



Making an Application for a Hazardous Substance Approval

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Part A

General information

1. HSNO—a co-ordinated approach to managing risks

The purpose of the Hazardous Substances and New Organisms (HSNO) Act 1996 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’. Before the Act was introduced in 1996, hazardous substances were separately managed by a number of different laws that focused on single dangerous characteristics eg flammability under the Dangerous Goods Act. The HSNO Act is a co-ordinated and integrated approach to managing the risks posed by hazardous substances. It has replaced the following Acts:

- Explosives Act 1957
- Dangerous Goods Act 1974
- Toxic Substances Act 1979
- Pesticides Act 1979 (with minor exceptions).

The HSNO Act established the Environmental Risk Management Authority (ERMA New Zealand). ERMA New Zealand’s main function under Part V of the Act is to make decisions on applications to introduce hazardous substances (and new organisms) into New Zealand.

1.1 A guide to help prepare your application

We’ve written this User Guide to help you prepare applications for hazardous substance approvals under the following sections of the HSNO Act:

- section 28 Import or manufacture a hazardous substance for release
- section 28A Import or manufacture a hazardous substance for release, rapid assessment
- section 31 Import or manufacture a hazardous substance in containment
- section 47 Import, release or use a hazardous substance in an emergency.

This guide assumes that an application under one of the above sections in the Act may be necessary. It is structured with a separate part for each application type (Parts B—F), and within each part we’ve included guidance for filling out the relevant application form. Information on transshipment approvals (section 51) is not provided in this document. If you need advice about this type of application, please contact one of our hazardous substance Applications Officers.

Section 2 in Part A of this guide briefly sets out the circumstances where an application may not be necessary—more information on this is available from ERMA New Zealand. If you aren’t sure whether you need to make an application, please contact us for advice.

1.2 Other publications can also help

This guide draws on information contained in other publications, listed below. All these documents, except for the HSNO Act and Regulations (available from Bennetts Bookshop), can be obtained by contacting our Information Services Co-ordinator. Alternatively, most of these documents are available from our website www.ermanz.govt.nz or associated links to other websites.

Information Services Co-ordinator
ERMA New Zealand
P O Box 131
Wellington
New Zealand

Phone: 64 4 916 2426 ext 851

Fax: 64 4 914 0433

Email: info@ermanz.govt.nz

The HSNO Act and Regulations:

The HSNO Act (and its amendments) and the HSNO Regulations are the main statutory references for hazardous substance approvals. If you expect to be a regular applicant, you should obtain copies, because these documents are the ultimate authority for what is required.

HSNO Act 1996

HSNO Amendment Act 2000

HSNO (Methodology) Order 1998

Hazardous Substances (Forms and Information) Regulations 2001

Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 (Threshold regulations)

Hazardous Substances (Classification) Regulations 2001

Hazardous Substances (Classes 1 to 5 Controls) Regulations 2001 (Physical Controls)

Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001 (Biological Controls)

Hazardous Substances (Identification) Regulations 2001

Hazardous Substances (Packaging) Regulations 2001

Hazardous Substances (Tracking) Regulations 2001

Hazardous Substances (Disposal) Regulations 2001

Hazardous Substances (Emergency Management) Regulations 2001

Hazardous Substances (Exempt Laboratories) Regulations 2001

Hazardous Substances (Personnel Qualifications) Regulations 2001

Hazardous Substances (Fireworks) Regulations 2001

ERMA New Zealand Protocols and associated documents:

These documents represent the formal policy of the Authority, and as such, stand immediately under the Act and Regulations in terms of authority. Regular applicants should have a copy of all these documents. Because of their importance, they are available from ERMA New Zealand at no charge.

- ***Annotated Methodology for the consideration of applications for hazardous substances and new organisms under the HSNO Act 1996*** (August 1998). This document is the expanded and annotated version of the Methodology Order.
- ***Taking Account of Maori Perspectives*** (Number 1, Series 2, September 1999). This protocol outlines how the Authority will take into account the principles of the Treaty of Waitangi and the relationship of Maori and their culture and their traditions with their ancestral lands, water, sites, wahi tapu, valued flora and fauna, and other taonga. The protocol also sets out the role of Nga Kaihautu Tikanga Taiao (Nga Kaihautu).
- ***Decision Paths*** (Number 2, Series 2, October 1999). This protocol sets out the decision paths that are followed for each type of application.
- ***Interpretations and Explanations of Key Concepts*** (Number 3, Series 2, October 1999). This protocol includes an explanation of the key concepts relevant to the Authority's decision-making as well as further explanation of both definitions in section 2 of the HSNO Act and the important concepts introduced in the Methodology but not described in the Act.
- ***Information Requirements for Applications to Import or Manufacture a Hazardous Substance for Release*** (Number 4, Series 2, Version 2, March 2001). This protocol provides further detail to the Methodology. It sets out the circumstances for different levels of information, describes what information will be required, and sets out how the decision may reflect the information to be provided. It also covers the difference between full assessment and rapid assessment applications.

ERMA New Zealand User Guides

The User Guides are practical guides for people who have to work with the Act. We expect applicants will find them more helpful and user-friendly than the formal documents described above. Because these documents are substantial, we charge for them. However, the charges are set to recover publication costs only, not the cost of preparation. In addition to this User Guide, others available are:

- ***User Guide to HSNO Thresholds and Classifications*** (2001) is a guide to the threshold and classification regulations and includes information to help decide whether a substance is hazardous. It also includes examples of test methods that provide acceptable data, and methods to calculate and extrapolate data. The guide is available in summary form as well; ***Summary User Guide to HSNO Thresholds and Classifications*** (2001). You will probably only need the full guide if you are going to do your own classification work.
- ***User Guide to HSNO Control Regulations*** (2001) is a guide to the controls prescribed in the HSNO control regulations. It includes material to help interpret the performance standards required by these controls, and it gives an indication of how to meet these standards.
- ***User Guide to Working with Maori under the HSNO Act 1996*** (December 1999) helps applicants to provide relevant and sufficient information to the Authority on Maori matters.

ERMA New Zealand Quick Guides

The Quick Guides are mainly for people who are becoming involved with the Act for the first time. They are available free of charge.

- ***Quick Guide to Making Applications*** (May 2001) has general background information on the application process and includes information on the reassessment process.
- ***Quick Guide to Applying for a Hazardous Substance Approval*** (May, 2001) provides information to applicants wishing to apply for a hazardous substance approval.
- ***Quick Guide to Making a Submission*** (May 2001) has information on making a submission on an application. This guide also includes information on hearings.

ERMA New Zealand Schedule of Fees and Charges

- ***Schedule of Fees and Charges*** (July 2001) explains how the fees and charges are applied when calculating the total price for an application. Always check to see whether you have the latest version of the schedule.

ERMA New Zealand Technical Guides

Our Technical Guides provide more detailed guidance to people involved with the HSNO Act than is available in the User Guides. They were initially written for people reviewing applications, but may also be useful for applicants and those interested in the detailed analysis of HSNO-related risks more generally. We charge for these publications.

- ***Identifying Risks for Applications under the Hazardous Substances and New Organisms Act 1996*** (September 1999) provides an overview of the requirements for risk assessment.
- ***Preparing information on Risks, Costs and Benefits for Applications under the Hazardous Substances and New Organisms Act 1996*** (July 2000) is a guide to identifying and assessing HSNO risks, costs and benefits.
- ***Assessment of effects of Hazardous Substances and New Organisms on Human Health*** (January 2000) provides a framework for reviewers to consistently appraise applications for their effects on human health.

ERMA New Zealand Information Sheets

Information Sheets are similar to Quick Guides but are aimed at particular subjects and are also likely to go out of date quite quickly. We provide paper copies free on request but the easiest way to access them is to download them from our website. Current relevant titles are:

- ***Exemptions from the Provision of the HSNO Act for Small-Scale Research on Hazardous Substances*** (May, 2001)
- ***Manufactured articles*** (May, 2001)
- ***Determining the status of a substance—do I need to get an approval?*** (May, 2001)
- ***Development and approval of HSNO Codes of Practice*** (May, 2001)

- *Confidential information* (May, 2001)
- *What will it cost?* (May, 2001)

ERMA New Zealand Application Forms for Hazardous Substance Approvals

Applications for approval to import or manufacture a hazardous substance must be made on one of our application forms listed below. These are available from us free on request, or you can download them from our website. They are designed to be used with this User Guide. (Note that this guide does not cover transshipment applications.)

- *ERMA New Zealand Application Form HS1* (application for approval to import or manufacture a hazardous substance for release)
- *ERMA New Zealand Application Form HS2/1* (application for approval to import or manufacture a hazardous substance for release that meets the requirements for rapid assessment under the criterion of low hazard)
- *ERMA New Zealand Application Form HS2/2* (application for approval to import or manufacture a hazardous substance for release that meets the requirements for rapid assessment under the criterion of similar substance)
- *ERMA New Zealand Application Form HS3* (application for approval to import or manufacture a hazardous substance in containment)
- *ERMA New Zealand Application Form HS4* (application for approval to import, release from containment, or use any hazardous substance in an emergency)
- *ERMA New Zealand Application Form HS5* (application for approval to tranship a hazardous substance).

ERMA New Zealand Sample Applications

We have prepared a series of *Sample Applications* for hazardous substance approvals to show applicants the type of information required for various application types. These applications have been reviewed as if they were real applications, but only represent one example of an acceptable form for that application type—they should not be seen as the only acceptable version, or even the best possible form that an application might take. A number of the *Sample Applications* have been carried through the review process with sample ERMA New Zealand Evaluation and Review reports and sample decisions also prepared. These documents are available from ERMA New Zealand on request or alternatively, you can download them from our website.

2. Do I need to apply for approval under HSNO?

Generally, every hazardous substance imported into, or manufactured in, New Zealand **for the first time** requires an approval from ERMA New Zealand. However, there are a number of circumstances where an approval is not required. In the first instance, you should refer to the definitions of substance, importation and manufacture in Appendix 1 of this guide to find out whether or not you need to make an application.

The next step is to go through each of the possible situations outlined below.

2.1 Is the substance exempt from the requirements of the Act?

Small-scale laboratory exemption

Under section 33 of the HSNO Act, hazardous substances intended solely for small-scale use in research and development or teaching are exempt from the provisions of the Act if **all** of the following apply:

- the substance is used in a laboratory that meets the prescribed requirements
- the use does not create or involve a hazardous substance for which any application has been declined under the Act
- the importation, storage, and transportation of the hazardous substances each meet the prescribed requirements
- no such hazardous substance, nor any substance created from its use, is sold as a substance or in a product containing or derived from that substance.

The prescribed laboratory requirements are set out in the *Hazardous Substances (Exempt Laboratories) Regulations 2001* and are aimed at reducing the possibility of any substance escaping from the laboratory. In practice, if your laboratory is ISO Guide 25 accredited and meets the requirements of AS/NZS2243:2 Safety in Chemical Laboratories, it would probably fulfil the prescribed laboratory requirements, and you may not need to make an application for approval. More information on this exemption is in our Information Sheet *Exemptions from the Provision of the HSNO Act for Small-Scale Research on Hazardous Substances (May 2001)*.

Food exemption

Food in ready-to-eat form (including food containing food additives) that has properties that trigger a HSNO threshold, is exempt from the requirements of the Act (unless it is a substance carried over into the transitional provisions by virtue of its coverage under the old legislation eg flammable alcoholic spirits in bulk). However, food additives that have not been mixed with, or added to, any other food or drink are **not** exempt from the Act. 'Food' and 'food additive' have the same meaning as in the Food Act 1981.

This food exemption is provided for in the *Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001* and is made under section 75 (1)(g) of the HSNO Act.

Medicine exemption

Medicines approved under the Medicines Act 1981 as at 2 July 2001 (with some exceptions) are also exempt from the requirements of the HSNO Act, unless they are already a toxic substance, dangerous goods or explosive substance. This exemption included ingredients used to make a medicine, as well as finished dose-form medicines and bulk formulated medicines as they are defined in section 3 (1) of the Medicines Act 1981.

Now, a new ingredient used for formulating a medicine is **not** exempt and will require a HSNO approval if it triggers a HSNO threshold, but new finished dose-form medicines and new bulk formulated medicines will remain exempt. Similarly, a new 'human' medicine that is intended

to be registered as a veterinary medicine under the ACVM Act 1997, is also **not** exempt and will require a Part V approval if it triggers a HSNO threshold.

This medicine exemption is provided for in the *Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001* and is made under section 75 (1)(g) of the HSNO Act.

2.2 Is the substance a manufactured article?

Manufactured articles containing or incorporating hazardous substances with properties other than explosiveness are **not** considered substances under the HSNO Act. Manufactured articles with explosive properties (such as flares or detonators) **are** hazardous substances under the Act. Manufactured products such as glues, paints, pesticides etc are also considered to be substances under HSNO and will require a Part V approval if they trigger a HSNO threshold.

The Authority has adopted the following working definition of ‘manufactured article’:

‘Something for which its intended use is primarily to do with its physical shape, rather than its chemical composition’.

This distinction is not always clear-cut and is open to interpretation. Therefore, we have expanded upon this definition and established that an item is a manufactured article if it satisfies **all** of the following criteria:

- the item is deliberately formed to a specific shape or design during manufacture
- the item has an end use function wholly or partly dependent on its shape or design
[solid substance which is manufactured or imported, formed to a particular shape and which undergoes only further limited processing into a finished article, is considered itself to be a manufactured article. ‘Limited processing’ covers cutting, bending, surface chemical reaction, etc, but excludes processes such as pulverising, melting, pelletising, etc, where the formed shape is completely destroyed. Other items to be regarded as manufactured articles are polymer blocks, sheets, films and filaments, unless these are classified internationally as dangerous goods]
- the item undergoes no change of chemical composition during end use, except as an intrinsic part of that end use
- the item is not a particle or a fluid
[‘Fluids’ refers to liquids (including suspensions and solutions) and gases. ‘Particles’ refers to any solid chemical substance or mixture that is in discrete aggregations of unspecified size, which may take the form of dust, powders, dispersions, granules, pellets, beads, lumps and flakes]

Fluids or particles contained within a vessel serving simply to store, transport and dispense its contents are considered to be substances. In general, all fluids and particles, such as cleaners, solvents, fuels, glues, sealants, inks, paints and other coatings, are substances if they are merely contained in some form of packaging ie the contents of containers, such as bottles, jars, cans,

aerosol cans, drums, barrels, tanks, bags, tubes and sachets are chemical substances or mixtures of chemical substances.

In the case of items where it is intended that the fluid or particulate contents remain in their container during normal use of the item, and where they serve an intrinsic part of the end purpose of the item, the fluids and particles are considered to be an integral part of the article and are not considered to be substances for the purposes of the HSNO Act. For example, a lubricant in a bottle, drum or aerosol can is a chemical substance (or mixture of chemical substances) and will need an approval if it is above a HSNO threshold, but a lubricant in a sealed bearing or other piece of mechanical equipment is part of an article and outside the scope of the Act.

The boundary between substance and manufactured article is 'fuzzy'. No matter how precise the definition is there will be room for interpretation. Common sense should prevail and ERMA New Zealand will take into account the following factors:

- the potential for intended release of the substance during the use of the article and, if it is released, whether there is a barrier preventing exposure of the user or the environment
- whether the article has a hazardous property that exceeds a HSNO threshold level and where the primary function of the article leads to a hazardous effect.

We have provided some practical examples of manufactured articles and substances below. However, the fact that an item is considered a substance does not necessarily mean that it will come under the HSNO Act. It has to be a **hazardous** substance for this to happen, ie it has to trigger at least one of the hazardous property threshold levels.

Examples of manufactured articles

Batteries, paper, leather, laminated materials, pottery, fabrics, fibres, filaments, films, pens, pencils, typewriter ribbons, carbon paper, electronic or electrical equipment, machinery.

Examples of substances

Crayons, matches, aerosol cans of paint, bottles of ink, cartridges of sealants, tubes of adhesives, fuel refill cartridges for lighters, fire extinguishers, rub-on dispensers of cleaning products or polishes, perfume atomisers.

More detailed information on manufactured articles is in our Information Sheet *Manufactured articles* (May 2001).

2.3 Is the substance covered by an existing approval?

If you are importing or manufacturing a hazardous substance for the first time, you'll need to determine whether it is legally present in New Zealand. If it is currently here as a legal substance, you will **not** need to make an application for approval.

However, an exception to this requirement, made under section 29A of the HSNO Act (as amended in 2000), is that a separate approval must be obtained by **each** person wishing to import or manufacture:

- an innovative agricultural compound (as defined by the ACVM Act 1997)

- an innovative medicine (as defined by the Medicines Act 1981).

The criteria for determining whether a substance is legally present in New Zealand are:

1. It must have a HSNO approval issued by the Authority under one of the sections (28A, 29, 32 and 48) of Part V of the Act, or
2. It must be covered by the transitional provisions (Parts XI to XV) of the HSNO Act. These are substances that were either approved or notified under previous legislation, and which need to be transferred over to the HSNO framework. Due to the large number of substances involved, this 'transfer process' will take some years. These substances include:
 - pesticides registered under the Pesticides Act 1979 (including pesticides subject to experimental use permits) (administered by the ACVM Group, Ministry of Agriculture and Forestry (MAF))
 - licensed animal remedies listed on the ACVM database of currently licensed animal remedies (administered by the ACVM Group, MAF)
 - authorised explosives listed on the Explosives Authorisation Order 1994 (including those substances authorised by Occupational Safety and Health (OSH) since 1994 and included in amendments to the Order)
 - dangerous goods that are covered in Part C of the Seventh Schedule to the HSNO Act (and that were lawfully present in New Zealand before 2 July 2001)
 - substances scheduled under the Toxic Substances Act 1979
 - substances that have been notified under section 32 of the Toxic Substances Act 1979 (NOTS). This database is kept by ERMA New Zealand and for reasons of confidentiality is not publicly available.

