

ENVIRONMENTAL RISK MANAGEMENT AUTHORITY



NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

Briefing Report for Incoming Government

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EXECUTIVE SUMMARY

1. The purpose of the Hazardous Substances and New Organisms (HSNO) Act is to prevent or manage the risks from new organisms (including GMOs) and hazardous substances. The Act commenced for new organisms on 29 July 1998 and for hazardous substances on 2 July 2001. The Act provides a transitional period of up to 5 years for the transfer to the HSNO framework of existing substances, but none have so far been transferred. There have been two major amendment acts, in 2000 and 2002.
2. The Environmental Risk Management Authority (the Authority) and its executive arm, ERMA New Zealand, have the principal responsibility for implementing the Act. The Authority is supported by the Maori Advisory Committee, Nga Kaihautu Tikanga Taiao. The principal role of the Authority is to make decisions on applications to introduce new organisms and hazardous substance, but there are a number of subsidiary roles as well. ERMA New Zealand is located in Wellington, has a staff of approximately 60 and annual total expenditure of about \$6.7 million. Profiles of Authority and Nga Kaihautu members and senior staff are set out in the Annex to this report.
3. A set of six strategic factors have been identified by the Authority which are expected to drive the work of ERMA New Zealand over the next few years. The factors include the need for an informed community, competent and cost effective decision-making, compliance with decisions, the transfer of existing substances, the reassessment of substances especially, and the monitoring of the effectiveness of the Act. However, the extent to which these factors are finding proactive expression in our work is constrained by resource availability.
4. Section 5 of this report gives a summary of the Nga Kaihautu and ERMA New Zealand work programmes for 2002/03. The ERMA New Zealand work programme is discussed under the following headings.
 - Development of the decision-making and compliance framework (including decision-making policies and procedures, Codes of Practice and Standards, and completion of the Maori generic issues project).
 - Part V decision-making (discussed in more detail in Section 6 of the Report).
 - Overview of enforcement, incidents and inquiries (including new organism enforcement in conjunction with MAF, and hazardous substance enforcement in conjunction with over 80 separate agencies).

- Transfer of substances (with the current work programme targeted at transferring explosives, most dangerous goods and scheduled toxic substances and some pesticides by 1 July 2003).
 - Chief Executive-initiated reassessments and other applications (but with only one reassessment targeted for completion in 2002/03).
 - Public awareness (resource limited in 2002/03 with a focus on key hazardous substance audiences, some awareness for Maori and little work on new organisms).
 - Policy and international (including policy and legislative projects, monitoring of effectiveness, some involvement in global harmonisation, and a focus on work with Australia under the TTMRA).
5. The basis of the Nga Kaihautu work programme is reporting on selected Part V applications, but other initiatives include the development of Maori networks, public awareness for Maori and participation in the Maori generic issues project.
 6. Accumulated reserves will enable a significant level of deficit funding for the overall work programme in 2002/03. Even so, there will be little work in some key areas (public awareness, investigations, reassessments), and work on transfer of substances will continue to be well below the level required to complete transfer within the statutory 5 year period. This is a major issue for the effective implementation of the Act.
 7. Section 6 gives a comprehensive summary of Part V decision-making. Since the respective commencement dates, the Authority has made 179 new organism decisions and 15 hazardous substance decisions. IBSCs have made 768 decisions on low risk GMO developments under delegated authority. Experience to date has raised a number of issues requiring further work or warranting comment and these include the provision of information by applicants, the record of the Authority in approving most decisions, dealing with Maori cultural concerns, the technical requirements for hazardous substance applications, the difficulties of working with the Act, and compliance costs. Forthcoming applications or decisions expected to attract interest or create issues include a development application for GM cattle, reassessment of methylated spirits and reassessment of 1080 poison.
 8. A number of issues warranting the immediate attention of the incoming Government are outlined in Section 7 of this Report. These comprise:
 - Transfer of substances: (Including timetabling and legislative issues and, in particular, the urgent need to amend s160 of the Act to provide a practicable basis for the transfer of dangerous goods by 1 April 2002.)

- Amendment of the HSNO hazardous substances regulations and of the hazardous substance elements of the HSNO Act: (In both cases to provide a more practicable and cost effective approach to decision-making.)
- Enforcement for hazardous substances: (And in particular the settlement of resourcing and other issues to enable continuing participation by territorial authorities.)
- Possible GE contamination of corn: (The aftermath of the events of Nov/Dec 2000, amongst other things, reinforcing the need for a comprehensive and community informed approach to regulation.)
- Implementation of the Royal Commission recommendations on genetic modification: (And in particular the need to complete changes to the HSNO Act and Regulations prior to the expiry of the moratorium.)
- Funding of the future work programme: (See paragraph 6 above).
- Pricing policy and cost-recovery from applicants: (And in particular the need to move toward a realistic policy for the longer term, and to deal with the funding implications of that).
- Promulgation of a revised decision-making methodology.
- Implementation of a practical policy based on the Royal Commission recommendation on Maori membership of IBSCs.
- And issues of concern in regard to the appointment of Members to the Authority.

1. INTRODUCTION

This paper provides a brief introduction to the Environmental Risk Management Authority and the implementation of the Hazardous Substances and New Organisms (HSNO) Act 1996. It describes issues which may have to be dealt with early in the life of the incoming administration. The material is short and to the point. We would expect to provide a more comprehensive briefing on matters selected by the incoming Minister for action.

In this document, the following terminology is used:

The **Environmental Risk Management Authority** (the **Authority**) comprises the Members appointed under the HSNO Act. The statutory functions set out in the Act apply to the Authority.

Nga Kaihautu Tikanga Taiao [Nga Kaihautu] is the advisory committee established by the Authority under Clause 42 of the First Schedule of the HSNO Act, to advise the Authority ERMA New Zealand on Maori issues and concerns.

ERMA New Zealand is the organisation established to carry out operations in support of the Authority, and is lead by the Chief Executive. The Members of the Authority plus the Chairperson of Nga Kaihautu also comprise the governing board of ERMA New Zealand.

2. STATUTORY MANDATE AND FUNCTIONS, AND STATUS OF THE HSNO ACT

2.1 The HSNO Act and its implementation

The purpose of the HSNO Act is to:

Protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.

The HSNO Act deals with both hazardous substances and new organisms, with a similar range of functions applying to both. The Act operates principally by requiring applications to be made for the introduction and management of new organisms and hazardous substances. Management is achieved by either declining applications or setting controls if applications are approved. There is also provision for enforcement and for the management of the transition from the old regime to the HSNO regime.

The Act has been amended through two major amendment acts since the main Act was passed in 1996, plus minor incidental amendments.

The HSNO Amendment Act 2000 contains a number of provisions for tidying up and improving the operation of the Act. Most but not all of these amendments relate to hazardous substances.

The HSNO (GMO) Amendment Act 2002 principally sets in place a moratorium on GMO release applications until October 29 2003. However, it contains a number of other GMO related provisions, especially relating to GMO field trials

The Act commenced for new organisms on 28 July 1998 and for hazardous substances on 2 July 2001.

The transitional provisions of the HSNO Act are currently in operation and will expire on 30 June 2004, unless extended by Order-in-Council. Two, 1 year extensions are possible. All existing hazardous substances are held “in transition” until they are transferred to the HSNO Act. No transfers have yet occurred.

2.2 Statutory functions of the Environmental Risk Management Authority

The mission statement of the Authority derives from the purpose of the HSNO Act and is as follows:

Achieve effective prevention or management of risks to the environment, public health and safety associated with importing or manufacturing hazardous substances and introducing new organisms, and their use.

This mission will be achieved principally through actions by the Authority and ERMA New Zealand to:

- *achieve cost-efficient and effective decisions on applications under the HSNO Act which take appropriate account of benefits and costs as well as risks, to New Zealand;*
- *promote compliance with the Act and with the Authority's decisions;*
- *promote public understanding and knowledge of the risks associated with new organisms and hazardous substances and how to prevent or manage them, and*
- *enhance the HSNO Act as an effective legislative framework for the prevention or management of HSNO risks.*

This mission statement is implemented through the statutory functions of the Authority, which are:

1. Under Part V of the Act, to approve or decline applications for the import or manufacture of hazardous substances, the import, development, field testing or release of new organisms (sections 25 to 27), reassessments (sections 63 and 64); and to decide on grounds for reassessments (section 62). This is the principal function of the Authority.
2. Under Part VI of the Act, to classify and place controls on hazardous substances (sections 75 to 77), issue Codes of Practice (section 78) and approve test certifiers (section 83); and to report on transferable permits (section 88) and environmental user charges (section 96).
3. Under Parts XI to XVI of the Act, to implement the transitional provisions for approvals and controls covering pesticides (Part XII), toxic substances (Part XIII), dangerous goods (Part XIV), explosives (Part XV) and new organisms (Part XVI); and to implement the transfer of existing approvals to the Act (section 160).

4. Under section 11(a) of the Act, to give advice to the Minister for the Environment (the Minister) on any matter relating to the purpose of the Act but especially compliance, inconsistencies in the treatment of hazardous substances and new organisms between the HSNO Act and other legislation, and environmental user charges.
5. Under section 11(b)(i) of the Act, to monitor and review the effectiveness of the Act in reducing adverse effects.
6. Under section 11(b)(ii) of the Act, to monitor and review the enforcement of the Act including the exercise of section 103 powers by enforcement officers; and to appoint or authorise the appointment of enforcement officers (section 99) or carry out enforcement functions directly (section 101).
7. Under section 11(c) of the Act, to promote awareness of the adverse effects of hazardous substances and new organisms on people or the environment, and of the prevention or safe management of those effects.
8. Under section 11(d) of the Act, to contribute to and cooperate with international forums and carry out international obligations, as directed by the Minister.
9. Under section 11(e) of the Act, to carry out inquiries into incidents or emergencies involving hazardous substances or new organisms.
10. Under section 11(f) of the Act, to keep registers of information relating to applications to, and decisions by, the Authority on hazardous substances and new organisms, and as is considered necessary to effectively administer the Act.

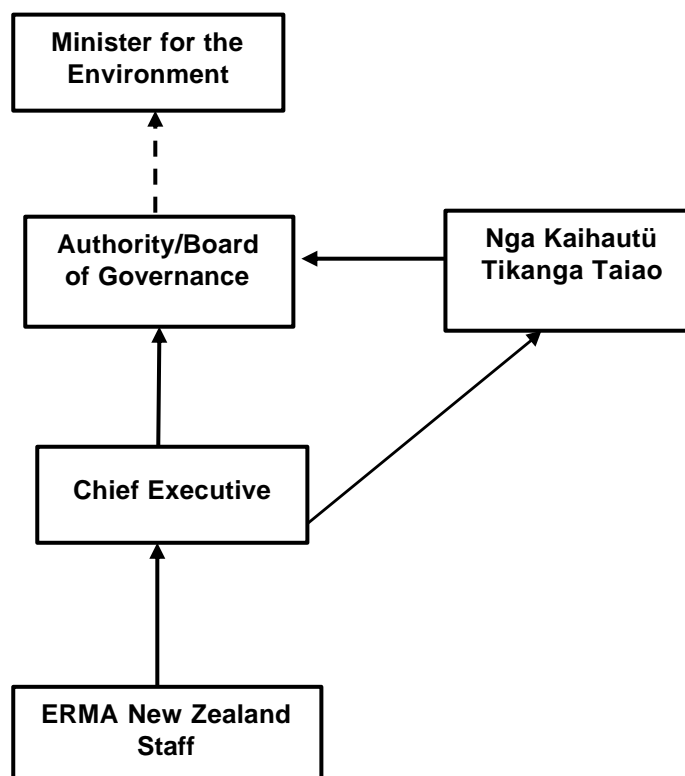
3. ORGANISATIONAL ASPECTS: PEOPLE, STRUCTURES AND RESOURCING

3.1 Overall structure

The Authority is the decision-making body under the HSNO Act. With the addition of the Chairperson of Nga Kaihautu it also functions as the Board of Governance for ERMA New Zealand. A particular feature of the overall structure is the Maori advisory committee, Nga Kaihautu Tikanga Taiao (Nga Kaihautu). Nga Kaihautu reports directly to the Authority.

