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Manatū Mō Te Taiao

Hazardous Substance Strategy

Proposals to Amend the Hazardous Substances and New Organisms Act 1996 – Specialist and Technical Issues

Volume Two

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Executive Summary

This paper is the second of two volumes describing proposals to amend the Hazardous Substances and New Organisms Act 1996 (HSNO).

The first volume presents proposals that came out of the development of the government's Hazardous Substances Strategy and will be of interest to a general audience. This second volume covers issues that will be of interest to more specialist, technical audiences. These issues have been identified as a result of our experience working with the hazardous substances part of the HSNO Act. Most of the issues were not included in the strategy because their potential impact was limited.

Specifically, volume two includes proposals to:

- improve the workability of exposure limit controls for protecting people and the environment from the effects of toxic and ecotoxic substances
- make it easier to move specialty substances between research institutions
- allow substances imported to New Zealand solely for re-export to be covered by the existing containment approvals mechanism in the HSNO Act
- improve compliance, monitoring and enforcement by:
  - requiring HSNO approval numbers on labels
  - providing for a register of test certificates
  - giving ERMA the power to revoke an approved handler test certificate
  - ensuring that if an unapproved substance is imported, it must be re-exported
  - providing for enforcement agencies, when doing HSNO work, to use powers of entry and inspection that they have under other legislation
  - taking a fresh look at HSNO systems to report hazardous substance-related injuries
- review data protection provisions for agrichemicals
- provide new pathways to:
  - enable rapid approval for substances needed in an environmental emergency
  - enable rapid reassessment to reassess a substance if the original approval was given via the non-publicly notified rapid assessment pathway.

We are now seeking community feedback. The submissions we receive will be considered when drawing up proposals to ministers for amending the HSNO Act. We would expect the resulting amendment bill to be introduced into Parliament before the end of 2004.

1 Introduction

This discussion paper is the next stage in implementing the Government's Hazardous Substances Strategy. The strategy aims to improve the workability of the hazardous substances side of the Hazardous Substances and New Organisms Act 1996 (HSNO). We seek your feedback on several proposals to improve HSNO processes, and thereby reduce compliance costs and improve protection of public health, safety and the environment.

The discussion paper is in two volumes. The first volume is intended for people with a general interest in the HSNO Act. This second volume is more technical and is intended for a specialist audience, such as people who make applications for approvals or otherwise frequently interact with the Environmental Risk Management Authority (ERMA).

The proposals in both volumes affect only hazardous substances. They do not affect the HSNO processes for managing genetically modified organisms or other new organisms.

1.1 The origins of our hazardous substances law

The HSNO Act was the end result of reforms in response to public concern internationally and in New Zealand about the management of hazardous substances. Chapter 19 of the Agenda 21 document, published following the United Nations Earth Summit in Rio de Janeiro in 1992, contained international best practice principles for the environmentally sound management of toxic chemicals. The key principles were incorporated into the HSNO Act. They are:

- acting cautiously in instances where there is scientific and technical uncertainty
- providing for the right of the public to know about the effects of substances
- considering the full life-cycle of a substance from manufacture to disposal.

The HSNO Act also embodies the United Nations' Globally Harmonised System for the Classification and Labelling of Hazardous Substances (GHS), which is now being adopted by countries around the world.

The HSNO Act has a clear purpose to protect the environment and the health and safety of people and communities by preventing or managing the adverse effects of hazardous substances. It does this in large part by having a single independent authority, ERMA, make decisions on whether or not hazardous substances can be imported, manufactured or used, and assign controls to ensure they are used, stored, handled and packaged in such a way as to manage any risks they pose to people, property and the environment.

1.2 The Hazardous Substances Strategy

The hazardous substances provisions of the HSNO Act have been operating since July 2001. In that time it has become clear that there are a number of teething problems with the Act, including systemic problems that affect the Act's workability. These have been identified through letters to ministers, case studies from industry, ERMA's own experience working with the Act, and an independent assessment undertaken by an overseas expert.[1]

In response, the Ministry for the Environment and ERMA formed a small working group with knowledge and experience in hazardous substances management to help develop a strategy for improving the Act's workability. The working group's report[2] was released in June 2003 and was positively received by the business community.

The working group identified five key areas for improving the workability of the hazardous substances provisions of the HSNO Act, and these have formed the basis for the action plan laid out in the strategy. They are:

- simplify transfer[3] to ensure that the HSNO transfer process is practical, clear and timely
- remove redundancies and costs from the hazardous substance approval process and management system where they do not add to the protection of the environment and the health and safety of people and communities, and reduce barriers to the introduction of new hazardous substances used in low-risk situations
- make controls understandable for users and enforcement officers by ensuring that they are practical, clear and cost effective, and that information on the legal requirements for hazardous substances is easy to access
- improve the way the HSNO Act fits with other legislation, including the Resource Management Act 1991 (RMA), the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM), the Health and Safety in Employment Act 1992, the Building Act 1991, and the Food Act 1981
- ensure that compliance monitoring and enforcement arrangements are sound and that they demonstrate effective risk management.

The strategy contained a number of short-term and long-term actions to address these issues. There has been significant progress since the strategy was announced in June 2003, with all the short-term legislative actions now completed.

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1 BC Environmental, *The Hazardous Substance and New Organisms Act 1996*, Ministry for the Environment, Wellington, New Zealand, 2002.

2 Ministry for the Environment, *Strategy for Improving the Workability of Hazardous Substances Provisions of the Hazardous Substances and New Organisms Act*, Ministry for the Environment, Wellington, New Zealand, 2003.

3 Transfer is the process whereby substances are assigned HSNO controls and the controls that applied under previous legislation cease to apply to the substance.

First, a bill to simplify transfer was introduced into Parliament in November 2003. Submissions on the Hazardous Substances and New Organisms (Transitional Provisions and Controls) Amendment Bill closed on 16 January and the bill was passed in mid-March 2004. Explosives and fireworks were transferred to HSNO controls in August 2003 – the first group of substances to come fully under the HSNO regime. The technical specifications for the final outstanding sets of control regulations have also been completed and now have legal effect, and dangerous goods were transferred to HSNO controls on 1 April 2004.

In addition, ERMA has been allocated extra funding to allow it to move to a more predictable and affordable pricing system for hazardous substance approvals, thereby reducing the costs of approvals.[4] ERMA has also undertaken an information project to look at how the costs of compiling information for new substances applications might be reduced.

To improve the enforcement arrangements, extra funding has been allocated to ERMA to fill gaps in local capacity for hazardous substances compliance monitoring, enforcement and emergency response. ERMA, in conjunction with Occupational Safety and Health, is now in the process of developing contracts with territorial authorities.

[4] For example, a rapid assessment now costs a fixed fee of $500 only.

2 Environmental and Tolerable Exposure Limits

Several problems have been identified with exposure limit controls under the HSNO Act for ecotoxic and toxic substances. In particular, there are concerns that these controls conflict with established methods for setting environmental concentration limits and that they will be very difficult to enforce.

The Hazardous Substances and New Organisms (Transitional Provisions and Controls) Amendment Act came into force on 24 March 2004. One of the outcomes of these amendments is to allow ERMA the flexibility not to set a control for a substance, provided certain criteria are met. The advantage is that environmental and tolerable exposure limits do not have to be set for substances where the setting such limits is not an effective or cost-effective means of controlling the effects of the substance.

In addition to the above Act amendment, the Ministry for the Environment has released a discussion paper concerning regulation amendments for pesticides transfer.[5] The paper proposes a number of amendments to the Hazardous Substances (Classes 6, 8, 9 Controls) Regulations 2001 that we consider would substantially improve the setting and workability of environmental and tolerable exposure limits.

In general, the proposed regulation amendments involve the removal of a number of the technical constraints currently in the regulations, in order to enable ERMA additional flexibility to:

- set a range of environmental and tolerable exposure limits (eg, for fresh water, a range of environmental limits can be set for different pHs)
- consider best international practice (in a prescribed manner) for the assessment of toxicological and ecotoxicological data when setting environmental and tolerable exposure limits
- where there is a lack of sufficient national data, adopt international values as environmental and tolerable exposure limits.

The proposed changes to regulations are due to be in force before 1 July 2004.

Both the HSNO Amendment Act and the proposed regulation amendments will improve the workability of the environmental exposure limit (EEL) and tolerable exposure limit (TEL) controls. However, there are some issues that these changes do not address, particularly around compliance and enforcement. These issues are discussed further below.