In the long term, you'll be able to find out whether your substance is legally present in this country by checking the ERMA New Zealand register, available on our website and at our Wellington office. In time, the register will list all HSNO approved substances (through either Part V approvals or the transfer process). However, the register will not be complete until all the transitional substances have been transferred to the HSNO framework.

In the short term, you can check most of the databases listed above yourself (excluding NOTS), some of which are accessible via our website, or you can contact us and ask that we check all our records, including the NOTS database. We'll only do this search if you can demonstrate a bona fide intent to import or manufacture the substance, provide the necessary details for the unequivocal identification of the substance, and pay a fee where appropriate. More information on this is in our Information Sheet *Determining the status of a substance* (May 2001).

2.4 Is the substance hazardous?

Substances that are **not** hazardous do not require an application for approval. Generally, a substance is hazardous if it has the potential to harm people or the environment. In HSNO terms, a substance is considered hazardous if it triggers any one of the threshold levels defined in the *Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001* for any of the following hazardous properties:

- explosiveness

- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

A substance is also hazardous if it generates a substance with any one or more of these hazardous properties when it comes into contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased).

It's your responsibility to determine whether or not your substance is a hazardous substance under the HSNO Act. You may wish to use a consultant to do this for you. We have written the *User Guide to HSNO Thresholds and Classifications* to help with this determination. This guide is based on the *Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001* and *Hazardous Substances (Classification) Regulations 2001*. We have also written a *Summary User Guide to HSNO Thresholds and Classifications*. The *Substance Evaluation Sheet* in the *Summary User Guide to HSNO Thresholds and Classifications* leads you through a process of assessing whether a substance is hazardous or not by considering each of the six hazardous properties listed above. Once it has been decided that the substance triggers a threshold level, the guide provides detailed information on how to classify the hazardous properties of the substance.

Under section 26 of the Act (as amended in 2000), you can also apply to the Authority for a formal determination on whether or not a substance is hazardous under the HSNO Act. If you want to take advantage of this option, check with us on the fees that apply. We also recommend that you make your application well before you want to import or manufacture so we can allocate technical resources most efficiently. You will need to provide us with enough information to unequivocally identify the substance. More details are in our Information Sheet *Determining the status of a substance* (May 2001).

3. Which section of the Act do I apply under?

There are five types of potential approvals for the importation/manufacture/use of hazardous substances, covered by five different sections of the HSNO Act (listed below). This User Guide covers making an application under four of these sections—information on transshipment approvals is not provided in this document.

Section 28: The import or manufacture of a hazardous substance for release

Under section 28, the import or manufacture of a hazardous substance, other than in containment, requires an approval from the Authority. Section 28 approvals deal with release applications that cannot be covered by a section 28A rapid assessment or a section 47 release in an emergency (see below).

Section 28 and 28A applications cover the introduction and subsequent distribution/use of commercial substances in New Zealand and therefore is the major application route for the approval of new hazardous substances under HSNO.

Section 28A: The rapid assessment of the import or manufacture of a hazardous substance for release

Under section 28A (2), the Authority may make a rapid assessment of applications to import or manufacture a hazardous substance for release if one of the following criteria applies:

- a substance having a similar composition and similar hazardous properties has been approved
- the substance has one or more hazardous properties and each hazardous property has the least degree of hazard for that property.

However, it will take some time for the ‘similar substance’ criterion to have any practical impact. This is because there will be no existing approvals to work from, until existing substances begin to be transferred to the HSNO Act as ‘deemed approvals’, or substances are approved directly under Part V.

Part C (Section 2.1) and Part D (Section 2.1) of this guide can help you decide whether your application fulfils the criteria for rapid assessment. This is based on our *Protocol Information Requirements for Applications to Import or Manufacture a Hazardous Substance for Release*.

Section 31: The import or manufacture of a hazardous substance in containment

The HSNO Act defines containment as restricting a substance to a secure location or facility to prevent escape. This is usually achieved through establishing barriers (physical and procedural) to prevent release of the substance to the uncontrolled environment.

Containment applications are not intended for substances that are for commercial manufacture or sale. Section 31 applications can only be made for approval to import or manufacture a hazardous substance(s) in containment for any one of the purposes outlined below:

- use of small amounts of any hazardous substance as an analytical standard where approval to import or manufacture that substance has been declined
- research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval
- research and development on any hazardous substance
- use in an emergency
- such other purposes as the Authority thinks fit.
-

Section 47: The import, release or use of a hazardous substance in an emergency

The Authority may approve applications to import for release, release from containment or use any hazardous substance(s) in an emergency for any one of the purposes listed below. The approval must be gained before the importation, release or use (ie, the approval is held ‘in the

bank'). A special exemption (section 49), however, applies to unforeseen emergencies. Emergency purposes include:

- importation of any hazardous substance for release in an emergency
- release of any hazardous substance from containment in an emergency
- use of any hazardous substance in an emergency in a manner which would otherwise contravene the provisions of this Act or any regulations.

For the purposes of the HSNO Act and section 47, an 'emergency' means one of the following:

- a state of emergency declared under the Civil Defence Act 1983
- an emergency as defined in section 2 of the Fire Service Act 1975
- a marine oil spill emergency under the Maritime Transport Act 1994
- actual or imminent danger to human health or safety
- a danger to the environment or chattels so significant that immediate action is required to remove the danger arising from a hazardous substance.

Section 51: Transhipment of a hazardous substance

The Authority may approve applications to tranship any hazardous substance through New Zealand. Transhipment is the importation of hazardous substances into New Zealand solely for the purpose of exporting within 20 working days to a destination outside New Zealand. This includes goods that remain on a craft or vessel, and those that are removed for short-term storage before re-export. If you intend processing the goods in any way, including repackaging, then this is not transhipment but importation and/or manufacture and the normal HSNO approval processes apply.

You can get more information on making an application for a transhipment approval from ERMA New Zealand. There is as yet no User Guide for this type of application.

4. How do I make an application?

4.1 Obtain the appropriate application form

Application forms are available either from our ERMA New Zealand office or from our website: www.ermanz.govt.nz. Hazardous substance applications must be made on the following forms:

- release (section 28) applications should be made on application form **HS1**
- rapid assessment applications under the criterion of low hazard (section 28A) should be made on application form **HS2/1**
- rapid assessment applications under the criterion of similar substance (section 28A) should be made on application form **HS2/2**
- containment (section 31) applications should be made on application form **HS3**

- emergency (section 47) applications should be made on application form **HS4**
- transshipment (section 51) applications should be made on application form **HS5**.

These forms may be used for all hazardous substances in general industrial or commercial use including agricultural compounds, industrial chemicals, chemicals in household use, dangerous goods, and explosives.

4.2 Talk to an Applications Officer

This guide has detailed information on how to fill out an application form. However, we advise you to talk to an Applications Officer at ERMA New Zealand about your application before submitting it. We can then give advice on the level of information required and help with any specific difficulties. You should be aware that actual and recorded time spent on pre-application discussions with ERMA New Zealand staff will be charged for once the application is formally lodged.

4.3 Provide the relevant information

The application must include information on the identification of the hazardous substance, its hazardous properties, its intended uses and its disposal. Information is also requested on the identification and assessment of risks, cost and benefits and on the management or control of risks (adverse effects). It is in your best interests to provide information that is as complete as possible, especially on the compulsory elements. Applications with inadequate or insufficient information will take considerably longer to process and will be more costly to applicants. Also, uncertainty arising from this lack of information may lead to the Authority stalling the application until more information is provided (see Section 6.5 below), declining an application, or approving the application with more stringent (and more costly) controls.

It is very important that the information you supply with the application is as comprehensive and as complete as possible. The level of information you need to provide depends on the nature of the substance and its potential effects. You can contact an ERMA New Zealand Applications Officer at any time for advice on the type and extent of information needed. Guidance on information requirements for different types of applications is provided in Parts B-F of this guide and also in our Protocol *Information Requirements for Applications to Import or Manufacture a Hazardous Substance for Release*.

4.4 Pay the fees and charges that apply

ERMA New Zealand works on a cost recovery basis. This means that you will be expected to pay for a part of the actual costs of processing your application. Initially the costs arising from the public participation components of the application process will be covered by a government contribution. The total price will vary from application to application. If your application is relatively straightforward, the price will be less than for a more complicated application that requires more extensive review and analysis.

It is important to note that charges apply whether or not the application is approved. We will give you an estimate, on request, of how much your application is likely to cost. This is an estimate only, and the final amount will depend on how long it has taken to assess and make a

decision on your application. We can give you regular updates and estimates as your application progresses.

Fees are usually paid in instalments. The first instalment should be paid when you submit your written application. You will be charged for pre-application discussions with ERMA New Zealand staff once you have formally lodged your application.

More detailed information on fees is in the current ERMA New Zealand *Schedule of Fees and Charges* available from our office. Further information is in our Information Sheet *What will it cost?* (May, 2001).

5. Submitting your application

You will need to submit your application well before you need to import or manufacture the substance, as the full statutory process can be lengthy, eg a section 28 application normally requires a minimum of 85 working days. If there are no submissions on the application and no hearing required, this time might be shortened (see Section 6 below).

You should provide us with one typed, unbound, single-sided copy of the signed application along with the required initial payment (see above). We recommend that you send the application by secure post or courier (contact details below). Applications may be submitted in English or Maori. However, if the application is in Maori, we will have to have it translated and this will add to the cost. We also ask that you provide us with an electronic copy of the application, preferably in MS Word, either by email or floppy disk. Later correspondence may be sent by facsimile or email to the appropriate Applications Officer.

Physical Location address

ERMA New Zealand
Level 1, BP House
20 Customhouse Quay
Wellington
New Zealand

Postal address

ERMA New Zealand
P O Box 131
Wellington
New Zealand

Phone: 64 4 916 2426
Fax: 64 4 914 0433
Email: info@ermanz.govt.nz

6. Processing and consideration of your application

Following receipt of your application, we'll send you written notification that your application and first instalment of the appropriate fees have been received.

Once the application is lodged, it will be processed to determine if it has all the information necessary for a decision to be made. During this period, we may contact you to clarify any of the information provided, or to ask for additional information if we identify issues of significant concern or missing information. If necessary, the application may be stalled under section 52 of the Act until the extra information is provided (see Section 6.5 below). Once we are satisfied that your application fulfils the minimum information requirements, we will notify you that the application has been verified.

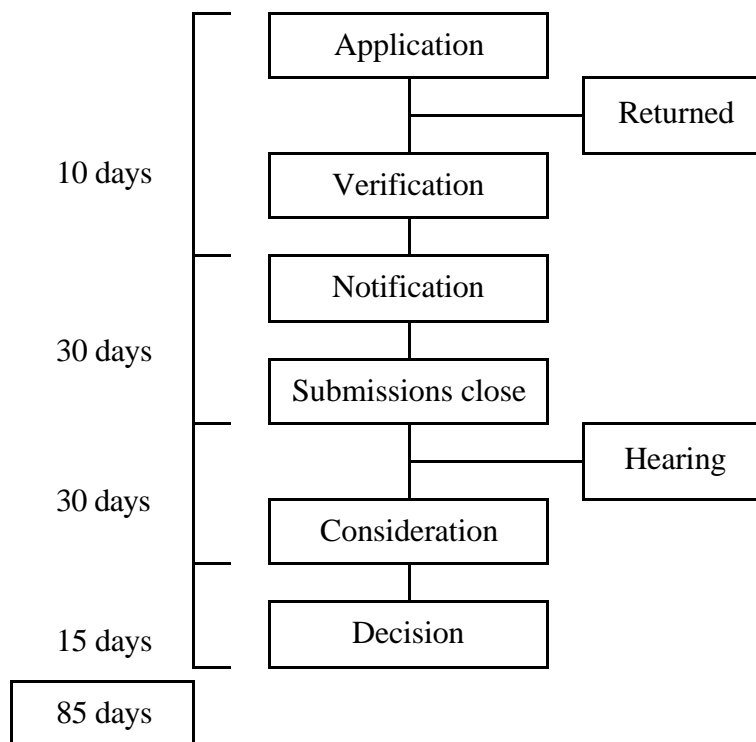
However, even after verification the Authority may at any stage decide it needs more information to reach a decision. The application may be stalled under section 58 of the Act until that additional information is provided (see Section 6.5 below).

Applications will generally follow one of two processing paths (notified and non-notified).

Notified applications

Release (section 28) and release in an emergency (section 47) applications need to be publicly notified. This means that after we have verified the application, it will be publicly notified and posted on our website. The public can then make submissions, after which time a date will be set for a public hearing if required. At the hearing, an ERMA New Zealand Evaluation and Review report will be presented to the standing committee for consideration. After its consideration, the Authority will publicly notify its decision. The statutory time period allowed for the entire notified application process is 85 days, shown in Figure 1. However, the Authority may extend this time if the application has been stalled pending further information, or requires extended consideration.

Figure 1: Statutory timeframes for notified applications (section 28 and 47)



Non-notified applications

Rapid assessment (section 28A) and containment (section 31) applications do not need to be publicly notified and therefore the process is much shorter. Within 20 working days of receiving an (completed) application, we'll prepare an Evaluation and Review report and send it to you and the Authority. The Authority must consider the application within a further 10 working days. The Authority will publicly notify its decision within 15 working days after its consideration. The statutory time period allowed for the entire non-notified process cannot

exceed 45 days. However, the Authority may extend this time if the application has been stalled pending further information, or requires extended consideration.

General information on the application process is in our *Quick Guide to Making Applications* (May 2001) and a *Quick Guide to Applying for a Hazardous Substance Approval* (May 2001).

6.1 Withdrawing your application

You may withdraw your application at any time by written request. However, you will have to pay for any costs we incur up to the time of withdrawal, and that may include time spent in pre-application discussions. If someone has supplied information to the Authority about an application that has been withdrawn, that information will either be returned on request to the person who supplied it, or destroyed.

6.2 Keeping it confidential

Commercially sensitive information will not be publicly released. If you supply commercially sensitive information to ERMA New Zealand, you need to clearly identify it and submit it as a separate document eg an appendix, which will not be available for public inspection.

Information supplied to the Authority before an application is lodged is not covered by the Official Information Act (OIA) 1982, which means that another person can't request this information under the OIA.

Once the application has been lodged, the OIA applies, and anyone can ask for copies of information held by the Authority. The OIA works on a presumption that all information can be made available unless there is good reason to withhold it. Section 9(2)(b) of the OIA provides that there is good reason for withholding information:

'....if, and only if, the withholding of the information is necessary to –

(b) Protect information where the making available of that information –

- (i) Would disclose a trade secret; or*
- (ii) Would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information;...'*

Section 57(1) of the HSNO Act provides that information which could be withheld under section 9(2)(b) of the OIA is not to be released when an application is publicly notified.

Sections 57(2) to (4) of the HSNO Act set out a process for the Authority to follow if a request is made under the OIA for information that may be commercially sensitive. The Authority will advise the person who supplied the information that a request has been made to release it under the OIA. The person who supplied the information then has 10 working days to respond and give justification as to why the information should be kept confidential. The Authority has 20 working days to respond to the request to release the information. The decision about whether the information meets the criteria for withholding under the OIA rests solely with the Authority. However, ERMA New Zealand is very conscious of the importance of confidentiality to commercial applicants and we will uphold legitimate confidentiality very strongly.

If an application that is subject to an OIA request is withdrawn, the application will be returned to the applicant and the OIA request will not be actioned.

It's your responsibility to clearly identify information you consider to be commercially sensitive and to supply this information as an appendix. A non-confidential summary of the information, clearly cross-referenced, should appear in the main application. You should also justify why the information should be kept confidential.

The following information will **not** be treated as confidential without good justification:

- trade name
- name of manufacturer/importer and applicant
- summary of physicochemical data such as physical state, melting/boiling point, density, vapour pressure, flash point, water solubility, partition coefficient
- summary of toxic and ecotoxic properties/test results
- disposal information for rendering the substance harmless
- if relevant to the hazardous properties, the degree of purity and the identity of impurities/additives (if hazardous)
- information on recommended methods and precautions concerning handling, storage, transport, safety and emergency measures.

Information provided in the 'Summary of Public Information' section of the application form is, by definition, not confidential.

You need to clearly understand the definitions of confidentiality **before** you lodge your application and supply any commercially sensitive information. The Authority needs to be able to release sufficient information so that the Register requirements of the Act can be met and so it can adequately explain its decision and any residual risks posed by the substance.

If you are unwilling to provide this information or insist on maintaining confidentiality unreasonably, then the Authority may decide that it has insufficient information to proceed, or it may determine that some of the information may need to be released in any case. Under such circumstances, you have the option of withdrawing your application. In this case, all information will be returned to you and no information will be released. It is stressed that maintaining confidentiality is not expected to be a problem in the vast majority of cases. The Authority will be sensitive to the need to respect confidentiality where there is justification for doing so.

Information supplied by third parties

If you are relying on commercially sensitive information supplied by a third party, it is your responsibility to make sure that the information is provided directly to ERMA New Zealand. This information should be marked with the relevant application number (available from the Applications Officer) and clearly cross-referenced to the relevant sections of the application form.

Further information on confidentiality is in the ERMA New Zealand Information Sheet *Confidential information* (May, 2001).

6.3 The Register

Under section 20 of the HSNO Act, the Authority is required to keep a public register of all applications. The register records:

- the name and address of the applicant
- the unique identification of the substance—this name should give the chemical identity to the maximum extent possible without revealing any confidential information
- the purpose of the application
- the Authority's decision
- any controls attached to an approval
- any controls imposed by any other Act (eg Food Act 1981 - Maximum Residue Limits).

