

The Chair, Cabinet

Government Response to the Royal Commission on Genetic Modification: Legislative Changes for New Organisms – Paper 7: Improving the Operation of the HSNO Act for New Organisms Including Zoo and Circus Animals.

Proposal

1. This paper proposes amendments to the Hazardous Substances and New Organisms (HSNO) Act 1996 to complete the transition of the management of zoo and circus animals into the HSNO regime and technical amendments to improve the operation of the Act.

Executive summary

2. The paper proposes amendments to the HSNO Act to improve the operation of this Act in light of experience (particularly experience with new organisms) and to complete the transition of the management of zoo and circus animals into the HSNO regime. These amendments include:

- changing the definition of new organism so that the definition includes but is not limited to ‘species’ as a means of classification
- assessing the fermentation of micro-organisms on risk and not volume
- extending the time for the Environmental Risk Management Authority (ERMA) to publicly notify its decision on an application from 15 days to no more than 30 working days
- removing the minimum 4 day period to comply with a compliance order, replacing it with a time limit that is specific to the application
- deleting the requirement that the compliance order state the last day on which an appeal can be lodged
- the option of giving ERMA the power to declare a new organism ‘no longer new’
- amending the second schedule (prohibited new organisms) to correct errors and inconsistencies
- clarifying the decision making criteria for approval of new organisms in containment

3. These changes are not as a direct result of the recommendations from the Royal Commission on Genetic Modification but were included in recent consultation on changes to the Act.

Background information

4. The HSNO Act commenced for new organisms on 29 July 1998. A number of issues have arisen in light of experience under the Act.

5. As part of its response to the Royal Commission on Genetic modification the government sought public comment on proposals to amend the HSNO Act to implement the Commission’s recommendations which it had agreed to progress. In addition, the

government used this opportunity to propose other changes to the HSNO Act to improve its operation, principally with respect to new organisms [CAB (02) 24/4 refers]. In addition, the transitional parts of the HSNO Act (Section 255) provide that animals at registered zoos and circuses are deemed to be new organisms and remain subject to the Zoological Garden Regulations 1977, which are retained by the Act. The Zoological Garden Regulations are about to expire and so amendment to the HSNO Act is necessary to complete the transition of the management of animals in existing zoos and circuses to the HSNO regime.

Submitters' views

6. 38 submissions were received on operational issues and no significant concerns were raised from groups identifying themselves as Maori. Due to the unrelated nature of the issues in this section, it is difficult to summarise the comments made.

7. Nine submissions were received on the management of zoo and circus animals. The majority of the submitters agreed with the proposed amendments. The ones that did not, had had misinterpreted the chapter and assumed that the government was proposing to provide for the display of "GM animals" in zoos and circuses.

Zoo and Circus Animals

8. Animals that were in registered zoos and circuses when the HSNO Act commenced are dealt with by section 255 of the Act, which is a transitional provision. Section 255 deems animals in registered zoos and circuses to be new organisms with containment approvals, and imposes a deemed condition requiring the animals to remain at the place of registration. In addition, the HSNO Act saved the Zoological Gardens Regulations, and provides that these regulations continue to apply.

9. Zoo and circus animals are also classified as restricted organisms under the Biosecurity Act, which means that they must be kept at a containment facility that complies with standards approved by ERMA.

10. Section 255 of the HSNO Act has expired, but the deeming effect of the section has survived its expiry. However, the Zoological Gardens Regulations will expire on 28 July 2003, and some of the detailed requirements for the keeping of zoo and circus animals will cease to apply after that date.

Additional containment controls for deemed approvals

11. When the Zoological Garden Regulations expire, existing zoos will only be subject to one control under the HSNO Act: that the organisms remain at the place of registration. The purpose of the amendments described below is to enable ERMA to impose the same kind of controls on zoo and circus animals that it can impose on any other new organism. Officials recommend that the ERMA be provided with the power to apply the controls specified in the 3rd Schedule (matters to be addressed in containing new organisms), and any other additional controls necessary to give effect to the purpose of the Act. These variations would, among other things, enable transfers of animals to containment facilities that meet the same standard, or to provide for temporary absences from the containment facility, e.g. for veterinary examination and treatment. The objectives of the proposed additional controls would be:

- to limit the likelihood of any accidental release of any organism
- to exclude unauthorised people from the facility
- to control the effects of any accidental release or escape of an organism
- to specify inspection and monitoring requirements for containment facilities
- to specify the qualifications required of the person responsible for implementing those controls

12. It is also recommended that ERMA be provided with the power to vary the deemed condition imposed by section 255, to allow for the transfer and temporary absence of animals from containment facilities, as long as the animal remains contained.

13. It was also considered whether there should be additional controls specific to **new approvals** for zoo and circus animals that should be considered by ERMA in the 3rd schedule. Officials do not consider this amendment necessary.