ERMA is in the process of consulting on controls for toxic and ecotoxic substances, in preparation for the transfer of pesticides scheduled for July 2004. Most of these substances trigger exposure limit controls. However, given the difficulty with their effectiveness, ERMA is presently proposing not to set EELs and TELs until the issues described below have been resolved.

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[5] Ministry for the Environment, *Proposed Regulation Amendments for Pesticides Transfer and Other Matters*, Ministry for the Environment, Wellington, 2004.

2.1 The purpose and benefits of environmental and tolerable exposure limits

The purpose of setting environmental and tolerable exposure limits is to establish safe levels of a substance that can be intentionally released into the environment, in order to protect people and the environment from any adverse effects.

EELs are intended to help manage the effects of ecotoxic substances on the environment. An EEL establishes the maximum concentration of an ecotoxic substance legally allowable in a particular environmental medium (eg, water, soil or sediment), and/or a maximum loading of a substance onto a surface (eg, as in spray drift deposition). They are currently single-value concentration or loading limits set for environmental media (water, soil, sediment and surface deposition) after reasonable mixing, outside the target area, or for organisms exposed to ecotoxic substances by secondary poisoning. The process for setting EELs is described in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001, and in Appendix 1 of this document.

TELs are controls set by ERMA to help manage the effects of toxic substances on human health. They are single-value concentration limits set for exposure sources to humans (eg, air, water, soil, surface deposition). The process for setting TELs is described in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001, and in Appendix 1 of this document.

Apart from providing a measure of safety for people and the environment from activities where hazardous substances are intentionally released or applied into the environment, there is another key benefit of the EELs and TELs approach. Environmental and tolerable exposure limit controls are performance requirements, rather than prescriptive statements of how you should manage ecotoxic or toxic substances. For example, an EEL set for water for pesticide x does not state that x cannot be sprayed aerially or cannot be used in certain weather conditions. However, a person using pesticide x must not exceed the EEL outside the target spray area at any time. The person using x also has to consider their spray method and satisfy themselves that they will keep to the EEL. The advantage of performance-based requirements such as TELs and EELs is that they allow users maximum flexibility as to the manner in which they carry out the task at hand.

2.2 Issues with environmental and tolerable exposure limits

There are four key issues for the workability of environmental and tolerable exposure limits:

1. reconciling the EELs 'pass/fail' approach with the usual risk management approach to environmental limits
2. demonstrating compliance or enforcing exposure limits when multiple sources of the same substance are present in one environment
3. demonstrating compliance or enforcing exposure limits when they are difficult to measure
4. consulting with all affected people when a component occurs in many different substances.

Each issue is discussed in more detail below.

2.2.1 Issue 1: Reconciling the EELs 'pass/fail' approach with the usual risk management approach to environmental limits

EELs are set as a single value that you are either above or below – in other words, pass or fail. This pass/fail approach of the HSNO Act is inconsistent with the site-specific 'trigger value' approach of ANZECC and other international applications of these kinds of values.

If the EEL is exceeded then the offender could be prosecuted – even though it is possible that the receiving environment is suffering no adverse effects from the presence of the hazardous substance. The converse is also possible. The general practice in the environmental field is to take a risk management approach where, if a trigger value is exceeded, then further work is required to determine whether adverse environmental effects are occurring or not.

The HSNO Act does not provide for enforcement agencies or regional councils to take into account the characteristics of the receiving environment. Councils may set more stringent values than the EEL, but they cannot set less stringent ones, even though specific site characteristic may warrant this (eg, high natural background concentrations to which the flora and fauna have adapted, or where the natural background levels are higher than the EEL). This is clearly contrary to the effects-based approach of the RMA.

The HSNO Act pass/fail approach will be in conflict with any risk management-based guidelines. Indeed, the Ministry for the Environment has been involved in developing a number of guidelines that could potentially be in conflict with HSNO environmental exposure limits, including:

- *Health and Environmental Guidelines for Selected Timber Treatment Chemicals* (Ministry for the Environment, 1997)
- *Guidelines for Assessing and Managing Petroleum Hydrocarbon Contaminated Sites in New Zealand* (Ministry for the Environment, 1998)
- *New Zealand Municipal Wastewater Monitoring Guidelines* (New Zealand Water and Environmental Research Foundation, 2002).

2.2.2 Issue 2: Demonstrating compliance or enforcing exposure limits when multiple sources of the same substance are present

The HSNO approach to environmental limits does not deal well with multiple sources of hazardous substances being released into the same environment. Sources of hazardous substances range from industrial activities to storm-water discharge. For example, there could be 10 people spraying the same substance in a catchment – who is responsible for exceeding the EEL if the substance is detected in the local stream?

It is worth noting that this issue is common to all approaches that involve setting exposure limits. Australian and New Zealand Environment and Conservation Council (ANZECC) guidelines, the guidelines commonly used in New Zealand for environmental limits, do not deal with this issue in setting trigger values.

2.2.3 Issue 3: The difficulty of measuring environmental and tolerable exposure limits in the environment

There is a significant issue with measuring environmental and tolerable exposure limits that are close to or well below analytical limits of detection. This problem also applies to many international exposure limits, which are very small. While non-compliance will be measurable, it will be difficult for people to demonstrate compliance with a concentration which cannot be reliably measured.

There is also a misconception that analytical methods will be capable of reaching much lower in the future than at present. In fact many instrumental methods are at or near their theoretical limits already. Issues also arise from an increased probability of sample contamination representing a larger part of the measurement as the measured number gets lower.

Even for higher measurable concentrations, different analytical and sampling methods can produce different results for the same samples. The timing of sampling can also be critical for some substances because they degrade very rapidly within or on plant tissues or soil and they may not leave characteristic residues. This makes demonstrating compliance or catching non-compliance very difficult. In addition, commercial laboratories measure concentrations, but none currently offer surface loading estimates.

2.2.4 Issue 4: Consulting with all affected people when a component occurs in many different substances

The process for setting EELs and TELs is tied to the approval of the first substance containing the particular compound or element (eg, ammonia or copper). It is difficult to consult all those who could be affected by the setting of an environmental or tolerable exposure limit for a compound or element that may be present in other substances. Also, the time requirements in the Act make it difficult for ERMA to delay consultation for the purposes of involving industry or councils.

2.3 Options for improving the workability of environmental and tolerable exposure limits

We propose a combination of approaches to address the issues with EELs and TELs we have been discussing. Table 1 below sets out the issues we are seeking to address (across the top) and the options for consideration (down the side). We then go on to discuss each option in detail.

Table 1: Options and issues for environmental and tolerable exposure limits

Issues to address → **Options for addressing the issues ↓**	**1. Pass/fail vs risk management EELs**	**2. Multiple sources of the same substance unenforceable**	**3. Difficult to measure EELs and TELs in the environment**	**4. Consultation with all affected people difficult when component occurs in many different substances**	**Advantages**	**Disadvantages**	**Implementation method**
A. Only set EELs for substances intentionally discharged into the environment (eg, pesticides not paints)	(X)	(X)			Would reduce potential areas of conflict with other risk management based guidelines or national environment standards. Would reduce the potential for conflict where ERMA sets an EEL for a naturally occurring substance with high background levels in some places.	Need to consider Hazardous Substance Disposal Regulation implications.	ERMA policy
B. Only set an EEL or TEL if the effect cannot be managed by the RMA	(X)	(X)				Difficult to determine how well effects are being managed by RMA at a national level. Would require extensive national consultation.	ERMA policy
C. Set EELs or TELs as 'default values' but allow regional councils to set less conservative numbers based on site-specific assessment	(X)				Would see numbers set for substances not necessarily covered by regional councils under the RMA.	Would require expensive site investigations, so who pays? – councils or RMA applicants?	Act amendment
D. Set an EEL or TEL but enforce against codes of practice only	X	X	X		Maintains flexibility. Relatively straightforward to implement given current work on codes of practice for pesticides. Reduce the cost of enforcement.	Would require a code to be developed before a substance could be used.	Act amendment
E. Set EELs and TELs separately from substance approvals so they apply to all substances containing that particular component				X	Everyone potentially affected by ERMA decision can be involved in the process. Could be done during transfer	Would potentially slow down the process for applicants. Questions around who pays for the process for setting an EEL if more than one 'applicant'.	Act amendment

KEY (X) = addresses issue for some substances X = addresses issue for all substances.