The Chief Executive is appointed by the Authority but has defined powers and functions under the Act. Aside from normal management powers, the most important function is that of being able to request that grounds be agreed or bring an application for a reassessment.

The overall structure is set out below.



3.2 Relationship with the Minister for the Environment

The Minister for the Environment has two statutory roles under the HSNO Act. The first is the appointment of members to the Authority, including the appointment of a Chairperson and a Deputy Chairperson. The second is the right to “call in” applications for a Ministerial decision (section 68). Under these circumstances, the Authority still undertakes the work but makes recommendations rather than a decision. There have been no “calls in” to date.

The Authority also has the role of providing advice to the Minister (s11(a) of the Act refers).

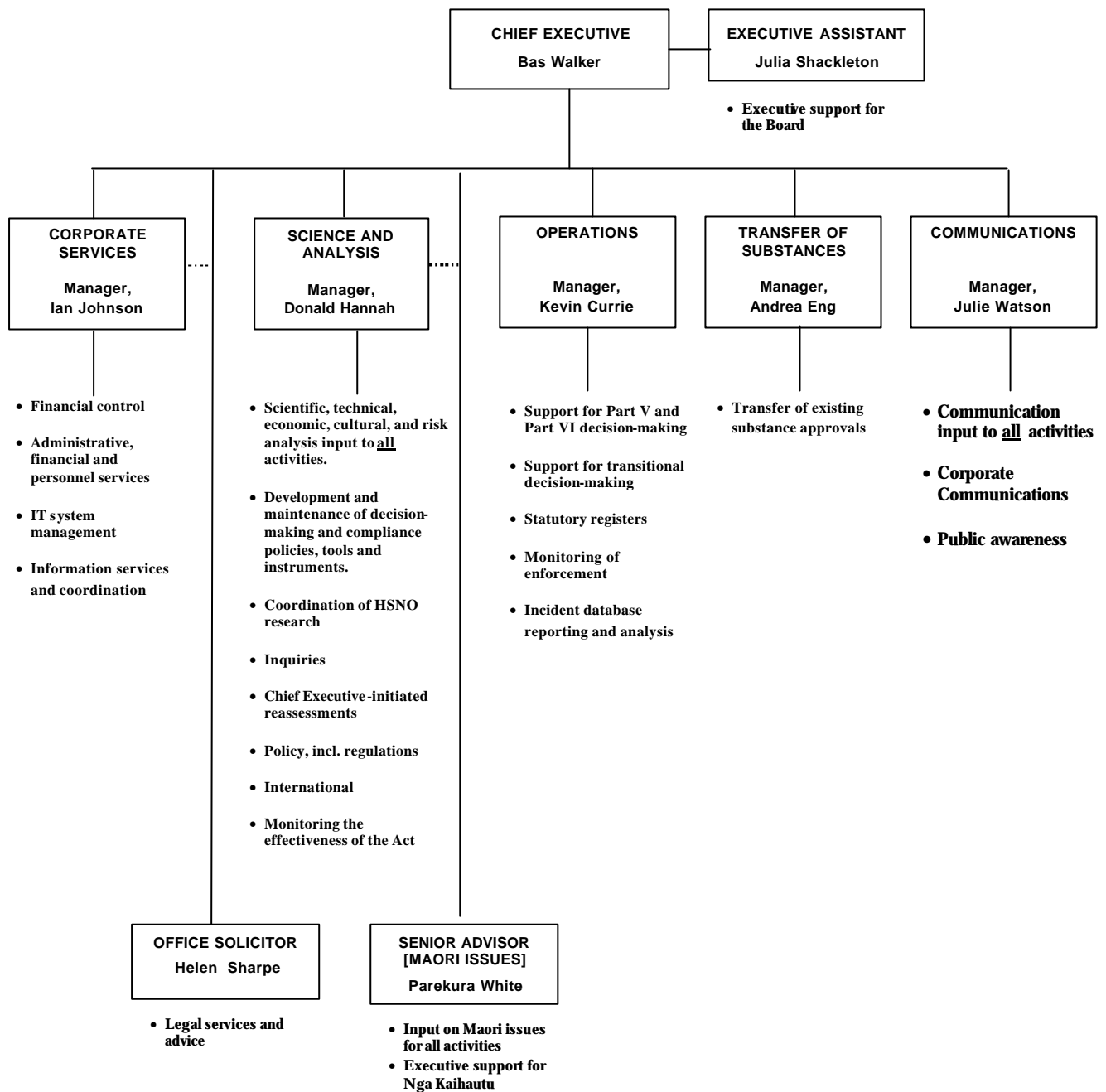
Just as importantly, most of ERMA New Zealand’s funding is provided from the Crown, and the allocation of funding is subject to a purchase agreement negotiated each year with the Minister.

The interactions between the Authority (ERMA New Zealand) and the Minister are thus multi-faceted. As one expression of this, a pattern of routine quarterly meetings between the Chairperson and Chief Executive, and the Minister with MfE officials, has been established. We would hope to see those routine meetings continue. They are of course supplemented by special meetings as and when circumstances justify this.

3.3 Organisational structure and human resources

ERMA New Zealand’s office is based in Wellington, on Levels 1,2 and 5 of BP House, 20 Customhouse Quay.

The organisational structure of ERMA New Zealand is set out in the diagram over the page. The management structure comprises principally the Chief Executive and five managers.



The organisation currently has a staff of 54 on an FTEs basis, with a mix of full time and part time people. Further staff growth is needed if the programme for transfer of substances is to be carried out on time. The split of effort between hazardous substances and new organisms work is about 65:35.

3.4 Nga Kaihautu Tikanga Taiao

Nga Kaihautu Tikanga Taiao (Nga Kaihautu) is an advisory committee of Maori appointed under the provisions of the First Schedule of the Act. The Methodology Order-in-Council provides statutory recognition of Nga Kaihautu.

The principal role of Nga Kaihautu is to provide input and advice directly to the Authority on applications made under Part V of the Act. (If applicants need assistance, it is given by ERMA New Zealand staff.) This advice enables the Authority to better evaluate risks, costs and benefits in relation to Maori interests, and to make informed decisions in accordance with the Act.

Nga Kaihautu has also increasingly had a wider role, particularly in the development of improved approaches to decision-making, the encouragement of relationships with the Maori community, and in promoting education for Maori on HSNO and HSNO issues. Nga Kaihautu also provides assistance on ERMA New Zealand's work programmes and contributes to the work of other organisations.

3.5 Resourcing

Table 1 is a summary of output costs and revenues taken from the 2002/03 statement of intent. The figures are for the 3 years from 2002/03. A comparison is given with estimated actual expenditure in 2001/02.

Table 2 shows the balance sheet as at 1 July 2002, and the projected position as at 30 June 2003.

ERMA New Zealand's operations have yet to stabilise to a reasonable degree, because of delays in commencing the Act and continuing changes in the operating environment. Financial results have thus fluctuated quite widely. A more stable result is expected in 2002/03. In the face of instability a very cautious approach has been taken to financial management so that annual results have been consistently more favourable than budget. Solid reserves have thus been established.

As one consequence of this it is planned to operate a deficit budget in 2002/03. The planned deficit of \$478,000 will enable urgent work on the transfer of substances to be brought forward. However, this level of deficit cannot be sustained, and is small compared with the overall shortfall in the funding necessary to fully implement the Act. Section 7.7 comments in detail on the long term shortfall in funding for full implementation of the Act.

The comparisons in the operating statement (Table 1) between 2001/02 and the current year indicate the increasing pressure on funding and the impact on the pattern of activity. The only area of deliberate increase is transfer of substances (up by 50%) and this reflects the high priority accorded to this activity. Even so funding is well short of that required for completion of transfer by the statutory deadline. Areas such as Part V decision-making and compliance have also been funded as a priority, but the level of expenditure is essentially externally driven.

Allocation of this funding has been achieved at a price despite the planned deficit. This price includes no new work on internally generated reassessments (down by 50% on the previous year), no new investigational work (down by 60% on the previous year) and a very restricted public awareness programme (down by 75% on the previous year).

Table 1: Operating Statement

\$'000	Financial Year to	30/06/2002		30/06/2003			30/06/2004	30/06/2005
		Draft Total Costs	Cost to the Crown	Fees & Other Income	Deficit	Total costs	Total costs	Total costs
1	Decision-making and compliance framework	822	463	-	-	463	468	428
2	Research and Investigations	100	37	-	-	37	101	95
3	New organism decision-making	758	738	345	250	1,403	1,594	1,508
4	Hazardous Substance decision-making	741	673	384	228	1,349	2,128	1,792
5	Chief Executive Initiated Reassessments	87	44	-	-	44	72	129
6	Transfer of Substances	1,417	2,170	-	-	2,170	4,401	5,568
7	Public Awareness	1,014	215	-	-	215	259	250
8	Policy Advice	249	182	-	-	182	129	94
9	Monitor effectiveness of the Act	42	91	-	-	91	69	65
10	International linkages	149	56	-	-	56	56	54
11	Inquiries	60	62	-	-	62	67	63
12	Compliance	241	579	15	-	594	443	358
				135				
		5,680	5,310	879	478	6,666	9,787	10,404

Table 2: Statement of Financial Position as at 30 June 2002

	Opening Position at 1 June 2002 \$000	Forecast Position at 30 June 2003 \$000
TAXPAYERS' FUNDS	2,480	2,000
Represented by:		
FIXED ASSETS	963	715
CURRENT ASSETS		
Bank	112	50
Short Term Investments	2,250	1,850
Debtors/Prepayments	240	185
	2,602	2,085
TOTAL ASSETS	3,565	2,800
CURRENT LIABILITIES		
Provision for Payment of Surplus	0	0
Accruals	1,085	800
TOTAL LIABILITIES	1,085	800
NET ASSETS EMPLOYED	2,480	2,000

3.6 Planning documents for 2002/03

Final drafts of the purchase agreement and the statement of intent for 2002/03 have been prepared and will be forwarded shortly for the consideration of the incoming Minister.

4. STRATEGIC OVERVIEW

The proposed statement of intent for 2002/03 sets out a set of six key strategic factors, which should drive the work of the Authority and ERMA New Zealand over the period ahead. Those factors are as follows.