Approval of containment facility standards

14. Section 39 of the Biosecurity Act (Registration of transitional facilities and containment facilities) requires MAF to use “relevant standards approved by [ERMA] in accordance with [the HSNO Act]” when considering applications for approval of individual containment facilities. However, there is no provision in the HSNO Act to deal with the approval of standards for containment facilities.

15. It is recommend that an amendment be made to the HSNO Act to enable relevant standards to be approved under the HSNO Act. This would mean that containment facilities could be approved if they met these relevant standards. Essentially this closes the gap in the legislation between the Biosecurity Act and the HSNO Act. More importantly, it will give a clear and transparent role for ERMA to approve standards for containment facilities.

Purpose of containment

16. The purposes listed in section 39 of HSNO include ‘the public display of any organism’ this purpose is sufficient for the approval of the importation of zoo and circus animals. Officials therefore advise that no amendments be made to allow for additional purposes under which new organisms may be imported into containment.

Transitional period between legislation

17. The Zoological Garden Regulations will expire on 28 July 2003. However, the amendments to the HSNO Act are not expected to be passed into law until after this date. The result of this is that, although both the HSNO Act and the Biosecurity Act require zoo and circus animals to remain at the zoo/circus, the detailed requirements on operators that are set out in the Zoological Garden Regulations will not be able to be replaced immediately by controls under the HSNO Act.

18. The Zoological Garden Regulations allow for the approval of temporary or permanent transfers of animals from zoos. Some concern has been raised about whether, without this provision, a zoo/circus could transport an ill or injured animal to a vet if it decided that the animal could not be appropriately treated at the zoo/circus.

[Withheld under section 9(2)(h) of the Official Information Act in order to maintain legal

professional privilege.] officials advise that if an ill or injured animal cannot be treated at the registered zoo or circus, then, in accordance with the provisions of the Animal Welfare, the animal can be transported to a vet for treatment.

Other Operational Issues

Use of term 'species'

19. The HSNO Act defines a new organism as an organism “belonging to a **species** that was not present in New Zealand before 29 July 1998”. However, “species” may not be the most appropriate taxonomic level for a risk assessment. ERMA needs to be able to assess applications on a case-by-case basis at the classification level **most appropriate** to consider the risks. In some cases, species is not an appropriate level to assess an organism from a perspective of risk. Examples include bacteria and plants.

20. Bacteria may be better assessed by sub species or strains. An example is the species of *E. coli*, which has many strains. Strain K12 is not pathogenic to humans and animals while strain 0157 is. Plants, on the other hand, may be better assessed at the genus level. For example, the nature of orchid breeding and nomenclature means that it is virtually impossible to identify the full range of species that orchids are bred from.

21. It is recommended that the definition of new organism be amended so that the definition includes, but is not limited to ‘species’ as a means of classification. This would allow ERMA to consider organisms at the most appropriate taxonomic level for risk assessment.

Including prions in the definition of organism

22. Prions are small infectious protein particles that can cause fatal neurodegenerative diseases in animals and humans. These prion proteins do not contain genetic material such as DNA and are not self-replicating, but instead induce changes in a specific host organism protein, resulting in disease. It was proposed that **consideration be given** to amending the HSNO Act to mirror the definition of organism in the Biosecurity Act. The Biosecurity Act includes “(f) any particle that is a prion” in the definition of ‘organism’.

23. However, an organism for the purpose of the HSNO Act (d) *Includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1999.* Therefore it is recommended that no further amendment is required in the HSNO Act.

Large-scale fermentation

24. The present HSNO Act includes large-scale fermentation of micro-organisms in the definition of ‘field test’. The effect of this provision is to specify the type of assessment of fermentation of **new** micro-organisms on the basis of volume and not on the level of risk.

25. The volume at which fermentation becomes ‘large scale’ is not defined in the Act. In current practice, ERMA defines ‘large-scale’ as a volume greater than 10 litres. Volume is not always a good indicator of risk and so in some cases there is over-

regulation of fermentation work that may be low risk but where the volume is greater than 10 litres. The majority of submissions agreed with this proposal.

26. It is recommended that the assessment of the fermentation of micro-organisms be based on risk and not on volume. To achieve this 'Large-scale fermentation' should be removed from the definition of field test. By doing this the fermentation of micro-organisms will be assessed in the same way as any other development in containment.

Time to decide on an application

27. The HSNO Act requires ERMA to publicly notify its decision on an application no later than 15 working days after the conclusion of the hearing or 15 working days after the consideration of an application for a HSNO approval if there is no hearing. In practice it has been found to be difficult to decide on complex applications in this time period.