In addition to maintaining a list of substances from Part V approvals, the Register will also include those substances that had existing approvals under previous legislation, as they are transferred to the HSNO framework. This transfer of substances is provided for under the transitional provisions of the Act (Parts XI to XV). The transitional period is expected to run for a period of three to five years from 2 July 2001. The register will therefore not have a complete list of all the substances that can be legally used in New Zealand until the transitional period has expired.

The register is held at ERMA New Zealand and is also available on our website. Before making an application, you can check the register to find out whether your substance has an existing approval. If it is not evident from the publicly available information on the register whether an approval exists, you may ask us to search the complete database. This search will only be done if you can demonstrate a bona fide intent to import or manufacture the substance, and you provide the necessary details for the unequivocal identification of the substance, and pay a fee where appropriate. If the substance has already been approved, we'll give you the ERMA New Zealand register approval code. You can use this code to help import the substance into New Zealand.

6.4 Other regulatory approvals may be needed

Other New Zealand legislation may also govern the importation or manufacture of some hazardous substances. For example, if a substance is intended for agricultural use, it may be necessary to make a concurrent application for registration under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. For details on this process contact the ACVM Group, Ministry of Agriculture and Forestry. (Email: www.maf.govt.nz/ACVM. Their address is P O Box 2526, Wellington, phone 64 4 474 4100, fax 64 4 460 8771).

Section 2 of the application form lists examples of other approvals that may be required.

6.5 More information may be needed

Under section 58 of the Act, the Authority can decide that it needs more information in order to decide the application. This is in addition to any information that ERMA New Zealand staff may have asked for under section 52 during the initial verification of the application. You may have to pay for the cost of this information even if needs to come from an independent source.

Whenever additional information is being asked for, we will always advise you of this so that you can consider the time and cost implications. You then have the option of withdrawing your application in which case we will immediately stop all work on the application.

6.6 Submissions and hearings for notified applications

All applications made under section 28 to import or manufacture any hazardous substance for release must be publicly notified (section 53 (1)(a) of the HSNO Act). Similarly, all applications made under section 47 to import, release or use a hazardous substance in an emergency must be publicly notified (section 53 (1)(e) of the HSNO Act). In contrast, rapid assessment (section 28A) and containment (section 31) applications do not need to be publicly notified.

Anyone can make a submission on an application and ask for a public hearing. If requested, a hearing must be held and the Authority has no discretion in this matter.

More information on the submission process and on hearings is provided in our *Quick Guide to Making a Submission* (May 2001).

Although there is a statutory requirement to hold public hearings if requested, it is considered unlikely that people will ask for hearings for most routine hazardous substance applications. Applications where hearings are considered more likely are those which pose marked risks to the environment and to human health and safety, and those which create widespread opportunities for exposure, eg for pesticides widely used in the environment.

Part B

Application for ‘release’

Read this guide before filling in your application form (Form HS1) for approval to import or manufacture any hazardous substance for release under section 28 of the HSNO Act.

We recommend you read this User Guide before filling out your application form. Further guidance is available in the *Sample Applications* (available on the ERMA New Zealand website or from our office). If you have any queries, please contact an ERMA New Zealand Applications Officer who will be able to help you.

You can apply for more than one hazardous substance on a single application form if the substances are related, eg a concentrated compound (active ingredient) and its related formulations.

The level of information you need to provide depends on the scale and significance of the risks, costs and benefits of the substance (see Section 2.3 below).

Note that all commercially sensitive material should be attached as an appendix.

Section one of application form—Applicant details

You must provide full contact details for the ‘applicant’. The ‘applicant’ may be the name of a company, organisation, or the name of an individual. If the applicant is not an individual, you should include a contact name (section 1.3). This should be a person available by telephone during normal business hours in New Zealand, and who has sufficient knowledge to respond to queries. This person should also have the authority to make decisions on behalf of the applicant, or be able to go to the appropriate source for a decision.

Section two of application form—Application type and related approvals

Section 2.1 of form—Import or manufacture

When an approval is given for a section 28 application, it is the substance that is approved. It doesn’t matter whether the substance is imported or manufactured. So, even if you intend to only import the substance, we will still need to know whether manufacture is possible or likely in New Zealand. You are therefore asked to identify whether the information in the application form is for import only, manufacture only, or import and manufacture. We can then decide whether we need more information. If you think that manufacture in New Zealand is never likely, it would be useful to say this and explain why.

Section 2.2 of form—Information on manufacturing process

If you are applying to manufacture a hazardous substance, describe the manufacturing process. You should provide enough information to show whether the manufacturing process itself is likely to create adverse effects, eg whether there are any hazardous by-products of the process.

It would also be useful to say whether other processes exist, are likely to be used, and what the risk characteristics are.

Section 2.3 of form—Level of information to be provided

In this section, you should comment on the amount of information you have provided with your application. If you’re not providing detailed information, you must explain why.

The information you provide should be relevant and appropriate to the scale and significance of the risks, costs and benefits of the substance. To help you prepare your application, the Authority has adopted three information categories for an initial judgement on the extent of the information required to satisfactorily consider an application. Your explanation should explicitly refer to these categories.

These information categories (below) were established on the basis of broad predictions about the likely nature of certain types of application, and the level of information needed for the Authority to make a decision. Full details on these information categories are provided in our Protocol *Information Requirements for Applications to Import or Manufacture a Hazardous Substance for Release*.

Table 2.1 Information Categories

Information category	Nature of application
<p>Category A</p> <p>Limited information package only</p>	<ul style="list-style-type: none"> • A1: low hazard classification and low intrinsic risk but with hazard higher than allowed for under rapid assessment under section 28A or • A2: moderate to high hazard but very low exposure
<p>Category B</p> <p>Information requirements limited under certain specified circumstances</p>	<ul style="list-style-type: none"> • B1: risks are well understood and can be well managed by controls, including controls set in other legislation or risks are not as well understood but circumstances enable controls to be set to cover uncertainty or • B2: information is available relating to a relevant approval from another jurisdiction or under HSNO
<p>Category C</p> <p>Comprehensive information package required</p>	<ul style="list-style-type: none"> • All other applications—high potential risk

Category A applications

Applications in this category must meet at least one of the following, A1, or A2 criteria.

A1 Substances that have low hazard/intrinsic risk

Applications may fall into this category if the degree of hazard of the substance is relatively low (but is not eligible for rapid assessment under the ‘least degree of hazard’ criterion) and the substance is of low-risk due to limited mechanisms for exposure to adverse effects from the intended use.

The following hazard classifications may apply in this category:

- 1.4G pyrotechnic substances and articles that present no significant explosive hazard
- 3.1C flammable liquids of medium hazard
- 4.1.2E & F self-reactive substances of type E and F
- 4.2C spontaneously combustible substances, self-heating substances of low hazard
- 5.1.1C oxidising substances, liquids or solids, of low hazard
- 5.2E & F organic peroxides of type E and F
- 6.3A substances that are irritating to the skin
- 9.1C substances that are harmful in the aquatic environment
- 9.2C substances that are harmful in the soil environment
- 9.4C substances that are harmful to terrestrial invertebrates.

A2 Substances that are of moderate to high hazard but with limited exposure

Substances that are of moderate to high hazard may be considered in this category if it can be established that the actual or potential environmental and human exposures are very limited. This could either be because of the way the substance is contained throughout its life, or because of the very small quantities that can be released at any location or point in time. This could be established if it meets one of the criteria below:

- (1) The intended uses of the substance are limited. The various types of use categories (and subcategories) are described in Appendix 2 to this guide.

For example:

- the substance may be used only within a closed system or process
- its use may be non-dispersive in that it is limited to particular types of sites, or
- its use may result in inclusion into or onto a matrix (from which release into the environment would not take place or would be substantially curtailed).

This adopts the approach taken by the European Union in defining categories of use to estimate environmental and health exposures. It is part of their regulatory process for the risk assessment of chemical substances.

In cases like this, because of the limited information accepted with the application, the exposure controls that apply from the control regulations may essentially limit exposures. This may be done, for example, by setting a restrictive Tolerable Exposure Limit (TEL) for human exposures, so that use is restricted to a particular type of facility or process; and/or setting a restrictive Environmental Exposure Limit (EEL), so that the substance can only be used in ‘contained’ circumstances. However, this will always be done in consultation with you to make sure that the purpose of making an application based on limited information is not defeated.

- (2) Only restricted quantities are to be imported/manufactured

In regard to volume (and so the extent of exposure likely from any ‘release’), the following hazard versus volume relationships can be taken as a guide for situations of ‘low risk’:

Table 2.2 Level of Hazard

Level of hazard	Volume per year	
	Specific site-limited	Site unrestricted
<p>High</p> <p>(Explosives Class 1.1 or 1.2; Flammables category A for all subclasses plus 3.2B, 4.1.2B, 4.1.3B; Oxidisers classification 5.1.1A, 5.1.2A, 5.2A and 5.2B; Toxic classifications 6.1A, 6.1B, 6.1C, Biological Corrosive classification 8.2A; Ecotoxic classifications 9.1A, 9.2A, 9.3A, 9.4A)</p>	< 100 kg	Nil
<p>Medium</p> <p>(Explosives Class 1.3, 1.4, 1.5; Flammables classifications 3.1B, 3.2C, 4.1.2C and D, 4.1.3C, 4.2B, 4.3B; Oxidisers 5.1.1B, 5.2C and D; Toxic classifications 6.1D, 6.5A and B; Biological corrosives 8.2B and 8.3A; Ecotoxic classifications 9.1B, 9.2B, 9.3B, 9.4B)</p>	< 1000 kg	< 100 kg

- (3) The substance, because of the nature of its intended use, is normally distributed and sold in very small packages that contain a smaller amount of the substance than that capable of causing a significant adverse effect. This inherently limits the level of exposure possible from accidental misuse or handling. An example would be very small tubes of a substance, the contents of which, if released into the environment or accidentally ingested, would not be enough to have a significant adverse effect.

Toxic substances classified in the following subclasses cannot be considered under Category A2 because their chronic nature requires that a more in-depth risk assessment be carried out.

- 6.6 (mutagens)
- 6.7 (carcinogens)
- 6.8 (reproductive/developmental)
- 6.9 (target organ/system).

Information requirements for Categories A1 and A2

In the cases that meet the categories above, you need to provide information that confirms that the hazard and/or exposure levels are sufficiently limited to reduce risk to a low level. You don't need to give extensive information on benefits but you should confirm that a benefit exists, and briefly describe its nature. Sufficient information to allow for the 'unequivocal identification' of the substance and for its classification will still be required.

You should provide:

- enough information to confirm the level of hazard
- enough information to confirm that the level of exposure is not excessive, relative to the degree of hazard, ie that the overall risk (hazard x exposure) is low
- information on methods of disposal that avoid adverse environmental effects
- information on the quantity of substance to which exposure is likely to occur, and how the substance will be packaged and/or handled, including information on the quantity of substance to be imported or manufactured per year.

Most of this information relates to the intended use of the substance and potential exposure scenarios arising from that use. As a trade-off for accepting limited data, particularly in relation to hazards, it may be necessary for the Authority to effectively ensure that exposures to the substance are limited.

Unless it is evident from the nature of the substance and/or its use that such an analysis is appropriate, it will also not normally be necessary to provide a full analysis of risks to Maori interests, or to consult with Maori. There should also be no need for community consultation.

Category B applications

Applications in this category may only need limited information if specific requirements are met.

B1 Use of controls to manage risks

Applications in this subcategory are for substances where the degree of hazards and the exposures to these hazards are higher than in Category A, but the risks can nevertheless be readily managed by controls. The information requirements for this category would be limited, depending on the ability to impose these controls. Applications in this category could cover the following circumstances:

- Risks are readily identified and well understood and can be well managed by the statutory controls. (For example, polyurethane paint. This is a substance of significant hazard that is

well-known and understood by the community and there is confidence in the ability to manage risks.)

- Risks are not completely identified or well understood, but the nature of the intended use or other factors means that measures can be introduced to adequately manage the risks despite the increased degree of uncertainty. (A hypothetical example is a substance that is of uncertain toxicity, but will be used in a situation where containment is very secure and exposure can be effectively limited.)

The risk assessment for this type of application should be predominantly driven by the exposure scenarios identified from the information provided on the intended uses (including whole lifecycle, as appropriate) of the substance. The assessment should focus on the probable or reasonably foreseeable impacts of the substance on occupational and public health, and on the environment. That is, the risk assessment only needs to be done to the extent and level of detail appropriate to the degree of significance of the risks identified.

However, as described for Category A above, as a trade-off for accepting limited data, particularly in relation to hazards, it may be necessary for the Authority to effectively make sure that exposures to the substance are limited.

B2 Use of information from other jurisdictions

In the international context few hazardous substances are likely to come to the Authority for approval for the first time. It is more likely that an approval will first have been given from another jurisdiction, eg the USA (EPA), EU or Australia (NICNAS, NRA). The Authority will, over time, issue a list of overseas jurisdictions that are an acceptable source of assessment information for a HSNO approval. This list will identify:

- the name of the jurisdiction
- the types of hazardous substances covered
- constraints or limits of acceptability on the transferability of risk assessments (transferability may for example be relatively limited in relation to risks for native flora and fauna).

It is the **assessment information** from the other jurisdictions that is important, not the approval itself.

It may be convenient, and still acceptable to the Authority, for information to come from more than one other jurisdiction. The decision on where to source information is, in the first instance, one for you to make.

The information you provide would need to show what was considered, the extent of the assessment by that jurisdiction, the result of the assessment with respect to controls, and how the New Zealand use and exposure scenarios align with those considered by the overseas jurisdiction.

An important consideration in applying Category B2 is whether risks exist that are specific to the New Zealand environment. If there are such risks, New Zealand-specific assessments will have to be carried out. This will also be the case if there are Maori or community concerns to consider.

Information requirements for B1 and B2

In applications relating to this type of substance the following information should always be provided (this would include the information required for a Category A application):

- identification, composition and properties of the substance
- summary of the toxicity, ecotoxicity and physical hazards of the substance
- intended uses of the substance, including lifecycle aspects and disposal of the substance
- expected information provisions for the substance (label and Material Safety Data Sheet (MSDS))
- proposed controls for managing adverse effects including emergency procedures, based on available information on likely levels of exposure (occupational health, public health and environmental, as applicable).

The extent of the information needed on risks, costs and benefits will be relatively limited in most cases, but you will need to make a judgement on a case-by-case basis. The basis for making a judgement should be by reference to the relevant clauses in Part II of the Act (also set out in clauses 9 and 11 of the Methodology). In general, there should be no need for consultation with Maori or with the community, but this is less sure than for Category A applications.

Category C applications

Substances in this category are either considered to be of ‘significant risk’ because of their properties or intended use, or have risks that are not well understood or are New Zealand specific (for example, no approval exists from another jurisdiction which can be used as a reference).

Applications for this category of substance would be expected to have comprehensive information in all the required sections in the application form. The hazard data supplied should also include detailed results on toxicological and ecotoxicological studies, including information on the biodegradability and bioaccumulation of the substance.

We would also expect more extensive information on the whole lifecycle management of the substance, including disposal, in addition to material on all the intended or likely uses of the substance. This will allow a more detailed and extensive assessment of risks to be carried out. We require appropriate detail on the means and controls proposed for managing the assessed risks.

Section 2.4 of form—Other approvals required

Although not essential, it would be useful if you could indicate whether the hazardous substance(s) is subject to other New Zealand legislation requirements. This may include the Agricultural Compounds and Veterinary Medicines Act 1997, the Food Act 1981, the Medicines Act 1981, the Chemical Weapons (Prohibition) Act 1996, the Radiation Protection Act 1965, the Biosecurity Act 1993, the Resource Management Act 1991, or any other Act.

This allows us to do any sensible cross-checking with other agencies so that we can keep bureaucracy and cost to a minimum.

Section three of application form—Information on the substance

All commercially sensitive information must be attached as an appendix. The application form should be cross-referenced to the appendix but must be a stand-alone document that will be publicly available.

When providing information, you should also briefly say where the information was sourced, eg from in-house databases, research, technical literature and so on.

If you are applying for more than one hazardous substance, you need to complete this section separately for each hazardous substance.

For mixtures, if you are not privy to the formulation composition, you will need to arrange for the third party to supply the information directly to ERMA New Zealand. You will need this clearly indicated in this section.

Section 3.1 of form—The unequivocal identification of the substance(s)

This section must contain information to unequivocally identify the hazardous substance(s). If the substance(s) is not unequivocally identified, the application will not meet the statutory requirements and will not be processed. The information may be supplied in any suitable format but may best be expressed in tabular form.

Where relevant, information identifying the substance in data packages provided for equivalent USA, EU and Australian processes is considered acceptable. You should provide the data package to ERMA New Zealand but if you can't, we may be able to source it on your behalf. However, we will charge for this service.

Listed below is an indication of the type of information required. It is not a comprehensive list, but shows the type of information needed. Provide any chemical names, synonyms, and relevant trade names whether or not they are registered brands/trade names.

- chemical name (eg the Chemical Abstracts Preferred Index name (CA name) or International Union of Pure and Applied Chemistry (IUPAC))
- common name (where relevant)
- synonyms (where relevant)
- trade names (where relevant)
- CAS registry number (where it is available)
- molecular formula (where relevant)
- structural formula (where relevant)
- information on impurities/contaminants. In most cases, you don't need to specify components present at levels less than 0.1% unless there are hazardous property reasons for including them. For example, any dioxin contaminants present, even in trace amounts, should be included if they are known to exist in the substance. If the substance contains a

polymer, you should identify any unreacted monomers that may be present and the relevant percentages.

If there are confidentiality reasons for not providing this type of information in the main part of the form, then you should discuss with us alternatives for dealing with this. Our preference will be for you to provide information in a confidential appendix. In this event, we would agree on a unique identifier to go into the public register.