2.3.1 Option A: Only set EELs for substances intentionally discharged into the environment

This option helps to address issues 1 and 2 by not setting EELs for some substances. For example, EELs are important and necessary controls for pesticides, but not important to manage the effects of paints.

This option could be implemented by developing an ERMA policy on which substances need EELs. However, in order not to set an EEL, ERMA would still need to satisfy the criteria set out in the Act.[6]

Taking this option would require the Hazardous Substances Disposal Regulations 2001 to be reconsidered. Currently, if an EEL exists for a substance then you can dispose of it into the environment provided the EEL is not exceeded. If an EEL is not set for a large group of substances, then you could not dispose of those substances by slow release into the environment. The implications of this need further consideration.

2.3.2 Option B: Only set environmental and/or tolerable exposure limits if the effects are not being managed by the RMA

As with option A, option B helps to address issues 1 and 2. Again this option could be implemented by developing an ERMA policy paper on which substances need an EEL, meeting the appropriate criteria set out in the Act.[7]

Unless permitted by a regional plan, discharges of substances into the environment require a discharge permit (a type of resource consent). During the permitting process, councils consider the effects that a discharge could have on the receiving environment, which allows councils to take into account background levels of the substance. This is something that environmental and tolerable exposure limits set at a national level cannot do.

Many regional plans contain standards or limits for substances (or 'contaminants' in RMA language) in the environment. The Ministry for the Environment is also in the process of developing national standards for some contaminants. In the absence of a national standard, ERMA would need to assess whether regional planning mechanisms are in place to manage the effects of particular substances across the whole country. Extensive consultation would be needed and it would in fact be a very difficult judgement to make.

Taking this option would require a significant change in the statutory process for handling applications due to the tight timeframes for consultation under the HSNO Act. Also, option B would only address the relatively few substances picked up by regional plans and national environment standards. Given its limited effect and difficulty in implementing, this is not a preferred option.

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6 See section 160B, Hazardous Substances and New Organisms (Transitional Provisions and Controls) Amendment Act, enacted on 23 March 2004.

7 See section 77A(4), Hazardous Substances and New Organisms (Transitional Provisions and Controls) Amendment Act, enacted on 23 March 2004.

2.3.3 Option C: Make use of environmental and tolerable exposure limits as default values, unless a resource consent is applied for

This option addresses issue 1. Under this option an environmental or tolerable exposure limit would apply as its does now, unless a resource consent is applied for. However, a subsequent risk-based RMA-type assessment could allow for the limit to be raised, if the local environmental conditions justified such a change. This would remove the upward restriction on the resource consent-setting process (currently, a limit can be set by a resource consent that is more strict than the relevant EEL or TEL, but not less strict).

This option would:

- allow HSNO protection to be put in place for large parts of the environment not covered through the resource consenting process, and at the same time would
- allow industrial and commercial operations that are discharging a hazardous substance to proceed or continue provided they have been through the RMA resource consenting process, which is already designed to ensure protection of human and environmental health.

This option allows the RMA and the HSNO Act to neatly complement each other, and resolves the issue that EELs set at a national level may be set well below the level where a risk-based site-specific assessment shows that adverse environmental effects would occur.

While this option allows for a risk management approach, it does not address the compliance and enforcement issues for cases where environmental and tolerable exposure limits are set and so is not a solution on its own.

2.3.4 Option D: Set an environmental or tolerable exposure limit, but enforce against codes of practice only

Option D addresses the first three issues identified: 1, 2 and 3.

Under option D, environmental and tolerable exposure limits would be set, but would not be legally enforceable. However, a person using the substance would be required to follow an approved code of practice and could be prosecuted for not following it. ERMA would approve the code of practice if following the code would meet the indicated environmental or tolerable exposure limits.

This approach would improve the ability of people to know how to comply with HSNO controls to prevent adverse environmental effects. It would also make it easier to address the problems of multiple sources of a substance, where it is not possible to identify the responsible individual(s). A code of practice would set controls for how the substance is used to prevent the adverse effects. It is easier to demonstrate that a person is following or not following a best practice procedure than to capture samples of a substance in a stream, for example.

This option would require that codes of practice be developed before a substance is used. However, considerable work has already been undertaken for codes on pesticide use, for example, so for this group of substances requiring development and approval of a code would not be onerous.

Given that this option addresses three of the issues above and would be relatively straightforward to implement, we consider this a strong proposal for further consideration.

2.3.5 Option E: Set exposure limits separately from substance approvals and apply to all substances containing the particular component

Option E addresses issue 4: the problem of how to consult with all people potentially affected by a decision on an EEL for a component of a substance that occurs in other substances as well.

Separation of the environmental and tolerable exposure limit-setting process from any particular application would facilitate robust development of the values. It would, however, create difficulties for ERMA's approval process. If the substance is new, it would take some time for a generic EEL-setting process to take place. This would delay the introduction of a new substance by many months. It would also be difficult to determine who should pay for the process.

To change environmental and tolerable exposure limits to apply to all sources of a particular ecotoxic and toxic substance would require a fundamental change to the HSNO Act and ERMA's role. However, this may be necessary to make exposure limits under the HSNO Act work.

2.3.6 Summary of options

In summary, to improve the workability of tolerable and environmental exposure limits, we propose to:

- set exposure limits as default values but allow regional councils to set less conservative numbers based on site-specific assessment when carrying out a resource consent application assessment (option C)
- set exposure limits, but **require** people to develop and meet a code of practice that demonstrates that the exposure limits should be met (option D)
- separate the exposure limits-setting process from the approval process (option E).

Options A[8] and B[9] can be implemented by ERMA through their internal policy processes. However, we consider that option B will be too difficult in practice to implement. Option C merits investigation as a way to address the conflict between ERMA setting environmental limits at a national level and local background considerations and improves the interface between the HSNO Act and the RMA. However, it does not address the key compliance issues, so is not a solution on its own. Therefore we also propose that options D and E be considered further.

QUESTIONS

1. To improve the workability of tolerable and environmental exposure limits, we propose to:
   - set EELs and TELs but require people to develop and meet a code of practice that demonstrates that the EEL or TEL should be met
   - separate the EEL- and TEL-setting process from the approval process
   - allow regional councils to set environmental limits for discharge permits higher than an ERMA-prescribed EEL, if they have carried out an appropriate risk assessment.

Are there any alternatives we have missed? Can you see any problems with the preferred proposals?

[8] Option A: to only set EELs for substances intentionally discharged into the environment.

[9] Option B: to only set environmental and/or tolerable exposure limits if effects are not being managed by the RMA.

3 Research on Hazardous Substances

Concerns have been raised with the Ministry for the Environment about section 33 of the HSNO Act. This provision potentially exempts research and teaching institutions and laboratories from the full range of HSNO controls. Four policy issues have been identified.

As this discussion paper is about possible amendments to the Act, issues concerning Hazardous Substances (Exempt Laboratories) Regulations are not discussed here. A separate policy process for this will be undertaken later in 2004.

3.1 Overview of how the HSNO Act provides for research under section 33

Section 33 states that a qualifying laboratory does not have to:

- obtain an approval for the importation or manufacture of an unapproved substance, or
- directly comply with the HSNO controls that have been assigned to each approved hazardous substance (eg, for test certification or approved handlers).

Section 33 is specifically for research and development (and teaching) and allows a substance to be developed to the point at which it might be used outside research laboratories. It does not, however, apply to all laboratories engaged in small-scale work. For example, laboratories doing quality assurance work probably do not qualify and have to operate under the full provisions of the HSNO Act, even though their work is 'small-scale'.

The term 'research and development' is defined in the Act so that it can apply to institutional research organisations and to research and development carried out in an industrial context. For more details on the definition of research and development, see section 3.3.2.

The term 'small-scale' is not defined, recognising the fact that quantities vary according to the type of research being undertaken. The point of section 33 is, however, that the quantities involved must be related to the requirements of a research or teaching programme. To ensure the exemption is not used to avoid the HSNO approvals process, section 33(d) stipulates that substances used or made under section 33 exemption cannot be sold. This provision was designed to constrain section 33 to the laboratory research and development phase.

