The Hazardous Substances and New Organisms Act 1996

The Hazardous Substances and New Organisms Act 1996 (HSNO Act) will affect all businesses, organisations and individuals that deal with hazardous substances or new organisms. This note gives a broad overview of the new regime, with a particular focus on the transitional provisions. [Editor's note: An earlier legislation note on the HSNO Act appears in (1997) 1 *NZJEL* 301.]

Scope of the Act

Under the HSNO Act, no person may:

- import or manufacture any hazardous substance; or
- import, develop, field test or release any new organism,

except with an "approval" issued under Part V of the Act, or in the case of *existing* substances and organisms, in accordance with the transitional provisions of the Act. Exceptions are made for small-scale chemistry in laboratories, and for unforeseeable emergencies. Persons who merely store or use hazardous substances are also caught by the Act. They do not need an approval to store or use a particular substance, but they must comply with any restrictions or controls that apply to that substance.

Definitions

The Act is potentially very wide in scope due to the broad definitions of "hazardous substance" and "new organism" in s 2.

A "hazardous substance" is defined as a substance that possesses (or which, upon contact with water or air, generates a substance that possesses) one or more of the following intrinsic properties: explosiveness; flammability; a capacity to oxidise; corrosiveness; toxicity; or ecotoxicity. Potentially, almost any substance could be caught by this definition. In practice, regulations will set thresholds for each of these intrinsic properties beneath which a substance is not deemed to be "hazardous" for the purposes of the Act. For example, both wood and petrol are flammable substances, but wood is not sufficiently flammable to need approval

and control under the Act. Specific substances can also be excluded from the Act by regulation.

In broad terms, a "new organism" is defined as a species of any organism (excluding human beings) that was not present in New Zealand on the date of commencement of the Act. The definition of new organism includes "genetically modified organisms" (GMOs), although specific types of organism may be excluded from the definition of a GMO by regulation. The Act places an absolute prohibition on the importation, release or development of specified organisms. Applications in respect of these organisms *must* be declined.

Background and Administration

The HSNO Act was passed by Parliament in June 1996, but the commencement of the main parts of the Act has been delayed to allow the government time to complete the regulations that underpin the Act. The provisions of the Act relating to new organisms came into force in July 1998, and the provisions governing hazardous substances will take effect in April 1999.

The Act rationalises and consolidates the management of hazardous substances and new organisms, and introduces legislative controls on genetic manipulation. It repeals the Explosives Act 1957, the Dangerous Goods Act 1974, the Toxic Substances Act 1979, and the Pesticides Act 1979. It repeals those provisions of the Animals Act 1967 and the Plants Act 1970 (both repealed) that are currently saved as a transitional measure under the Biosecurity Act 1993. It also repeals parts of the Animal Remedies Act 1967. The functions under those Acts that were previously carried out by a number of different agencies, each applying different (often conflicting) criteria, will now be conducted by a single agency applying just one set of rules — the HSNO Act. In essence, the Act introduces a "one-stop-shop" approach, although some parallel approvals will still be required.

A new agency called the Environmental Risk Management Authority (ERMA) will implement and administer the Act. The Authority's principal function will be to determine applications under Part V of the Act to import or manufacture hazardous substances, or to import, develop, field test, or release new organisms. ERMA has appointed an advisory committee known as Nga Kaihautu Tikanga Taiao to provide advice on Maori perspectives of applications under the Act. During the transitional period, the Authority will also be responsible for administering the transitional provisions of the Act.

Part V Applications

Most applications under Part V will proceed along one of four main decision pathways:

(a) Standard notified applications;
(b) Standard non-notified applications;
(c) Rapid assessment (new organisms only); or
(d) Ministerial call-in.

The majority of applications are required to be publicly notified, including all applications to import or manufacture a hazardous substance for release. Where an application is notified, any person may make a submission on that application. A public hearing will be held if the applicant or any submitter requests one, or if the Authority considers that a hearing is necessary.