If you didn't want to provide any detailed information at all, eg just a coded identifier, this would seriously hinder the application process. We would need to discuss situations like this case by case.

Mixtures—provide information on each component

As well as providing the above information on the actual mixture, you must provide the following information on the composition of the mixture for **each** component, including non-hazardous components and impurities. This information may be best expressed in tabular form (see Table 3.1).

- the name of each component
- the CAS number of each component (where relevant)
- the function (eg active ingredient, emulsifier, surfactant, solvent, filler) of each component
- the percent contribution of each component, ie the complete composition of the product/mixture. The total percentage should add up to 100 %.

Table 3.1 Example of composition information required for a mixture eg pesticide formulation

Name of component	CAS Number	Function	Composition (%)
<i>Glyphosate</i>	<i>1071-83-6</i>	<i>Pesticide</i>	<i>50%</i>
<i>Aluminium silicate</i>	<i>12141-46-7</i>	<i>Dispersant</i>	<i>30%</i>
<i>Silicon dioxide</i>	<i>7631-86-9</i>	<i>Anti-caking agent</i>	<i>10%</i>
<i>Nonyl phenol</i>	<i>25154-52-3</i>	<i>Surfactant</i>	<i>10%</i>

Application for a product range

The interpretation of 'substance' in the HSNO Act includes 'defined mixture of elements' or 'defined mixture of compounds'. Section 2(2) of the Act elaborates that 'the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance'.

Correspondingly, you can make a single application covering a group of products with similar compositions and similar hazard classification. For example, a line of paint products, which varies only in colour due to relatively minor variation in pigments, could all be grouped together.

The maximum concentrations of all the components listed will generally be used when assessing the hazardous properties of the substance, unless the hazard posed by increased concentration is non-linear. Therefore, you should make sure that the hazard classifications

that will be applied (and hence the controls) will be suitable for all members of the group covered by the application. The percentages of the components can be given in ranges with the total percentage adding up to 100 % or more. The percentage ranges should generally not be so wide as to allow significant variation in the hazardous properties of the products covered by the application. This information may be best expressed in tabular form (see Table 3.2).

Table 3.2 Example of composition information required for a product range eg paint range

Name	CAS Number	Function	Composition (%)
<i>Polyester Resin</i> ¹	41641-17-7	<i>Resin</i>	25-45%
<i>Solvent</i>		<i>Solvent</i>	30-60%
<i>Methyl isobutyl ketone</i>	108-10-1		5-15%
<i>Toluene</i>	108-88-3		10-25%
<i>Xylene</i>	1330-20-7		15-25%
<i>Acetone</i>	67-64-1		0-10%
<i>Pigments</i>		<i>Colouring Agent</i>	10-15%
<i>Barium sulphate</i>	7727-43-7		0-15%
<i>Cupric sulphate</i>	7758-98-7		0-15%
<i>Orange II</i>	633-96-5		0-15%

1. 1,3-Benzenedicarboxylic acid, polymer with 2,2-dimethyl-1,3-propanediol and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol.

If the composition of a similar substance falls outside the range of the approved substance group, then it would be considered to be a new substance and would need a separate application. However, in this case the application for a similar substance would probably be dealt with through the rapid assessment process.

Section 3.2 of form—The chemical and physical properties of the substance(s)

In this section you should provide as much information as possible on the chemical and physical properties of the substance(s). This information may be relevant to the unequivocal identification of the substance(s) but is also relevant to the determination of specific hazard classification endpoints (eg water solubility is relevant to aquatic toxicity, boiling point is relevant to flammability, and viscosity and physical form are relevant to aspiration hazard (toxicity)).

Where possible, these properties should be those evident at 20°C and 101.3 kPa, but if this information is unavailable, you must specify the relevant temperature and pressure conditions of the data provided. Where appropriate, you should include the relevant units for each test. This information may best be expressed in tabular form.

For mixtures, we would ideally like information on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of **each** hazardous component of the mixture.

Examples of properties we would like information about include:

- appearance (colour, odour, physical state or form)
- pH
- density

- vapour pressure
- boiling/melting point
- solubility in water
- water-octanol partitioning coefficient.

Section 3.3 of form—Hazardous property information

Provide information in this section on the hazardous properties of the substance(s). You must consider **each** of the six hazardous properties listed below and, if possible, determine which of these properties trigger any threshold level.

For mixtures, we would ideally like information on the hazardous properties of the mixture itself. However, if this information is not available, you should provide information on the hazardous properties of **each** hazardous component of the mixture. You can then calculate the overall mixture hazard classifications (see our *User Guide to HSNO Thresholds and Classifications* for information on how to do this assessment).

The six hazardous properties are:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

You should also consider whether any one or more of the hazardous properties above would be generated if the substance came into contact with air or water (excluding situations where the temperature or pressure has been artificially increased or decreased).

In some cases, it may not be feasible for you to provide full information on the hazardous properties and we recognise that this will be the case for some imports. In these cases, we would suggest the following:

- Make as much comment as possible. If no information is available, then say so rather than not writing anything at all.
- If the material was sourced from overseas, for example, identify the name and location of the supplier and say what response you have had from the supplier in trying to obtain information.
- In some cases, it might be helpful to provide comparative information eg identify other substances which can be demonstrated to be more or less hazardous and about which more is known.

It is necessary to relate the hazardous properties of the substance to the thresholds and classification system developed under section 74 of the Act. Each hazardous property that triggers any given threshold level is assigned a HSNO hazard classification. A substance may have more than one hazard classification. You don't have to assign the relevant hazard classifications; we will complete this section if necessary. However, the more time we spend processing your application the higher the charges will be.

The *User Guide to HSNO Thresholds and Classifications* has been prepared to assist you with interpreting the threshold regulations (that determine whether a substance is hazardous), and the classification regulations (that assign levels of hazards to hazardous substances). A summary of this document has also been prepared, *Summary User Guide to HSNO Thresholds and Classifications*, and it includes a *Substance Evaluation Sheet* to lead you through a process of assessing whether a substance is hazardous or not by considering each of the six hazardous properties listed above. Both guides provide information on appropriate data sources and preferred test methods for evaluation of substances against threshold levels.

You should provide as much information as you can on each of the six hazardous properties. The need for data will be related to the hazards and risks identified for the substance. In the first instance, you don't need to generate physical/chemical test data if it doesn't exist. If no studies are available, you should note this and not leave it blank, eg 'we have not been able to find any information on the flammable properties of the substance'. However, if you don't give information about a hazardous property, the Authority may decide there is not enough information to approve the application. Or it could decide there is enough uncertainty to be more cautious and risk-averse by assigning an appropriate hazardous property classification and its associated controls to the substance.

If you say that a particular hazardous property does not exceed any threshold, you should give appropriate supporting information, clearly referenced. In many cases a simple statement will do eg 'the substance is not covered by the UN book so is not considered flammable'. However, in other cases, more comprehensive information will be necessary, eg 'the substance is not an acute oral toxic as the LD50 in all species tested was greater than 5000 mg/kg body weight'. When citing reference sources, you should, if possible, provide the primary reference for the data rather than a secondary reference, ie give the full citation of a paper rather than referencing the Hazardous Substance Database (HSDB).

For those hazardous properties that trigger any threshold level, you should provide all relevant information, ie give a description of, or reference to, the test methods used, as well as citing the data sources and any appropriate references. Remember to include all relevant units. It's unlikely that an MSDS (Material Safety Data Sheet) alone will satisfy the data requirements, unless it is comprehensive and fully referenced. We consider that an applicant can reasonably obtain data in the possession or control of a parent company or an affiliated subsidiary outside New Zealand. If for any reason you can't, say why. We have listed below the type of information we'd ideally like you to provide for each hazardous property that exceeds any threshold level.

Our *User Guide to HSNO Thresholds and Classifications* has information on preferred test methods. Test methods for substances that are biological corrosives or have toxic or ecotoxic properties are primarily derived from international test guidelines such as the OECD. The threshold and classification criteria for these biological hazards are primarily derived from the

Globally Harmonised System (GHS), which has harmonised hazard classifications for human health and environmental effects of chemical substances. Test methods for substances that have explosive, flammable or oxidising properties are primarily derived from the *United Nations Recommendations on the Transport of Dangerous Goods (UNRTDG) Manual of Tests and Criteria*. The threshold and classification criteria for these physical hazards come from the *UNRTDG Model Regulations*.

Explosive properties

- explosive properties in accordance with the test criteria of the *UNRTDG Manual of Tests and Criteria*.

Flammable properties

- initial boiling point and flash point for liquids (refer to the test methods used for this determination), lower and upper flammability limits in air for gases, or combustibility data for solids
- vapour pressure at standard conditions of any substance that is a liquid at those conditions.

Oxidising and self-reacting properties

- auto-ignition temperature
- potential to increase rate of burning time of combustible substances
- reactivity including oxidising properties, incompatibility with other substances, conditions under which the substance is unstable (eg self-accelerating decomposition temperature) and information on decomposition products and their hazards.

Corrosive properties

- pH and reactivity with metals
- biological (skin and eye) corrosiveness.

Toxic properties

- acute toxic effect (LD₅₀) including oral, dermal, and inhalation levels as appropriate
- skin and eye irritation properties
- sensitisation properties
- mutagenicity
- reproductive, developmental, carcinogenic effects or other target organ orientated systemic toxic properties.

For each toxic property, describe or reference the test methods used (data for the most sensitive species should be used). If no studies are available then this should be noted. If you aren't sure whether to generate test data, consult with ERMA New Zealand.

Ecotoxic properties

- LC₅₀, EC₅₀, LD₅₀ and chronic ecotoxic data as appropriate

- abiotic degradation rate (hydrolysis as a function of pH)
- bioaccumulation potential (biological concentration factor or n-octanol/water partition coefficient)
- soil absorption/desorption characteristics
- surface tension where the substance is liquid at standard conditions
- water solubility of the substance at a defined temperature.

A summary table should be included at either the beginning or the end of section 3.3, listing each of the six hazardous properties, whether each is triggered and, if desired, provide the hazard classification for those that triggered any threshold levels (see Table 3.3).

Table 3.3 Example of summary table of hazardous properties, thresholds and classification of Substance X

Hazardous Property	Threshold	Classification category and criteria
Explosive	Not triggered	
Flammable <ul style="list-style-type: none"> • Liquid 	Triggered	3.1C – closed cup flashpoint 50 °C
Oxidising	Not triggered	
Corrosive	Not triggered	
Toxic <ul style="list-style-type: none"> • Acute oral • Acute dermal • Acute inhalation • Skin irritation • Eye irritation • Sensitisation • Mutagenic • Carcinogenic • Reproductive/developmental • Target organ/systemic 	<ul style="list-style-type: none"> Triggered Triggered Triggered Triggered Triggered Not triggered Not triggered Not triggered Triggered Triggered 	<ul style="list-style-type: none"> 6.1E - LD₅₀ rat 2800 mg/kg 6.1E - LD₅₀ rat 3400 mg/kg 6.1D - LC₅₀ mice 3130 ppm 6.3A – Draize Grade 4 6.4A – Draize Grade 2 for corneal opacity reversed within 21 days of exposure 6.8B – Reproductive toxicant (foetal effects) 6.9A - Liver effects
Ecotoxic <ul style="list-style-type: none"> • Aquatic • Soil • Terrestrial vertebrate • Terrestrial invertebrate 	<ul style="list-style-type: none"> Triggered Not triggered Not triggered Not triggered 	<ul style="list-style-type: none"> 9.1D – LC₅₀ fish 80 mg/L (acute)

Section 3.4 of form—Identification of default controls

Section 77 of the HSNO Act provides for default controls to be attached to a substance in accordance with its hazard classification. These are summarised in our *User Guide to HSNO Control Regulations*. If you wish, you can provide details on the range of HSNO default controls that are triggered by the hazardous property classifications attached to the substance (identified in section 3.3 of the form). If you don't provide this information, we will complete

this section on your behalf but will charge for the extra time spent on your application. Regardless of whether you provide this information, you need to be aware of what the default controls are so that you can take them into account when assessing risks.

You should also provide details on any controls triggered by other legislation eg ACVM Act, Health and Safety in Employment Act, Land Transport Rules, Maritime Safety Rule, Resource Management Act, Ozone Layer Protection Act, Food Act, Health Act, and various district plans.

Section 3.5 of form—Information on the life of the substance, from import/manufacture to intended uses and disposal

We need information on all stages of the lifecycle of the substance for the development of exposure scenarios and the assessment of risks, costs and benefits. You should provide complete details about all the intended uses. This area must be as comprehensive as possible as ERMA New Zealand will determine whether there might be significant risk (adverse effects) based initially on the information you provide in this section.

The required information includes:

- transport and storage information
- the intended substance use(s)—consider the formation of potential by-products/metabolites/waste products during use
- other (reasonable) potential uses, recycling options
- who may use the substance (eg industrial or domestic users)
- how it is intended to be used (eg a two-pot paint requiring mixing by the user)
- any known adverse effects from unintentional use
- the disposal of the substance.

The information should be derived in a systematic and comprehensive manner and may be presented in a variety of ways. For example, you can present it as a flow diagram including all reactants and starting materials of the manufacturing process, following these through the whole lifecycle, including transport and storage, uses, re-use and disposal.

You should provide information covering the lifecycle from the stage at which the substance becomes hazardous through to when it is no longer hazardous (as defined by the HSNO Act and Regulations). For example, the responsibility for a reactive dye ends when it is a chromophore in a resin polymer. When a substance is included into another substance, include information on any persistent hazardous properties, eg lead chromate manufacturers need to provide information to the paint manufacturers about the on-going hazards of heavy metal toxicity, for disposal in particular. Similarly, manufacturers of lead-containing paint would need to provide information relating to managing the hazards from lead arising from the use, maintenance and ultimate disposal of the paint.

The owner of the substance is responsible for the safe and effective disposal of the substance. However, you must provide information on the correct disposal methods. This should be

appropriate to New Zealand, eg New Zealand does not have high temperature incineration facilities available for general industrial hazardous wastes.

Disposal information should also relate to products in which the substance is used where the hazardous properties of the substance persist in the product. Include options for re-use or recycling. Instructions on dealing with used containers as well as the substance itself should be included as appropriate. Disposal options should relate to the relevant performance requirements for disposal contained in the *Hazardous Substances (Disposal) Regulations 2001*.

Section four of application form—Identifying and assessing risks, costs and benefits

General Introduction

This part of the application form asks you to identify and assess the effects (risks, costs and benefits) of the substance. The Authority will evaluate these and other assessments, and other relevant information, in making a decision on whether to approve or decline the substance.

General aspects of carrying out this process are discussed immediately below. More detailed guidance relating to each section of the application form is given in the various subsections of Section 4. We recommend you read the whole of this section before starting to fill out the application form.

Level of information required

The level of detail required should sensibly match the nature and significance of the risks, costs and benefits that will have to be considered. It's not our intention to make unreasonable demands on applicants and we wish to be reasonable about the amount of information you need to supply. On the other hand, if there are serious gaps in the information supplied, we may either ask you to do more work and provide further data, or do the work ourselves. However, all the time spent on processing your application will contribute to the charges. In particular, there will be extra costs if the information we need is not readily available, eg if we have to request information from an overseas expert, or the community or Maori consultation is required.

In reading the guidance information below, you need to remember that we are catering for every situation we can envisage, including the most extreme. So the suggestions we make may not apply to your application. Section 2.3 (of Part B) of this guide outlines the circumstances when these assessments should be comprehensive and when we need less information, eg a substance that falls into information Category B requires less detail than a substance in Category C.

If you aren't sure how much information to provide, please come and talk to us before you go too far.

Sourcing your information

It is important to say where your information came from. You should also say what resources were not available or not used if you think it might be important. Information sources may include in-house or independent research, assessments carried out for or by overseas jurisdictions, prior experience or the experience of others, technical literature, Maori (for matters relating to section 6(d) of the Act) or the community, or other consultation. For community

effects, means for gaining this information include surveys, impact assessments and other social science tools.

If consultation was carried out, it would be useful to know why that course of action was taken, specifically who was consulted, and how the process was carried out.

Quality of information

It's helpful for us to have your view on the quality of the information provided and whether it is disputed. How reliable is the source? Did it come from well-conducted peer reviewed research? How certain is the information? These are questions we will have to answer in making decisions.

General approach to risk identification and assessment

The overall process is designed to determine the residual risks that remain after options for treating or managing the risks have been applied. As a result, the process is iterative; risks are first identified, risks thought to be significant are assessed for likelihood of occurrence and magnitude of effect; treatment or management options are considered; and the risks then re-assessed to determine residual risks. Therefore, you are unlikely to work through this process once only and may need to re-visit certain sections before you reach a conclusion. Some examples of how to present information are provided below and in the *Sample Applications*.

Before completing section 4, you should consult the Authority's Annotated Methodology and the Protocols that support the Methodology. The following ERMA New Zealand Technical Guides provide detailed guidance on this subject and also refer to other authoritative works.

- *Identifying Risks*
- *Preparing Information on Risks, Costs and Benefits*
- *Assessment of Effects of Hazardous Substances and New Organisms on Human Health.*

The Authority expects you to demonstrate that you have:

- identified all reasonably foreseeable risks, costs and benefits relating to matters specified in the Methodology
- adequately assessed those risks, costs and benefits (either quantitatively or qualitatively) which are, or might be, significant
- considered how significant risks can be managed.

Particular matters to be identified and assessed

The primary references to matters which must be considered—in thinking about risks, costs and benefits—are those in sections 5, 6 and 8 of the HSNO Act. These same references occur in clauses 9 and 11 of the Methodology. You may decide to address these matters in a number of ways. For example, following the headings as outlined below, or undertaking a process either in an integrated format or in a modular format, addressing each of the matters separately then providing an overall conclusion.