Existing section 33 provisions do not compromise the risk management outcomes the HSNO Act is designed to deliver. Section 33 requires:

- managers and workers to have the necessary knowledge to handle substances safely
- hazardous substances to be contained within the laboratory and not allowed to escape into the environment
- substance management plans to be well developed and include provisions for tracking and record keeping.

3.2 Teaching and research laboratories may opt out of section 33

If section 33 is invoked, the person in charge must ensure compliance with section 33 and with the exempt laboratory regulations. If section 33 is not invoked, the person in charge must ensure compliance with the HSNO controls assigned to each hazardous substance in the laboratory.

Organisations with more than one laboratory on a single campus may find it works to their advantage to have laboratories operating under both systems. Such a strategy could overcome the problem that section 33 laboratories cannot on-sell substances to another lab after importation or manufacture.

Schools and other institutions with limited expertise in managing hazardous substances may also find it to their advantage to stay outside the section 33 provisions entirely. For them, it may be better to have third-party verification of compliance through the test certification of facilities and to have key staff certified as approved handlers.

3.3 Policy issues

Four issues have been identified from material given to us by stakeholders concerning the operation of section 33 of the HSNO Act:

- the section 33 prohibition on sale is too restrictive given current practices in research and development, and teaching
- the definition of 'research and development' needs to be modified
- the definition of 'laboratory' should be widened to include those on ships and other water craft used in research
- section 33 should be amended to allow the use of declined hazardous substances.

The Ministry for the Environment has, following discussion with other departments, formed a preliminary view on what should be done with respect to each of these issues. Where there was a range of possible policy options, we considered each option against the following criteria:

- risk management
- equity (we want to prevent the possible exploitation of section 33 provisions for 'backdoor' manufacture of hazardous substances creating an uneven playing field)
- enforceability (any amendment must be legally enforceable)
- practicality (an amendment must not impose excessive costs, either on laboratories operating under section 33 or on ERMA in terms of its administration of the Act).

Please let us know if your particular issue is not covered by our list, or if you disagree with our suggested evaluation criteria. We now turn to examine each of the section 33 issues in more detail.

3.3.1 The section 33 prohibition on sale is too restrictive given current practices in research and development, and teaching

Institutions have pointed out that this provision (section 33(d)) poses problems for certain research establishments where substances being used for research and development may need to be transferred from one lab to another in a different department, with transfer payments being made in line with internal accounting procedures. The clause also fails to recognise that some institutions develop substances that are to be used by other organisations for their research. While technically still research and development on a small scale, the resulting substance is destined to be sold on, in some cases, to companies overseas.

Our preliminary view is that section 33 laboratories should be able to freely sell substances to other section 33 laboratories in New Zealand. By limiting sales to laboratories operating under section 33, we can be certain that substances are only being used for the purposes of research and development or teaching. We can also be certain that HSNO controls manage any unapproved substances, as only the exempt laboratory regulations assign controls to unapproved substances.

Once substances are exported, however, there is no way of knowing or enforcing whether substances are being used for research and development or teaching only. Consequently, we think there should be a system to allow ERMA to authorise a one-off export or a series of exports. To gain an authorisation, the laboratory would have to convince ERMA that any export would solely be for the purpose of research and development or teaching. We foresee that amendments along these lines may require laboratories invoking section 33 to introduce more stringent record keeping and tracking systems for the substances they import, produce and sell so that the small scale and research and development provisions of section 33 could be monitored.

Note that from an equity point of view, approved hazardous substances or any product made from a hazardous substance should be manufactured under the full provisions of the Act if not being used in a section 33 laboratory for the purposes of research and development or teaching.

QUESTIONS

2. Does the Ministry for the Environment's suggestion satisfactorily address the concerns of researchers without unfairly disadvantaging importers and manufacturers operating under the main provisions of the Act?
3. If not, what is your preferred option and why?

3.3.2 The current definition of 'research and development' needs to be modified

Some researchers have suggested that the definition of 'research and development' needs to be clarified so that an investigation into the properties of a substance, the analysis of materials using analytical standards, and a clinical trial are all explicitly deemed research and development activities. We have also been informed that the definition of 'research and development' is not as clear as it could be.

The Act defines 'research and development' as "systematic investigation or experimentation activities that involve innovation or technology transfer for the purpose of gaining knowledge about the properties or uses of that substance". From a clarity standpoint, we understand that the meaning of the phrase "that involve innovation or technology transfer" is unclear for many researchers. Our view is that this phrase reinforces the fact that research and development in HSNO terms is not just about completely new ideas but is also about developing existing technologies.

In the case of an investigation into the properties of a substance, as long as this is done in a systematic manner, the current definition of research and development seems sufficient.

Regarding the analysis of materials, there is a question around whether the current definition of research and development precludes the use of approved or unapproved substances as analytical standards under section 33. While analytical standards are used in systematic experimentation for the purpose of gaining knowledge about, for example, a new substance (ie, an innovative substance), the standards themselves are not the focus of the research and development. This may mean that the section 33 exemption from the need to obtain an approval cannot be applied.

Our view, however, is that section 33 can be applied. When carrying out "systematic investigation or experimentation activities", a range of reagents that are hazardous substances will be required to carry out the research where the focus is on gaining knowledge about the properties or uses of a substance that would otherwise need an HSNO approval. The clause in the definition of research and development, "for the purpose of gaining knowledge about the properties or uses of that substance", makes it clear that the purpose of research and development must be substance based but does not limit the applicability of section 33 only to the substance being researched.

Section 33 is not applicable to finished dose products to be used in clinical trials, even though clinical trials are, without doubt, a form of research and development that may involve hazardous substances. While medical ingredients that are hazardous substances are regulated by the HSNO Act[10] and could be made under section 33, the Medicines Act rather than the HSNO Act regulates the production and use (including clinical trials) of all human medicines. Organisations wishing to manufacture products for clinical trial should have manufacturing facilities that are licensed under the Medicines Act. If an ingredient of the medicine for clinical trial is hazardous, there is no reason why such a facility could not also invoke the section 33 HSNO exemption. An approval under the Medicines Act will still be required to conduct any clinic trial.

[10] See regulation 5 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 for how the HSNO interfaces with the Medicines Act.

The Ministry's preliminary view is therefore that the current definition of 'research and development' is sufficient and does not need amendment.

QUESTION

4. Are there activities for which the current definition of 'research and development' is too restrictive?

3.3.3 The current definition of 'laboratory' needs to be modified to include those on ships and other water craft used in research

The Act defines laboratory as "a vehicle, room, building, or any other structure set aside and equipped for scientific experiments or research, for teaching science, or for the development of chemical or medicinal products". While it does not specifically mention ship or water craft, a ship's laboratory would be covered by "any other structure" as long as it was "set aside and equipped" for the listed purposes.

Our preliminary view is therefore that there is no need to amend the definition in the manner that has been suggested. (Note that the HSNO Act does not apply beyond New Zealand's 12-mile territorial limit in any event.)

QUESTION

5. Do you believe the definition of 'laboratory' needs to be changed, and if so, why?

3.3.4 Section 33 should be amended to allow the use of declined hazardous substances

While section 33 rules out the manufacture and use of any hazardous substance for which an HSNO approval has been declined, it is possible to use these substances as analytical standards on a case-by-case basis under a containment approval (see sections 30–32 of the Act).

Our preliminary view is that the use of declined substances in laboratories is already adequately provided for and there is no need to amend section 33 of the HSNO Act in this regard.

QUESTION

6. Do you believe section 33 should be amended to allow the use of declined substances, and if so, why?

4 Substances Imported for Export Only

Submitters to the New Organisms and Other Matters (NO&OM) Bill and industry stakeholders are concerned that the 20-day limit on transhipment is somewhat arbitrary, and that something coming into New Zealand to be exported within 21 days is still, in effect, transhipment. There have been requests from industry to remove the 20-day limit.

This is particularly of concern for those importers who import substances into New Zealand and put labels on these substances in Pacific Island languages, for example, and export them to the Pacific Islands without selling the product into New Zealand. Usually these substances are similar to or the same as substances already in use in New Zealand. However, occasionally these substances are not substances in use in New Zealand and may be targeted to a particular crop or pest that does not occur in New Zealand.

Currently the HSNO Act allows ERMA to approve the manufacture or importation of any hazardous substance in containment (section 30) for analytical standards, research and use in emergencies. However, the Act is not clear on whether ERMA can consider an application for a containment approval for other purposes.