28. It is recommended that the HSNO Act be amended to extend the time to publicly notify the decision on an application, in particular to allow additional time for complex applications. Based on present experience officials recommend an extension of no more than 30 working days after the conclusion of the hearing or, where there is no hearing, after the consideration of the application. However in order to encourage timely decision making any amendment will need to make clear that the decision should be made and notified as soon as practicable, with no obligation for ERMA to take the entire time if a decision can be made quickly. This would apply to applications for both new organisms and hazardous substances.

Time to comply with a compliance order

29. The HSNO Act requires that a compliance order state a time-period for compliance, which **cannot be less than four days** from the time the notice is served. In practice, a minimum four-day period makes it difficult to deal promptly with non-compliance or incidents that do not qualify as an emergency.

30. It is recommended that the HSNO Act be amended to remove the minimum four-day period. This would allow an enforcement agency to decide, on a case-by-case basis, the time limit for that the compliance with an order. However, the period must be of a reasonable length to take the action required or to cease the action in the circumstances. The Resource Management Act was amended in 1997 with a similar provision for abatement notices and this has been found to work effectively in practice.

Last day for notice of appeal

31. The HSNO Act requires a compliance order to state the last day on which a notice of appeal can be lodged. The 1997 amendment to the Resource Management Act removed this requirement for abatement notices. It was removed because, in practice, there were often delays between the dates when the notice was prepared and when it was served. Thus there was a possibility for confusion if the order stated a date that was not consistent with the time period allowed in the District Court Rules.

32. It is recommended that the requirement that the compliance order state the last day on which an appeal can be lodged be deleted from the HSNO Act.

Time to lay information for prosecution

33. The HSNO Act enables any information relevant to offences to be laid within 120 working days of the time the offence “first became known, or should have become known”. This time period has apparently prevented some offences for new organisms being pursued under the HSNO Act, since specialist legal advice or specialist evidence relating to the identification of the new organism or of its genetic modification may take more than 120 days to gather. It has been proposed that the Act be amended to lengthen the 120-day period.

34. It is recommended not to change the time to lay information for prosecutions. The suggestion to change this time period from “at the time the offence became known or should have become known” to “the time when the matter of the information arose” would extend the end-point of the time period. However, of more significance, for hazardous substances and new organisms, the starting point would potentially be shortened from “at the time the matter became **known**” to “the time when the matter arose”. If there is likely to be a delay in discovering the offence, as there is with both hazardous substances and new organisms, it is better to use the “time of knowledge” as the starting point.

Non-deliberate introduction of new organisms

35. In addition to deliberate introductions, new organisms may also arrive in New Zealand through natural means or as accidental ‘hitchhikers’. The detection of organisms that are new to New Zealand occurs quite regularly. The kinds of organisms that are detected are not necessarily high profile, and include such organisms as plant viruses.

36. It is not always practicable or cost-effective to eradicate new organisms, and therefore some of these new arrivals may become established in the New Zealand environment. Despite establishment, they still remain new organisms under the HSNO Act and any deliberate importation of such species requires a HSNO approval, which in many cases could not be given because the statutory criteria for approval would not be met.

37. The continued new organism status creates two significant issues. First, in order to comply with the HSNO Act, further importation of the organism would be prohibited without an approval. [Withheld under section 9(2)(h) of the Official Information Act in order to maintain legal professional privilege.] Secondly, it is an offence under section 109 of the HSNO Act to knowingly possess a new organism imported in contravention of this Act. Under section 109(2) any person may commence a prosecution for this offence and possession of the unapproved new organism could result in prosecution. If civil penalties and strict civil liability for non-complying activities (as proposed in the accompanying liability paper) are adopted, these would also have the potential to apply.

38. It is recommended that the HSNO Act be amended to provide the ability by order in council to change the status of a new organism to one that is ‘no longer new’. This would mean that any provision to change the status of a new organism to being no longer new would be subject, before the decision was made, to both consultation with those people reasonably affected and the full rigors of the regulation making process. Criteria to be used for assessing whether an organism should be declared ‘no longer new’ should include, but not be limited to, where an organism has formed a self-sustaining population

in New Zealand, and is not the subject of an eradication attempt, an enforcement action or action under the civil penalty regime (see paper 5 in this suite).

39. It is acknowledged that this proposal still has some risks in that it could still provide a perverse incentive for illegal importations. Therefore a discretion **not** to use the power should be retained for certain circumstances (for example, where use of the power would inappropriately reward illegal activity). It is important to note that the organism's change in status would not be retrospective, so that deliberate breaches of the Act prior to that date would still be subject to criminal sanctions and, if approved, the proposed civil penalty regime. However the rigor of the order in council making process under the HSNO Act would seem the best way to minimise any potential problem.