- Above all else the effective implementation of the HSNO framework requires an informed community which understand HSNO risks and can participate constructively in the overall process.
- Decision-making, no matter how competent in itself, is a waste of resources if it does not lead to the achievement of compliance.
- Competent and cost effective decision-making, in dealing with both new organisms and new substances is essential to establishing and then monitoring the credibility of the HSNO framework and to provide a platform for compliance and public education
- The transfer of existing hazardous substances to the HSNO framework, within the statutory time limit of 5 years, will have a more comprehensive and dramatic impact on the management of HSNO risks than any other element in the overall hazardous substances programme.
- The reassessment provisions of the Act need to be proactively engaged with so that HSNO can achieve its potential in reacting to changing risk circumstances and progressively reducing risks to the community
- The comprehensive monitoring of the effectiveness of the HSNO Act is required to provide focus and direction for all of the other strategic drivers set out above.

However, the extent to which these factors find practical expression in our work is critically dependent on the availability of resourcing. At present levels of resourcing, the Authority is forced to focus on the basic decision-making functions, which are largely reactive.

If a more proactive element is to be introduced, and in our opinion it must be if the HSNO regime is to be fully effective, then resourcing must be provided accordingly. Resourcing is essential if we are to:

- complete the transfer of existing substances to the HSNO framework, so that **all** substances can be managed under this regime and not just the trickle of new substances coming in under Part V;
- start using the ability to reassess as the powerful tool it should be for proactively improving the prevention and management of risk;
- proactively investigate and address the challenging and important issues raised by new organism, GMO and hazardous substance decision-making;
- take a meaningful role in public awareness, both to improve understanding of HSNO issues and to achieve high levels of voluntary compliance.

5. CURRENT WORK PROGRAMME

5.1 Nga Kaihautu work programme

Giving effect to the Authority's obligations under sections 6(d) and 8 of the HSNO Act 1996 requires the maintenance of a continuing level of advice to, and dialogue with, the Authority on the part of its Maori advisory group, Nga Kaihautu Tikanga Taiao (Nga Kaihautu). Basic activity in this area includes participation in governance, joint meetings with the Authority, participation in the development and review of policies and procedures for the functions of the Authority, and the development and maintenance of basic networks with Maori and organisations involved with Maori issues.

In carrying out basic functions in 2002/03, there will be three standing joint meetings with the Authority and seven general Nga Kaihautu meetings.

Under sections 6(d) and 8 of the HSNO Act 1996, Nga Kaihautu provides advice to the Authority on Maori perspectives in Part V applications relating to the management of hazardous substances and new organisms. Overall, the work of Nga Kaihautu in this area is threefold:

- review of all decision-making processes to ensure that these are not inconsistent with tikanga Maori;
- development of appropriate tikanga report templates;
- facilitation of tangata whenua participation.

A major commitment for Nga Kaihautu, in conjunction with ERMA New Zealand, in 2002/03 is the establishment of a more formal network of Maori contacts, and arrangements for involving those contacts in the work of ERMA New Zealand. The focus will be on Maori resource managers within hapu/iwi and Maori representatives on Institutional Biological Safety Committees. The objective is to establish and maintain a network of contacts within the Maori community, with the objectives of:

- providing a means of routine consultation with Maori on policy and operational issues, which is cost effective for both the Maori community and ERMA New Zealand;
- enabling the Maori community to have a ready avenue for putting forward issues for consideration by ERMA New Zealand or by the Authority;
- providing a larger pool of experts for the provision of advice and expert input on HSNO matters, to extend and supplement the advice from Nga Kaihautu.

Nga Kaihautu, in conjunction with representatives from the Authority and ERMA New Zealand staff, are involved in the Maori Generic Issues Project. The objective of the project is to develop an approach for taking into account Maori spiritual concerns and a framework based on tikanga Maori in the decision making process of the HSNO Act.

5.2 Development of the decision-making and compliance framework

Because of the technical complexity and statutory rigour of HSNO decision-making, a substantial investment needs to be made in the establishment and maintenance of the decision-making and compliance framework. This investment will need to continue at a substantial level for some time, both to accommodate lessons from experience and to reflect changes in the requirements. A considerable workload has, for example, been generated in implementing the requirements of the HSNO (GMO) Amendment Act 2002.

Work on the decision-making framework includes the development of interpretations and procedures for use in decision-making and the provision of guidance to applicants. This year a number of new policies will be published in our Protocol series. User Guides will need to be prepared or updated covering making applications (both Hazardous Substances and New Organisms), working with Maori, use of the Threshold and Classification Regulations, and use of the Hazardous Substances Control Regulations.

Work on the compliance framework includes Standards for new organisms and Codes of Practice for hazardous substances. Ultimately the effectiveness of the HSNO Act is dependent on the extent to which compliance with controls is achieved. Providing industry and users with practical means of meeting the regulatory requirements is probably the most important method of ensuring this compliance.

Development of Codes that cross all industry sectors is our first priority with some specialised Codes where there is not a ready industry sponsor. Codes currently under preparation (some in conjunction with industry) include:

- Workplace signage (with NZ Chemical Industry Council)
- Labelling of hazardous substances (with NZ Chemical Industry Council)
- Safety Data Sheets (with OSH and NZCIC)
- Managing Fireworks Displays
- Testing of Fireworks
- Field trials for hazardous substances (with AGCARM)

The existing new organism Standards are also being updated to reflect changes to the Act and its Regulations.

5.3 Part V decision-making

Since the Act commenced for new organisms, a total of 206 new organism applications have been received by ERMA New Zealand and 179 decisions made. The corresponding numbers for hazardous substances are 42 and 15, reflecting the comparatively recent commencement date of 2 July 2001 for hazardous substances. A summary and analysis of decisions to date is given in section 6 below.

New organism applications now follow a reasonably predictable pattern with the large majority being to import into or to develop in containment. Most of these relate to GMOs. There have been no applications to release a GMO, and the last application to field test GMOs was approved in December 2000 (Forest Research Trees). The majority of the applications to release a new organism were for the biological control of weeds and pests.

Most GMO development decisions are made by Institutional Biological Safety Committees (IBSCs), acting under delegated authority. Up to July 2002, 776 delegated decisions have been made since the Act commenced. Although such decisions are for “low risk” organisms, a significant number involve human genes and genes from native flora and fauna.

The Authority supervises the operation of IBSCs through the terms of delegation. These have been periodically revised, with particular regard to the means of effectively considering issues of significance to Maori. We have a regular programme for auditing IBSC decisions.

The number of hazardous substance applications was initially slow following commencement of this part of the HSNO Act in July 2001. The number has picked up in recent months, though the number of applications lodged under the Act’s rapid assessment route remains well below expectations. While we were prepared as we could be for processing hazardous substance applications, the first applications have raised a number of issues. This was hardly surprising, given the new and complex regime established by the Act and its extensive regulations, and has led to many of these applications taking longer and/or costing more than we would expect in the longer term.

Decision-making is discussed in more detail in Section 6 of this report.

5.4 Overview of enforcement, incidents and inquiries

New organisms

New organisms enforcement is carried out by MAF, acting under the Biosecurity Act. Practical arrangements for inspection of containment facilities are set down in a MoU negotiated between ERMA New Zealand and MAF and in an agreed annual inspection and reporting programme.

There is a particular interest at present in enforcement at the border because there have been very few HSNO approvals to import new plants since the Act commenced for new organisms on 28 July 1998. Casual importers have probably been deterred by the rigour and cost of the HSNO regime, but smuggling may also be occurring.

We have liaised with MAF over border operations generally, and more specifically in response to seizures and incursions. This functional relationship has been formalised in an operational agreement between MAF and ERMA New Zealand which is currently being revised. There is a particular concern to ensure that there are effective surveillance arrangements for possible GMO contamination of seed imports.

A recent incident of apparent smuggling (of a parrot) has highlighted legal difficulties in undertaking joint enforcement action under both the Biosecurity Act and the HSNO Act. We believe that the legislation requires attention in this area, as it is currently very difficult to prosecute under HSNO for such offences.

The regular MAF inspection of containment facilities has provided assurance that such facilities are well managed. The corrective actions identified by MAF have been fairly minor, and not indicative of significant risk of escape.

Hazardous substances

Enforcement is undertaken by a variety of enforcement agencies under the HSNO Act, with the major enforcement role falling to the Occupational Safety and Health Service (OSH) of the Department of Labour. Initially ERMA New Zealand's role is to ensure an effective enforcement programme is in place, with adequate coverage of all areas. In subsequent years the focus will change to coordination and monitoring of the enforcement regime.

We are currently working with all enforcement agencies to ensure monitoring and enforcement programmes will be in place, at the time of transfer, for all substances in all areas. To avoid gaps or overlaps enforcement agencies have developed Memoranda of Understanding (MOUs) between themselves. ERMA New Zealand has taken an overview of these to ensure adequate coverage.

At the present time we are in a transitional phase in the HSNO legislation. When this phase is complete some enforcement responsibilities will change. In particular enforcement of substances previously covered by the Dangerous Goods legislation will change from the Territorial Authorities (TAs) to OSH. This change has raised several major issues and is covered further in Section 7.5.

Incidents and Enquiries

The Authority may inquire into any incident or emergency.

This has been the first year of collecting incident reports from the enforcement agencies. Currently all incidents reported to us are entered onto a database enabling subsequent analysis. Data on incidents should help to highlight areas where controls may need to be reviewed.

We are working with enforcement agencies to ensure we receive reports on all incidents that occur, although there is no legislative requirement for them to do so. Enforcement agencies have just been requested to provide an annual report on incidents that occurred during the last year. This will be compared to our records and analysed on receipt.

Where incidents are of a serious nature (e.g. serious harm, death or serious environmental contamination) the Authority may hold an inquiry to fully review the circumstances and lessons to be learnt by ERMA New Zealand. Several inquiries have been or are being completed.

Incidents reported to us currently form a significant component of our monitoring strategy (refer to section 5.8).

5.5 Transfer of substances

The transitional parts of the Act enable substances, which are lawfully used under existing legislation, to be transferred and deemed to be approved substances under the HSNO Act. The transfer process is very important because transferred approvals will probably account for over 95% of the substances in actual use for the next several years. Transfer must be achieved within 5 years [3 years + 1 + 1] of the commencement date of 2 July 2001.

The transfer of substances programme has been under way since July 1998, when ERMA New Zealand took over the management of notifications under the Toxic Substances Act from the Ministry of Health. The substances to be transferred fall into two broad groups: those that have been assessed for hazard and/or risk under existing legislation (about 5,000 substances), and those that have only been notified under the Toxic Substances Act and have had no assessment. This latter group (called NOTS – notified toxic substances) comprises about 215,000 notifications. This number is more than an order of magnitude greater than the number of notifications formally logged when the HSNO Act was passed in 1996 [about 9,000 notifications].

As well as processing over 200,000 notifications, technical work has progressed on the transfer of the first groups of substances comprising authorised explosives, single component dangerous goods and registered pesticides. The process involves identifying the substances, classifying them according to their intrinsic hazardous properties, and assigning controls to manage those hazardous properties. Once a substance has been classified, controls are attached to that substance based on a comparison of the default HSNO controls (contained in the HSNO regulations and derived from the assigned classifications) and controls that existed under previous legislation (e.g., the Dangerous Goods, Toxic Substances, Explosives, and Pesticides Acts and Regulations). Extensive consultation with affected parties is required before the regulations that will transfer the substances can be promulgated.

The programme for the current year is aimed at achieving the following transfer targets.