We consider that the Act should be clarified so that new substances that:

- are imported into containment
- are either relabelled, repackaged or reformulated
- will be exported only, an not used or sold in New Zealand

can be considered under the containment approval pathway.

All imported goods arriving in New Zealand are required by the Customs and Excise Act 1996 to be cleared through the New Zealand Customs Service. Regulation 21 of the Customs and Excise Regulations 1996 requires that the entry to clear the goods must be lodged with Customs within 20 working days after the date of the goods importation. Therefore, to remain consistent with the Customs and Excise Regulations, we do not propose to remove the 20-day time limit.

The issue also arises via another mechanism: a change in the definition of ‘importation’. There is concern that the HSNO Act may now apply to substances imported into New Zealand en route to another destination where historically they would have been excluded from consideration. This is because the meaning of the term ‘importation’ has changed.

The HSNO Act defines ‘importation’ in relation to hazardous substances to have the same meaning as section 47 of the Customs Act 1966. The Customs Act 1996 excludes goods (from the definition of importation) whose destination is outside the territorial limits of New Zealand, provided they do not leave the ship or aircraft. The Customs Act 1966 has been replaced by the Customs and Excise Act 1996, which redefined ‘importation’ without this exclusion. This change will need to be reflected in the HSNO Act and we propose to make an amendment to accomplish this.

As a consequence, however, a number of hazardous substances passing through New Zealand are now caught by the HSNO Act and will require a normal approval or a transhipment approval. Again, these substances could be covered by containment approvals if section 30 of the Act were clarified.

QUESTIONS

7. Do you agree that the Act should be clarified so that new substances that:
   - are imported into containment
   - are either relabelled, repackaged or reformulated
   - will be exported only, not used or sold in New Zealand

   should be able to be considered under the containment approval pathway?

5 Improving Compliance Monitoring and Enforcement

This chapter describes six proposals for improving the hazardous substance compliance monitoring and enforcement regime:

- requiring HSNO approval numbers on labels
- providing for enforcement agencies, when doing HSNO work, to use powers of entry and inspection that they have under other legislation
- providing for a register of test certificates
- giving ERMA the power to revoke an approved handler test certificate
- ensuring that if an unapproved substance is imported, it must be re-exported
- taking a fresh look at HSNO systems to report hazardous substance-related injuries.

We will now look at each of these proposals in detail.

5.1 HSNO approval numbers on labels

The Hazardous Substance (Identification) Regulations 2001 require that a hazardous substance be identified by a common name, a chemical name or a registered trade name. This information is then stored on the ERMA Hazardous Substances Register. The register is available on the ERMA website (www.ermanz.govt.nz).

Users of the register could potentially include:

- Customs officers checking consignments at the border
- test certifiers applying the HSNO regulations
- enforcement officers checking compliance with HSNO controls
- members of the public wanting to know more about a particular product
- companies wanting to know that trade competitors have complied with HSNO requirements.

There has been a call for an amendment to the law to require that an HSNO approval code also be shown on the label to make it easier to find the substance on the ERMA register. The number of substances on the register is growing rapidly. While it can be searched by entering the trade name (unique identifier), this is not always the same as the common name, especially for branded products. Some people simply want reassurance that a substance/product is HSNO-approved and, for them, searching a register is an unnecessary step. This is particularly likely to be an issue during transfer.

The purpose of the register is to provide evidence that a substance/product has been approved in order to assist compliance efforts, and any change to include an approval number would need to have safeguards to prevent anyone using it to trace the details of the original ERMA decision for commercial purposes. For instance, it may be that the original applicant would be allocated one number and subsequent users of the approval another.

In any event, this policy will require an amendment to the HSNO regulations. The detail of the system would be consulted on in the context of policy for regulation amendment.

There appears to be wide support for this change, but there are compliance cost implications. For the policy to deliver the expected benefits, all users of an approval would have to display the HSNO approval number on the label, not just the original applicant for the approval. Thus, generic manufacturers/marketers of 'image' products would need to display an HSNO number.

The cost of designing and printing labels is not insignificant. Allowing a transition period for old labels to be used up could perhaps mitigate this problem. Another option would be the use of a stick-on number to be placed on top of the existing label until old stocks were used up.

Lastly, there are issues concerning imported hazardous substances. Substances imported in bulk are not labelled as such, but a requirement to quote an HSNO number could be applied to supporting documentation. Imported consumer products are sometimes labelled in the country of origin. It is proposed that importers/wholesalers would be required to comply before sale within New Zealand rather than before importation. As a result, re-labelling in New Zealand might be necessary.

QUESTIONS

8. Do you think it would be helpful to require that ERMA-approved numbers to be included on labels?
9. What benefits do you perceive in this proposal?
10. What are the costs to business?
11. Are there better ways to tackle the problem?
12. Should there be any exemptions to the policy?

5.2 Powers of entry and inspection

As discussed in Volume 1, section 97 of the HSNO Act lists the agencies that are to enforce the Act and the places or subject areas for which they are responsible. The roles were designed to ensure maximum overlap with existing agency functions, thereby making best use of resources and avoiding numerous overlapping or conflicting compliance activities and enforcement actions by multiple agencies.

Consistent with this approach, it was also originally intended that, wherever possible, enforcement agencies were to enforce HSNO controls using their existing powers under their existing legislation.

A breach of the HSNO Act may not necessarily be a breach of the enforcement agency's primary legislation (and vice versa). In such a case, the enforcement agency must take action for the breach under the appropriate legislation, using that Act's powers of inspection and enforcement. This may present difficulties if there are significant differences in the powers of inspection or enforcement between the HSNO Act and the agency's primary legislation.

In particular, the HSNO Act powers of entry and inspection distinguish between inspections:

- for the purpose of assessing compliance (section 103 of the HSNO Act)
- where an enforcement officer has reasonable grounds to believe that an offence has been committed under the HSNO Act and wishes to obtain evidence of that offence, which requires a search warrant (section 119 of the HSNO Act).

This distinction means that if an enforcement officer has reasonable grounds to believe an HSNO offence has been committed and wants to obtain evidence of that offence, the officer cannot use the compliance inspection power of entry and inspection, but must first obtain a search warrant (section 119). Also, the powers of entry and inspection under section 103 can be used only for the purpose of assessing compliance and must not be used longer than is necessary for that purpose. If during a compliance assessment an enforcement officer has reasonable grounds to believe there is an HSNO breach, the officer should not continue the inspection simply to get further evidence of that offence, but should instead consider getting a search warrant.

For some enforcement agencies, this approach is very similar to that of their own legislation, such as the territorial authorities operating under the RMA. However, for other agencies the approach is very different. For example, the Department of Labour's Occupational Safety and Health Service (OSH) operates under the Health and Safety in Employment Act 1992, which does not distinguish between proactive inspections to assess compliance and reactive inspections in response to a possible breach, but simply provides inspectors with general powers of entry and inspection. As a result, under the Act OSH inspectors have flexibility to respond to a wide variety of health and safety issues that may arise during a workplace visit, including the ability to respond immediately to breaches with appropriate enforcement action and to gather evidence to support enforcement action without having to stop to obtain a search warrant.

It is proposed that the HSNO Act be amended to provide that section 97 enforcement agencies can exercise the powers of entry and inspection under their own legislation when carrying out their responsibilities as an enforcement agency under the HSNO Act. This is consistent with the original intent of enforcement by section 97 agencies. It is also consistent with the Hazardous Substances Strategy by contributing to improving the workability of HSNO.

QUESTION

13. Do you agree that the HSNO Act should be amended to allow section 97 enforcement agencies to exercise the powers of entry and inspection under their own legislation when carrying out their responsibilities as an enforcement agency under the HSNO Act? What is your reasoning?

5.3 Register of test certificates

An important part of the approval and compliance regime for hazardous substances is the requirement that test certificates be obtained for equipment and locations where hazardous substances are used and held, and that people handling certain hazardous substances are certified. The Act provides that test certifiers be responsible for issuing these test certificates.

While there is a requirement in the Act for test certifiers to keep records of the certificates they issue, there is no obligation to make this information available to ERMA (or anyone else).

A centralised register of the information contained in test certificates would help:

- ERMA to deliver its statutory overview functions
- enforcement agencies to know what certificates have been issued and where hazardous substances are located in their area – enforcement agencies cannot at present easily validate claims that a certificate is held by a handler or a location.