Applications to import a new organism (other than a GMO) for release or to develop a GMO in containment, which meet certain low-risk criteria, may be decided via a non-notified "rapid assessment" process. However, the Minister for the Environment can "call in" applications for determination by the Minister where the decision on the application will have significant effects, or where the Authority lacks sufficient expertise or knowledge in the area.

All decisions will be publicly notified and all approvals will be added to the Authority's register, which will be publicly accessible through its website. There is no right of appeal against the Authority's decision on an application, except on a point of law.

Recovery of costs
ERMA may recover the costs of processing applications from applicants, and has notified the following standard fees based on an initial estimate of likely costs:

- Standard non-notified application: $750;
- Standard notified application: $2,500;
- Public hearing (up to one day): minimum $6,300;
- Public hearing (more than one day): additional days charged at cost ($830/day for each Authority member; $120/hr for each ERMA NZ staff member; external consultants' fees; disbursements); and
- Further information/processing: $250 administration fee; $120/hr for each ERMA NZ staff member; external consultants' fees; disbursements.

These amounts are interim only, and will be reviewed by the Authority once it has some operational experience of actual costs. Where a submitter requests a hearing, the Authority may apportion the hearing costs between the applicant and the submitter.

Decision-making framework
The Authority's decisions under Part V will be governed by the Act, regulations made under the Act, the Methodology, and various protocols developed by ERMA.

(i) The Act:
The Act sets out detailed decision-making criteria and information requirements for each type of application. All decisions must be consistent with the overriding purpose and principles of the Act set out in Part II.

(ii) Regulations made under the Act:
The Ministry for the Environment is preparing a range of regulations for the purposes of the Act. These include regulations:

- establishing thresholds for hazardous substances and GMOs;
- establishing a "hazard classification system" and associated controls for hazardous substances (discussed below);
- providing guidance on the assessment of adverse effects for applications to develop GMOs; and
- prescribing application forms and information requirements.

(iii) The Methodology:
The Act required ERMA to develop a methodology document to govern its decisions on applications under Part V. The Methodology had to be consistent with the Act and be approved by Order-in-Council. The Methodology describes the Authority's approach to Part V decision-making. Among other things, it provides guidance on how the Authority will evaluate risks, costs and benefits (both monetary and non-monetary), and how it will deal with uncertainty.

(iv) Protocols:
The Authority has developed a series of protocols that expand on the Methodology and address key issues of the decision-making process. Protocols issued to date cover:

- International obligations;
- Combined consideration of risks, costs and benefits;
- Interaction with other statutory processes in New Zealand;
- Interpretations and explanations of key concepts;
- Acceptability of information from other processes and agencies (New Zealand and overseas);
- General requirements for identifying and assessing risks, cost and benefits; and
- Decision paths.

These will be updated and further protocols developed as ERMA gains practical experience and new issues come to light. ERMA is currently working on a draft protocol on Maori perspectives in HSNO decision-making.

(v) Quick Guides:
The protocols are intended to act as a guide to the Authority, not the public. ERMA is preparing a series of step-by-step guidelines known as "Quick Guides" to assist applicants and submitters.

Controls on hazardous substances and new organisms
(i) Hazardous substances *for release*:
The government is working on regulations that will establish a "hazard classification system" and a "toolbox" of associated controls for hazardous substances.

The system will assign a number of degrees or types of hazard to each of the six intrinsic properties of a "hazardous substance". It will also set thresholds for each intrinsic property below which the Act does not apply. Regulations will prescribe controls for each hazard classification, including controls in relation to packaging, containing, identification, labelling, advertising, disposal, managing emergencies, tracking, and qualifications for handling hazardous substances.

When a substance is approved, ERMA will give the substance one or more hazard classifications (depending on the intrinsic properties of the substance). The controls prescribed for each of the relevant hazard classifications will then attach to the substance, unless varied by ERMA. Once approved, the controls that apply to a particular substance will bind all subsequent manufacturers, importers, and users of that substance. The controls will be performance-based. They will define the standard to be achieved but not how to comply with that standard. One option would be to use methods set out in approved codes of practice.

