

11 Issues Arising from Operation of the HSNO Act

11.1 Summary

The HSNO Act commenced for new organisms on 29 July 1998 and for hazardous substances on 2 July 2001. The following issues have arisen in light of experience under the Act, and are considered in this section:

- The time to release a decision – it is proposed that this be extended from 15 to 30 days in order to allow ERMA sufficient time to adequately consider, decide and publicly notify its decisions on significant applications.
- The definition of ‘new organism’ – there are issues with the identification of organisms at a species level. Possible amendments could be to improve the ability to use the risk species provision of the Act to distinguish between subspecies, varieties, strains and cultivars presenting different risks and/or changes to the definition.
- The definition of ‘organism’ – this could be amended to include prions.
- Compliance orders – (a) the current minimum four-day period, from the time the notice is served for compliance to occur, could be changed to a reasonable period in the circumstances; (b) the requirement that the notice state the last day on which a notice of appeal can be lodged could be deleted (thereby relying on the requirements of the District Court Rules).
- The time to lay information for a prosecution – there are issues of consistency with the Biosecurity Act on the one hand and the Resource Management Act and Health and Safety in Employment Act on the other. Changes could be made to both the time period (from 120 working days to two years) and to when the time period commences (from time of knowledge of the offence to time the offence occurred).
- A review of the Second Schedule (prohibited new organisms).
- Large-scale fermentation – criteria could be developed for what can be considered large scale that better reflect the risk, rather than relying on a figure of 10 litres.
- Clarification of the decision-making criteria for new organisms in containment – to address questions as to the operation of section 45.

11.2 The time to release a decision

The Act requires ERMA to publicly notify its decision on an application not later than 15 working days after the conclusion of the hearing, or, where there is no hearing, after the consideration of an application for a HSNO approval.

In practice ERMA has found that it is often impossible to consider, decide and publicly notify a decision within 15 days of the conclusion of a hearing. The High Court in the Bleakley decision on the GM cattle application by AgResearch also noted that in a case of that significance the time limit was impracticable. However, the Court also noted that the timelines in the Act are directory only, and therefore the breach of the time limit did not invalidate the decision.

Proposed amendment

It is proposed that the time period be extended to not later than 30 working days after the conclusion of the hearing.

This extension would provide more time for ERMA to undertake consideration of significant applications, but would retain some security of timeline for applicants. The other time periods (for public notification, submissions, etc) would remain the same. The maximum time for ERMA to process a publicly notified application with hearing would therefore be increased from up to 85 days to up to 100 working days. However, ERMA is not obliged to take the full period available to release its decision. In using ‘not later than’ 30 working days, decisions on other applications may be released earlier.

11a Do you agree that the time to release a decision be extended to 30 days?

If not, please suggest alternative ways to enable ERMA to have adequate time to consider, decide and publicly notify its decisions on significant applications, and explain these as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

11.3 Definition of ‘new organism’

The HSNO Act defines a ‘new organism’ as follows:

- (1) *A new organism is –*
- (a) *An organism belonging to a species that was not present in New Zealand immediately before 29 July 1998;*
 - (b) *An organism belonging to a species, subspecies, infrasubspecies, variety, strain, or cultivar prescribed as a risk species, where that organism was not present in New Zealand at the time of promulgation of the relevant regulation;*
 - (c) *An organism for which a containment approval has been given under this Act;*

- (d) *A genetically modified organism:*
 - (e) *An organism that belongs to a species, subspecies, infrasubspecies, variety, strain, or cultivar that has been eradicated from New Zealand.*
- (2) *An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism.*
 - (3) *Despite the provisions of this section, an organism present in New Zealand before 29 July 1998 in contravention of the Animals Act 1967 or the Plants Act 1970 is a new organism.*
 - (4) *Subsection (3) does not apply to the organism known as rabbit haemorrhagic disease virus, or rabbit calicivirus.*

11.3.1 Non-deliberate introduction of new organisms

New organisms may arrive in New Zealand through natural means or as accidental ‘hitchhikers’. While these new arrivals may become established in the New Zealand environment, they still remain new organisms under the HSNO Act and any deliberate importation of such species requires a HSNO approval.

Possible amendment

A possible amendment is to provide a power to declare that an organism is established in New Zealand and is no longer ‘new’, despite the fact that it meets the strict definition of new organism (in the sense that it was not present in New Zealand immediately before 29 July 1998).