In the past, local authorities have used the information provided through dangerous goods licences for planning, resource consents and land information memoranda (LIMs) purposes. Unless a central register is maintained, local authorities will no longer have access to this information.

Recognising the utility of such information, ERMA now requires test certifiers to provide information to ERMA on the test certificates they issue as a condition of their approval. Some test certifiers argue that there is no explicit statutory requirement to provide that information in the HSNO Act. In any event, there will potentially still be gaps in the ERMA register because the first test certifiers were not required to provide information to ERMA.

We therefore propose that ERMA have explicit statutory authority to require the following information from test certifiers:

- the affected site
- the nature and status of the certificate
- the certificate's date of issue and expiry.

This information could be placed on a publicly searchable register.

QUESTIONS

14. Do you agree there is a need for a centralised register of the information contained in test certificates?
15. Do you agree the Act needs to be amended to give ERMA explicit statutory authority to require this information from test certifiers?
16. Should there be any restrictions on what ERMA can require, what should be on the register; or who can access the register?

5.4 Revoking an approved handler test certificate

ERMA appoints test certifiers under section 84 of the Act. The test certifiers then have the duty to issue test certificates to approved handlers under section 82. At present an approved handler is granted a test certificate for five years, at which point a renewal must be sought from a test certifier. Section 86 sets out when a test certifier's approval may be revoked by ERMA but not when an approved handler's certificate may be cancelled.

There are a number of circumstances in which an approved handler test certificate should possibly be revoked, including when:

- an approved handler is shown to be incompetent
- the information used in support of an approved handler application was later found to be false or misleading
- the person has been convicted of a criminal offence of a kind that calls into question competence to be an approved handler.

We propose that ERMA have the ability to cancel a test certificate. What is proposed here is a mechanism for approved handlers similar to the current section 86 provisions that apply to test certifiers (only). Section 86 reads:

> *86. Complaints to Authority – (1) If the Authority receives any complaint about, or has cause to query the conduct or ability of a test certifier the Authority may investigate the complaint or query and, if it considers the complaint or query to be justified, may amend or cancel the approval.*

QUESTIONS

17. Do you agree ERMA needs to have the ability to directly cancel an approved handler test certificate issued by a test certifier?
18. Do you agree that a query about conduct or ability should trigger investigation by ERMA?

5.5 Ability to require an importer to re-export

Section 122 of the HSNO Act provides that where a Customs officer has reasonable cause to believe that a hazardous substance is being imported in breach of the Act, the officer may direct that the hazardous substance remain on the ship or aircraft and leave New Zealand.

Typically Customs will not be aware of the shipment until after it has been offloaded from the ship or aircraft. Once the goods have been offloaded, Customs is not able to use the current section 122 to direct that the importer re-export the goods. In a situation where hazardous substances that do not have an ERMA approval are offloaded, Customs can still use powers under the Customs and Excise Act to seize the goods. The difficulty is that seized goods become the responsibility of the Crown, with Customs being responsible for their storage and disposal.

It is proposed the importer should have a clear responsibility for re-exporting unapproved hazardous substances whether the goods are intercepted before or after being offloaded. This would provide added assurance that hazardous substances not covered by an approval do not remain in New Zealand.

QUESTIONS

19. Do you agree that in a situation where unapproved hazardous substances are intercepted by Customs, the obligation should be on the importer to re-export the goods?

5.6 Under-reporting of hazardous substance injuries

Section 143 of the HSNO Act requires notification of all hospital admissions from hazardous substance injuries by the person in charge of the hospital to the medical officer of health. This requirement was derived from section 76 of the Toxic Substances Act 1979, which required notification of all hospital admissions from poisoning. The definition of hazardous substances includes some substances that were previously not notified, such as explosives, and the term 'injury' also widens what was previously notified.

It is thought likely that there is significant under-reporting of injuries, and that part of the reason for this is inadequacies in HSNO notification and reporting provisions. Present provisions do not include presentations to a general practice or accident and emergency clinics, including after-hours clinics. General practice is the more likely place of care rather than emergency departments for all but the most serious injuries. Even attendances at hospital emergency departments are excluded if 'admission to hospital' is interpreted narrowly as at least being an overnight stay.

There are at least three options for addressing the issue of inadequacies in the Act:

- require all diagnosing medical practitioners to notify hazardous substance injury
- make explicit that 'admission to hospital' also includes hospital attendances rather than just overnight stays
- abandon notification as the method of obtaining monitoring information in favour of methods such as health surveys or sentinel general practice surveillance (this might still require a legislative mechanism to enable HSNO enforcement officers appointed by the Ministry of Health to take appropriate action to protect public health).

QUESTIONS

20. Do you agree that under-reporting of hazardous substance-related injury is a significant issue?

21. How do you think it should it should be addressed?

6 Data Protection Issues

Data protection for pharmaceutical and agricultural chemicals was (first) introduced as an issue in the General Agreement on Tariffs and Trade (GATT) Uruguay round. Issues were further discussed by the international community, and an agreement was reached in the form of the Trade Related Aspects of Intellectual Property (TRIPs) agreement, to which New Zealand is a signatory. The TRIPS agreement, and in particular Article 39.3 concerning the utilisation of new chemical entities, was passed into New Zealand law via the Medicines, Pesticides, and Animal Remedies Acts[11] in 1995.

The HSNO Act provides data protection by cross-referencing the relevant provisions in the ACVM and Medicines Acts. Where these provisions apply, information cannot be released to another party or used by regulatory agencies, including ERMA, in the consideration of other applications.

During the development of the Hazardous Substances Strategy, some industry sectors argued that:

- while HSNO/ACVM provisions generally implement TRIPS satisfactorily, there are some exceptions, such as turf care products
- significant national benefits would accrue if data protection were given to applications involving new uses of existing formulations (eg, where new information is provided to support an application for the use of glyphosate to control aquatic weeds)
- while the HSNO Act and ACVM are complementary, the HSNO Act should have stand-alone data protection provisions to give greater certainty. (The data package is often split between regulatory agencies, with environment and public health data submitted to ERMA but not to the New Zealand Food Safety Authority as ACVM regulator.)

6.1 What is 'data'?

'Data' covers the required studies and information (sometimes referred to as the data package) supplied to regulatory authorities such as ERMA by applicants for approvals. The size of the package varies depending on the type of application. For a new agrichemical, the package of supporting studies may extend to hundreds of thousands of pages of written material. The data package, therefore, represents a very significant investment in intellectual capital by the applicant company, and one that could potentially be of considerable value to competitors.

[11] In 1997 these last two Acts were incorporated to the Agricultural Compounds and Veterinary Medicines Act.

Data protection is well-established in the agrichemical regimes of all Organisation for Economic Co-operation and Development (OECD) countries. The aim is to:

- prevent unauthorised access by others
- prevent the use of data by the regulator in a way that might benefit others ('cross-referencing')
- establish a specific period of time for the owner to realise the value of the investment (the 'protection period').

Data exclusivity periods commonly run concurrently with patent protection.

Data protection is concerned with the investment of companies in generating data; a patent, on the other hand, rewards a party for an invention (investment in innovation) by preventing another party from using that invention in any form, again for a defined period of time.

6.2 Consideration by government: past and present

The HSNO Act's purpose concerns environmental protection, health and safety. Commercial considerations do not sit easily in the HSNO framework. The government's decision at the time the HSNO Bill was considered was to deal with commercial aspects by referring to the ACVM and Medicines Acts and the public's right to know via the Official Information Act.

More recently, government gave limited consideration to data protection in the context of the New Organisms and Other Matters (NO&OM) Bill. This consideration was confined to the recommendations of the Royal Commission on Genetic Modification. Two of the key issues here were whether data protection should be extended to new organisms and, concerning the public's right to know, whether there should be an explicit definition of 'confidential supporting information'.

Other work under way with a bearing on this issue is the review of the Patents Act. Agrichemicals are not in the scope of this review, whereas pharmaceuticals are.

Data protection will also be considered in the context of developing policy for amendments to the ACVM Act.

6.3 Policy in other OECD countries

During May 2002, and in the context of a study of the application of data protection in other countries, an officer from the Australian Department of Agriculture, Fisheries and Forestry (DAFF) visited Canada, the USA, Germany and the UK. Among the observations reported for the countries visited were:

- at least 10 years of data exclusivity had been in place for many years (New Zealand has five years only)
- there is a propensity for larger companies to manipulate the chemical market and eliminate smaller companies
- schemes that provide periods of exclusivity for extension of use and significant formulation changes can potentially allow larger companies to extend the data protection indefinitely
- the proportion of generic companies in the agrichemicals market of the countries studied was very low
- the US and Australia were the only countries with schemes to enable compensated cross-referencing (CCR[12]).