(ii) Hazardous substances and new organisms *in containment*:
Controls on approvals for hazardous substances and new organisms in containment are prescribed in the Third Schedule to the Act. The emphasis of these controls is on the adequacy of containment.

(iii) New organisms *for release*:
There are no controls (statutory or regulatory) on approvals to import a new organism for release or to release a new organism from containment. Given the ability of organisms to reproduce, such controls would be relatively futile.

Reassessment
The Act provides for the formal reassessment of approvals relating to any hazardous substance and any new organism in containment. The reassessment provision applies to both existing approvals and approvals granted by ERMA under Part V of the Act. The provision reflects the Act's "cradle-to-grave" philosophy.

Transitional Provisions

There will be a transitional period between the start of Part V decision-making and the end of decision-making under existing arrangements. The transitional period expires on 1 January 2001 at the latest, but may need to be extended if the transfer of existing substances to the HSNO Act is not completed by that date (see below). The transitional provisions apply mostly to hazardous substances.

Hazardous substances
When the hazardous substances provisions of the Act come into force in April 1999, there will be a two-stage transition from the old law to the new regime. On 1 April 1999, existing legislation will be repealed and hazardous substances that are notified, licensed or permitted under those Acts will become subject to the transitional provisions of the HSNO Act. The transitional provisions substantially carry over controls under the repealed Acts. ERMA will be responsible for administering the transitional regime, but the Toxic Substances Board and the Pesticides Board will complete any applications they have in progress. After this, these Boards will be abolished. During the transitional period, it will be an offence to contravene the requirements of any regulations, orders or notices promulgated under the previous legislation, the terms or conditions of any permission granted under the previous legislation, and the substantive requirements of the transitional provisions.

Throughout the transitional period, existing approvals will be transferred by regulation to the HSNO Act. Substances will be removed from the transitional regime and become subject to the controls of the HSNO Act and regulations. In many cases, the transfer process will simply involve confirming existing controls or modifying them to accord with the HSNO regulations. In some cases, however, a formal reassessment of the substance may be required (for example, where there is new information about the risks of the substance). The intention behind the transfer process is to ensure that existing approvals can continue to be used with confidence while ensuring that they are consistent with controls under HSNO. The aim is to bring both past and future approvals within one risk management framework.

(i) Non-notified toxic substances:
A substance can only be transferred to the HSNO Act if it is *legally* present in New Zealand. It must be authorised under current legislation and therefore covered by the transitional provisions. If it is not, then it will become illegal at the start of the Act and an application for approval under Part V will be required to continue importing or manufacturing the substance. This, in turn, means that no person will be able to use or store the substance until it has been approved under the HSNO Act.

Non-notified toxic substances are caught by this requirement. The Toxic Substances Act 1979 requires every person who intends to import, manufacture, prepare, or pack any "toxic substance" (as defined in the Act), either for the first time or under a new trade name, to notify the Ministry of Health and provide certain information about the substance. It is an offence not to comply with this requirement. Nonetheless, there are a great number of non-notified substances throughout New Zealand.

Those who import or manufacture potentially toxic substances should notify the Ministry of Health or ERMA before April 1999 if they have not already done so. This should not be necessary for persons who only use or store hazardous substances, although it may be prudent to confirm notification of the substance with the supplier or the Ministry.

(ii) Notified toxic substances:
Notified toxic substances (NOTS) create a further problem for the transfer process. As they have not been assessed at any stage, at least crude assessments will need to be carried out on all NOTS. If significant risks are indicated, a full assessment will be required. To make matters worse, there are estimated to be over 50,000 NOTS in New Zealand currently, but there is no database of these substances.

ERMA intends to develop an electronic database of all NOTS in New Zealand. It hopes that this will reduce the number of substances that need to be assessed by eliminating duplications and substances that fall beneath the prescribed thresholds for hazardous substances.

(iii) Timetable:
ERMA has prioritised the transfer of hazardous substances to the new regime. In the first few years, it will concentrate on transferring dangerous goods and explosives, and establishing the NOTS database. In subsequent years, it will focus on the transfer of pesticides and toxic substances.