The material below groups the matters to be considered in a way which might help you to deal with them. However, you may also use the layout in the Methodology and the Act.

The physical environment

The first group of matters are to do with the physical environment and they include mainly:

- safeguarding the life-supporting capacity of air, water, soil and ecosystems
- the sustainability of all native and valued introduced flora and fauna
- the intrinsic value of ecosystems (those aspects of ecosystems that have value in their own right, eg biological and genetic diversity).

In considering these matters, it's probably enough to ask one main question: Does the substance have the capacity to adversely or positively affect the environment—including air, land and waterways—and the plants and animals that live in those environments? It needs to be remembered that positive as well as negative effects are important. Thus a herbicide that selectively kills a noxious weed may well be beneficial to the environment. All effects should be measured against the status quo.

Human health and welfare

The second group of matters are to do with effects on humans and broadly includes:

- human health (including public exposure and occupational exposure)
- the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations
- economic and related benefits (and costs) derived from the use of the hazardous substance.

The requirements to look at public health, and at economic and related benefits and costs, are relatively straightforward. However, remember that health includes mental health as well as physical health. The reference to 'benefits' in this section of the Act should also not be interpreted too literally. Thus if a proposal produces economic costs as opposed to benefits, those should be discussed as well. Economic costs could cover matters like increased drain on local infrastructure eg water supply or sewerage.

Equally, if a proposal produces benefits to human health this should be covered as well. For example, if a new pesticide was going to replace one in existing use, and the new pesticide posed lower risks to health, this should be discussed.

The reference to 'economic, social and cultural well being' (section 5(b) of the Act) should be read in conjunction with the definition of environment (section 2 of the Act), which refers to 'amenity values' and 'social, economic, aesthetic and cultural conditions'. An important point to remember here is that it is necessary to identify demonstrable effects. Amenity values include aspects such as the ability to access and enjoy the natural environment, and to participate in sporting, cultural, and social activities. There might be wider effects on people and communities that should be considered, and where relevant, this might suggest community consultation. If

you include information gathered as a result of a consultation programme or a community survey, then you should provide details of the consultation programme.

Many of these wider effects will probably be captured quite well in looking at the matters that are more explicitly set out in the Act. Thus impacts such as unemployment or additional employment can be considered quite well as a subset of economic effects. In other cases there will be a link to environmental or ecosystem effects. For example, a proposal for an insecticide that reduces wasp numbers could have a social effect (less disruption to tourists, more employment), an environmental effect (less damage to native birds), an economic effect (more tourist dollars are spent), and public health effects (less damage from wasp stings). Bear in mind that HSNO addresses the effects of the substance, which are not location-specific. In situations where there are location-specific effects, these may be more appropriately dealt with under the Resource Management Act and therefore only a brief mention of such effects is required here.

Maori concerns

The Act requires that account be taken of the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred place), valued flora and fauna and other taonga (sacred treasures, prized possessions, property, anything which is highly prized). Detailed guidance on this is provided in Section 4.3.

International obligations

Account must be taken of New Zealand's international obligations. Detailed guidance on this is provided in Section 4.4.

Important: The information below covers the most extensive requirements possible for any application (ie for category C applications). For many applications the requirements will be less than this and you should use common sense, along with the information in Section 2.3 (of Part B) of this guide, to interpret these guidelines for each situation.

Section 4.1 of form—Identifying risks, costs and benefits

To identify risks, costs and benefits you must consider all possible effects (positive and adverse) of the substance on the natural environment (ecosystems), people and communities. The identification of effects is critical, as adverse effects that are not identified cannot be assessed and controlled or managed. You must demonstrate that you have considered all reasonable effects arising during the entire lifecycle of the substance—from manufacture or importation, through to storage, transport, subsequent use of the substance (including post-use and re-use) and disposal.

Identifying risks

Risk is the combination of the magnitude of an adverse effect and the probability of its occurrence. Risks arise through interactions between people, their activities and the general social and physical environment. There are a number of general techniques available for helping to identify risks. These are discussed in detail in our Technical Guide *Identifying Risks*.

When identifying risks, try to think as widely as possible about all potential scenarios. You should take into account who or what is affected, along with details on when, where, why, and how the adverse effects are likely to occur. Matters to consider are:

- situations where any controls imposed on the substance may not be adhered to eg the safety precautions printed on a label are not followed correctly
- the source of each risk (what is the hazardous property of the substance and what incident/event has the potential to happen?) eg a spillage of a toxic chemical
- the possible reasons for the event occurring eg a road accident involving the truck carrying the substance. It is also useful to identify all stages of the substance lifecycle where the event may occur eg import, transport
- who or what is affected, and how? For each risk identified, you must consider any potential impacts/effects on:
 - human health, including both public exposure and occupational exposure
 - the environment (contamination of air, water, soil leading to effects on aquatic and terrestrial ecosystems)
 - social and community well-being eg potential increase in unemployment in specific area or industry
 - Maori and their culture eg adverse effect on the sustainability of a native species of bird
 - the economy eg adverse effect on particular export industry
 - New Zealand’s international obligations eg situations where the Rotterdam Treaty on Prior Informed Consent or the Basel Convention on the Control of Transboundary Movements of Hazardous Waste are relevant
- what are the exposure pathways (eg oral, dermal, inhalation, discharge to air, water, soil)?

The provision of meaningful and reliable information is important in reducing the level of uncertainty associated with the effects of the substance. The information can be presented in a variety of ways but should be in a systematic format eg by considering all the possible events that may happen during the lifecycle of the substance to cause an adverse effect as is shown in the summary table below (Table 4.1). Further examples of how to present this information are provided in the *Sample Applications*.

Once you have identified all the possible risks, you should rank them and then decide which ones need to be further controlled ie identify which is potentially **significant** based on your understanding of the default controls, and your experience and knowledge of the substance and how it will be used throughout its lifecycle (Table 4.2). You must consider the likelihood of each possible event occurring at each of the relevant lifecycle stages independently from any other ie in the example provided in Table 4.1, you might consider that there is a significant risk posed by release of the substance due to damaged packaging during transportation, but not during importation, storage or use.

Deciding whether a risk is significant or not should be based on experience and expert judgement. If there is any doubt whether a risk is significant, you should include it. If you determine that a risk is not significant, you must provide reasons to support your assumptions. If relevant, provide references to sources of data you used. A detailed risk assessment is only necessary for those risks that have been identified as significant. Thus, if there are **no** significant risks, there is no need to carry out an assessment of risks, costs and benefits in section 4.2 below.

Identifying costs and benefits

As mentioned above, if there are no significant risks identified, you don't need to do a detailed assessment of costs and benefits. Similarly, a detailed cost/benefit assessment is not required if you have identified significant risks but the residual risks resulting from the subsequent risk assessment process are considered to be negligible. In these cases, it is sufficient to indicate in a general way that benefits exist so that there is valid information to enable the Authority to make a decision on the application.

However, in all other cases, more detailed information is required on costs and benefits in order for the Authority to weigh up whether the benefits of the substance outweigh the costs and risks.

The identification of costs and benefits must include the nature of the costs and benefits associated with the proposed hazardous substance and whether these are monetary or non-monetary. When identifying costs and benefits, you should consider the same matters as those addressed in the risk identification section ie consider costs and benefits that will affect public health, the environment, the community and the New Zealand economy. You should also consider any benefits lost if the application was not approved (ie the opportunity cost to New Zealand).

Table 4.1 Summary of risk identification of Substance X.

Source of risk Event/incident	Haz property	Possible reasons for event (including lifecycle)	Effect/impact	Exposure pathway
Release/spillage of substance (either onto land, in or near water, or into the air via vapours or aerosols)	Toxic Ecotoxic	<ul style="list-style-type: none"> • Forklift accident (import, storage, transport, disposal) • Transport accident (import, transport) • Accident during use (use) • Natural hazard eg earthquake (any stage) • Sabotage (any stage) • Damaged packaging (import, storage, transport, use) • Failure to follow safety precautions (any stage) • Incorrect disposal (disposal) 	1. Adverse (acute) effect on human health (workers and public): nausea, headache.	Inhalation and dermal absorption
			2. Adverse effect on aquatic environment: fish die	Substance enters waterway
			3. Adverse effect on terrestrial environment: invertebrates die	Substance absorbed into ground surrounding spill

Table 4.2 Summary of identification of potentially significant risks of Substance X (assuming default controls in place)

Potentially significant risk	Lifecycle	Hazardous property	Adverse effect/impact
Transport accident causing spillage of substance (over land)	Transport	Toxic Ecotoxic	Human health
			Aquatic environment
			Terrestrial environment
Damage to packaging causing spillage of substance	Storage	Toxic Ecotoxic	Human health
			Aquatic environment
			Terrestrial environment
Spillage of substance during dispensing/use	Use	Toxic Ecotoxic	Human health
			Aquatic environment
			Terrestrial environment
Incorrect disposal of surplus substance	Disposal	Toxic Ecotoxic	Human health
			Aquatic environment
			Terrestrial environment

Section 4.2 of form—Assessing significant risks, costs and benefits

This section only needs to be filled in if significant risks were identified in section 4.1 above.

The HSNO Act looks at the assessment of effects (risks, costs and benefits) for two reasons:

- to enable the Authority to decide whether or not the adverse effects (the risks and costs) outweigh the positive effects (the benefits)
- as a means of managing the risks if the application is approved.

Assessing risk

Risk assessment is the process of:

- estimating the magnitude of effects and likelihood of occurrence
- examining pathways and conditions of exposure
- using this information to rank the risks and evaluate them against predetermined criteria.

An in-depth risk assessment is only required for those risks identified in section 4.1 as significant. In carrying out your assessment, you should consider:

- what the nature of the hazardous substance is and how serious the risks are ie what are the potential consequences from the hazard? eg burns, fatal poisoning
- what is the likelihood/probability of the adverse effect occurring? If quantitative data is not available, you may find it useful to use the terms outlined below:

Probability	Description
Very unlikely	Not impossible but only occurring in exceptional circumstances
Unlikely	Could occur but not expected to occur under normal conditions
Equally likely/unlikely	Equally likely or unlikely to occur
Likely	Will probably occur at some time
Very Likely	Is expected to occur

- What the magnitude of the effect is. In estimating the magnitude, you should consider:
 - Will the risk be localised geographically or will the effects be distributed more widely eg nationwide?
 - Will particular groups in the community be affected more than others eg will children be more at risk? Women? Specific ethnic groups? (demographic distribution of effects)
 - Will the risk persist over time ie will the effects be short-term, long-term, spread over more than one generation etc (temporal distribution of effects)?
 - To what extent are the potential adverse effects irreversible (eg death, permanent scarring) or reversible (nausea, skin rashes)?

- To what degree is exposure to the risk voluntary (do the affected parties have some measure of control/choice over being exposed) or involuntary (do the affected parties have little or no control/choice over being exposed)?
- To what extent are the risks known or understood by society? Also consider whether there is a lack of experience in managing the potential adverse effects.
- What are the uncertainty bounds of the information used in the assessment (how reliable is it)?
- What is the likelihood of indirect or secondary adverse effects occurring as a result of the risk?
- What are the options and proposals for managing the (significant) risks identified? (This is discussed in detail in section 4.5 below.)

There are a number of different ways to present this information. One example is shown in the summary Table 4.3 below. Further examples are provided in the *Sample Applications*.

For significant risks, assessments can be quite involved and are best done by experienced risk assessors. ERMA New Zealand has produced three Technical Guides (see section 4 above), which have detailed help on this subject. General guidance on areas to consider for specific types of hazardous substances follows:

- In general, for an industrial chemical, the assessment is likely to focus primarily on occupational health and safety and disposal. Public health and environmental effects are unlikely to require any in-depth assessment. If the chemical can also be used in a domestic or public setting then these effects will need more in-depth assessment.
- A domestic chemical application needs to consider the public health effects on users and others who may be at risk in (relatively) uncontrolled situations (children) as well as occupational health effects (manufacture) and other environmental effects resulting from use, especially how it may be disposed of.
- Risk assessment of agricultural chemicals would need to address the relevant environmental, occupational health and public health effects.

These risk assessments need to take account of potential releases and the impacts of the substance on environmental, occupational and health endpoints. For substances with wide dispersive use with the potential for significant impacts, it may be necessary to carry out a quantitative risk assessment. Various OECD, USEPA and European Union information sources have detailed guidance on how to do this.

Table 4.3. Summary of risk assessment of Substance X (includes determination of residual risk following review of controls).

Source of potentially significant risk	Adverse effect/impact	Likelihood	Distribution of effects (geographic)	Distribution of effects (demographic)	Distribution of effects (temporal)	Reversible/irreversible	Voluntary/involuntary	Magnitude ¹	Level of residual risk ¹ (following review of controls as detailed in Section 4.5)
Transport accident (over land)	Human health	Very unlikely	Localised	Not expected	Short term	Reversible	Involuntary	Minor	Insignificant
	Aquatic environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
	Terrestrial environment	Very unlikely	Localised		Short term	Reversible	Involuntary	Minor	Insignificant
Damage to packaging during substance storage	Human health	Unlikely	Localised	Workers	Short term	Reversible	Involuntary	Minimal	Low
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Low
	Terrestrial environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Low
Spillage of substance during dispensing and use	Human health	Unlikely	Localised	Not expected	Short term	Reversible	Voluntary	Minimal	Low
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Low
	Terrestrial environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Low
Incorrect disposal of surplus substance	Human health	Unlikely	Localised	Not expected	Short term	Reversible	Voluntary	Minimal	Low
	Aquatic environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Low
	Terrestrial environment	Unlikely	Localised		Short term	Reversible	Involuntary	Minimal	Low

1. Refer to the Technical Guide on *Preparing Information on Risks, Costs and Benefits* for information on qualitative measures of magnitude and risk

Assessing costs and benefits

A detailed assessment of costs and benefits is only needed if the residual risks are considered to be not negligible. The Authority will use this assessment of costs and benefits to weigh the risks and costs against the benefits of the application. For applications with significant risks, an experienced assessor should assess the costs and benefits. The assessment should consider:

- the nature of the costs and benefits (ie whether they are monetary and/or non monetary).
- whether the costs and benefits are direct or indirect. Direct costs and benefits are those that flow immediately from the proposal. Indirect costs and benefits are those that flow as a consequence of the direct impacts.
- whether the distribution of costs and benefits is short-term or long-term, eg there may be major up-front costs, with benefits not seen until a few years later.
- how the costs and benefits are distributed geographically eg will the effects be felt in a localised area, or will the whole country be affected?
- the individuals, organisation or communities that will receive the benefits.
- the individuals, organisation or communities that will bear the costs.
- the reliability of the information.

Section 4.3 of form—Assessing risks, costs and benefits significant to Maori

In this section, you must assess those risks, costs and benefits identified in Section 4.1 that may significantly effect the relationship of Maori and their culture and traditions with their taonga (eg ancestral lands, water, valued flora and fauna and other sacred treasures).

You should assess the likelihood (probability) of any adverse impact on Maori and estimate how severe that impact may be. The magnitude of risks may be influenced by whether the risk is limited to a geographical region or will affect Maori generally. We have written the following documents to help you provide information to the Authority on matters involving Maori:

- *User Guide to Working with Maori under the HSNO Act 1996*
- *Protocol 1 Series 2 Taking Account of Maori Perspectives.*

You should also take into account the principles of the Treaty of Waitangi. In assessing the significance of Treaty issues, you should consider whether your application will impact on the ability of Maori to control their natural resources (including indigenous flora and fauna, waterways, and land), language or culture.

If you aren't sure how to fill out this section, contact an ERMA New Zealand Applications Officer who can tell you the kind of information needed and whether or not it is likely to be necessary to consult with Maori. If consultation with Maori is undertaken, you should give details of that consultation in this section.

An assessment of the risks with specific regard to Maori should address the following:

- Is exposure to the risk involuntary (this will almost always be the case unless you have entered into a joint venture with Maori)?
- Are the risks known or understood (by Maori) and how much experience or understanding of possible measures for managing the potential adverse effects is there?
- What is the distribution of effects ie is the impact likely to be confined to a local hapu, to other iwi or will it affect Maori generally, which is most likely if substances are to be nationally distributed?
- How can the proposal be modified to lessen the impact on the relationship of Maori culture and traditions with taonga? Maori may sometimes suggest how to modify a proposal in order to lessen its net environmental and cultural impact.

You should also assess any benefits to Maori and their relationship with their taonga, where these are apparent. Consider how the benefits relate to this relationship. Benefits that are more directly focussed on other aspects should be assessed in the appropriate section eg benefits that improve the survival of native flora and fauna would be assessed in this section, whereas benefits that improve crop yield would be more appropriately assessed in section 4.2.

Section 4.4 of form—Assessing risks, costs and benefits significant to New Zealand’s international obligations

This is a specialist area that ERMA New Zealand will handle once you have provided the initial information. Where you are aware that New Zealand’s international obligations may be relevant to the application, indicate the nature of the obligation and the effect this may have on the application. Such obligations may include the Trans Tasman Mutual Recognition Arrangement, Montreal Protocol, Rotterdam Treaty on Prior Informed Consent or Basel Convention on the Control of Transboundary Movements of Hazardous Waste.

Section 4.5 of form—Proposed management of the substance

In this section, you should provide information on managing the effects identified and assessed in sections 4.1 - 4.4 of the application form. The starting point for this is the range of default controls (identified in section 3.4) assigned to the substance in accordance with its hazard classification. You should provide information on the appropriateness of the default controls and whether you consider they will not be sufficient to manage the risks, or are too restrictive. If you propose changes to the default controls, you should explain why.

You should also detail how the controls will be implemented and indicate other ways of managing risks. The information provided must be specific to the substance(s) and cover all areas of intended use. You should refer to Codes of Practice or standard operating procedures that will be followed.