This declaration could be done by Order in Council, or by ERMA after consultation with the appropriate agencies (for example, the Department of Conservation and MAF). There may also need to be an amendment to the definition of ‘new organism’ to exclude from the definition any organisms that have been declared to be ‘not a new organism’.

There may also need to be a set of criteria by which to decide that an organism should be declared ‘no longer new’. This could include being satisfied that the organism has formed a self-sustaining population and that the population is not undesirable. Similarly, the Act states minimum standards for the approval of new organisms applications. Some or all of these minimum standards could be adapted as criteria.

A further criterion might be that the organism was not deliberately imported or released in contravention of any Act. However, consideration would need to be given to achieving the correct balance between making the criteria too strict (therefore making it difficult to prove that an organism has not been brought here illegally) or too loose (then possibly providing an incentive to smuggle new organisms into New Zealand in order to subsequently claim they had become established).

- 11b Do you agree that there is a need to provide for organisms that arrive by natural means or as accidental hitchhikers? Can you provide examples of where a HSNO approval has been considered necessary for such organisms?**
- 11c What mechanism would you favour: by an Order-in-Council or by ERMA after consultation with other agencies? What alternative mechanism do you suggest?**
- 11d What criteria do you consider appropriate for deciding that such an organism is no longer 'new'?**

Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

11.3.2 Use of the term 'species'

Experience has shown that while the identification of organisms at the species level is appropriate in most cases, especially for organisms in the animal kingdom, the term is less appropriate from a risk assessment perspective for plants and micro-organisms.

In the case of plants, the nature of plant breeding means that it is often difficult to accurately identify some plants at the species level; for example, some hybrids can be more usefully identified (from a risk assessment perspective) at a higher level, such as by genus. Orchids are a good example. Because of the nature of orchid breeding and nomenclature, it is virtually impossible for applicants to identify the full range of species that orchids are bred from. As a result, ERMA has not received one application that raises the risk of new orchids being actively imported without approval. It would be useful for ERMA to have the flexibility to consider and approve plant organisms at a higher taxonomic classification than species and then use the risk species provision in the Act to manage sub-groups that may pose unacceptable risks.

The case of micro-organisms such as bacteria is the reverse, in that there are crucial differences within species: some strains of some species are pathogenic to humans and animals, while other strains are not (for example, *E. coli* strain K12 is not but *E. coli* strain 0157 is). In such cases it is inappropriate to approve micro-organisms at the species level. It is preferable to be able to expressly identify the strain of micro-organism for which approval has been given, thereby requiring a separate application and exclusion of those strains posing an unacceptable level of risk.

The risk species provision in the Act is intended to enable differentiation between subspecies, infraspecies, varieties, strains or cultivars. The provision allows regulations to be made by Order in Council for the purpose of prescribing:

- (i) *Any species as a risk species where any subspecies, infraspecies, variety, strain or cultivar of that species may have adverse effects on the health and safety of people or the environment; or*
- (ii) *Any subspecies, infraspecies, variety, strain or cultivar as a risk species, where that subspecies, infraspecies, variety, strain or cultivar may have adverse effects on the health and safety of people or the environment.*

This provision allows ERMA to distinguish between organisms at any level below the species level. However, the current mechanism of promulgating regulations is time consuming because of the statutory processes required, and is therefore clumsy to put in place in response to a risk species event. It also requires ERMA to be proactive, to have knowledge of the range of risks for a range of organisms, and to have risk species regulations in place before any importation occurs. No such regulations have been promulgated.

Possible amendments

(i) *Approving at a level below the species level*

The use of ‘risk species’ could be re-examined, for example, by allowing the declaration of a species or subspecies as a risk species by Gazette notice rather than by regulation. A declaration could then be made at any time. Such an amendment would also need to specify criteria against which ERMA would make the declaration, and require prior consultation with appropriate agencies (for example, Department of Conservation and MAF).

An alternative option is to include the phrase ‘any subspecies, infraspecies, variety, strain or cultivar’ in the definition of ‘new organism’. Any unapproved subspecies infraspecies, variety, strain or cultivar would remain a new organism.

11e Is the risk species process adequate to deal with organisms at a level below the species level? How could it be improved?

11f Do you see any problems with the inclusion of the phrase ‘any subspecies, infraspecies, variety, strain or cultivar’ in the definition of new organism?

11g What other mechanisms might be used to address the above issues?

Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

(ii) *Assessment at the genus level*

One option is to allow ERMA the flexibility to consider plant organisms at a higher taxonomic classification than species, and then use the risk species provision (as above) to manage sub-groups that may pose unacceptable risks.

11h What other examples are there in addition to orchids where it might be appropriate to have approvals at a level above the species level?