New organisms
The transitional regime will be much simpler for new organisms than for hazardous substances. In particular, various permits issued under the old legislation (most of which has been replaced by the Biosecurity Act 1993) in respect of animals and plants are simply deemed to be approvals issued under the HSNO Act at the commencement of the transitional provisions relating to new organisms. The only new condition imposed is a requirement that the animal or plant remains in the place where it is kept for the purposes of the original permit.

The situation is different for GMOs. Currently, there is no formal legislative procedure for the approval of GMOs. Until now, the Advisory Group on Novel Genetic Techniques and the Minister for the Environment have considered

applications on a voluntary basis and granted approvals. These approvals can become deemed approvals under the HSNO Act by Order-in-Council and will be subject to the same original conditions. Presumably, persons dealing with GMOs who do not hold an informal approval when the Act comes into force will be required to make an application for approval under Part V of the Act.

Some Key Issues

"Every person"

The Act as currently worded requires "every person" intending to import or manufacture a hazardous substance to apply to the Authority for approval. A literal interpretation would require multiple applications in respect of the same substance. A similar problem exists in respect of new organisms. This is not what Parliament had intended. The intention was that, once a particular substance or organism is approved under Part V, other persons can deal with that substance or organism provided they comply with the controls attaching to the original approval. No further approvals will be required. The government is moving to resolve this issue by amending the Act.

The latter approach is obviously more efficient and cost-effective, although it may create a disincentive to be the first to seek approval for a new substance or organism and therefore stifle innovation. ERMA is hoping that business and industry will take a cooperative approach to avoid this.

The problem remains regarding how to keep track of all persons dealing with a particular substance or organism, and enforce the relevant conditions and controls. ERMA has proposed a practical solution whereby persons other than the original applicant dealing with a substance or organism would be required to notify ERMA before making use of the approval.

"Compliance costs"

There is no doubt that the new regime will be significantly more costly than the previous one. This is due to the extensive information requirements on applicants under Part V of the Act, the opportunities for public participation in the application process, and the provision for public hearings on applications. Of particular note is the issue of consultation with Maori, a new concept in this area of law. There is no express duty in the Act requiring applicants to consult with iwi about applications for approval under Part V. However, it is made clear in the Methodology and draft protocols that consultation will be expected where an application is likely to be of significance to Maori.

ERMA is sensitive to the concerns over compliance costs, especially for small businesses, and is committed to making the application process as simple and cost-effective as possible. Methods to achieve this include:

(i) Methodology, protocols and quick guides:
The Methodology and protocols provide applicants with some certainty about how ERMA will make decisions on applications under Part V. They promote consistency of decision-making and reduce the time for consideration. The series of Quick Guides being developed by ERMA are intended to be a step-by-step, plain English guide to the application process.

(ii) Liaison with ERMA:
ERMA is encouraging people to consult with its staff members at all stages of the application process, particularly at the pre-application stage. ERMA can help streamline the process by advising what supporting information is needed and what parallel approvals may be required from other agencies, identifying any significant risks or effects that need to be considered, identifying who might need to be consulted, and explaining the process and timeframes. ERMA is happy to review draft applications before they are formally submitted. Businesses should also make use of industry groups and other representative bodies when preparing applications. These groups can provide information and resources, as well as opportunities for collective applications (ie, several parties to a single application).

(iii) Consultation:
ERMA is also encouraging applicants to talk with affected or interested parties while preparing applications. It is happy to facilitate consultation, and to conduct pre-application and pre-hearing meetings. ERMA recognises the particular difficulties with iwi consultation and identifying potential concerns to Maori when preparing applications. It intends to work with Nga Kaihautu Tikanga Taiao and the Maori community to develop guidelines identifying general issues that may be of significance to Maori. This will assist in determining what level of consultation is required (if any), and how much consideration should be given to the risks, costs and benefits of the application for Maori. Nonetheless, the Authority encourages applicants to consult directly with Maori because they can best define how a particular substance or organism will impact upon them. ERMA also intends to develop a schedule of contact representatives for Iwi Authorities and other Maori groupings for the purpose of iwi consultation. Essentially, the extent of consultation required in any case will depend on the nature and scope of the application and its significance to Maori.