All explosives (including fireworks) by 1 February 2003

Most dangerous goods and single component scheduled toxic substances by 1 April 2003

A first group of pesticides, including especially vertebrate poisons, by 1 July 2003

A strict legal interpretation of that part of the Act dealing with the setting of controls on substances for transfer (section 160(3)) is an issue that requires urgent attention. The workload and funding implications of dealing with NOTS is also a major concern, which has yet to be properly addressed. These issues are discussed further in the **Current Issues** section.

5.6 Chief Executive-initiated reassessments and other applications

One of the most important provisions in the Act is that for reassessment of contained organisms and hazardous substances. Through this route, approvals can be reconsidered leading to changes in controls or withdrawal of approvals. The Act specifically provides for the Chief Executive to take the initiative in this area, by seeking the Authority's agreement that there are grounds for reassessment (s62). It is also possible for the Chief Executive to initiate new applications, and provisions in the Amendment Act 2000 enable the Authority to make minor changes to approvals on its own initiative (s67A).

For convenience work on defining certain organisms as "risk species" is also included in this part of the work programme.

The Chief Executive maintains a priority list of substances that may be candidates for reassessment. Substances are added to the list from a variety of sources including nominations from a public consultation process. Substances will become candidates for reassessment as funding allows.

Currently there is only one Chief Executive - initiated reassessment underway, that for methylated spirits. Once this has been completed no other reassessments are budgeted for in 2002/03. However, there is expected to be an externally generated reassessment of 1080 poison.

5.7 Public awareness

An important part of the Act is to promote awareness of the adverse effects of hazardous substances and new organisms on people and the environment, and of the prevention or safe management of those effects. The intense public interest and scrutiny, particularly for genetically modified organisms but also for hazardous substances, means that we have to have an active role in communications and awareness. Communication is handled by ERMA New Zealand through our consultation process and active engagement with stakeholders and the general public through our newsletter *Perspective*, *The Bulletin* – a gazette of all applications to ERMA New Zealand and decisions made - and our website, www.ermanz.govt.nz. We also maintain an active and open media relations policy.

A public awareness programme is also carried out but this is severely resource limited.

With additional funding from the Sustainable Management Fund at MfE we have however established an educational website www.hsno.govt.nz and this will be maintained and extended as far as possible.

The public awareness programme for the coming year will focus mainly on informing the hazardous substance community including applicants and users. This focus reflects the fact that other agencies [MfE, MAF] are explicitly funded for new organisms work. Means adopted will include the mail out of information and the holding of or participation in workshops and seminars. As far as possible this will be done in conjunction with industry organisations.

Another area with a small amount of funding is public awareness for Maori. The objective is keep a network of “key influencer” contacts within the Maori community informed of issues of significance within the HSNO regime.

Work on public awareness for new organisms will mainly involve informing the applicant community of legislative changes resulting from recommendations from the Royal Commission, for example changes from the HSNO (GMO) Amendment Act 2002.

5.8 Policy and International

Policy advice

Policy advice involves two main sets of activity; advice to the Minister on legislation and regulations and involvement in relevant activities of departments and other government agencies. Examples for the first include input into the government response to the recommendations of the Royal Commission on Genetic Modification, advice on the legislation required for ratification of international treaties such as the Cartagena Biosafety Protocol, the Rotterdam Convention on Prior Informed Consent for Chemicals and the Stockholm Convention on Persistent Organic Pollutants.

The Authority is involved in a number of initiatives led by other agencies, but with the potential to impact on its operation and/or effectiveness. These include representation on the Biosecurity Council, the Biosecurity Council Technical Forum, and the Agricultural Compounds and Veterinary Medicines Advisory Committee. A specific activity has been input into the MAF Biosecurity Import Health Standards for Seeds where there may be contamination by genetically modified seeds.

A further aspect of this activity is providing information for answers to ministerial correspondence and parliamentary questions.

Monitoring of effectiveness

We are at the early stages of implementing a programme to monitor and evaluate the performance of the HSNO Act in achieving its objectives. As well as being a statutory function of the Authority, we anticipate that this will provide key insights into how the Act and its operation can be improved.

An initial monitoring strategy has been prepared and implemented involving a range of hazardous substances and new organism indicators. Data collection for baseline purposes is underway, as too is the development of a second phase of indicators. This involves interactions with regional councils and Crown research institutes in identifying appropriate indicators and the collection of information to monitor them.

Over the next two years we expect to develop this activity so that better information on the effectiveness of the HSNO Act can be obtained.

International

There is a strong international element in the implementation of HSNO because of factors such as the interaction with trade, the trend toward global harmonisation, and the commonality of issues and information needs between different jurisdictions. Internationalisation is particularly evident with hazardous substances and is particularly important to New Zealand because we are such a small part of the global market.

ERMA New Zealand is giving emphasis at present to work under the Trans Tasman Mutual Recognition Agreement (TTRMA). Regular meetings are occurring between Australia and New Zealand agencies as part of the co-operation programme looking at chemicals management. One outcome of this will be to identify the matters that can be readily mutually recognised and what would need to change if full mutual recognition were to occur.

A number of counterpart agreements have been established between ERMA New Zealand and regulatory agencies in Australia and the UK. When resources allow further agreements are planned involving agencies in USA, Canada and Europe.

ERMA New Zealand participates as the New Zealand delegate to the UN Subcommittee involved in the Globally Harmonised System for the Classification and Labelling of Chemicals (commonly referred to as the GHS). The GHS is the cornerstone of the HSNO threshold and classification regulations. To the extent that resources permit, we are also participating in the global harmonisation initiatives occurring through the OECD.

In addition ERMA New Zealand keeps a watching brief on other international developments that may have an impact on our operation. One key initiative is the progress of the new European Chemicals Policy. We are watching the development of this important activity and have good contact with the staff involved in the European Commission. We also provide advice to MFAT on the new APEC Chemicals Dialogue that was initiated at the recent ministerial meetings in Mexico.

6. PART V DECISION-MAKING: EXPERIENCE TO DATE

6.1 The nature of Part V decision-making

Decision-making by the Authority is quasi-judicial and must occur in accordance with the criteria in the HSNO Act. This provides a considerable constraint on what the Authority can or cannot do. Decision-making is independent of political processes and decisions cannot be appealed. However, appeals can be made on points of law and judicial review can be sought.

The process is strongly **applicant driven**. The Authority can only consider what is put in front of it, and must do so in accordance with the criteria and timelines in the Act.

However, a more proactive approach is possible in the case of reassessments, which can be initiated by the Chief Executive. Even in this case, the Authority itself cannot take the initiative. This prohibition was legislated for, for reasons of judicial convention.

6.2 Decisions by the Authority, Authority committees or the Chief Executive

New organisms

The new organism applications received and processed since 29 July 1998 and up until 15 July 2002 are summarised in the following table. In most cases to date the result of the decision has been to approve, with controls where appropriate.

Type of Application	No. of Applications Received	No. of Applications Decided
Import or develop GMO in containment Many of the import approvals relate to GM mice for medical research but also include import of GM sugarbeet seeds GM maize seeds, microorganisms and yeast. GMO developments cover mainly laboratory work on microorganisms. This category includes low risk development applications submitted while IBSC delegations were suspended (3 May 2000).	128	110
Field test GMO in containment There have been four approvals for field trials of genetically modified animals (PPL sheep and AgResearch cattle and sheep). There have been several plant approvals covering GM sugarbeet, potatoes, petunias and maize; pine and spruce trees and one fermentation approval.	13	13
Release GMO	0	0

Type of Application	No. of Applications Received	No. of Applications Decided
<p>Import new organism into containment</p> <p>Applications have been approved mostly for the testing of biocontrol agents, but also a display butterfly house, micro-organisms, fungus, Fijian Crested Iguana, wollemi pine, plant viruses and viroids and Hawaiian plants.</p>	30	26
<p>Release new organism (not GMO)</p> <p>Applications have been approved mostly for the release of insects as biocontrol agents, and one a grass tree. One application not approved under the rapid assessment route for agathis (same family as NZ kauri).</p>	7	6
<p>Section 26 Determination</p> <p>One camphor basil, two for daffodils, a lily, a herb, two fungus and one iris, nematodes, succulents, grass, fish, cycad, Marine phytoplankton, dianthus and anthrax, have been determined not to be new organisms. A cycad and 3 butterflies have been determined to be new organisms.</p>	22	18
<p>Grounds for reassessment</p> <p>Requests approved for transferred approval for transgenic salmon development, field trials of GM canola, GM blowflies and transgenic mice. Grounds for reassessment for GM sheep and GM cattle were not granted.</p>	6	6
<p>Reassessments</p> <p>Reassessment applications approved for GM salmon, GM blowflies and transgenic mice</p>	3 (these figures are included in the containment figures above)	3 (these figures are included in the containment figures above)
Totals	206	179

Of these 179 decisions, 43 were made by the Chief Executive acting under delegated authority. This delegation applies only to rapid assessments.

Hazardous substances

The hazardous substance applications received and processed since 1 July 2001 and up until 15 July 2002 are summarised in the following table.

Type of Application	No. of Applications Received	No. of Applications Decided
Import hazardous substance into containment Application approved for a plant growth regulator, animal remedy and insecticide.	5	3
Hazardous substance release Applications approved for 2 timber treatments and an insecticide.	18	2
Hazardous substance release (by rapid assessment) Application approved for biopesticides, thermit igniters, herbicide.	11	3
Transshipment Approvals mainly for explosive devices.	4	4
Determine status of hazardous substance Status determined of thiomersal containing vaccines.	1	0
Grounds for reassessment of a hazardous substance Grounds agreed for reassessment of 1080, clopyralid based herbicides and methylated spirits.	3	3
Reassessments - no applications have yet been received	0	0
Totals	42	15

Of these 15 decisions, only 3 were made by the Chief Executive acting under delegated authority. This delegation applies only to rapid assessments on the grounds of low hazard.

6.3 Decisions made by Institutional Biological Safety Committees under delegated authority

The HSNO Act enables the Authority to delegate responsibility for making rapid assessments of applications to develop “low risk” GMOs in containment. “Low risk” is defined by regulation. As a matter of relative routine, delegations have been made to the IBSCs of 19 institutions. Most of the institutions are CRIs or universities.

Since commencement and up until 24 July 2002, IBSCs have made 776 decisions in total, with 768 applications approved and 8 applications declined. The approvals made are summarised in the table below, on the basis of the characteristics of the organisms involved.

IBSC	Total Number of decisions made	No of decisions declined	No of decisions involving native flora and fauna	No of decisions involving human genes
AgResearch, Wallaceville	23	0	0	1
AgResearch, Palmerston North	14	0	0	1
AgResearch, Ruakura	38	1	0	18
Carter Holt Harvey	13	0	0	0
Crop and Food Research, Palmerston North	11	0	2	0
Crop and Food Research, Lincoln ¹	18	0	2	0
Dairy Research Institute	6	0	0	0
Forest Research Institute	0	0	0	0
Genesis Research and Development	36	0	0	3
HortResearch, Auckland ²	56	0	3	0
HortResearch, Palmerston North	13	0	0	0
Industrial Research Limited	5	0	0	0
Landcare Research, Lincoln ¹	6	1	1	1
Landcare Research, Auckland ²	0	0	0	0
Lincoln University	16	0	0	0
Massey University	155	0	7	12
Trees and Technology	15	0	0	0
University of Auckland	162	6	2	91
University of Canterbury	4	0	0	0
University of Otago	157	0	9	42
University of Waikato	20	0	3	0
Totals	768	8	29	169

¹ Joint IBSC

² Joint IBSC

Audits of all IBSCs were completed during 2000/2001. A new round of audits has begun.