In most cases, the default controls will be appropriate, but the Authority may vary these controls if the assessment of risks, costs and benefits shows that this is warranted. For example:

- where the assessment of risks indicates that the default controls will not be sufficient in managing those risks

- where the availability of the substance should be restricted
- where the uncertainty about the adverse effects cannot be identified accurately
- where the assessment of risks indicates that all the default controls are unnecessary to manage the risks
- where the assessment of risks, costs and benefits shows that there is a benefit to be obtained by varying the controls while not significantly increasing the risks.

Section 4.6 of form—Overall evaluation of risks, costs and benefits

This overall evaluation is the Authority’s main task. However, you may wish to comment on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision.

The Authority must make a judgement on whether the positive effects (benefits) of the substance outweigh any adverse effects (risks and costs). The Authority will take into account any controls that may be imposed on the substance and the likely effects of the substance being unavailable.

If the Authority deems that the positive effects outweigh any adverse effects, it may approve the application, conditional upon controls being attached to the approval. Alternatively, if the Authority deems that any adverse effects outweigh the positive effects, it will decline the application.

In general, the Authority will be more cautious and risk-averse if any of the following characteristics exist:

- the exposure to the risk is involuntary
- the risk is relatively persistent
- the risk could spread uncontrollably
- the potential adverse effects are irreversible
- the risk is not understood by society
- there are risks to human health
- there are risks to the survival of native species or their habitats.

Section five of application form—International considerations

Section 5.1 of form—Consideration by any other regulatory authority

We are interested in whether the substance (or any of its components) has been considered by any other regulatory authority in New Zealand or any other country. We’ll take into account any decisions made if the details of the decision are provided. If you are aware that an assessment has been made on the substance by any other jurisdiction, you should provide this information or a reference to it, eg state the registry or inventory numbers. Include specific information about where, what and by whom the decision was made. Just stating ‘approved by US EPA’ is not

enough. However, until regulations are enacted that prescribe countries and organisations for this section, provision of this information is not mandatory.

Section six of application form—Miscellaneous

Section 6.1 of form—Glossary

If you use terms from the interpretation in section 2 of the HSNO Act, you don't need to define those terms. However, we expect you to give definitions of all other technical terms used in your application.

Section 6.2 of form—Other relevant information

You should provide any other information that you consider relevant to the application but which does not fit clearly into any of the previous sections.

Section seven of application form—Summary of public information

Section 20 (1) of the HSNO Act requires the Authority to keep a public register of all applications. Summary information provided in section 7 of the application form may be used for the register.

We also use this summary information to inform those people and agencies (eg Ministry for the Environment, Department of Conservation, Department of Labour, Ministry of Health, etc), who may be notified of the application. It's also sent to potential submitters who are interested in the application. Summary information will also be used to prepare the public notice of the application.

For these reasons, you should make sure that your summary information does not contain any commercially sensitive material.

Section 7.1 of form—Name of the substance for the public register

Section 20 (2) (b) of the Act requires the public register of applications to contain a sufficient description to uniquely identify the substance. You should provide sufficient details of the name of the substance to meet this requirement (maximum of 80 characters).

If the identity of the new substance is commercially sensitive or if the application is for several similar (composition and property) substances, you may provide a generic chemical name or trade name, as long as this uniquely identifies the substance. The name should reveal the chemical identity of the substance to the maximum extent possible without giving away commercially sensitive information.

ERMA New Zealand will check the adequacy of any generic chemical name and if the name does not uniquely identify the substance, we will contact you to develop another name.

Section 7.2 of form—Purpose of the application for the public register

Section 20 (2) (c) of the Act requires the public register to specify the purpose of the application. This should explain (in a maximum of 255 characters) the intended use of the substance and why an application is needed, based on the hazardous properties.

Section 7.3 of form—Use categories of the substance

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identifies various functional uses of substances. This information is relevant to the assessment of exposure scenarios and for determining risk. It's also useful for building up a profile of the substance. There are three types of use categories, some of which include a number of subcategories (see Appendix 2 of this guide). We ask that you state which categories (and subcategories) are relevant to all the intended uses of the substance(s).

Section 7.4 of form—Executive summary

In this section, you need to provide a summary of the significant parts of your application. It is stressed that this information will be available for public scrutiny and as such, should not contain any commercially sensitive or confidential material. You should include a summary of:

- the identification of the substance, its hazardous properties and intended uses
- an assessment of the risks, costs and benefits
- the methods implemented to manage the risks, particularly in relation to emergency management and disposal.

Appendix one of application form—Confidential information

Any information that is commercially sensitive should be attached as an appendix. The main application should be cross-referenced and should be able to be read as a stand-alone document.

Part C

Application for ‘rapid assessment’—low hazard criterion

Read this guide before filling in your application form (Form HS2/1) for approval to import or manufacture any hazardous substance for release under section 28A of the HSNO Act under the criterion of low hazard.

We recommend you read this User Guide before filling out your application form. Further guidance is available in the *Sample Applications* (available on the ERMA New Zealand website or from our office). If you have any queries, please contact an ERMA New Zealand Applications Officer who will be able to help you.

You can apply for more than one hazardous substance on a single application form if the substances are related, eg a concentrated compound (active ingredient) and its related formulations.

You can make a rapid assessment application if your substance meets one of the criteria for rapid assessment ie it is either similar to an already approved substance or it is of low hazard. This part of the guide applies only to rapid assessment applications that meet the ‘low hazard’ criterion. Part D of the guide applies to the ‘similar substance’ criterion.

Level of information to be provided:

For this type of application, you don’t need to provide as much information as for a full assessment (section 28). This will streamline the application process. However, you still need to give full information on the identification of the substance, its properties and methods of disposal. We also need information on the uses of the substance and you still need to consider the provisions set out in Part II of the Act, especially sections 5 and 6. However, you only need to address those matters that are relevant and significant to your application, and you do **not** need to provide information relating to the benefits of the substance.

Note that all commercially sensitive material should be attached as an appendix.

Warning: Rapid assessments are meant to be quick, clear cut and low cost. This relies on the provision of good quality information that clearly confirms that rapid assessment applies. If it is not clear that rapid assessment is applicable, the application will most likely be declined. If this is the case, you can if you wish, ask for it to be re-considered as a full assessment under section 28. It’s therefore very important that you establish with ERMA New Zealand whether or not your application is likely to meet the rapid assessment criteria.

Section one of application form—Applicant details

You must provide full contact details for the ‘applicant’. The ‘applicant’ may be the name of a company, organisation, or the name of an individual. If the applicant is not an individual, you should include a contact name (section 1.3). This should be a person available by telephone during normal business hours in New Zealand, and who has sufficient knowledge to respond to

queries. This person should also have the authority to make decisions on behalf of the applicant, or be able to go to the appropriate source for a decision.

Section two of application form—Application type and related approvals

Section 2.1 of form—Low hazard criterion

Under section 28A(2), the Authority may make a rapid assessment of applications to import or manufacture a hazardous substance for release if **one** of the following criteria applies:

- (a) the substance has a similar composition and similar hazardous properties to one that has been approved
- (b) the substance has one or more hazardous properties and each of those hazardous properties has the least degree of hazard for that property.

This part of the guide applies only to rapid assessments that meet the ‘low hazard’ criterion (b). You must provide information to verify that your application meets this criterion. In addition to the guidance provided below, you can find further information in our Protocol *Information Requirements for Applications to Import or Manufacture a Hazardous Substance for Release*.

If you think your information may not be sufficient, please talk to us before lodging your application. We may advise you to go immediately to a full assessment under section 28. If you lodge your application but it falls short of satisfying the low hazard criterion, you can still re-apply for a full assessment.

If there is not enough information on hazardous properties, particularly those for which any level of hazard above the thresholds is not acceptable, the application for rapid assessment may be declined on those grounds alone. It’s therefore essential that you provide good information.

The low hazard criterion for rapid assessment covers substances that have one or more hazardous properties, each of which has the least degree of hazard for that property. In the first instance, this is determined by direct evaluation against the criteria for the lowest classification levels contained in the *Hazardous Substances (Classification) Regulations 2001*. However, the Authority has determined that only some of the classification classes and subclasses are appropriate for consideration by the rapid assessment route. This is because not all the least ‘degrees of hazard’ classifications represent equivalent degrees of severity of the hazardous property concerned. For example, classification 6.7B, suspected human carcinogen, represents a higher level of concern than does 6.3B, mild skin irritant. Also, some classification subclasses have only one degree of hazard—thus the least degree of hazard is also the greatest degree of hazard.

This discretion by the Authority is allowed by the wording of the amendment to the Act:

Section 28A(2) ‘The Authority **may** approve a hazardous substance under this section if the Authority is satisfied that –

(b) the substance has one or more hazardous properties and each hazardous property has the least degree of hazard for that property.’

The least degrees of hazard considered appropriate for this rapid assessment criterion are:

Explosive articles	classification 1.4S
Flammable gases	classification 2.1.1B
Flammable liquid	classification 3.1D
Readily combustible solid	classification 4.1.1B
Self-reactive substances	classification 4.1.2G
Dangerous-when-wet substances	classification 4.3C
Organic peroxides	classification 5.2G
Acute toxicity	classification 6.1E
Skin irritant	classification 6.3B
Eye irritant	classification 6.4A*
Metallic corrosives	classification 8.1A
Biological skin corrosive	classification 8.2C
Ecotoxic	classifications 9.1D, 9.2D, 9.3C

- * There is only one degree of hazard for the toxic subclass of eye irritancy. However, this essentially represents the lowest degree of hazard for the property of damaging to the eye, as the classification criteria for this level relates to reversible damage. More severe, irreversible damage is covered by classification 8.3A, eye corrosive.

You need to demonstrate that you have considered all hazardous properties. It is not enough to show that only classifications from the above list have been triggered in order for this criterion to apply. The Authority will consider all the ‘least degree of hazard properties’ triggered when it makes its decision on the application.

Section 2.2 of form—Import or manufacture

You must identify whether the information in your application form covers import only, manufacture only, or import and manufacture. This is so we can decide what extra information might be required, given that any resulting approval would cover import and manufacture, and would, in principle, cover all manufacturing processes. If you think the substance is not ever likely to be manufactured in New Zealand, it would be useful to say this and explain why.

Section 2.3 of form—Information on manufacturing process

If you are applying to manufacture a hazardous substance, describe the manufacturing process. You should provide enough information to show whether the manufacturing process itself is likely to create adverse effects, eg whether there are any hazardous by-products of the process.

It would also be useful to say whether other processes exist, are likely to be used, and what the risk characteristics are.

Section 2.4 of form—Other approvals required

Although not essential, it would be useful if you could indicate whether the hazardous substance(s) is subject to other New Zealand legislation requirements. This may include the Agricultural Compounds and Veterinary Medicines Act 1997, the Food Act 1981, the

Medicines Act 1981, the Chemical Weapons (Prohibition) Act 1996, the Radiation Protection Act 1965, the Biosecurity Act 1993, the Resource Management Act 1991, or any other Act.

This allows us to do any sensible cross-checking with other agencies so that we can keep bureaucracy and cost to a minimum.

Section three of application form—Information on the substance

All commercially sensitive information must be attached as an appendix. The application form should be cross-referenced to the appendix but must be a stand-alone document that will be publicly available.

If you are applying for more than one hazardous substance, you need to complete this section separately for each hazardous substance.

For mixtures, if you are not privy to the formulation composition, you will need to arrange for the third party to supply the information directly to ERMA New Zealand. You will need this clearly indicated in this section.

Section 3.1 of form—The unequivocal identification of the substance(s)

This section must contain information to unequivocally identify the hazardous substance(s). If the substance(s) is not unequivocally identified, the application will not meet the statutory requirements and will not be processed. The information may be supplied in any suitable format but may best be expressed in tabular form.

Where relevant, information identifying the substance in data packages provided for equivalent USA, EU and Australian processes is considered acceptable. You should provide the data package to ERMA New Zealand but if you can't, we may be able to source it on your behalf. However, we will charge for this service.

Listed below is an indication of the type of information required. It is not a comprehensive list, but shows the type of information needed. Provide any chemical names, synonyms, and relevant trade names whether or not they are registered brands/trade names.

- chemical name (eg the Chemical Abstracts Preferred Index name (CA name) or International Union of Pure and Applied Chemistry (IUPAC))
- common name (where relevant)
- synonyms (where relevant)
- trade names (where relevant)
- CAS registry number (where it is available)
- molecular formula (where relevant)
- structural formula (where relevant)
- information on impurities/contaminants. In most cases, you don't need to specify components present at levels less than 0.1% unless there are hazardous property reasons

for including them. For example, any dioxin contaminants present, even in trace amounts, should be included if they are known to exist in the substance. If the substance contains a polymer, you should identify any unreacted monomers that may be present and the relevant percentages.

If there are confidentiality reasons for not providing this type of information in the main part of the form, then you should discuss with us alternatives for dealing with this. Our preference will be for you to provide information in a confidential appendix. In this event, we would agree on a unique identifier to go into the public register.

If you didn't want to provide any detailed information at all, eg just a coded identifier, this would seriously hinder the application process. We would need to discuss situations like this case by case.

Mixtures—provide information on each component

As well as providing the above information on the actual mixture, you must provide the following information on the composition of the mixture for **each** component, including non-hazardous components and impurities. This information may be best expressed in tabular form (see Table 3.1).

- the name of each component
- the CAS number of each component (where relevant)
- the function (eg active ingredient, emulsifier, surfactant, solvent, filler) of each component
- the percent contribution of each component, ie the complete composition of the product/mixture. The total percentage should add up to 100 %.

Table 3.1 Example of composition information required for a mixture eg shampoo

Name of component	CAS Number	Function	Composition (%)
<i>Water</i>	<i>7732-18-5</i>	<i>Solvent</i>	<i>91.5%</i>
<i>Sodium lauryl sulphate</i>	<i>151-21-3</i>	<i>Surfactant</i>	<i>2%</i>
<i>Cocamidopropyl betaine</i>	<i>61789-40-0</i>	<i>Surfactant</i>	<i>4.0%</i>
<i>Cetearyl alcohol</i>	<i>67762-27-0</i>	<i>Surfactant</i>	<i>2.0%</i>
<i>Cocamide DEA</i>	<i>61791-31-9</i>	<i>Surfactant</i>	<i>0.35%</i>
<i>Sodium Benzoate</i>	<i>532-32-1</i>	<i>Preservative</i>	<i>0.15%</i>
<i>Pigment Green 7 (CI 74260)</i>	<i>1328-53-6</i>	<i>Colour Agent</i>	<i>0.001%</i>

Application for a product range

The interpretation of ‘substance’ in the HSNO Act includes ‘defined mixture of elements’ or ‘defined mixture of compounds’. Section 2(2) of the Act elaborates that ‘the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance’.

Correspondingly, you can make a single application covering a group of products with similar compositions and similar hazard classification. For example, a line of paint products, which varies only in colour due to relatively minor variation in pigments, could all be grouped together.

The maximum concentrations of all the components listed will generally be used when assessing the hazardous properties of the substance, unless the hazard posed by increased concentration is non-linear. Therefore, you should make sure that the hazard classifications that will be applied (and hence the controls) will be suitable for all members of the group covered by the application. The percentages of the components can be given in ranges with the total percentage adding up to 100 % or more. The percentage ranges should generally not be so wide as to allow significant variation in the hazardous properties of the products covered by the application. This information may be best expressed in tabular form (see Table 3.2).

**Table 3.2 Example of composition information required for a product range
eg acrylic paint range**

Name	CAS Number	Function	Composition (%)
<i>Acrylic Resin</i> ¹	9011-14-7	<i>Resin</i>	25-45%
<i>Water</i>	7732-18-5	<i>Solvent</i>	40-50%
<i>Diethylene glycol</i>	111-46-6	<i>Solvent</i>	5-10%
<i>Hydoxyethyl cellulose</i>	9004-62-0	<i>Flow additive</i>	5-10%
<i>Diatomaceous Earth</i>	68855-54-9	<i>Filler</i>	5-10%
<i>Pigments</i>		<i>Colouring Agent</i>	10-30%
<i>Titanium Dioxide</i>	13463-67-7		0-30%
<i>Iron Oxide</i>	1309-37-1		0-10%
<i>Zinc Oxide</i>	1314-13-2		0-10%

1. Polymethyl methacrylate

If the composition of a similar substance falls outside the range of the approved substance group, then it would be considered a new substance and would need a separate application.

Section 3.2 of form—The chemical and physical properties of the substance(s)

In this section you should provide as much information as possible on the chemical and physical properties of the substance(s). This information may be relevant to the unequivocal identification of the substance(s) but is also relevant to the determination of specific hazard classification endpoints (eg water solubility is relevant to aquatic toxicity, boiling point is relevant to flammability, and viscosity and physical form are relevant to aspiration hazard (toxicity)).

Where possible, these properties should be those evident at 20°C and 101.3 kPa, but if this information is unavailable, you must specify the relevant temperature and pressure conditions

of the data provided. Where appropriate, you should include the relevant units for each test. This information may best be expressed in tabular form.

For mixtures, we would ideally like information on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of **each** hazardous component of the mixture.

Examples of properties we would like information about include:

- appearance (colour, odour, physical state or form)
- pH
- density
- vapour pressure
- boiling/melting point
- solubility in water
- water-octanol partitioning coefficient.

Section 3.3 of form—Hazardous property information

Provide information in this section on the hazardous properties of the substance(s). You must consider **each** of the six hazardous properties listed below and, if possible, determine which of these properties trigger any threshold level.

For mixtures, we would ideally like information on the hazardous properties of the mixture itself. However, if this information is not available, you should provide information on the hazardous properties of **each** hazardous component of the mixture. You can then calculate the overall mixture hazard classifications (see our *User Guide to HSNO Thresholds and Classifications* for information on how to do this assessment).