11i What other mechanisms might be used to address this issue?

Please explain your comments as clearly as possible, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

11.4 Including prions in the definition of ‘organism’

A related issue is whether or not prions should be included in the definition of ‘organism’.

Prions are small, infectious protein particles that cause fatal neurodegenerative diseases in animals (for example, scrapie, mad-cow disease) and humans (kuru, Creutzfeldt-Jakob disease). 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.

Until 1997 the Biosecurity Act and the HSNO Act used the same definition of ‘organism’. However, in 1997 the Biosecurity Act definition was amended as follows: “(f) includes any particle that is a prion”. The same amendment was not made to the HSNO Act definition. As a result the HSNO Act does not currently cover prions.

Given the infectious nature of prions, consideration should be given to amending the HSNO Act to mirror the definition of an organism in the Biosecurity Act. Such an amendment would cover prions derived from both humans and animals. This is because prions do not contain genetic structures, and under subparagraph (a) of the definition only a “human being or a genetic structure derived from a human being” is excluded.

Possible amendment

Amend the HSNO Act in line with the Biosecurity Act to include prions in the definition of ‘organism’.

- | |
|---|
| <p>11j Should the HSNO Act definition of ‘organism’ include prions?</p> <p>11k Do you see any negative implications for such an amendment? What are they?</p> |
|---|

11.5 Compliance orders

11.5.1 Time to comply with an order

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. ERMA has indicated that a minimum four-day period makes it difficult to deal promptly with non-compliance or incidents that do not qualify as an emergency requiring immediate action.

The issue was raised before the select committee considering the original HSNO Bill. The Bill had a minimum seven-day period. At that time it was considered that any matter deemed to require more immediate attention should be attended to by an officer exercising their emergency response powers. An emergency may be declared for two consecutive 48 hours periods, and the time was reduced from seven to four days. However, it is doubtful in some cases whether the circumstances would actually meet the criteria for declaring an emergency (actual or imminent danger to human health or safety; or a danger to the environment or chattels so significant that immediate action is required to remove the danger). OSH and some territorial authorities also report that they have resorted to non-HSNO powers to deal with HSNO matters because the compliance order procedure (and the four-day rule) is impractical.

An 'infringer' may appeal a compliance order. However, filing a notice of appeal does not act as an automatic stay of the order, and the person must apply to the district court for a stay at the time the appeal is lodged. Observance of the principles of natural justice would require that the person be given a realistic time within which to respond before they are considered to be in non-compliance.

Proposed amendment

The equivalent provisions in the Resource Management Act for abatement notices were originally subject to similar requirements (a minimum seven-day period), and were also found to be impractical. The Resource Management Act was amended in 1997 so that the abatement notice came into effect at a period stated on the notice, and so that that period must be a reasonable period to take the action required or to cease the action in the circumstances. It is proposed that the HSNO Act should be similarly amended.

11l Do you agree or disagree with this proposal?

Please give your reasons, including examples and referring, where necessary, to the relevant parts of the HSNO Act.

11.5.2 Last day for notice of appeal

The 1997 amendment to the Resource Management Act also removed the requirement that an abatement notice state the last day on which a notice of appeal can be lodged, whereas the HSNO Act (still) has that requirement for compliance orders.

Possible amendment

An option is to delete the requirement that the compliance order state the last day on which an appeal can be lodged. The time period would remain that stated in the District Court Rules.

11m Do you agree or disagree with this option?

Please give your reasons.

11.6 The time to lay information for prosecutions

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.

The current period is in line with the equivalent provision in the Health and Safety in Employment Amendment Bill and the Resource Management Act (six months, which approximates 120 working days), but not with the Biosecurity Act 1993 nor with the ACVM Act. In section 10 of this discussion paper it is proposed that MAF be formalised as an enforcement agency for new organisms. The main other Act and agency for enforcement for new organisms are the Biosecurity Act and MAF, whereas for hazardous substances they are the Health and Safety in Employment Act and OSH. Consideration may therefore also need to be given to differentiating between offences involving hazardous substances and those involving new organisms.

The Biosecurity Act and ACVM provisions are “at any time within two years of/after the time when the matter of the information arose”, which means they differ both in the starting and ending times. The rationale of ‘time of knowledge’ versus ‘time of offence’ relates to views on how soon the offence is likely to be discovered. If there is likely to be a delay in discovering the offence, as with chemical hazards, then ‘time of knowledge’ would be the better option.