6.4 General issues arising from experience to date

Provision of information by applicants

A general pattern is that applications have not provided all the information needed for effective decision-making and this has lengthened the period for processing applications and led to a high number of requests for additional information. The Authority has recognised that this is partly due to inexperience with a new regime and has been accommodating to applicants. However, a sometimes difficult balance has to be maintained between being helpful and keeping costs both under control and recoverable.

A harder line is progressively being taken and applications which are deficient will risk being considered anyhow and declined.

Why applications have generally been approved

An issue for some observers of the HSNO process is the fact that virtually all applications have been approved. Does not this suggest that the Authority is biased in favour of approval? The issue is particularly pointed in the case of GMOs because of the strong positions taken by interest groups on this technology.

The perception of bias is wrong!

In the particular case of GMOs, all applications considered to date have been “in containment”. The Authority has focused on setting controls which manage any risks down to a very low level. Under these circumstances, benefits do not weigh heavily in decision-making and the result can be expected to be more often an **approval** rather than a **decline**. While this is entirely logical, it has given the quite mistaken impression that all applications will be approved. That is **not** the case.

An important fact that is overlooked in this is that most applications go through a long “pre-application” phase. During this phase advice is given by ERMA New Zealand on the expectations of the Authority and on the information required. Some applications drop out at this stage.

Further, the current cost recovery policy makes cost a significant factor for applicants who are therefore encouraged to only submit applications that are likely to meet the HSNO criteria and be successful

Dealing with Maori cultural concerns

An issue which has taken up a large part of the Authority's time and has yet to be fully resolved, is that of dealing with Maori cultural concerns over GMOs. The concerns are spiritually based rather than just in tangible effects, and link to Section 6(d) of the HSNO Act. This section requires the Authority to take into account:

The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.

A special project (the Maori generic issues project) has been set up to look for more cost-effective ways of considering Maori cultural (and especially spiritual) perspectives. This work is targeted for completion in March 2003.

We are conscious that in parallel with this, the previous Government began a process of examining changes that might be made to the HSNO Act to provide a tighter framework for examining Maori perspectives. The outcome of this may well impact on the outcome of the Maori generic issues project.

Technical requirements for hazardous substance applications

Hazardous substance applications are demanding for applicants and for ERMA New Zealand in terms of the information required to classify according to hazardous properties, and to assess risks, costs and benefits. This is particularly so where the information is often not available (e.g. ecotoxicity data), or is not focussed on HSNO requirements. For example overseas data often concentrates on the main active ingredients whereas HSNO looks at the whole substance. While the effort and costs required to obtain and assess such information can be justified for applications involving significant risks, the lower risk cases also incur such costs, and they can be out of proportion to the risks involved.

While the Authority tries to strike a sensible balance between information requirements and proper management of risk, there are legislative limitations to this.

The difficulties of working with the Act

The HSNO Act is comprehensive and right in line with best international practice. It is also very rigorous. In the case of GMOs for example it is rightly claimed to be one of the most rigorous regulatory regimes anywhere in the world

However, it very prescriptive and demanding in many of its features. This is the case with the Act and with many of the Regulations, especially those for hazardous substances. The difficulties this creates add time and cost to the handling of applications, and significantly increase the risks from appeal and legal review.

Compliance costs

Compliance costs have been rightly raised as an issue with HSNO, although some of the concerns expressed (by the hazardous substances industry for example) are still motivated by perception rather than actual experience.

Significant compliance costs arise for a number of reasons:

- The inherent information and other requirements for the proper management of new organisms and hazardous substances
- The complexity and level of prescription in the HSNO Act and its Regulations.
- The lack of differentiation in the Act between low risk and higher risk situations (the Act treats both in the same way).
- The degree of cost recovery required from applicants.
- The need to learn and apply that learning for very new legislation / although costs from this source are expected to reduce rapidly for similar types of application)
- The very extensive provisions for public participation

Compliance costs are generated in three ways; from the direct costs charged by ERMA New Zealand for applications, costs incurred in preparing applications and the costs of complying with approvals. No solid information is available on this last point yet.

In regard to the costs incurred in preparing applications, experience to date indicates that, as a rough rule of thumb, applicants spend about \$1.50 on their own account for every \$1 charged by ERMA New Zealand.

The table below indicates the charges generated by ERMA NZ for different types of applications. Ranges are shown rather than single values and where learning has reduced costs already the reduced costs are shown.

Type of Application, new organisms	Typical Charges
Import a GMO into containment	\$2,500 to \$5,000
Develop a GMO in containment (by rapid assessment)	\$1,150 to \$2,400
Import new organism into containment	\$7,500 to \$20,000
GMO field trial	\$70,000 to \$80,000
New organisms (non-GMO) release	\$40,000 to \$50,000

Type of Application, hazardous substances	Typical Charges
Hazardous substance release *	\$8,500 to \$12,000
Hazardous substance release (by rapid assessment)	\$1,500 to \$5,000
Import hazardous substance into containment	\$5,000 to \$7,000
Transshipment	\$1,500 to \$2,300

* It is cautioned that only relatively simple applications have been considered to date.

Costs have been particularly high for GMO field trials (and this can be extended to include outdoor developments) and to a slightly lesser extent for new organism (non-GMO) releases. This level of cost is a huge barrier to what is most often scientific work in the case of GMOs, and work with a large public good component in the case of many releases.

6.5 Forthcoming decisions: likely issues

An application by AgResearch to develop GM cattle incorporating genes from several species (including humans) is due to be heard in Hamilton on 13 August. This application has generated significant public interest and attracted 863 submissions. It raises (again) issues of significance for Maori. It also raises issues about including a range of genetic modifications in a single application, and the distinction between the development and field testing of a GMO (the GM cattle will be contained outdoors). This will be the first application considered under the HSNO (GMO) Amendment Act 2002 in relation to applications to develop a GMO outside of a “containment structure”.

A Chief Executive initiated application for the reassessment of methylated spirits is in preparation. While this is not in itself a difficult application it will raise some important issues in terms of weighing risk against benefits. This is because methylated spirits, in its current formulation and uses, is a direct cause of death.

The Animal Health Board (AHB), in conjunction with DoC, is expected to lodge an application for the reassessment of 1080 in the first half of 2003. This follows a decision by the Authority (in response to a request from the AHB) that there are grounds for reassessment. Processing this application will pose technical and logistical challenges. The degree of public interest and participation may easily outstrip anything yet seen for GMOs! In any event, it is expected to be a major test of the operation and credibility of the HSNO process. A particular concern in this case is over the ability of the HSNO framework to deliver decisions which adequately reflect the circumstances of cases like 1080. This issue will be explored further in the lead up to the consideration of the application.

7. CURRENT ISSUES FOR MINISTERIAL ATTENTION

7.1 Transfer of substances: Timetabling and legislative issues

Summary of issues and action sought

A key element in the process of preparing substances for transfer to the HSNO regime is the assignment of controls. Controls dictate how substances must be transported, handled, stored, used, and disposed of to properly manage any risks. Transfer is effected by Regulation and the assignment of controls is governed by s160 of the Act.

Section 160 is intended to enable controls to reflect a sensible compromise between the so-called default controls set out in the HSNO Regulations and current requirements. In practice s160 does not give the flexibility required and there is an **urgent need** to amend the Act accordingly. An amendment is needed by end December 2002, so that the transfer of dangerous goods can proceed as planned on 1 April 2003. If transfer is delayed it will cause major problems.

Comment and background

The goal of the transfer programme is to transfer all existing hazardous substances from the transitional provisions of the Act to the framework of the main part of the HSNO Act, through the HSNO classification process and the assignment of controls. In order to minimise compliance costs and because these substances are already in use in New Zealand, the process of assigning controls requires the default HSNO controls (assigned as a result of the substances' hazard classifications) to be compared with the controls that were required under previous legislation.

[Note that the transfer process does not involve the reassessment of substances. Any major differences in the 2 regimes or significant gaps in information result in the substance being flagged for reassessment – a process quite separate from transfer].

In working through the process of assigning practical controls to the first set of substances (explosives), it has become apparent that a strict legal interpretation of section 160(3) has resulted in a significant restriction of the ability of the Authority to assign controls that are sensible and practical. In some cases assigning default HSNO controls could result in unnecessary compliance costs or the imposition of new requirements that are unreasonable and not necessary. In other cases, continuing previous requirements could result in an increase in risk because of the change in focus of the compliance regime from strict enforcement to increased self-responsibility. Neither of these options is acceptable.

The lack of flexibility to vary the controls will in the first instance significantly affect the controls that can be assigned to dangerous goods – currently planned for transfer on 1 April 2003. It is important that this transfer occurs on time. Existing systems will not be able to continue past that date, so any delays will have major implications for industry and for the compliance and enforcement regime.

7.2 Amendment of the HSNO hazardous substances Regulations: Dealing with practical impacts on decision-making

Summary of issues and actions sought.

The HSNO hazardous substance regulations are a large and complex set of technical requirements, which influence and constrain the determination of the status of substances and the setting of controls. Not surprisingly, experience has quickly indicated gaps and mistakes, and areas where policy needs to be reconsidered for reasons of practicality and/or proper risk management. The need to do this is becoming increasingly urgent.

The Regulations setting out information requirements are also very comprehensive and demanding and need revision, and difficulties have also arisen with the Regulations on competency (enforcement officers, test certifiers).

In some areas regulations have yet to be written at all.

It is urged that action be taken as soon as possible to complete outstanding Regulations and put through a package of revisions to the existing Regulations.

Comment and background

It is a matter of concern that more than a year past the commencement date of the Act, some necessary regulations have yet to be completed. In this context work on compressed gases, stationary bulk tanks and tank wagon regulations needs to be finalised as soon as possible. This is priority work over the next few months if the transfer of dangerous goods is to occur as planned on 1 April next year.

There are a number of areas where experience has shown that the hazardous substances regulations need to be substantially amended or rewritten. The development of the explosives transfer regulations highlighted a number of areas where significant amendments will need to take effect at the time of transfer. Transfer is targeted for February 2003, and action on the Regulations **must** be taken before the end of the current year.

In addition, there are a host of minor but nevertheless important changes to progress. Omissions need to be corrected such as the schedules to the emergency management regulations and provisions for the setting of exposure limits on non-food stuffs (eg crayons and other graphic provisions for the materials).

Errors need to be corrected such as the inappropriate setting of protective clothing controls against too high a classification. At least one of the thresholds (that for contact sensitisation) has been prescribed in a way which is capturing substances that probably ought not to be covered by the HSNO Act. There is generally a lack of flexibility and discretion in the regulations which is inhibiting sensible and cost-effective risk management.

New regulations need to be prepared for the transport and storage of substances exempt through section 33 of the Act. This was an area of work derived from the 2000 amendment that was not included in the initial regulations and has fallen to ERMA New Zealand to progress.

A full list of proposed amendments is being developed and will be put forward for consideration, as soon as the scope for Government action is indicated.