6.4 Discussion

Data protection issues are complex, but there are two distinct sets of issues. The first relates to the right to know about a substance or product. The public must be adequately informed in order to best contribute to HSNO processes. However, there is a tension between the right to know and considerations of commercial sensitivity. In New Zealand law, the Official Information Act provides the bridge between these two opposing points of view. In the context of the NO&OM Bill, government rejected the need for any new legislation in this area.

More recently, ERMA has developed criteria for defining 'confidential supporting information' and protocols for improving the public's access to information that is not confidential.

The second broad set of issues concerns competition policy and regulation of commercial behaviour in the national interest. Data packages represent a significant commercial investment for the multinational companies in the agrichemicals market and are a means of gaining competitive advantage. If that investment is not adequately secured, companies may well decide to bypass the New Zealand market.

There has been no recent first principles consideration of the national interest in New Zealand other than the decision to sign and implement the TRIPs agreement. If government agrees that an overhaul of data protection policy is warranted, decisions need to be taken on the scope and purpose of the exercise. Our preliminary view is that the scope of any such review should be restricted to agrichemicals. There is no indication that data protection is a significant issue for industrial chemicals, and issues relating to pharmaceuticals are already under consideration.

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[12] A scheme whereby, provided suitable compensation is paid, the owner of a data package cannot prevent a regulatory authority from making use of the data in the assessment of applications from competitor companies.

Issues to be considered in a review might include the need to consider:

- our implementation of TRIPS – should we pick up turf care products by expanding the definition of 'agricultural compound'? should we give data protection to applications for new uses, new formulations and/or data provided as part of a reassessment?
- our alignment with Australia (and other OECD countries) in the matter of the data protection period[13]
- the need for compensated cross-referencing, and mechanisms to achieve this
- how any new policy decisions might be implemented (eg, should the HSNO and ACVM Acts be de-linked?).

These five issues could be picked up in a terms of reference for the review.

6.5 A policy overhaul process described

A policy overhaul process might unfold as follows:

- formation of an officials group, including the Ministry for the Environment, ERMA, Ministry of Agriculture and Forestry, New Zealand Food Safety Authority, Ministry of Economic Development, Ministry of Foreign Affairs and Trade
- formation of an external reference group, including suppliers and users of agrichemicals, community interest groups
- review of background studies such as the Australian DAFF study and, if necessary, commissioning a parallel study of the New Zealand agrichemical market
- issue identification (eg, would more data protection increase the range of agrichemicals in the marketplace, and what would be the effects on prices?)
- discussion within the reference group
- preparation of a report
- policy proposals to Cabinet that could result in amendment of the HSNO and ACVM Acts.

QUESTIONS

22. Do we need an overhaul of data protection policy?
23. Do you agree that the scope of any such review should be restricted to agrichemicals, and focus mainly on the commercial aspects?
24. Section 6.4 suggests some issues to be covered in a review. Do you wish to add or delete anything from this list?
25. What comments to you have on the policy process proposed in section 6.5?

[13] Data protection provisions are important in trade negotiations. The recent Australia -US Free Trade Agreement necessitates changes in Australian law.

7 New Pathways

This section considers two new pathways to:

- enable rapid approval for substances needed in an environmental emergency
- enable rapid reassessment if the approval pathway was rapid assessment.

7.1 Reassessment by rapid assessment

Presently reassessments for hazardous substances must be considered using the full assessment provisions of the Act, even if the original approval went through the rapid assessment route. This means that a full weighing of adverse and positive effects needs to be undertaken and the application publicly notified.

This situation is rigorous, but it is also slow and cumbersome, which can tie up resources unnecessarily. There is also an element of inconsistency if the substance that was originally approved using the rapid assessment provision needs to be reassessed because, say, new information becomes available, and the only available pathway requires public notification.

We believe there is a case for some kind of rapid reassessment pathway, but our thinking is at an early stage. Your input would be appreciated.

QUESTIONS

26. We propose there should be a non-notified rapid reassessment pathway for hazardous substances applications that were originally approved without public notification. What is your opinion?

7.2 Environmental emergencies: emergency approvals

The NO&OM bill amended the HSNO Act to provide a new process for fast-track approvals for agricultural compounds (pesticides) and animal and human medicines needed for biosecurity or public health emergencies. New pesticides or medicines are sometimes needed at very short notice because of the exotic nature of the risks to be managed. Existing emergency provisions in the Act were considered unsatisfactory.

While considering policy for biosecurity or public health emergencies, officials noted that there are no similar emergency provisions for environmental disasters such as oil spills. The concept was not further investigated at the time because:

- the NO&OM bill was a response to the recommendations of the Royal Commission and the Commission had not considered this issue
- there was insufficient information about products used in environmental emergency situations and, in particular, the possibility of a product (or formulation) being needed that did not already have an HSNO approval (eg, the detergents used to clean up oil spills are already widely used in industry)
- creating an emergency approval pathway runs the risk that applicants could attempt to use it to bypass normal ERMA assessment processes.

QUESTIONS

27. Do we need a fast-track provision in the HSNO Act so that new products could be approved for use in environmental emergencies as they are for biosecurity and public health emergencies? If yes, can you supply evidence showing such a provision is necessary?

8 Regulatory Impact Statement – Data Collection

The final proposals for amendment of the HSNO Act will require a regulatory impact statement to present to Cabinet for approval. The regulatory impact statement will provide Cabinet with an assessment of the net benefit of the preferred option for each issue. This requires us to estimate the costs and benefits associated with each of the proposals in this paper.

We would welcome your assistance with this. Please feel free to supply us with any firm data or general comments you may have on the effect the amendment proposals might have on your costs compared with the current situation, and any benefits you think there may be in the various options. Information meeting criteria laid out in the Official Information Act will be kept confidential on request.

9 Having Your Say

9.1 Ministry contact

If you have any questions about any of the points raised in this discussion paper please contact:

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ian.cairns@mfe.govt.nz
Phone: 04 916 7657
Fax: 04 916 7641.

9.2 Closing date

Submissions close on **Friday 11 June 2004**.

9.3 Information for submitters

Please include a postal address, telephone number and email contact address in case we need to get in touch with you to clarify any part of your submission. In the introduction to your submission, please tell us a little about yourself. For instance, if you are making the submission as an individual:

- where do you live?
- what is your interest in the proposed amendments?
- mention any relevant knowledge, experience or qualifications you may have.

If you are making a submission on behalf of a business or an organisation:

- what particular sector is your business or organisation involved in?
- how many people do you represent?
- what process has your organisation gone through to arrive at the views in the submission?

Please make it clear whether you support, oppose or see other options to achieve the objective of each proposal. To help us in our analysis of the submissions, please reference the question number or the relevant paragraph or section of the discussion paper in your submission.

Ministry policy is to treat submissions as being in the public domain. If you want your submission kept confidential, please indicate, with reference to the Official Information Act (1982), reasons for this.