Possible amendments

Possible amendments are to lengthen the 120-day period currently in the HSNO Act and alter the starting time from ‘time of knowledge’ to ‘time of offence’.

- 11n Do you consider that there should be a change in the:**
- (a) starting time – from ‘time of knowledge’ to ‘time of offence’?**
 - (b) period of 120 working days in which to lay information?**
- 11o Should these times be aligned with those in the Health and Safety in Employment Act or the Biosecurity Act?**
- 11p Do you consider it necessary to differentiate between offences for hazardous substances and for new organisms?**

Please explain your comments as clearly as possible, referring, where necessary, to the relevant parts of the HSNO Act.

11.7 Second schedule (prohibited new organisms)

The Second Schedule to the HSNO Act lists new organisms, the importation or release or development of which is prohibited under the Act. However, a number of the organisms listed in the Second Schedule are already present in New Zealand in an uncontained environment; some have been explicitly approved by MAF under previous legislation before the HSNO Act commenced.

Note that the context of the Second Schedule is that of a 'new' organism. Native species or species already present in New Zealand before 29 July 1998 are not affected by the prohibition.

Proposed amendments

It is proposed that the Second Schedule be revised as follows.

- (a) Organisms to be removed:
- *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).
- (b) Correction of errors in scientific names. Replace:
- *Bufo marinus* with *Bufo marinus*
 - *Rhammus purschiana* with *Rhammus purshiana*
 - *Tourretia volubilis* with *Tourrettia volubilis*.

There is also inconsistency in the way the list is presented. Animal organisms are listed by common name then scientific name, whereas plant organisms are listed by scientific name then common name. This could be amended to be more consistent.

11q Do you agree or disagree with the proposed changes?

Please give your reasons.

11r Are there other changes you consider should be made?

11.8 Large-scale fermentation

Large-scale fermentation of micro-organisms is included in the definition of ‘field test’, but ‘large scale’ is not defined in the Act. ERMA, in its *Interpretation and Explanation of Key Concepts* document has interpreted ‘large-scale fermentation’ as involving volumes greater than 10 litres. All such applications require public notification and full assessment and consideration by ERMA.

Possible amendment

Criteria and containment requirements could be developed for large-scale fermentation of micro-organisms that better reflect the risks, rather than relying on the 10-litre figure. This would enable, for instance, applications for the fermentation of micro-organisms that meet the criteria for low-risk GMOs (see section 2.3 of this document) and that have additional controls to address the use of larger volumes, to be rapidly assessed.

11s Do you agree or disagree with this proposal?

Please give your reasons.

11t What other mechanism(s) might be used to address this issue?

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

The HSNO Act sets out the criteria to be used in making different types of decision. For applications involving new organisms (including GMOs) in containment, the relevant part of the Act is section 45. There are two main criteria in section 45 – first that the beneficial effects (benefits) associated with the application must outweigh the adverse effects (risks and costs) should the organisms escape, after taking account of a range of matters. These matters include the ability of the organism to escape and to establish an undesirable self-sustaining population. Secondly, ERMA must be satisfied that the organism can be adequately contained.

Questions have arisen as to the operation of section 45 – in particular the relationship between the (innate) ability of the organism to escape and the adequacy of containment in the requirement to weigh up the adverse effects against the beneficial effects. This issue was raised in the High Court in late 2001 in an appeal on the decision made by ERMA to approve the field testing of GM cattle by AgResearch. The Court did not make a formal determination on the operation of section 45 but did express its views.

In these views the Court expressed its satisfaction that: “This approach [*taken by the ERMA*] to the section avoids the potential absurdity of balancing benefits of field testing in containment against adverse consequences in event of escape with no regard at all to likelihood in fact of escape”. It upheld the approach that had been adopted by the ERMA in regard to the decision on the field testing of cattle.

ERMA's approach was to merge consideration of both the ability of the organism to escape from containment and the adequacy of containment as one. ERMA's view is that the impact of containment controls on mitigating risks (including the risk of escape and any resulting consequences of that escape) should be considered as a 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 that should be able to influence the weighing up process directly.

Given that section 45 is a key decision making provision and remains open to varying interpretations, it is highly desirable that this section is clarified so that an unambiguous decision-making path is specified.

Proposed amendment

It is proposed to amend section 45 of the HSNO Act so that it is clear that in weighing up of beneficial effects against adverse effects (benefits against risks and costs) an integrated view is to be taken of all of the 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.

11u Do you agree or disagree with this proposal?

Please give your reasons, including examples and referring, where necessary, to the relevant parts of the HSNO Act.