7.3 Amendment of the HSNO Act to deal with hazardous substance issues

Summary of issues and action sought

The HSNO Act is conceptually well thought through, but the hazardous substances component especially is prescriptive and complex. Unravelling of that complexity in practical decision-making has indicated the urgent need for changes.

Changes are needed to better achieve sensible and cost-effective risk management, and to keep compliance costs at reasonable levels. If changes are not made the credibility of the Act will be undermined and it will fail to achieve its purpose.

We would urge that a hazardous substances amendment bill is placed on the legislative programme for 2003.

Comment and background

The hazardous substances component of the Act has been commenced since 2 July 2001. Although a limited number of decisions have been made since then (15 of all types), experience has indicated and/or confirmed the urgent need for amendments. These changes follow on from initial changes that were made in HSNO Amendment Act 2000.

The principal changes that need to be made fall into the following broad categories.

Setting of HSNO controls:

The current structure for setting HSNO controls is cumbersome, inflexible and too prescriptive. It is frustrating the attempts of the Authority to provide appropriate risk management, results in bureaucratic and complex sets of controls, and is unnecessarily increasing compliance costs. Some, but not all, of these attributes were foreseen, but it was difficult to argue for change without at least some hard evidence.

A package of changes is needed. Section 77 of the Act needs to be modified so that the Authority has genuine flexibility in setting controls. There needs to be a better ability for the Authority to work from its own practical Standards in prescribing controls, rather than the present rigid adherence to the Control Regulations. And there needs to be scope for setting use-related controls so that situations of “unusual” use can be adequately managed. [The current Regulated Controls are largely hazard-related.]

Providing more appropriate approvals for lower risk situations:

Some relaxation in the approvals structure was made in HSNO Amendment Act 2000 (by introducing low hazard rapid assessments), but it was felt at the time that the changes did not go far enough, and so it is proving. The Act needs to cope with a large range of situations, which may be as simple as a common paint or adhesive at one extreme, and a widely used pesticide which is significantly toxic at the other. The risks presented by these situations are orders of magnitude apart, but the Act does not properly reflect this.

Changes need to be made to provide a more sophisticated range of approval options. At the low risk end of the spectrum, containment approvals should be applicable to a wider range of circumstances and there should be an ability to give facility approvals, i.e. an approval for the containment regime rather than for the substance, if the criteria can be met. Under defined circumstances, it should be possible to identify the important hazardous component in substances, but not all components. Rapid assessments should be extended to cover low risk commercial circumstances. And the provisions for “emergency” approvals need to be modified to give a better match with the circumstances under which they will be able to be applied for.

Miscellaneous changes

A number of miscellaneous changes need to be made and these include broadening of the grounds for reassessment and enabling reassessments to be made by rapid assessment. The need to modify s160 to enable the more practicable transfer of existing substances has already been referred to. A major cause for concern is the inability to capture within the transitional provisions substances in existing use that were not notified prior to commencement (usually through oversight). Extension of the s26 power to determine the status of a substance would deal with this and similar issues.

Means need to be introduced to cover the destruction of illegal or unwanted materials (provisions in the Toxic Substances Act were not properly carried over to HSNO).

7.4 Enforcement for hazardous substances: Resourcing issues and the involvement of Territorial Authorities (TAs)

Summary of issues and action sought

The HSNO Act does not mandate an on-going role for Territorial Authorities (TAs) in hazardous substances enforcement. The principal role lies with OSH. Also, the loss of income from dangerous goods licensing (will occur when dangerous goods are transferred to HSNO on 1 April 2003), will undermine the financial basis for participation. Both factors run a high risk of forcing TAs out of involvement when there are strong reasons, eg. local knowledge, for keeping TAs involved.

A review of enforcement funding was initiated by the previous Government which will, amongst other things, examine the role of TAs. An initial report is expected by 1 September 2003.

It is, in our view, essential that this initial report is made on time and that it is used to confirm a basis for on-going TA involvement. We would caution strongly against deferring decisions on this aspect until a final report is received.

Comment and background

As advised in Section 5.4, enforcement of HSNO in places of work, of substances previously covered by the Dangerous Goods legislation, will change from the Territorial Authorities (TAs) to OSH when the transfer to HSNO occurs on 1st April 2003.

It will, however, be advantageous to maintain involvement of the TAs in this area of enforcement for various reasons:

- OSH does not have the resource or capability (currently) to provide adequate coverage of these substances, both geographically and skill base.
- OSH does not have funding provided to take on this, additional, monitoring and enforcement role.
- TAs currently have experienced and skilled staff currently undertaking this role.
- TAs need to maintain a local level of knowledge of the whereabouts of hazardous substances and the enforcement role would enable them to do so.
- TAs need to be involved in emergencies involving hazardous substances and require skilled and experienced staff to do so.
- Without the enforcement role the TAs will not be able to maintain sufficient work to support the continued employment of a hazardous substances specialist. This will result in a severe loss of expertise in the field with the result that there will be inadequate enforcement in the short to medium term (no matter who is responsible for enforcement).

For these, and other internal reasons, OSH wish to contract the enforcement role back to the TAs. This would maintain the status quo. However, there is no funding for this additional role to be undertaken by OSH, and hence no money available for contracts.

To address these issues a review of the funding requirements for the enforcement of all hazardous substances under HSNO, in all premises/locations, is currently underway. The review is being coordinated by the Ministry for the Environment. An initial report for funding of TAs involvement will be completed by 1 September with the full report completed by the 31st January 2003.

We have two concerns about this review. The first is that the initial report is completed on time. The second is that decisions on TA involvement are made on the basis of the initial report and not delayed until January 2003. January will be too late in our opinion. Decisions on TA involvement need to be made as soon as possible.

7.5 Possible GE contamination of corn: The events of Nov/Dec 2000

Summary of issues and action sought

The release of the book “Seeds of Distrust” by Nicky Hager, during the election campaign, drew attention to the events, in November/December 2000, surrounding a shipment of sweet corn which was suspected of being GE contaminated. Decisions were made on the treatment of the shipment. The events underlined the need to have systematic procedures in place for dealing with such incidents in the future, and an interim testing protocol for sweet corn seed imports was thus set in place. This protocol is currently being updated and extended.

It is not the purpose of this commentary to revisit the events of November/December 2000. However, the recent debate does indicate some lessons for the future. In particular, there is a need for a better understanding of the “risk context” for GMO decisionmaking in New Zealand, so we can be sure that there is an effective but practicable reflection of this in the structure and operation of the regulatory regime, and so that there is a better community awareness of how the system operates and what it can be expected to achieve. We believe that action on this should be taken to complement the work already in train on the recommendations of the Royal Commission.

Comment and background

The events of November/December 2000 had a number of immediate and positive consequences, developments from which are still occurring today. The most obvious consequence was the development of more structured approach to the border surveillance of imported seed, leading to the so called “interim testing protocol”.

This protocol is currently being tightened up and systematic surveillance is being progressively extended to other seed types. The incident also served to re-emphasise the need for ERMA New Zealand and MAF to have a “seamless” approach to GMO regulation. Working level connections were already in place, but since December 2000 there have been regular liaison meetings at senior level between the agencies, and work is continuing on possible ways of improving consistency and compatibility between the HSNO and Biosecurity Acts.

Worthwhile as they are, these developments are largely procedural. They do not address some underlying issues.

Although it was probably not the intention, the Hager book has made this evident because of the character and content of the debate it has provoked. The underlying GM issues have been largely absent from this debate, and this prompts the question of why and what might be done about it.

The why is straightforward enough. In essence the public debate over GM has developed a life of its own and has swept all efforts at structure aside. Even the Royal Commission report, substantial as it is and resulting as it did from such extensive public consultation, has struggled to establish a consensus on a forward agenda. The debate engendered by Hager represents more of the same.

The question of what should be done about it is more difficult, but must be addressed if the regulatory regime is to work satisfactorily. As has been pointed out, good regulation is as much about community acceptance as it is about law and structure

There are some pointers to what needs to be done. It is for example evident from watching the debate that some parts of the community are generating messages about the benefits of GM, other parts of the community are generating messages about the potential risks of GM, and there is not enough connection between the two. Without connection we will struggle to achieve resolution.

It is also evident that collectively there is still a poor appreciation of the nature of the risks posed by GM and how they relate to different situations, and where the sources of risk lie. There is for example little appreciation of the chance of a significant and unwanted GMO release from a HSNO approved field trial, compared to accidental or illegal entry across the border. The example of potentially GM contaminated corn was specifically put in front of the Royal Commission by the Authority, but largely sank without trace. A rather bizarre but more recent example is in the very tight regulation of vaccines containing GMOs set out in the recent Amendment Act, when there is no barrier at all to a person being vaccinated overseas and then releasing the GMOs into the environment though natural processes upon arrival in New Zealand. The illusion also continues that work carried out in a laboratory is inherently safer than work carried out in other situations, when in reality a critical factor is the character of the organisms involved. Sensible and effective regulation depends on developing a good appreciation of the dilemmas represented by these kinds of situations, how important they are and how they might be dealt with.

We still lack good quality and accessible scientific and other information on some of the issues of the day. In many cases the information is there, but it is not being brought together in a comprehensible way.

There are clearly steps being taken in the right direction.

IBAC has produced some thoughtful and well-written publications on GMO issues (although they seem to have had little impact). Departments such as MfE, MoRST and MAF are engaged in following through on specific issues raised by the Royal Commission. The establishment of the Bioethics Council will provide a much needed avenue for exploring ethical and cultural dimensions. Research on GMO issues is now being funded more comprehensively by the FRST. And to the extent that limited funding has permitted, ERMA New Zealand has contributed, for example through the seminars run over the past year on the precautionary approach and horizontal gene transfer and through a limited series of investigations.

But there is a sense of this effort still being fragmented, not necessarily targeted at the key issues, and most importantly lacking an overall context.

A more comprehensive platform for future regulation and implementation of GM technology needs to be set in place. The first step is to establish an overall context, which might start where the Royal Commission finished but moves on from that to provide a more complete picture. Better collation and analysis of existing information, and research aimed at explicitly filling the gaps are essential. And the end-point needs to be a regulatory system which is fully integrated, and is widely accepted as fulfilling the reasonable expectations of the community as a whole.

7.6 Implementation of the Royal Commission recommendations on GMOs: Legislative and related issues

Summary of issues and action sought

The HSNO (GMO) Amendment Act 2002 sets in place a moratorium on releases until 31 October 2003. The implication is that a package of actions needs to be completed before the moratorium expires.

In particular a significant number of amendments to the HSNO Act have been recommended by the Royal Commission. In response MfE has prepared a discussion document on these and related amendments, but this has not yet been released for public discussion. Given the short time frame of the moratorium period early release of the public discussion document is urged.

The Authority has completed a review of the low risk regulations for developments of genetically modified organisms. Changes to the regulations have received government policy approval and are not controversial. We would urge the immediate finalisation of legal drafting and promulgation, so that the benefits of the revised regulations can be realised.

Comment and background

In the wake of the Royal Commission on Genetic Modification a number of work programmes were initiated to investigate the feasibility of the recommendations made. The most significant result of these to date was the passing of the HSNO (GMO) Amendment Act 2002. This set in place the moratorium on releases and additional provisions relating to developments and field tests of GMOs. In addition a number of recommendations were made on improving the regulatory regime for genetically modified organisms.