(iv) Flexibility:
ERMA will only require information that is relevant and proportionate to the scale and significance of the application and its risks, costs and benefits. It intends to take a "horses for courses" approach when considering applications as far as information and consultation requirements are concerned. Similarly, ERMA

intends to be flexible and practical when dealing with applications. For example, it welcomes "broad spectrum applications" for hazardous substances (ie, grouping a range of compositions of a substance under one substance definition, and obtaining only one approval for the entire group) as well as collective applications.

(v) "Reinventing the wheel":
This is something ERMA will try to avoid by taking into account information that has been generated by other processes and agencies in New Zealand or overseas. This will include having regard to the quality of the information, and the extent to which it reflects New Zealand circumstances and the requirements of the HSNO Act.

Enforcement
One of the strongest criticisms of the Act concerns its fragmented enforcement regime. First, there are concerns about the large number of agencies with enforcement responsibilities under the Act, each with varying levels of expertise. They include the Department of Labour, the Ministry of Commerce, the Land Transport Safety Authority, the Police, the Civil Aviation Authority, the Ministry of Health, and all territorial authorities. The involvement of so many agencies will make it difficult to achieve consistency and coordination in enforcing the Act, and could be very costly.

Secondly, there is uncertainty about the responsibilities of the different agencies, which appear to overlap in some cases. For example, the responsibility of the Ministry of Health for public health overlaps with that of the Department of Labour for health and safety in the workplace, and the Land Transport Authority and the Police are both responsible for motor vehicles, roads, trains and railway lines. The role of territorial authorities is particularly unclear. The Act defines specific areas of responsibility for the various government departments and then simply leaves all residual premises to territorial authorities. Territorial authorities are also responsible for dangerous goods on any premises during the transitional period. Again, there is potential for overlap with other enforcement agencies.

While the roles of the different enforcement agencies could certainly be clarified, there will inevitably be potential overlap of their functions. It is for the agencies themselves to make arrangements with other agencies for the coordination of their enforcement functions. The Act also provides for agencies to transfer all or any part of their functions to another enforcement agency under the Act.

ERMA acknowledges the "challenges" of the enforcement arrangements and has some strategies in mind to deal with them. Initially, it will concentrate on addressing any gaps or weaknesses in the enforcement regime, and working with

the different enforcement agencies to help define their responsibilities. In the medium term, ERMA considers that a national compliance strategy will be needed to achieve consistency and coordination, and that enforcement responsibilities should be significantly rationalised using the powers in the Act to delegate or transfer enforcement powers.

In the long term, ERMA envisages working with industry to identify "best practice" and promote voluntary compliance. The aim is to develop a more efficient system by using approved codes of practice and industry standards and guidelines as a means of demonstrating compliance with the Act.

Conclusion

For most people dealing with hazardous substances, the transitional provisions are the most important part of the Act in the short term. The main parts of the Act apply only to applications to import or manufacture *new* or *illegal* substances — that is, substances that are not in current or legal use in New Zealand.

For *existing legal substances*, people should focus on complying with existing approvals and controls, and with the transitional provisions of the HSNO Act. They will not be required to make any applications under Part V of the Act in respect of these substances. The onus is on ERMA to initiate the transfer of particular substances to the HSNO regime. Those dealing with toxic substances should ensure the substances have been notified.

Similarly, the Act will not change things in practical terms for most persons currently dealing with approved organisms. The main difference is that approved organisms (with the exception of GMOs) will be brought under the HSNO Act immediately upon the start of the Act, whereas approved hazardous substances will be gradually transferred to the new regime over a number of years.

*Justine Sefton**

* LLB (Hons)/BA, Solicitor, Simpson Grierson, Auckland.