The six hazardous properties are:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

You should also consider whether any one or more of the hazardous properties above would be generated if the substance came into contact with air or water (excluding situations where the temperature or pressure has been artificially increased or decreased).

In some cases, it may not be feasible for you to provide full information on the hazardous properties and we recognise that this will be the case for some imports. In these cases, we would suggest the following:

- Make as much comment as possible. If no information is available, then say so rather than not writing anything at all.
- If the material was sourced from overseas, for example, identify the name and location of the supplier and say what response you have had from the supplier in trying to obtain information.
- In some cases, it might be helpful to provide comparative information eg identify other substances which can be demonstrated to be more or less hazardous and about which more is known.

It is necessary to relate the hazardous properties of the substance to the thresholds and classification system developed under section 74 of the Act. Each hazardous property that triggers any given threshold level is assigned a HSNO hazard classification. A substance may have more than one hazard classification. You don't have to assign the relevant hazard classifications; we will complete this section if necessary. However, the more time we spend processing your application the higher the charges will be.

The *User Guide to HSNO Thresholds and Classifications* has been prepared to assist you with interpreting the threshold regulations (that determine whether a substance is hazardous), and the classification regulations (that assign levels of hazards to hazardous substances). A summary of this document has also been prepared, *Summary User Guide to HSNO Thresholds and Classifications*, and it includes a *Substance Evaluation Sheet* to lead you through a process of assessing whether a substance is hazardous or not by considering each of the six hazardous properties listed above. Both guides provide information on appropriate data sources and preferred test methods for evaluation of substances against threshold levels.

You should provide as much information as you can on each of the six hazardous properties. The need for data will be related to the hazards and risks identified for the substance. In the first instance, you don't need to generate physical/chemical test data if it doesn't exist. If no studies are available you should note this, and not leave it blank, eg 'we have not been able to find any information on the flammable properties of the substance'. However, if you don't give information about a hazardous property, the Authority may decide there is not enough information to approve the application by rapid assessment. Any significant uncertainty is likely to lead to the application being declined.

If you say that a particular hazardous property does not exceed any threshold, you should give appropriate supporting information, clearly referenced. In many cases a simple statement will do eg 'the substance is not covered by the UN book so is not considered flammable'. However, in other cases, more comprehensive information will be necessary, eg 'the substance is not an acute oral toxic as the LD50 in all species tested was greater than 5000 mg/kg body weight'. When citing reference sources, you should, if possible, provide the primary reference for the data rather than a secondary reference, ie give the full citation of a paper rather than referencing the Hazardous Substance Database (HSDB).

For those hazardous properties that trigger any threshold level, you should provide all relevant information, ie give a description of, or reference to, the test methods used, as well as citing the data sources and any appropriate references. Remember to include all relevant units. It's unlikely that an MSDS (Material Safety Data Sheet) alone will satisfy the data requirements, unless it is comprehensive and fully referenced. We consider that an applicant can reasonably obtain data in the possession or control of a parent company or an affiliated subsidiary outside New Zealand. If for any reason you can't, say why. We have listed below the type of information we'd ideally like you to provide for each hazardous property that exceeds any threshold level.

Our *User Guide to HSNO Thresholds and Classifications* has information on preferred test methods. Test methods for substances that are biological corrosives or have toxic or ecotoxic properties are primarily derived from international test guidelines such as the OECD. The threshold and classification criteria for these biological hazards are primarily derived from the Globally Harmonised System (GHS), which has harmonised hazard classifications for human health and environmental effects of chemical substances. Test methods for substances that have explosive, flammable or oxidising properties are primarily derived from the *United Nations Recommendations on the Transport of Dangerous Goods (UNRTDG) Manual of Tests and Criteria*. The threshold and classification criteria for these physical hazards come from the *UNRTDG Model Regulations*.

Explosive properties

- explosive properties in accordance with the test criteria of the *UNRTDG Manual of Tests and Criteria*.

Flammable properties

- initial boiling point and flash point for liquids (refer to the test methods used for this determination), lower and upper flammability limits in air for gases, or combustibility data for solids
- vapour pressure at standard conditions of any substance that is a liquid at those conditions.

Oxidising and self-reacting properties

- auto-ignition temperature
- potential to increase rate of burning time of combustible substances
- reactivity including oxidising properties, incompatibility with other substances, conditions under which the substance is unstable (eg self-accelerating decomposition temperature) and information on decomposition products and their hazards.

Corrosive properties

- pH and reactivity with metals
- biological (skin and eye) corrosiveness.

Toxic properties

- acute toxic effect (LD₅₀) including oral, dermal, and inhalation levels as appropriate

- skin and eye irritation properties
- sensitisation properties
- mutagenicity
- reproductive, developmental, carcinogenic effects or other target organ orientated systemic toxic properties.

For each toxic property, describe or reference the test methods used (data for the most sensitive species should be used). If no studies are available then this should be noted. If you aren't sure whether to generate test data, consult with ERMA New Zealand.

Ecotoxic properties

- LC₅₀, EC₅₀, LD₅₀ and chronic ecotoxic data as appropriate
- abiotic degradation rate (hydrolysis as a function of pH)
- bioaccumulation potential (biological concentration factor or n-octanol/water partition coefficient)
- soil absorption/desorption characteristics
- surface tension where the substance is liquid at standard conditions
- water solubility of the substance at a defined temperature.

A summary table should be included at either the beginning or the end of section 3.3, listing each of the six hazardous properties, whether each is triggered and, if desired, provide the hazard classification for those that triggered any threshold levels (see Table 3.3).

Table 3.3 Example of summary table of hazardous properties, thresholds and classification of Substance X

Hazardous property	Threshold	Classification category and criteria
Explosive	Not triggered	
Flammable	Not triggered	
Oxidising	Not triggered	
Corrosive	Not triggered	
Toxic <ul style="list-style-type: none"> • Acute oral • Acute dermal • Acute inhalation • Skin irritation • Eye irritation • Sensitisation • Mutagenic • Carcinogenic • Reproductive/developmental • Target organ/systemic 	Triggered Triggered Triggered Triggered Triggered Not triggered Not triggered Not triggered Not triggered Not triggered	6.1E - LD ₅₀ rat 2800 mg/kg 6.1E - LD ₅₀ rat 3400 mg/kg 6.1E - LC ₅₀ mice 6500 ppm 6.3B – Draize Grade 2 6.4A – Draize Grade 2 for corneal opacity reversed within 21 days of exposure
Ecotoxic <ul style="list-style-type: none"> • Aquatic • Soil • Terrestrial vertebrate • Terrestrial invertebrate 	Triggered Not triggered Not triggered Not triggered	9.1D – LC ₅₀ fish 80 mg/L (acute)

Section 3.4 of form—Identification of default controls

Section 77 of the HSNO Act provides for default controls to be attached to a substance in accordance with its hazard classification. These are summarised in our *User Guide to HSNO Control Regulations*. If you wish, you can provide details the range of HSNO default controls that are triggered by the hazardous property classifications attached to the substance (identified in section 3.3 of the form). If you don't provide this information, we will complete this section on your behalf but will charge for the extra time spent on your application.

You should also provide details on any controls triggered by other legislation eg ACVM Act, Health and Safety in Employment Act, Land Transport Rules, Maritime Safety Rule, Resource Management Act, Ozone Layer Protection Act, Food Act, Health Act, and various district plans.

Section 3.5 of form—Information on the life of the substance, from import/manufacture to intended uses and disposal

We need information on all stages of the lifecycle of the substance for the development of exposure scenarios that may lead to significant risk despite the low hazard of the substance. You should provide complete details about all the intended uses. This area must be as

comprehensive as possible as ERMA New Zealand will determine whether there might be significant risk (adverse effects) based initially on the information you provide in this section.

The required information includes:

- transport and storage information
- the intended substance use(s)—consider the formation of potential by-products/metabolites/waste products during use
- other (reasonable) potential uses, recycling options
- who may use the substance (eg industrial or domestic users)
- how it is intended to be used (eg a two-pot paint requiring mixing by the user)
- any known adverse effects from unintentional use
- the disposal of the substance.

The information should be derived in a systematic and comprehensive manner and may be presented in a variety of ways. For example, you can present it as a flow diagram including all reactants and starting materials of the manufacturing process, following these through the whole lifecycle including transport and storage, uses, re-use and disposal.

You should provide information covering the lifecycle from the stage at which the substance becomes hazardous through to when it is no longer hazardous (as defined by the HSNO Act and Regulations). The owner of the substance is responsible for the safe and effective disposal of the substance. However, you must provide information on the correct disposal methods for the substance. These should be appropriate to New Zealand, eg New Zealand does not have high temperature incineration facilities available for general industrial hazardous wastes.

Disposal information should also relate to products in which the substance is used where the hazardous properties of the substance persist in the product. Include options for re-use or recycling. Instructions on dealing with used containers as well as the substance itself should be included as appropriate. Disposal options should relate to the relevant performance requirements for disposal contained in the *Hazardous Substances (Disposal) Regulations 2001*.

Section four of application form—Information on significant risks (adverse effects)

It is expected that substances that meet the low hazard criterion will not normally need an assessment of risks (adverse effects) as part of the application. Low hazard will normally be accepted as prima facie evidence of risks that are sufficiently low to be adequately managed by the default controls. However, you should consider whether the circumstances of use or any other factors might lead to significant risk, and provide information accordingly. In doing this, you should refer to the definition of environment and the all the matters set out in Part II of the Act, especially sections 5, 6 and 8.

We suggest you consider whether any significant risks exist in each of the areas set out below. You can present the information in a variety of ways but it must be systematic. A simple table would be ideal. Information on the benefits of the substance is **not** required for rapid assessment applications.

- 1) The physical environment:
 - safeguarding the life-supporting capacity of air, water, soil and ecosystems
 - the sustainability of all native and valued introduced flora and fauna
 - the intrinsic value of ecosystems (those aspects of ecosystems that have value in their own right).
- 2) Effects on humans:
 - human health (including public exposure and occupational exposure)
 - the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.
- 3) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred place), valued flora and fauna and other taonga (sacred treasures, prized possessions, property, anything which is highly prized).
- 4) New Zealand's international obligations eg situations where the Rotterdam Treaty on Prior Informed Consent or the Basel Convention on the Control of Transboundary Movements of Hazardous Waste are relevant.

If you identify any risks that you feel may be potentially **significant** based on your understanding of the application of default controls and your experience and knowledge of the substance and its use throughout its lifecycle, you should discuss your application with us. If we consider there are significant risks, the substance is likely to be declined for rapid assessment and you will need to do a full (section 28) risk assessment.

Section five of application form—International considerations

Section 5.1 of form—Consideration by any other regulatory authority

We are interested in whether the substance (or any of its components) has been considered by any other regulatory authority in New Zealand or any other country. We'll take into account any decisions made if the details of the decision are provided. If you are aware that an assessment has been made on the substance by any other jurisdiction, you should provide this information or a reference to it, eg state the registry or inventory numbers. Include specific information about where, what and by whom the decision was made. Just stating 'approved by US EPA' is not enough. However, until regulations are enacted that prescribe countries and organisations for this section, provision of this information is not mandatory.

Section six of application form—Miscellaneous

Section 6.1 of form—Glossary

If you use terms from the interpretation in section 2 of the HSNO Act, you don't need to define those terms. However, we expect you to give definitions of all other technical terms used in your application.

Section 6.2 of form—Other relevant information

You should provide any other information that you consider relevant to the application but which does not fit clearly into any of the previous sections.

Section seven of application form—Summary of public information

Section 20 (1) of the HSNO Act requires the Authority to keep a public register of all applications. Summary information provided in section 7 of the application form may be used for the register. For these reasons, you should make sure that your summary information does not contain any commercially sensitive material.

Section 7.1 of form—Name of the substance for the public register

Section 20 (2) (b) of the Act requires the public register of applications to contain a sufficient description to uniquely identify the substance. You should provide sufficient details of the name of the substance to meet this requirement (maximum of 80 characters).

If the identity of the new substance is commercially sensitive or if the application is for several similar (composition and property) substances, you may provide a generic chemical name or trade name, as long as this uniquely identifies the substance. The name should reveal the chemical identity of the substance to the maximum extent possible without giving away commercially sensitive information.

ERMA New Zealand will check the adequacy of any generic chemical name and if the name does not uniquely identify the substance, we will contact you to develop another name.

Section 7.2 of form—Purpose of the application for the public register

Section 20 (2) (c) of the Act requires the public register to specify the purpose of the application. This should explain (in a maximum of 255 characters) the intended use of the substance and why an application is needed, based on the hazardous properties.

Section 7.3 of form—Use categories of the substance

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identifies various functional uses of substances. This information is relevant to the assessment of exposure scenarios and for determining risk. It's also useful for building up a profile of the substance. There are three types of use categories, some of which include a number of subcategories (see Appendix 2 of this guide). We ask that you state which categories (and subcategories) are relevant to all the intended uses of the substance(s).

Section 7.4 of form—Executive summary

In this section, you need to provide a summary of the significant parts of your application. It is stressed that this information will be available for public scrutiny and as such, should not contain any commercially sensitive or confidential material. You should include a summary of:

- the identification of the substance, its hazardous properties, its intended uses and disposal
- information on the significant risks (adverse effects) of the substance.

Appendix one of application form—Confidential information

Any information that is commercially sensitive should be attached as an appendix. The main application should be cross-referenced and should be able to be read as a stand-alone document.

Part D

Application for ‘rapid assessment’ —similar substance criterion

Read this guide before filling in your application form (Form HS2/2) for approval to import or manufacture any hazardous substance for release, ‘rapid assessment’ under Section 28A of the HSNO Act for the criterion of similarity to an existing approved substance.

We recommend you read this User Guide before filling out your application form. Further guidance is available in the *Sample Applications* (available on the ERMA New Zealand website or from our office). If you have any queries, please contact an ERMA New Zealand Applications Officer who will be able to help you.

You can apply for more than one hazardous substance on one application form if the substances are related, eg a concentrated compound (active ingredient) and its related formulations.

You can make a rapid assessment application if your substance meets one of the criteria for rapid assessment ie it is either similar to an already approved substance or it is of low hazard. This part of the guide applies only to rapid assessments that meet the ‘similar substance’ criterion. Part C of the guide applies to the ‘low hazard’ criterion.

Level of information to be provided

The level of information we need for this type of rapid assessment is much less than for a full assessment (section 28). However, you still need to give adequate information on the identification of the substance, its properties and methods of disposal. We also need information on the uses of the substance and you still need to consider the provisions set out in Part II of the Act, especially sections 5 and 6. However, you only need to address those matters that are relevant and significant to your application, and you do **not** need to provide information relating to the benefits of the substance.

Note that all commercially sensitive material should be attached as an appendix.

Warning: Rapid assessments are meant to be quick, clear cut and low cost. This relies on the provision of good quality information that clearly confirms that rapid assessment applies. If it is not clear that rapid assessment is applicable, the application will most likely be declined. If this is the case, you can if you wish, ask for it to be re-considered as a full assessment under section 28. It’s therefore very important that you establish with ERMA New Zealand whether or not your application is likely to meet the rapid assessment criteria.

Section one of application form—Applicant details

You must provide full contact details for the ‘applicant’. The ‘applicant’ may be the name of a company, organisation, or the name of an individual. If the applicant is not an individual, you should include a contact name (section 1.3). This should be a person available by telephone during normal business hours in New Zealand, and who has sufficient knowledge to respond to

queries. This person should also have the authority to make decisions on behalf of the applicant, or be able to go to the appropriate source for a decision.

Section two of application form—Application type and related approvals

Section 2.1 of form—Similar substance criterion

Under section 28A(2), the Authority may make a rapid assessment of applications to import or manufacture a hazardous substance for release if **one** of the following criteria applies:

- (a) the substance has a similar composition and similar hazardous properties to one that has been approved
- (b) the substance has one or more hazardous properties and each of those hazardous properties has the least degree of hazard for that property.

This part of the guide applies only to rapid assessments that meet the ‘similar substance’ criterion (a). You must provide information to verify that your application meets this criterion. In addition to the guidance provided below, you can find further information in our Protocol *Information Requirements for Applications to Import or Manufacture a Hazardous Substance for Release*.

‘Approved’ in the context of (a) above, means approved under the HSNO Act by the Authority. This means the reference substance has either been approved by an earlier Part V HSNO approval, or it is a ‘deemed approval’ through the transfer process under section 160(1)(a) of the Act. It will therefore take some time after the start of the Act for this criterion to have much practical impact. A number of Part V approvals or deemed approvals of transferred substances will first need to be built up as reference points.

The other key issue relating to this criterion is the interpretation of **‘similar’** in the context of similar composition and similar hazardous properties. The provision is intended to give the Authority scope to streamline the application process, without compromising the health and safety of people, or risking damage to the environment.

Substances coming under this criterion should lead to similar effects to the previously approved substance, or more particularly, should not lead to effects not found with the previously approved substance. The Authority has little scope for flexibility when making judgements about similarity, in the direction of increased adverse effects. It has more flexibility where adverse effects are reduced. Some guidance on the interpretation of this criterion is given below.

Similar composition

For the composition to be similar, the major hazardous components of the substance must be the same as the major hazardous components in the previously approved substance. The hazardous components are those that determine the hazardous properties of the substance.

However, there may be variations in the proportions of these components, provided in each case that the general nature and character of the hazardous properties of the substance are not changed in a material way.

A new significant hazardous component cannot be introduced, ie one that does not exist in the previously approved substance and which would increase the hazard classification of the substance. However, you can introduce new components if they are minor constituents (eg in total are less than say 10% of the total substance) or if they are of low hazard and the substitution involved reduces rather than increases overall hazard. More latitude will be allowed if new components are not hazardous, ie they do not trigger any HSNO threshold.