Implementing the HSNO (GMO) Amendment Act

The Authority has already acted to implement those parts of the “GMO Act” which relate to field trials and developments. A package of information containing interpretations of the Act, revised application forms, a user guide for application and a revised decision path will be released within the next month.

Other legislative changes

The next step is to deal with broader legislative changes flowing from the Royal Commission report. These are set out in the draft MfE discussion paper referred to above. A priority for the Authority is to continue to seek improvements to the HSNO legislation and to this end we will be working closely with officials to progress the HSNO related amendments recommended by the Royal Commission and related amendments. Some of the key amendments proposed are briefly discussed below.

One of the more significant recommendations from the Royal Commission is the proposal for a new conditional release approval category. At the present time the HSNO Act only provides for either tightly contained field tests and developments or completely unconstrained releases. Laboratory research and field tests of cattle are examples of the former while the release of biological control agents is an example of the latter. There is no option or middle ground for the Authority to place controls on a release so that the impact of unexpected risks can be constrained or uncertainty properly managed. The lack of this middle option is likely to be a severe barrier to commercial implementation, because the current system requires too big a step from the very controlled field trial stage to open release.

A number of other changes, which apply to not only GMOs but also to new organisms more generally, are strongly supported by the Authority. These include clarification of the decision-making paradigm in s45 of the Act, the power to delegate decisions on low risk imports, and the power to make general determinations covering categories of new organisms. Changes are also needed to provide better connections between the HSNO and Biosecurity Acts, and to make MAF an enforcement agency under HSNO.

Low Risk Regulations

We have undertaken a comprehensive review of the regulations for undertaking low risk development work on genetically modified organisms. This review was initiated at about the same time as the Royal Commission commenced and has involved a significant amount of consultation with Universities and CRI's. The purpose of the review is to review the scope of research classified as low risk and to reduce the prescriptive nature of the regulations so that researchers are not required to continually seek approvals for the range of organisms developed in a normal research programme. The impact is to remove some of the costs from the system without reducing the regulatory oversight of low risk GMO developments.

7.7 The future work programme: Funding issues

Summary of issues and action sought

ERMA New Zealand is not currently funded at a level that will enable it to carry out its legislative functions at a satisfactory level. Current funding from the Crown amounts to \$5.31 million p.a. (excl. GST). For the three years ahead in particular the shortfall, i.e. additional funding required, is about \$4 million p.a.. Full details will be provided in the Budget bid for 2003 which is currently in preparation.

The most critical shortfall is in the transfer of existing substances programme. Transfer is statutorily required to be completed by July 2006 (assuming that full use is made of the provision to extend the transitional period). Current estimates are that \$8.3 million over three years will be required to increase the rate of transfer to the necessary level. If additional funding is not made available, then the whole concept and design of the transfer process will need to be fundamentally re-thought.

Other areas of serious shortfall are for Chief Executive-initiated reassessments (there is **no** substantial work planned for the foreseeable future), public awareness and the investigation of key issues.

Comment and background

When ERMA New Zealand was established in 1997, little attention was given to the cost of operating the HSNO regime. It was simply assumed that resources would transfer from existing programmes and that any additional costs would be largely counterbalanced by the cost-effectiveness of having a single central agency.

These assumptions were grossly incorrect for two main reasons. First, it was not properly appreciated that the HSNO regime was substantially more complex and challenging than the regimes it replaced. As examples the existing regimes had no provisions for public participation and did not come even close to covering the range of hazardous properties covered by HSNO. Secondly, it was not at all appreciated that some sections of the old regime (notably the Toxic Substances Act) were almost inoperative. The most graphic example of this is that when ERMA New Zealand was established, there were only 9,000 toxic substance notifications recorded on the Ministry of Health's database. When HSNO commenced for hazardous substances in July 2001, the database was closed off with 215,000 listings.

The reality of the funding shortfall for proper implementation of HSNO became progressively more evident from about 1998. This culminated in the preparation of a business case for additional funding in November 2000. This business case indicated that medium term funding needed to be raised to about \$10m p.a. At that stage, baseline funding was \$4.3m.

Some increases in funding have occurred since then and these have enabled a core programme to be carried out. Current funding for 2002/03 is \$5.31m (GST exclusive). However, the longer term issues raised in the November 2000 report have not been addressed.

The most critical shortfall is in the transfer of substances area. Output expenditure in this area for 2002/03 is budgeted to be \$2.17m (GST exclusive), although this is inflated by some unfinished contract work carried over from the previous year. If this general level of funding is sustained then only 40% of existing substances will have been transferred by the statutory expiry date of 2 July 2006 (assuming that full use is made of the provision to extend the transitional period by two years). Our current estimate is that additional funding of \$8m spread over the remaining 3 years will be required to bridge the gap.

There are critical shortfalls in other areas as well, most notably with reassessment work, the investigation of key issues underlying decision-making and public education. Additional funding in all these areas is essential if the Act is to work properly. However, these areas are, by their nature, more open-ended in terms of what can be done and what it should cost. The correct approach is not to start by stipulating \$\$ numbers, but to critically examine what should justifiably be done, cost it out and fund accordingly. It is in our view that this work be done urgently.

7.8 Pricing policy and cost recovery from applicants

Summary of issues and actions sought.

For some time the Authority has been seeking a comprehensive review of the pricing policy applying to applications for new organisms and hazardous substances. The current government policy requires full cost recovery in the longer term, but the previous Government agreed to defer full implementation of the policy for full cost recovery until 1 January 2004. However, in our view there is a strong rationale for moving away from a policy of full cost recovery for HSNO applications and a more satisfactory policy needs to be set in place as soon as possible. Failure to do this will cripple the effective implementation of the Act.

The Ministry for the Environment along with MED, Treasury and MAF were directed to report back by 30 September 2003 on whether ERMA should go to full cost recovery in January 2004. Our strong preference is to seek an early report back so that any funding implications can be factored into the 2003/2004 budget cycle. This would require a report by the end of 2002.

Comment and background

In November 2000 a business case was submitted to ministers outlining the funding issues facing ERMA and also the case for reviewing the policy of full cost recovery. The result of ERMA's submissions to Ministers was that the policy for full cost recovery was deferred until 1 January 2004 with a review date of 30 September 2003.

In the interim, the current transitional period will continue of applying a subsidy to new organism and hazardous substances applications. In summary, applicants are charged for staff and Authority time at \$100 per hour and the cost of public participation (public notification, conducting hearings and processing submissions) is fully subsidised. The result of this charging policy is that, on average, up to 54% of the total costs of applications are subsidised (45% maximum cost recovery). In practice the level of cost-recovery has been lower than this for establishment reasons.

Our view is that a policy of full cost-recovery is not appropriate for HSNO decision-making. There are environmental, innovation and economic efficiency reasons for providing a permanent contribution from the Crown toward the cost of Part V decision-making.

Specific proposals are set out in the November 2000 Business Case. In essence, the proposals are that new organism applications, other than those with a direct commercial basis, should be fully subsidised, i.e. zero-priced, and that hazardous substance prices should be capped at a level equivalent to those applying for equivalent approvals in Australia. Because of the funding implications, it is important that baseline funding and cost recovery policy issues are considered together. For this reason it is sensible to bring forward the review of pricing so that any implications can be considered as part of the 2003 Budget cycle.

7.9 Promulgation of revised decision-making Methodology

Summary of issues and actions sought

The Authority has completed a review of the HSNO Methodology Order. The Methodology is a regulation and sets out the processes the Authority must follow when making decisions under Part of the Act. To amend the regulation we require Cabinet approval for an Order in Council to be promulgated to give effect to the changes.

In accordance with the requirements of section 9(c) of the HSNO Act the Authority is required to advise the Minister of any submissions received and any comments made by the Authority on these submissions. We are currently finalising the summary of submissions and the Authority's comments on these. These will be forwarded to you along with the proposed revised methodology for your consideration.

Considerable effort has gone into this exercise both by ERMA New Zealand and submitters. The revised methodology will streamline and improve decision-making. We would urge that it is formally approved and promulgated as soon as possible.

Comment and background

Section 9 of the HSNO Act requires the establishment of a methodology, by Order in Council, to guide decision-making. An initial methodology was established in July 1998, prior to the commencement of the Act for decision-making. Since then the Authority has had 4 years of experience in the use of the methodology. In addition the HSNO Amendment Act 2000 has introduced new forms of decision, and the results of the GM cattle appeal have become available. The appeal result underlined the need for the methodology to better accommodate different situations as opposed to a "one size fits all" approach. All of these factors lead the Authority to review of the methodology.

The key changes are:

- The simplification and condensing of wording where possible.
- The deletion of clauses which are considered to be unnecessary, either because they state the obvious or simply repeat the Act without some counterbalancing merit.
- Addition of material to better reflect practical experience in decision-making over the past 4 years and the need to cover gaps that have become apparent.

As part of the review process consultation was undertaken with stakeholders. This comprised expert peer review and review by Government agencies, a series of workshops and hui and a written submission process. The consultation provided some excellent feedback and where appropriate changes have been made to reflect comments received.

7.10 Maori membership of IBSCs

Summary of issues and actions sought.

One of the recommendations of the Royal Commission on Genetic Modification concerned the appointment of Maori to institutional biological safety committees (IBSCs). IBSCs have delegated authority to make decisions on low risk GMO developments.

The recommendation was endorsed by the previous Government and accepted in principle by the Authority. However, a number of practicalities had to be addressed in translating decisions in principle into operating policy. The Maori community was consulted over this as was Nga Kaihautu.

We expect a final policy on this to be approved at the end of August and will move to implement this as soon as possible after that. Prior to implementation, we wish to provide the policy to both the Minister for the Environment and the Maori Caucus.

Comment and background

The recommendation of the Royal Commission on Maori membership of IBSCs was as follows.

That IBSCs include at least one Maori member, appointed on the nomination of the hapu or iwi with manuhenua in the locality affected by an application.

This recommendation was endorsed by the Government and accepted in principle by the Authority. However the recommendation raised a number of practical issues, including the willingness or ability of hapu or iwi to make nominations, issues surrounding claims of manuhenua status and the reality that several locations might be relevant to a single application. On this last point it was possible for an application to involve an IBSC in one location, research in a second location, involving native flora and fauna from a third (or more) location(s).

A proposed policy that dealt with these practical issues was approved in November 2001 and consulted on in the early part of 2002. Comments were also sought from the Maori Caucus. A final policy will probably be approved by the Authority in August 2002. The essence of the policy proposed is as follows:

- Maori membership is mandatory unless a specific exemption is approved by the Authority in consultation with Nga Kaihautu. Exemptions will only be granted for good reason and there will still be a requirement for alternative means for involving and consulting the Maori community.
- The membership requirement is specific to the location of the IBSC, but where the research involves other locations, there must still be appropriate consultation.

The intention is to promulgate the policy as soon as it is approved and to have revised arrangements in place for all IBSCs by December 2002.

7.11 Appointment of Members to the Authority

Summary of issues and action sought

Because of the complexity of HSNO decision making and the workload involved, it is essential that the Authority is maintained at its full membership of 8, that the members have a full range of relevant skill, and backgrounds, and that appointments are made in a way that provides continuity. All of these aspects are currently of concern.

Of the 8 Authority members, 5 of the 8 are either beyond the expiry date of their term or will be shortly. The 3 remaining Members have the least experience in terms of time with the Authority, and the skill range has some gaps. Urgent action needs to be taken to deal with the 5 positions referred to, and to simultaneously deal with the issues of range of skills and continuity.