40. Further, if there are valid risk-management reasons to continue to regulate its importation or control its movement in New Zealand, this can be achieved. Regulating the organism's importation can be done by providing for or continuing its status as a "risk good" under the Biosecurity Act. This will prevent further specimens from being imported and released in New Zealand should, an individual wish to do so. If the organism was subsequently eradicated, it will again become a new organism. This is because the definition of a new organism in the HSNO Act includes "*any organism ... that has been eradicated from New Zealand.*" Regulating the organism's movement in New Zealand can be done with mechanisms such as the present movement restriction provisions for pest management (e.g. as is presently done for bees to control the varroa bee mite or cattle to control tuberculosis).

Amendments to the Second Schedule

41. The second schedule to the HSNO Act lists prohibited new organisms. However, a number of the organisms were listed here in error, as they were already present in NZ in an uncontained environment. The schedule also contains scientific names that are inconsistent with current taxonomic knowledge, and the names are listed in an inconsistent manner.

42. It is recommended that the Second Schedule be amended to

1) Remove the names of the following organisms which are already present in New Zealand:

- *Asclepias tuberosa* (pleurisy root)
- *Castanospermum australe* (Moreton Bay chestnut; black bean)
- *Echinacea angustifolia*
- *Eleocharis dulcis* (Chinese water nut)
- *Monarda punctata* (horsemint)
- *Rhamnus purshiana* (cascara sagrada).

2) Correct the following scientific names:

- *Bufo marinus* with *Bufo marinus*
- *Rhamnus purshiana* with *Rhamnus purshiana* (unless removed)
- *Tourettia volubilis* with *Tourettia volubilis*.

3) List the animal organisms and plant organisms in a consistent manner (either common name, scientific name or vice versa, and include the taxonomic authority).

Clarification of the decision-making criteria for approval of new organisms in containment

43. Questions have arisen on the operation of section 45(1) of the HSNO Act: *the requirement to weigh up the adverse effects of an application versus the beneficial effects* when assessing an application for a new organism **in containment**. In particular, there were concerns about how the relationship between the ability of the organism to escape and the impact of containment controls should be considered in ERMA's assessment. Section 45(1) is a key decision-making provision and remains open to varying interpretations and at present it is unclear whether the section required consideration of controls before or after weighing up the benefits of the application against the risks and costs.

44. Officials recommend amending section 45(1) of the HSNO Act so that it is clear that in weighing up of beneficial effects against adverse effects an integrated view is taken of all relevant matters. These matters include (among the other matters referred to in the Act) the risks that would arise should the organism escape from containment or the controls otherwise fail, but also the impact of containment and other controls in mitigating risks. Submitters generally agreed that the probability of the hazard occurring (the risk) needs to be taken into consideration along with the controls on the containment designed to mitigate that risk. Others were opposed to any changes that might weaken the focus on full containment.

45. Currently ERMA's approach is to consider both the ability of the organism to escape from containment alongside the adequacy of the containment controls. The impact of containment on mitigating risks (including the risk of escape and any resulting consequences of that escape) is considered part of the process of weighing benefits against risks and costs. However, the consequences of potential escape should also be considered. If these consequences are sufficiently severe they should influence the weighing of benefits against risks and costs directly. This approach was upheld by a High Court judgement in late 2001 in an appeal on the decision made by ERMA to approve the field testing of GM cattle by AgResearch.

46. It is recommended that the HSNO Act be amended to clarify and make unambiguous, the decision-making path. This will allow ERMA to take an integrated view of all relevant matters when weighing up beneficial effects against adverse effects. These relevant matters should include (among other matters referred to in the Act):

- the risks that would arise should the organism escape from containment or the controls otherwise fail, and
- the impact of containment and other controls in mitigating risks.

Timetable implications

47. All timetable implications associated with this paper, have been outlined in *Paper 1: Overview*.

Financial implications

48. There are no financial implications associated with this paper.

Human rights

49. All human right implications associated with this paper, have been outlined in *Paper 1: Overview*.

Legislative implications

50. All legal implications associated with this paper, have been outlined in *Paper 1: Overview*.

Regulatory impact and compliance cost statement

51. The Regulatory Impact and Business Compliance Cost Statements, for the management of zoo and circus animals and operational issues are attached to this paper in Annex 1 and 2, respectively. These comply with the requirements of Cabinet Office Circulars CO (98) 5 and CO (01) 2.

52. A Business Compliance Cost Statement has not been prepared for the management of zoo and circus animals, as the proposals do not have compliance cost implications for business.

53. Based on the information provided in the attached RIS/BCCS, the Business Compliance Costs Unit considers that the disclosure of information is adequate, and the level of analysis is appropriate given the likely impacts of the proposal.

