requirements for containment facilities.	19	The containment facility must be secured and monitored to ensure the exclusion of undesirable organisms that might compromise the containment of the approved organism(s).
		23	To ensure containment is being achieved, containment measures must be: a) inspected, monitored and reviewed as appropriate b) inspected as soon as possible after any event that could compromise the containment regime such as an Act of God (such as flood, earthquake) or any unauthorised attempt to enter the containment facility.
5	Controls imposed by an approval may specify the qualifications required of the person responsible for implementing those controls.	2	The organisation, entity or person(s) responsible for the ownership, control and management of the containment facility where the approved organisms are held (including Board members and/or directors) must ensure compliance with the controls of this approval.
		20	Any person (including contractors, staff, students, visitors, and volunteers) entering the containment facility and/or containment areas must have received sufficient instruction on the containment regime to enable the person to meet their responsibilities in relation to containment.