Comment and background

The mechanics of membership expiries are as follows:

- 1 Member completed their term at the end of July 2002
- 1 Member completes their term at the end of August 2002
- 3 Members will complete their terms at the end of November 2002

It is essential to the proper operation of the Authority that new appointments or reappointments are made as soon as possible.

In setting terms of appointment, it is strongly recommended that consideration be given to the novelty and complexity of the task, and to the need to maintain continuity.

HSNO decision-making is quite unique and the general experience is that Members need to go through a considerable learning period. For this reason the minimum term for any Member should be 3 years, and serious consideration should be given to at least one reappointment for each Member.

To ensure continuity, it is also strongly suggested that no more than two memberships should expire at any one point in time, and that the expiry of terms should otherwise be staged so that there is **always** a core of (at least 4) Members with at least 3 years experience.

A good mix of skills is essential and it needs to be remembered that those skills need to cover both hazardous substance and new organism decision-making. The Authority itself is in a strong position to form a view on the most desirable skill mix. It is thus very strongly urged that no appointments should be made without first seeking the views of the Authority on skill gaps and desirable skill additions.

Annex 1

PROFILES OF AUTHORITY MEMBERS, NGA KAIHAUTU TIKANGA TAIAO AND SENIOR MANAGEMENT

AUTHORITY MEMBERS

Jill White (Chairperson), B.A, BSc, NZRGON, MNZM

Jill has previously been the Mayor of Palmerston North City Council, a Member of Parliament for Manawatu and a Labour Party list MP. She has been the Labour spokesperson for Research, Science and Technology, Environment and Biosecurity and Crown Research Institutes. During her time in Parliament, Jill was a member of the select committee that considered the original HSNO Bill. Her early background and qualifications are in teaching and nursing and she holds qualifications in each of these areas as well as Bachelor of Science and Bachelor of Arts degrees. Jill is currently studying for a Masters of Arts degree in History at Massey University.

Lindie Nelson, MSc, PhD

Lindie is a senior policy analyst with the Ministry of Fisheries, working in strategic Policy. Her academic background is in resource management and agricultural economics.

Tony Haggerty, HNC (Chem)

Tony is the Hazardous Substances Adviser to the NZ Fire Service on operational, training and fire safety matters. He was a member of the Toxic Substances Board (which has been replaced by the HSNO Act) and Chair of the Auckland Region Hazardous Substances Technical Liaison Committee. Tony has also chaired a number of committees relating to hazardous substances, including an industry working group on the review of the HSNO Act Hazardous Substances Regulations, and the New Zealand Standards Committee on Transport of Hazardous Substances and Healthcare Waste.

Prue Kapua, BA LLB (Te Arawa/Ngati Whakaue)

Prue has her own legal practice, Tamatekapua Law, with a strong focus on environmental law and Maori issues. She was previously a senior legal adviser at the Race Relations Office and an executive legal assistant to Rt Hon Geoffrey Palmer, providing advice about resource management and Treaty issues. Prue was a member of the Review Group on the Resource Management Bill, is a member of the Refugee Status Appeals Authority and Deputy Chair of the Medical Practitioners Disciplinary Tribunal. In 2000 she was appointed to represent Maori women affected in the Gisborne Cervical Screening Inquiry. <http://www.ermanz.govt.nz/about/> - top

George Clark, BSc, MSc, PhD, DSc, FNZIC

George holds a Personal Chair in the Department of Chemistry at Auckland University. His career has been largely with Auckland University, with periods as a Visiting Scientist or Fellow at a number of overseas universities and institutions. George has served as Head of the Chemistry Department, and is currently Associate Dean for Human Resources in the Science Faculty. He is a past President of the New Zealand Institute of Chemistry. George's research interests are in inorganic and bioinorganic chemistry with a particular focus on the crystallography of DNA/anti-cancer drug complexes

Colin Mantell, B Med Sc, MBChB, MRCOG, FRCOG, FRNZCOG, PhD

Colin is Head of Department at the Maori and Pacific Health Department, at the University of Auckland. From 1977 he was Professor of Obstetrics and Gynaecology at National Women's Hospital and headed the department from 1988 to 1994. During this time Colin established the Centre for Reproductive Research. From 1994 to 1997 Colin was Clinical Director, Child and Women's Health at Middlemore Hospital in South Auckland. Since then he has been Clinical Director, Maori and Pacific Island Health as well as Head of Department. Colin is a past member of the Health Research Council of New Zealand and a member of the Maori Health Research Committee. Colin's Iwi affiliation is Ngai Tahu.

Jane Lancaster, BSc (Hons), MNZIFST, MNZIAS

Jane is Director of Catalyst R&D Ltd, a consultancy company specialising in working with businesses to develop their R&D capability, prioritisation of projects, business cases for research programmes, project design and management, and applications for investment funding. She is also an Innovation Leader with ZESPRI Innovation Co Ltd, and a Research Associate with Landcare Research Ltd. Jane has previous extensive experience as a research scientist and science manager in the public sector. She has been a past member of FRST advisory committees between 1990 and 2000. Jane has a strong interest in New Zealand agribusiness, and is co-owner of a berry fruit farm. She has an academic background in food and plant biotechnology.

Lin Roberts, BSc Hons, PhD

Lin is Director of Business and Environment Consultants, and acts as an advisor to companies and central and local government agencies on sustainability. She is on the board of The Natural Step (TNS) New Zealand and TNS International, and manages the TNS Pathfinder Programme, a group of leading New Zealand organisations that are addressing sustainability. Lin also teaches the MBA course "Building sustainable businesses" at the University of Canterbury and a similar Masters course at Lincoln University. Lin has extensive experience in the public sector and has been actively involved in policy development in areas such as science strategies, resource management, waste management, and hazardous substances and new organisms, and as a scientist in the biological control of pests and weeds.

NGA KAIHAUTU TIKANGA TAIAO

The establishment of Nga Kaihautu Tikanga Taiao as a forum for providing Maori input to the work of ERMA New Zealand is a requirement of the Methodology set down by Order-in-Council under section 9 of the HSNO Act. Nga Kaihautu is formally an advisory committee established under clause 42 of the First Schedule to the Act. The Members are:

John Hohapata-Oke (Chairperson)

Tribal affiliation: Ngati Awa

A former director of the Whakatane Resource Recovery Centre, John has a long time interest in hazardous waste and other environmental issues. A member of the Environment Bay of Plenty Maori Standing Committee, he is a Bay of Plenty Conservation Board member and chairman of the Ngati Awa Environment Committee.

John is currently halfway through a Science degree, Bachelor of Environmental Studies at Te Whare Wananga O Awanuiarangi, Whakatane. It is a three year degree finishing at the end of 2003. The degree studies Matauranga Maori and Western science.

Mere Roberts, BSc, M.Sc, PhD, Post graduate certificate in Medical Parasitology

Tribal affiliation: Tainui

Mere is a lecturer at the School of Environmental and Marine Sciences at the University of Auckland.

Sam Napia, MBA (Distinction), DipBusStud, NZCS (Chemistry)

Tribal affiliation: Nga Puhi and Ngati Kauwhata

Sam is the Chief Executive of the Hauraki Maori Trust Board. A former member of the Tai Tokerau Maori Trust Board, he maintains tribal networks in the North. Prior to coming to Hauraki, Sam worked in local government for some 12 years and has extensive experience in working with Maori and local government under the Resource Management Act. Sam has a particular interest in corporate governance in the context of Maori organisations and has done a considerable amount of research and work in this area.

Hirini Paerangi Matunga, B.A, B.T.P

Tribal affiliation: (Ngai Tahu, Ngati Kahungunu, Ngati Porou and Ngati Paerangi (Atiu, Cook Islands))

Hirini is currently Associate Professor in Maori and Indigenous Studies at Lincoln University, and Director in the Centre for Maori and Indigenous Planning and Development. His academic background is in Social Anthropology and Planning. Hirini has been a university lecturer in Maori Planning and Resource Issues for 10 years. Prior to this he worked for 10 years as a planner, specialising in Maori planning issues with regional and central government.

Kei Merito

Tribal affiliation: Mataatua -Te Arawa-Tainui

Kei has a background of 25 years in the New Zealand Army. Upon retiring from the Army, he was employed by the Department of Labour as Staff Training Officer, the Whakatane District Council as Maori Land and Rates Officer and Revenue Accountant. Kei is currently employed by the Department of Conservation as Kaupapa Atawhai Manager, Bay of Plenty Conservancy and is also Deputy Chairman for Te Runanga o Ngati Awa and kaumatua for Ngati Awa and Ngati Pukeko of Whakatane.

Darcia Solomon

Tribal affiliation: Ngai Tahu, Rangitane, Ngati Kuia, Ngati Apa, Ngati Toa, Ngati Raukawa, Te Atiawa,

Darcia has represented Ngai Tahu on the Nelson/Marlborough Conservation Board for 11 years. She is also a member of Te Runanga o Kaikoura. Her background is in environmental management and customary rights of Maori and she is actively involved in hapu and iwi development and with activities of the Takahanga Marae in Kaikoura.

SENIOR MANAGEMENT

Bas Walker, Chief Executive, BE (Hon), PhD (Cantab) MChemE, FIPENZ

Bas has consulted in public sector management and policy development and has held several chief executive positions in the public service. These included the Ministry of Research, Science and Technology, the Ministry of Defence and the Ministry of Energy. His earlier career was spent as a scientist in the Department of Scientific and Industrial Research (DSIR).

Ian Johnson, Manager Corporate Services, CA BCA

Ian holds a BCA majoring in accountancy and is a Chartered Accountant. He has had 24 years finance and administrative experience in a variety of industries and sizes of companies. Prior to joining ERMA New Zealand, he worked in Telecom Mobile Communications for nine years, mainly as Financial Controller.

Kevin Currie, Manager Operations, BSc, Certificate in Water and Soil Management

Kevin has extensive experience in local government in the field of resource management, including periods with the Otago Catchment Board and the Otago Regional Council. Prior to joining ERMA New Zealand, he was Manager, Resource Investigations with the Wellington Regional Council.

Julie Watson, Manager Communications, B Arts, Post Graduate Certificate in Writing

Julie has over fifteen years experience in communications. Her particular expertise is in writing, editing and publishing. She has worked in diverse areas including the Development Resource Centre (NZ), Australian Film Television and Radio School, PriceWaterhouseCoopers (Australia), and University of New South Wales.

Donald Hannah, Manager Science and Analysis, BSc, Post Grad Dip Sci, PhD (Otago), MNZIC

Donald's most recent scientific work has been in the field of toxic chemicals. He was the Principal Scientist at the Institute of Environmental Science and Research Ltd (ESR). He joined ESR in 1992 as Group Leader, Environmental Organic Chemistry, and prior to this he worked at DSIR in both food and environmental organic chemistry.

Andrea Eng, Manager Transfer of Substances BSc, Dip OSH

Andrea began her scientific career in the Environmental Chemistry Laboratory at the National Health Institute (NHI) and, after a break, resumed this career in the analytical laboratory at Environmental Science and Research Ltd (ESR). Before joining ERMA New Zealand, Andrea was a Senior Scientist and Team Leader (Health Strategy) at Occupational Safety and Health (OSH).