54. No Regulatory impact statements have been prepared for;

- Transitional period between legislation
- Approval of containment standards
- Time to decide on an application
- Time to comply with an order
- Last day for notice of appeal
- Non-deliberate introduction of new organisms
- Amendment to the Second Schedule
- Clarification of the decision-making criteria for approval of new organisms in containment

because these proposals are minor or machinery in nature and do not substantially alter existing arrangements.

Gender implications

55. There are no gender implications associated with this paper.

Disability perspective

56. There are no disability perspective implications associated with this paper.

Publicity

57. All publicity implications associated with this paper have been outlined in *Paper 1: Overview*.

Consultation

58. Details of the consultation for this suite of papers have been outlined in *Paper 1: Overview*.

Recommendations

59. It is recommended that Ministers:

Transition for existing zoo and circus animals

- a) **Agree** that ERMA be given the discretion to apply, on a case-by-case basis containment controls and any other controls necessary to give effect to the purpose of the HSNO Act for existing zoo and circus animals
- b) **Agree** that ERMA be given the power to vary the deemed condition imposed by section 255 of the HSNO Act to allow for the transfer and temporary absence of animals from containment facilities, as long as containment is maintained
- c) **Agree** that ERMA be provided with an enabling provision to approve relevant containment facilities standards under the HSNO Act
- d) **Note** that no amendment is needed to extend the effect of the Zoological Garden Regulations

Operational improvements

- e) **Note** that “species” may not be the most appropriate taxonomic level for the risk assessment of a new organism application
- f) **Agree** to amend the definition of new organism in the HSNO Act so it is not limited to ‘species’ to allow ERMA to consider organisms at the most appropriate taxonomic level for risk assessment
- g) **Agree** to amend the HSNO Act so that that the assessment of the fermentation of micro-organisms is treated in the same way as any other application for development approval
- h) **Agree** that the HSNO Act be amended to extend the time to publicly notify the decision of an application to no later than 30 working days following the conclusion of any hearing, and that this amendment be so framed as to make clear that a shorter time should be used where possible
- i) **Agree** that the HSNO Act be amended to remove the minimum four-day period on a compliance order
- j) **Agree** to delete the requirement in the HSNO Act that states the last day on which an appeal can be lodged in the compliance order
- k) **Note** that the HSNO Act enables any information relevant to offences to be laid within 120 working days of the time the offence “first became known, or should

have become known” and applies to both hazardous substances and new organisms. This time period has apparently prevented some offences for new organisms from being pursued

- l) **Agree** not to amend the Act to lengthen the 120 days because it would require that the time period start “at the time when the matter of the information arose” and not at the time the offence “first became known”. If there is likely to be a delay in discovering the offence, as there is for both hazardous substances and new organisms, it is better to use the “time of knowledge” as the starting point and not to lengthen the 120-day period
- m) **Agree** that the HSNO Act be amended to provide for a power to declare by order in council that an organism is ‘no longer new’
- n) **Agree** that criteria to be used for assessing whether an organism should be declared ‘no longer new’ as referred to in **recommendation m** should include, but not be limited to, where an organism has formed a self-sustaining population in New Zealand, and is not the subject of an eradication attempt, an enforcement action or action under the civil penalty regime. Discretion **not** to use the power should be retained for certain circumstances (for example, where use of the power would inappropriately reward illegal activity)
- o) **Agree**

(cascara sagrada)
- p) **Agree**
- q) **Agree** to amend the HSNO Act to allow ERMA to take an integrated view of all relevant matters when weighing up beneficial effects against adverse effects in deciding on applications to approve a new organism **in containment**

Hon Marian L Hobbs
Minister for the Environment

Annex 1

Regulatory Impact Statement

Management of Zoo and Circus Animals

Additional controls on deemed approvals

Statement of the problem and the need for government action

Currently, animals that are in registered zoos and circuses are regulated under the Zoological Garden Regulations (Zoo Regs) 1977. They are further regulated by section 255 of the HSNO Act, which only requires that the animals remain at the place of registration. Section 255 has now expired, although the controlling effect of this section still applies to existing registered zoo and circus animals.

The Zoo Regs expire on 28 July 2003 and when they do, some of the detailed requirements for the keeping of existing registered zoo and circus animals will cease to apply after that date (existing registered zoo and circus animals are termed *deemed approvals*). This will mean that there will no longer be any provision to place any kind of additional controls on these animals (such as controls to prevent escape of the animal).

As mentioned, the requirement that the animals remain at their place of registration, is one control that will still apply after the expiry of s255 and the Zoo Regs. This creates the problem that zoos and circuses have no legal means by which they can transfer animals to different approved containment facilities or allow for temporary absences. Reasons for wanting to transfer an animal could include visits to the vet or the transfer of an animal to another zoo to facilitate a breeding programme.

Statement of the public policy objectives

The key objective is to provide ERMA with the ability to update controls on existing zoo and circus animals in a manner consistent with the controls for the containment of approved new organisms.