10 Glossary

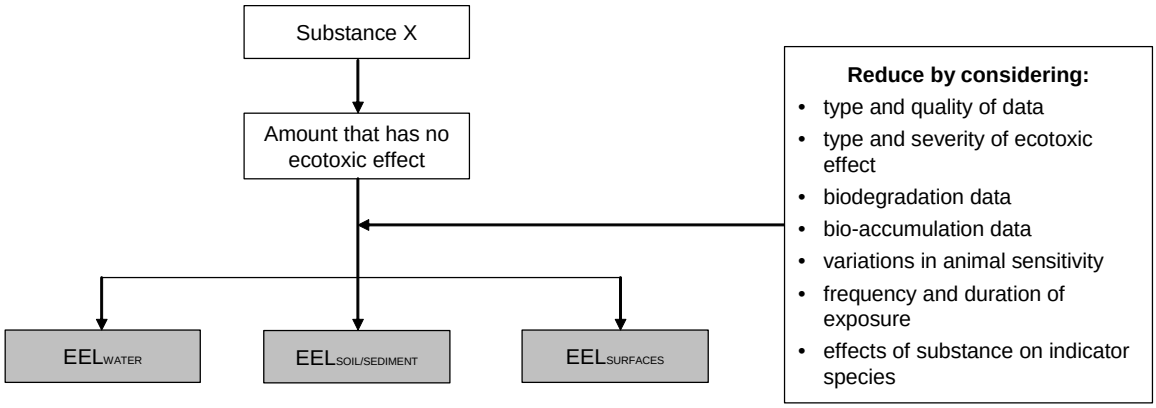
ACVM	Agricultural Compounds and Veterinary Medicines Act (1997)
Agrichemicals	agricultural chemicals
ANZECC	Australian and New Zealand Environmental and Conservation Council
ERMA	Environmental Risk Management Authority
EEL	Environmental exposure limit
HSNO	Hazardous Substances and New Organisms Act 1996
NO&OM	New Organisms and Other Matters Bill (amendments to the HSNO Act became law in October 2003)
OECD	Organisation for Economic Co-operation and Development
OSH	Occupational Safety and Health Service, Department of Labour
RMA	Resource Management Act 1991
SDS	safety data sheet
TA	territorial authority – city or district councils
TEL	Tolerable exposure limit
TRIPS	Trade-Related Aspects of Intellectual Property

Appendix 1: How Environmental and Tolerable Exposure Limits are Set

Exposure limits for hazardous substances may be set by ERMA under the HSNO Act and regulations to protect the general public and the environment.[14] They are enforceable controls, applied to new substances when they are approved under Part V of the Act and to existing substances when they are transferred to the Act.

The www.ermanz.govt.nz website provides access to the EELs that have been set by ERMA. However, these are listed as components of a substance and it is not always clear what compound/product the EEL relates to. For example, the website lists an EEL for copper, but it is not clear that this EEL applies only to copper in specific new, approved substances, not to all sources of copper. This was *not* the intention for EELs when the HSNO policy was originally drafted. (In this document, we suggest the limit for copper should be set in a RMA site-specific context.)

Figure 5.1: Environmental exposure limit development process

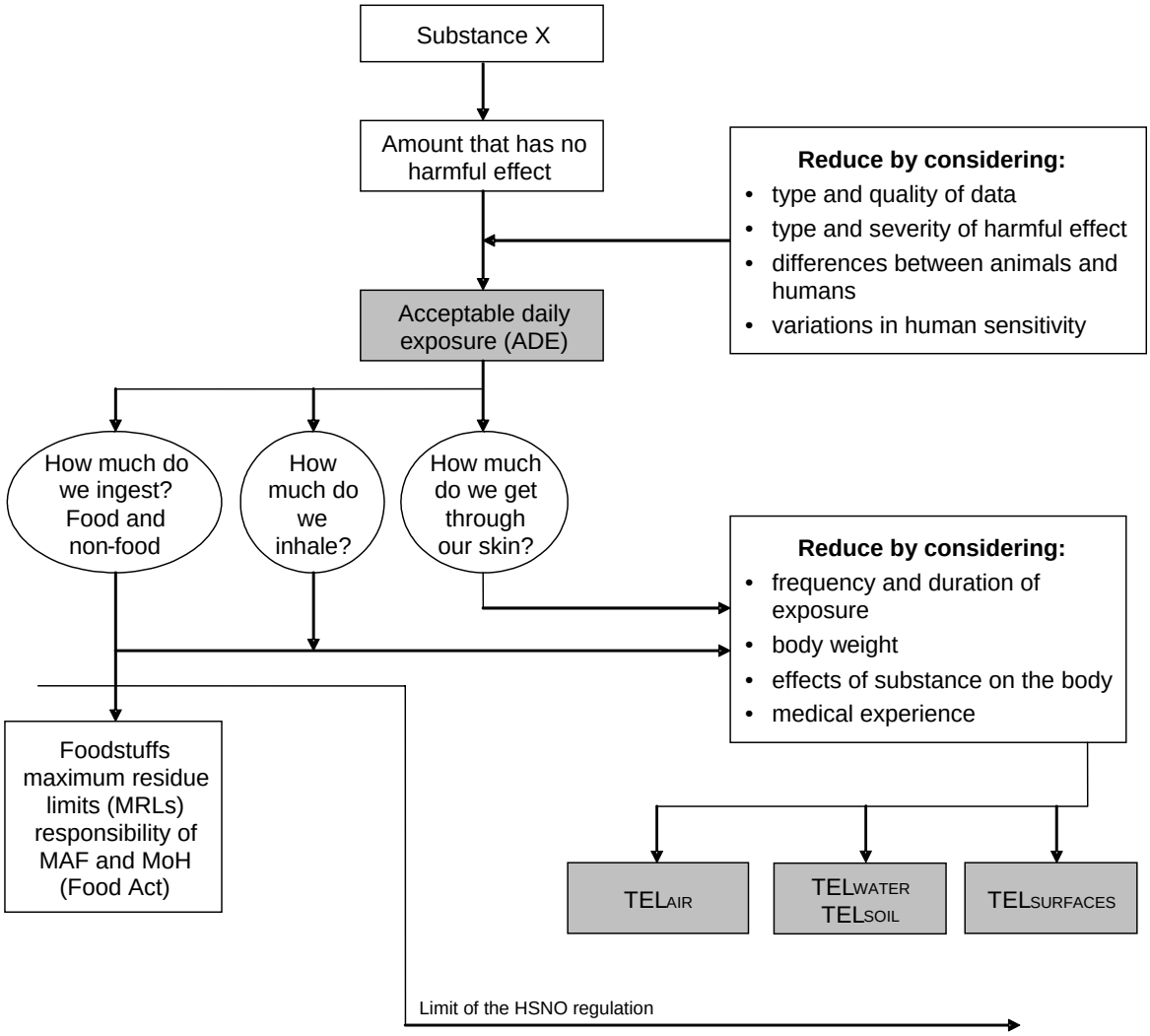


TELs are controls set by ERMA to manage the risks posed by toxic substances to human health. Single-value concentration limits are set for exposure sources to humans (eg, air, water, soil, surface deposition). TELs are derived from potential daily exposure (PDE) values, which in turn are derived from acceptable daily exposure (ADE) or reference dose (RfD) values. The process for setting TELs is described in the Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001. In general, TELs follow a weight of evidence approach and are a means to protect the general population from involuntary exposure and accidental exposure (eg, a child ingesting a crayon).

An example of how TELs can be used is in agricultural spray modelling. If an applicator has the technology available to them, they can input the TEL into their model, along with current weather conditions (wind speed, wind direction, temperature) and come up with required buffer zones to ensure that the TEL is not exceeded at the property boundary.

[14] HSNO also provides for the setting of "workplace exposure standards" to ensure worker safety. These have been excluded from the discussion because no significant compliance and enforcement problems have arisen.

Figure 5.2: Tolerable exposure limit development process



Please note: TELs do not currently cover non-food source ingestion. Amendments have been proposed to the Hazardous Substances (Classes 6, 8, and 9) Controls Regulations 2001 to allow TELs to be set for non-food sources. This will result in protection of the general public from exposure to non-food source poisoning (eg, ingestion of soil or dust).

Appendix 2: Issues with the Exempt Laboratories Regulations

To date, the following issues with the Hazardous Substances (exempt Laboratories) Regulations 2001 have been cited.

- Should the regulations be amended to account for the transition period? (The regulations make the distinction between approved and unapproved substances. Until substances are transferred from transitional provisions, there will be few approved substances and, strictly speaking, laboratories should comply with the much more restrictive provisions that apply to unapproved substances).
- Should the disposal restrictions for unapproved hazardous substances be made less stringent? (Currently, unapproved hazardous substances have to be stored in containment until they are approved or have been treated so that they are no longer hazardous. Unapproved hazardous substances can also be disposed of via 'lawful export'.)
- Are the requirements for laboratory managers and laboratory security reasonable given that many existing laboratories are contained within a single building but are used for different sorts of research by people from different departments or organisations? (The regulations can be read to apply to a single laboratory in a single building managed by a single organisation.)
- Are the requirements for labelling too onerous given that laboratory access is restricted to personnel with specialist knowledge?
- Are requirements to keep an up-to-date inventory of certain approved hazardous substances and all unapproved hazardous substances too onerous?
- Do prescribed requirements for the transport of substances under section 33 have to be prescribed in the exempt laboratory regulations? (This is advocated in this discussion document.)