Statement of Options for Achieving the Desired Objectives

Non-Regulatory Measures

No non-regulatory measures exist that would be capable of achieving the specified objectives.

Regulatory Measures

Retaining the Status quo

One option that was considered was to retain the status quo. All animals registered with zoos and circuses are classified as restricted organisms under the Biosecurity Act 1993,

which means that they must be kept at a containment facility that complies with standards approved by ERMA. This could be considered as a sufficient level of control for deemed approvals, however it does not fully meet the policy objective.

Additional controls for existing zoo and circus animals

Another way of achieving this objective (the recommended option) was to:

- Amend the HSNO Act to be able to specify additional controls for deemed approvals under part 2 of the 3RD Schedule (Matters to be addressed by containment controls for new organisms in containment excluding genetically modified organisms – these include accidental release, exclusion of unauthorised persons, inspection and monitoring requirements); and
- Provided ERMA with the ability to vary the deemed condition imposed by section 255, to allow for the transfer (e.g. between zoos for breeding programmes) and temporary absence of animals (e.g. visiting the vet) from containment facilities, as long as the animal remains contained.

Statement of the Net Benefit of this Proposal

The benefits of this proposal include the consistency between the controls on existing and new approvals of zoo and circus animals in containment under the HSNO Act. By maintaining consistent controls for new organism approvals and deemed approvals, a high level of containment is maintained for all zoo and circus animals, which is safer for both the public and the environment.

This proposal will also allow for the transfer and temporary absence of animals from containment facilities. This provision to allow transfers will benefit society indirectly, for example, allowing for breeding programmes, which may facilitate conservation and biodiversity objectives. There will also be a benefit to New Zealand internationally if more breeding programmes could be implemented to save endangered species not native to New Zealand. This could have positive impacts on the economy as a whole.

Costs include the need to review deemed approvals and apply additional controls where necessary. There may be a cost to an existing zoo or circus where additional controls are imposed that are outside current practice and the facility has to make substantial changes to comply.

Additionally, by providing a legal means by which zoos and circuses may transport or transfer animals, there may be costs involved in the development of controls, and the application of controls, needed to maintain containment. There may also be a cost to the zoo or circus operator of seeking approval to transfer the animals, or to allow temporary absences.

The expected benefits to zoo and circus operators outweigh any expected costs associated with the proposed measure.

Consultation

To date, the following government agencies have been consulted in relation to the options presented in this paper: Ministries of Agriculture and Forestry; Economic Development; Foreign Affairs and Trade; Health; Justice; Research Science and Technology; Department of Conservation, Department of Prime Minister and Cabinet, Te Puni Kokiri, the Treasury, the Environmental Risk Management Authority, and the New Zealand Food Safety Authority.

Nine submissions were received on the management of zoo and circus animals in response to the issues in the public discussion paper *“Improving the Operation of the HSNO Act for New Organisms: Including Proposals in Response to Recommendations of the Royal Commission on Genetic Modification”*. These submissions came from crown research institutions, the association for zoo operators, and some individuals. The majority of the submitters agreed with the proposed amendments. The ones that did not had misinterpreted the chapter and assumed that the government was proposing to provide for the display of “GM animals” in zoos and circuses.

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Annex 2

Regulatory Impact Statement

Operational Issues

Statement of the nature and magnitude of the problem and the need for government action

The HSNO Act is a major piece of legislation. A number of issues have arisen in light of experience with the operation of the Act. Two of these issues will have a regulatory impact.

Use of term 'species'

The HSNO Act defines a new organism as an organism “belonging to a **species** that was not present in New Zealand before 29 July 1998”. Therefore, when considering an application for a new organism, ERMA are required to consider the new organism at the taxonomic level of ‘species’. While this is an appropriate level to consider some organisms, it is not as appropriate for others.

For example, applicants need to provide risk information at some cost to them on all organisms in the species when they may only wish to import a sub-species. This means that the problem is more that the risk assessment at the species level generally does not match the level of regulation to the level of risk presented by the organisms. This leads to excessive compliance costs for applicants having to provide information that is not necessarily relevant to their particular application. While the current situation is appropriate for animals, it is less appropriate for plants and bacteria, which make up over half of the new organism applications to ERMA.

Currently, ERMA have the power to impose controls on any application for a new organism. However, if the assessment is inaccurate, any controls placed upon the organism may be too restrictive or unnecessary if the assessed risk was higher than the actual risk. This will lead to an unnecessary cost on the applicant. If the opposite was true, and the actual risk was higher than the assessed risk, then the controls placed on the organism may be too lax. This could lead to an escape of the organism and a cost imposed on the applicant to recover or destroy the escaped organism. The costs to society/the economy as a whole under the current system could include (but are not limited to) health costs (if the escaped organism was pathogenic), and costs to the taxpayers (with a burden on the health system).

Large-scale fermentation

Currently, anyone wishing to conduct a large-scale fermentation of a new organism is required to obtain a HSNO approval for a field test. However, the volume at which fermentation of a new organism becomes ‘large scale’ is not explicitly defined. ERMA, when assessing an application for a large-scale fermentation, ‘large-scale’ is defined as a volume greater than 10 litres¹.

There are two key issues here:

¹ ERMA New Zealand, Interpretations and Explanations of Key Concepts, December 2002

- i. firstly volume is not always a good indicator of risk therefore by using the 10 litre cut-off there may be an over-regulation of fermentation work that may be low risk but where the volume is greater than 10 litres;
- ii. any application for a 'field test' is costly and may include a public hearing as the application must be publicly notified.

ERMA could change its definition of 'large-scale', however this would require the development of criteria (by ERMA) to assess the risk of the fermentation and it would still require an application for a field test, imposing unnecessary compliance costs for fermentation of low-risk organisms.

Statement of public policy objective

The key objective is to improve the overall effectiveness of the operation of the HSNO Act and to allow an accurate assessment of the risks to be conducted by ERMA when assessing an approval for a new organism under the HSNO Act.

Statement of feasible options (regulatory and/or non-regulatory) and net benefit of the proposals that may constitute viable means for achieving the desired objective

Non-Regulatory Measures

No non-regulatory measures exist that would be capable of achieving the specified objective.

Use of term 'species'

Status quo

When an application is made for a new organism, enough information has to be provided by the applicant for ERMA to make its assessment. By the definition in the HSNO Act (stated above) the organism has to be assessed at the level of 'species' and therefore the information has to be provided on the 'species'.

Regulatory Measures

Two regulatory measures were developed to fulfil the policy objective:

- Option A: Amend the HSNO Act to provide ERMA the power to determine the organisms which can be classified at a level other than species and to declare which organisms they are either by *Gazette* notice or by Order in Council
- Option B (the preferred option): Amending the definition of new organism, so that the taxonomic level at which ERMA could make an assessment includes, but is not limited to, species.

Option A was not the preferred option as this process was deemed to be lengthy and involved unnecessary government decision-making. If this option was implemented, it would require a dual process to achieve the policy objective i.e. it would require an amendment to the HSNO act plus it would require ongoing assessments followed by declarations which would be more costly to ERMA in the longer term in terms of time. Option B requires a single amendment to the HSNO Act, with assessments required when requested for an approval for a new organism.

The benefit of option B will mean that a more accurate assessment will be able to be conducted on the risk of the organism. The ability of ERMA to assess an organism at a level other than species will ensure better processing of applications – ERMA can process the application faster with better information. This will lead to decision-making that is more related to the risks of the organism and therefore more appropriate controls can be imposed on the organism, and will result in a reduction in any unforeseen adverse effects that may occur as a result of an organism escape from under-regulation. This will benefit society in that the potential for organisms to escape will be reduced from a more appropriate level of regulation.

There may be an increase in staff time (for the applicant) at the pre-application stage, to provide ERMA with enough information to work out the appropriate taxonomic level for assessment. Currently an applicant is required to provide enough information for ERMA to be able to make an accurate assessment. It is anticipated that while the volume of pre-application work may increase, the amount of work required to provide the information for an application for approval will decrease, leading to a neutral cost in time.

If a pre-application assessment is required by ERMA, then there will be a cost to both ERMA (in terms of staff time) in both assessing the organism to determine the taxonomic level at which it should be assessed and determining whether the organism is 'new' as a result of a change in taxonomic level.

The expected benefits to applicants, government agencies, regulatory agencies and the economy/society as a whole outweigh any expected costs associated with the proposed measure.

Large-scale fermentation

Status Quo

Anyone wishing to conduct a fermentation of a new organism that is greater than 10 litres, is required to obtain a HSNO approval for a field test. This option was not considered as it does not allow an accurate assessment of risks to be conducted by ERMA. It also imposes unnecessary costs on the applicant (see discussion on benefits for the preferred option.)

Regulatory Measures

Two regulatory measures were developed to fulfil the policy objective:

- Option A: Remove 'Large-scale fermentation' from the definition of a field test and redefine it in the HSNO Act. This would require criteria and containment requirements to be developed for the assessment of the level of risk of the fermentations.
- Option B (the preferred option): Reclassify a large-scale fermentation as a development. As the HSNO Act has regulations for determining if a **development** is 'low-risk' (but not a field test), fermentations of new organisms could be assessed under existing criteria.

Option A was not recommended as it would result in a parallel assessment for fermentations that are assessed as developments and 'large-scale' fermentations. This would also impose unnecessary costs on the applicant as a more expensive application would be required. Option B utilises the existing regulatory HSNO framework and is simply a means of streamlining the approval process for laboratory-based organisms and hence reducing compliance costs.

The main benefit from reclassifying a fermentation to a development is a reduction in application costs. These costs are outlined more explicitly in the business cost compliance statement. Other benefits from any reduction in application fees include a better potential for industry – with lower application fees, they may make more applications. The low application fees also has the potential to bring research into New Zealand from overseas. This will indirectly benefit the economy as a whole and also society.

As stated above, ERMA have the ability to apply controls on an approval for a new organism. Amending the assessment of fermentations to take account of the risk of the organism (rather than having an arbitrary cut-off point) would mean that the correct level of controls were applied. This would have the same benefits (with respect to risk management) as for ‘use of term species’.

Currently fermentations of a volume that is less than 10 litres are assessed as a development. Therefore no additional costs will be incurred for this proposed change when the volume of fermentation is less than 10 litres.

Without any data at this point, it seems reasonable to assume that the impact on the ERMA’s budget and workload would be neutral, that is, the increase in the volume of applications would counteract the reduced revenue per application.

Consultation

To date, the following government agencies have been consulted in relation to the options presented in this paper: Ministries of Agriculture and Forestry; Economic Development; Foreign Affairs and Trade; Health; Justice; Research Science and Technology; Department of Conservation, Department of Prime Minister and Cabinet, Te Puni Kokiri, the Treasury. The Environmental Risk Management Authority, and the New Zealand Food Safety Authority were also consulted.

About 40 submissions were received in response these issues in the public discussion paper “*Improving the Operation of the HSNO Act for New Organisms: Including Proposals in Response to Recommendations of the Royal Commission on Genetic Modification*”. These submissions came from a range of organisations including crown research institutions, universities, various associations, environmental groups and some individuals. Submitters were divided on whether the proposed amendments would improve the system.

For *use of term ‘species’* some submitters could not see how allowing classifications at different levels would work in practice while others felt that the current system was too restrictive. This problem was addressed by providing ERMA the flexibility to determine, on a case-by-case basis, the level at which the organism will be assessed. For *large-scale fermentation* all of the submitters agreed with the proposed amendment.

The government agencies responsible for the operation of the HSNO Act with regard to the use of the term ‘species’ and large-scale fermentation were key advocates for these proposals and fully support the recommended options.

Business Compliance Cost Statement

Sources of compliance costs

Use of term species: These will result from the requirement to do a pre-application assessment on the taxonomic level.

Large-scale fermentation: These will result from the different type of approval that will be required under the HSNO Act.

Parties likely to be affected

A number of private research organisations² that all have the potential to be conducting research into new organisms. The exact number of the research organisations, and the size of those organisations, is not known.

Estimated compliance costs of the proposal

Use of term species: ERMA's policy is to charge an applicant for pre-application costs, once an application has been received. The charge is based on the time taken on the pre-application work and the charge-out rates for staff time is \$100 per hour (GST excl)³. As there is no history of ERMA conducting this type of assessment, there is **no information** on the total costs to business for this type of assessment.

Large-scale fermentation: Currently the fees for a large-scale fermentation can range from \$30,000 – 60,000 (the current fees for all field tests). An application for a development ranges from \$3,000 – \$12,000 (non-notified) and \$25,000-\$35,000⁴ (notified)⁵. Under the proposed system, there would be a reduction in application fees as a fermentation would be assessed as a development. Given the nature of fermentations (they are highly contained to prevent contamination and therefore prevent the organism from escaping) it could be anticipated that the majority of applications will be non-notified.

Longer term implications of the compliance costs

Use of term species: Once ERMA has gained experience in assessing the taxonomic level for applications for new organisms, then it is anticipated that these costs will reduce overtime.

Large-scale fermentations: These cost reductions will continue into the future.

Level of confidence of compliance cost estimates

Use of term species: There is no information available to provide compliance cost estimates.

² <http://www.morst.govt.nz/guide/research.html>

³ Environmental Risk Management Authority, Fees and Charges Schedule, July 2002

⁴ ERMA New Zealand Information Sheet, Number 15, February 2002

⁵ ERMA New Zealand Information Sheet, Number 15, February 2002

Large-scale fermentations: There is a high level of confidence in the cost estimates as the costs have been sourced directly from ERMA.

Key compliance cost issues identified in consultation

Consultation with interested and affected parties identified the areas where compliance costs were likely to occur. No compliance issues were raised during consultation.

Overlapping compliance requirements

There are no overlapping compliance requirements with other agencies following these proposals.

Steps taken to minimise compliance costs

ERMA will ensure potential applicants receive information on the revised assessment process through information sheets available on their website and through their newsletter.

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