Similar hazardous properties

A substance may be regarded as having similar hazardous properties to a previously approved substance if it:

- Does not exceed a hazardous property threshold for any hazardous property not triggered by the previously approved reference substance.
- Does not have a higher hazard classification than the previously approved substance in respect of any hazardous property. Where there is only one degree of hazard available for a type of hazard and where this classification is triggered in both the new substance and the previously approved substance, a decision on whether or not the criterion has been met will be made on a case-by-case basis, depending on the range of effects of the hazardous property covered by that degree of hazard. This is because, in some cases, the degrees of hazard are not narrowly based enough to be able to be used as a basis for a statutory definition of ‘similar’ hazardous properties.

For example, classification 8.3A is the sole degree of hazard for eye corrosiveness. However, this classification covers a wide range of severity of this hazardous property, from permanent destruction of ocular tissue to severe eye irritation effects that have not fully reversed within 21 days. Substances that are classified as 8.3A eye corrosives could have chemical properties that would also see them classified as severe skin corrosives (8.2A), or they could have properties that would result in them also being classified as only skin irritants (6.3A). It does not follow, therefore, that two substances with the classification 8.3A can be assumed to have ‘similar’ hazardous properties.

- Does not require any variations of controls that differ from any variations applied to the previously approved reference substance.

In providing evidence that the criteria are met, you may find it helpful to cross-reference to sections 3.1, 3.2 and 3.3 of the form, eg ‘as shown in section 3.3, all the hazard classifications of the proposed substance are the same as those for the reference substance and the substance is below the thresholds for all hazardous properties for which there is only one classification level’.

Section 2.2 of form—Identification of ‘similar’ substance used as a reference

You need to identify the previously approved ‘similar’ substance that is being used as a reference, and provide the HSNO approval number. In later sections of the form, you should set out the extent to which the proposed substance differs from the reference substance. This is so we can establish that any differences still fall within the similar criteria. Give a brief description of the reference substance so it is clear what it is. If necessary, put the description in a confidential appendix.

Section 2.3 of form—Import or manufacture

You must identify whether the information in your application form covers import only, manufacture only, or import and manufacture. This is so we can decide what extra information might be required, given that any resulting approval would cover import and manufacture, and would, in principle, cover all manufacturing processes. If you think the substance is not ever likely to be manufactured in New Zealand, it would be useful to say this and explain why.

Section 2.4 of form—Information on manufacturing process

If you are applying to manufacture a hazardous substance, describe the manufacturing process and whether it differs from the previously approved substance. In this situation, you need to show whether the manufacturing process itself is likely to create different adverse effects eg whether there are any hazardous by-products of the manufacturing process compared to the previously approved substance.

You also need to provide information on any alternative manufacturing processes for the substance that differ from the previously approved substance, including the likelihood of their use and what their risk characteristics are.

Section 2.5 of form—Other approvals required

Although not essential, it would be useful if you could indicate whether the hazardous substance(s) is subject to other New Zealand legislation requirements. This may include the Agricultural Compounds and Veterinary Medicines Act 1997, the Food Act 1981, the Medicines Act 1981, the Chemical Weapons (Prohibition) Act 1996, the Radiation Protection Act 1965, the Biosecurity Act 1993, the Resource Management Act 1991, or any other Act.

This allows us to do any sensible cross-checking with other agencies so that we can keep bureaucracy and cost to a minimum.

Section three of application form—Comparative information on the substance(s)

All commercially sensitive information should be attached as an appendix. The application form should be cross-referenced to the appendix but must be a stand-alone document that will be publicly available.

If you are applying for more than one hazardous substance, you need to complete this section separately for each hazardous substance.

Clearly identify the similarities and differences between this substance and the previously approved substance.

For mixtures, if you are not privy to the formulation composition, you will need to arrange for the third party to supply the information directly to ERMA New Zealand. You will need this clearly indicated in this section.

Section 3.1 of form—The unequivocal identification of the proposed substance(s) and the reference substance(s)

As far as possible, give comparative information for the substance(s) being applied for and for the reference substance(s). A table might help in doing this, for example:

Item	Proposed substance	Reference substance
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This section of the form must contain the unequivocally identification of the hazardous substance(s). If the substance(s) is not unequivocally identified, the application will not meet the statutory requirements and will not be processed. The information may best be expressed in a table but may be supplied in any suitable format.

Where relevant, information identifying the substance in data packages provided for equivalent USA, EU and Australian processes is considered acceptable. You should provide the data package to ERMA New Zealand but if you can't, we may be able to source it on your behalf. However, we will charge for this service.

Listed below is an indication of the type of information required. It is not a comprehensive list, but shows the type of information needed. Provide any chemical names, synonyms, and relevant trade names whether or not they are registered brands/trade names.

- chemical name (eg the Chemical Abstracts Preferred Index name (CA name) or International Union of Pure and Applied Chemistry (IUPAC))
- common name (where relevant)
- synonyms (where relevant)
- trade names (where relevant)
- CAS registry number (where it is available)
- molecular formula (where relevant)
- structural formula (where relevant)
- information on impurities/contaminants. In most cases, you don't need to specify components present at levels less than 0.1% unless there are hazardous property reasons for including them. For example, any dioxin contaminants present, even in trace amounts, should be included if they are known to exist in the substance. If the substance contains a polymer, you should identify any unreacted monomers that may be present and the relevant percentages.

If there are confidentiality reasons for not providing this type of information in the main part of the form, then you should discuss with us alternatives for dealing with this. Our preference will be for you to provide information in a confidential appendix. In this event, we would agree on a unique identifier to go into the public register.

If you didn't want to provide any detailed information at all, eg just a coded identifier, this would seriously hinder the application process. We would need to discuss situations like this case by case.

Mixtures—provide information on each component

As well as providing the above information on the actual mixture, you must provide the following information on the composition of the mixture for **each** component, including non-hazardous components and impurities. This information may be best expressed in tabular form (see Table 3.1).

- the name of each component
- the CAS number of each component (where relevant)
- the function (eg active ingredient, emulsifier, surfactant, solvent, filler) of each component
- the percent contribution of each component, ie the complete composition of the product/mixture. The total percentage should add up to 100 %.

Table 3.1 Example of composition information required for a mixture eg pesticide formulation

Name of component	CAS Number	Function	Composition (%)
<i>Glyphosate</i>	<i>1071-83-6</i>	<i>Pesticide</i>	<i>50%</i>
<i>Aluminium silicate</i>	<i>12141-46-7</i>	<i>Dispersant</i>	<i>30%</i>
<i>Silicon dioxide</i>	<i>7631-86-9</i>	<i>Anti-caking agent</i>	<i>10%</i>
<i>Nonyl phenol</i>	<i>25154-52-3</i>	<i>Surfactant</i>	<i>10%</i>

Application for a product range

The interpretation of 'substance' in the HSNO Act includes 'defined mixture of elements' or 'defined mixture of compounds'. Section 2(2) of the Act elaborates that 'the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance'.

Correspondingly, you can make a single application covering a group of products with similar compositions and similar hazard classification. For example, a line of paint products, which varies only in colour due to relatively minor variation in pigments, could all be grouped together.

The maximum concentrations of all the components listed will generally be used when assessing the hazardous properties of the substance, unless the hazard posed by increased concentration is non-linear. Therefore, you should make sure that the hazard classifications that will be applied (and hence the controls) will be suitable for all members of the group covered by the application. The percentages of the components can be given in ranges with the total percentage adding up to 100 % or more. The percentage ranges should generally not be so wide as to allow significant variation in the hazardous properties of the products covered by the application. This information may be best expressed in tabular form (see Table 3.2).

Table 3.2 Example of composition information required for a product range eg paint range

Name	CAS Number	Function	Composition (%)
<i>Polyester Resin</i> ¹	41641-17-7	<i>Resin</i>	25-45
<i>Solvent</i>		<i>Solvent</i>	30-60%
<i>Methyl isobutyl ketone</i>	108-10-1		5-15%
<i>Toluene</i>	108-88-3		10-25%
<i>Xylene</i>	1330-20-7		15-25%
<i>Acetone</i>	67-64-1		0-10%
<i>Pigments</i>		<i>Colouring Agent</i>	10-15%
<i>Barium sulphate</i>	7727-43-7		0-15%
<i>Cupric sulphate</i>	7758-98-7		0-15%
<i>Orange II</i>	633-96-5		0-15%

1. 1,3-Benzenedicarboxylic acid, polymer with 2,2-dimethyl-1,3-propanediol and 2-ethyl-2-(hydroxymethyl)-1,3-propanediol.

If the composition falls outside the range of the approved substance group, then it would be considered to be a new substance and would need a separate application.

Section 3.2 of form—The comparative chemical and physical properties of the proposed substance(s) and the reference substance(s)

In this section, you should provide information on the chemical and physical properties of the substance(s) if it is relevant to the unequivocal identification of the substance(s). Identify similarities and differences from the reference substance.

Where possible, these properties should be those evident at 20°C and 101.3 kPa, but if this information is unavailable, you must specify the relevant temperature and pressure conditions of the data provided. Where appropriate, you should include the relevant units for each test. This information may best be expressed in tabular form.

For mixtures, we would ideally like information on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of **each** hazardous component of the mixture.

Examples of properties we would like information about include:

- appearance (colour, odour, physical state or form)
- pH
- density
- vapour pressure
- boiling/melting point
- solubility in water
- water-octanol partitioning coefficient.

Section 3.3 of form—The comparative hazardous properties of the proposed substance(s) and the reference substance(s)

In this section, you should provide information on the hazardous properties of the proposed substance(s) and compare them to those of the reference substance. Again, a tabular format might be the best way of doing this.

It is emphasised that the proposed substance should not trigger any hazardous property threshold not triggered by the reference substance. Also, the proposed substance must not have a higher hazard classification than the reference substance for any hazardous property.

You must consider **each** of the six hazardous properties listed below and if possible, determine which of those hazardous properties trigger any threshold level.

For mixtures, we would ideally like information on the hazardous properties of the mixture itself. However, if this information is not available, you should provide information on the hazardous properties of **each** hazardous component of the mixture. You can then calculate the overall mixture hazard classifications (see our *User Guide to HSNO Thresholds and Classifications* for information on how to do this assessment).

The six hazardous properties are:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

You should also consider whether any one or more of the hazardous properties above would be generated if the substance came into contact with air or water (excluding situations where the temperature or pressure has been artificially increased or decreased).

In some cases, it may not be feasible for you to provide full information on the hazardous properties and we recognise that this will be the case for some imports. In these cases, we would suggest the following:

- Make as much comment as possible. If no information is available, then say so rather than not writing anything at all.
- If the material was sourced from overseas, for example, identify the name and location of the supplier and say what response you have had from the supplier in trying to obtain information.
- In some cases, it might be helpful to provide comparative information, eg identify other substances which can be demonstrated to be more or less hazardous and about which more is known.

It is necessary to relate the hazardous properties of the substance to the thresholds and classification system developed under section 74 of the Act. Each hazardous property that triggers any given threshold level is assigned a HSNO hazard classification. A substance may have more than one hazard classification. You don't have to assign the relevant hazard classifications; we will complete this section if necessary. However, the more time we spend processing your application the higher the charges will be.

The *User Guide to HSNO Thresholds and Classifications* has been prepared to assist you with interpreting the threshold regulations (that determine whether a substance is hazardous), and the classification regulations (that assign levels of hazards to hazardous substances). A summary of this document has also been prepared, *Summary User Guide to HSNO Thresholds and Classifications*, and it includes a *Substance Evaluation Sheet* to lead you through a process of assessing whether a substance is hazardous or not by considering each of the six hazardous properties listed above. Both guides provide information on appropriate data sources and preferred test methods for evaluation of substances against threshold levels.

You should provide as much information as you can on each of the six hazardous properties. The need for data will be related to the hazards and risks identified for the substance. In the first instance, you don't need to generate physical/chemical test data if it doesn't exist. If no studies are available you should note this, and not leave it blank, eg 'we have not been able to find any information on the flammable properties of the substance'. However, if you don't give information about a hazardous property, the Authority may decide there is not enough information to approve the application by rapid assessment. Any significant uncertainty is likely to lead to the application being declined.

If you say that a particular hazardous property does not exceed any threshold, you should give appropriate supporting information, clearly referenced. In many cases a simple statement will do eg 'the substance is not covered by the UN book so is not considered flammable'. However, in other cases, more comprehensive information will be necessary, eg 'the substance is not an acute oral toxic as the LD50 in all species tested was greater than 5000 mg/kg body weight'. When citing reference sources, you should, if possible, provide the primary reference for the data rather than a secondary reference, ie give the full citation of a paper rather than referencing the Hazardous Substance Database (HSDB).

For those hazardous properties that trigger any threshold level, you should provide all relevant information, ie give a description of, or reference to, the test methods used, as well as citing the data sources and any appropriate references. Remember to include all relevant units. It's unlikely that an MSDS (Material Safety Data Sheet) alone will satisfy the data requirements, unless it is comprehensive and fully referenced. We consider that an applicant can reasonably obtain data in the possession or control of a parent company or an affiliated subsidiary outside New Zealand. If for any reason you can't, say why. We have listed below the type of information we'd ideally like you to provide for each hazardous property that exceeds any threshold level.

Our *User Guide to HSNO Thresholds and Classifications* has information on preferred test methods. Test methods for substances that are biological corrosives or have toxic or ecotoxic properties are primarily derived from international test guidelines such as the OECD. The threshold and classification criteria for these biological hazards are primarily derived from the Globally Harmonised System (GHS), which has harmonised hazard classifications for human

health and environmental effects of chemical substances. Test methods for substances that have explosive, flammable or oxidising properties are primarily derived from the *United Nations Recommendations on the Transport of Dangerous Goods (UNRTDG) Manual of Tests and Criteria*. The threshold and classification criteria for these physical hazards come from the *UNRTDG Model Regulations*.

Explosive properties

- explosive properties in accordance with the test criteria of the *UNRTDG Manual of Tests and Criteria*.

Flammable properties

- initial boiling point and flash point for liquids (refer to the test methods used for this determination), lower and upper flammability limits in air for gases, or combustibility data for solids
- vapour pressure at standard conditions of any substance that is a liquid at those conditions.

Oxidising and self-reacting properties

- auto-ignition temperature
- potential to increase rate of burning time of combustible substances
- reactivity including oxidising properties, incompatibility with other substances, conditions under which the substance is unstable (eg self-accelerating decomposition temperature) and information on decomposition products and their hazards.

Corrosive properties

- pH and reactivity with metals
- biological (skin and eye) corrosiveness.

Toxic properties

- acute toxic effect (LD₅₀) including oral, dermal, and inhalation levels as appropriate
- skin and eye irritation properties
- sensitisation properties
- mutagenicity
- reproductive, developmental, carcinogenic effects or other target organ orientated systemic toxic properties.

For each toxic property, describe or reference the test methods used (data for the most sensitive species should be used). If no studies are available then this should be noted. If you aren't sure whether to generate test data, consult with ERMA New Zealand.

Ecotoxic properties

- LC₅₀, EC₅₀, LD₅₀ and chronic ecotoxic data as appropriate
- abiotic degradation rate (hydrolysis as a function of pH)

- bioaccumulation potential (biological concentration factor or n-octanol/water partition coefficient)
- soil absorption/desorption characteristics
- surface tension where the substance is liquid at standard conditions
- water solubility of the substance at a defined temperature.

A summary table should be included at either the beginning or the end of section 3.3, listing each of the six hazardous properties, whether each is triggered and, if desired, provide the hazard classification for those that triggered any threshold levels (see Table 3.3).

Table 3.3 Example of summary table of hazardous properties, thresholds and classification of Substance X

Hazardous property	Threshold	Classification category and criteria
Explosive	Not triggered	
Flammable <ul style="list-style-type: none"> • Liquid 	Triggered	3.1C – closed cup flashpoint 50 °C
Oxidising	Not triggered	
Corrosive	Not triggered	
Toxic <ul style="list-style-type: none"> • Acute oral • Acute dermal • Acute inhalation • Skin irritation • Eye irritation • Sensitisation • Mutagenic • Carcinogenic • Reproductive/developmental • Target organ/systemic 	<ul style="list-style-type: none"> Triggered Triggered Triggered Triggered Triggered Not triggered Not triggered Not triggered Triggered Triggered 	<ul style="list-style-type: none"> 6.1E - LD₅₀ rat 2800 mg/kg 6.1E - LD₅₀ rat 3400 mg/kg 6.1D - LC₅₀ mice 3130 ppm 6.3A – Draize Grade 4 6.4A – Draize Grade 2 for corneal opacity reversed within 21 days of exposure 6.8B – Reproductive toxicant (foetal effects) 6.9A - Liver effects
Ecotoxic <ul style="list-style-type: none"> • Aquatic • Soil • Terrestrial vertebrate • Terrestrial invertebrate 	<ul style="list-style-type: none"> Triggered Not triggered Not triggered Not triggered 	<ul style="list-style-type: none"> 9.1D – LC₅₀ fish 80 mg/L (acute)

Section 3.4 of form—Identification of default controls

Section 77 of the HSNO Act provides for default controls to be attached to a substance in accordance with its hazard classification. These are summarised in our *User Guide to HSNO Control Regulations*. If you wish, you can provide details on the range of HSNO default controls that are triggered by the hazardous property classifications attached to the substance (identified in section 3.3 of the form). If you don't provide this information, we will complete this section on your behalf but will charge for the extra time spent on your application.

The default controls should be the same or less stringent than those applied to the previously approved reference substance. This will clearly be the case if the proposed substance has the same or lower hazard classification as the reference substance. If the default controls on the reference substance have been varied, then the same variations should apply to the proposed substance. If these criteria do not apply, then the new substance is **not** eligible for rapid assessment and you must make a full release application under section 28 (Part B of this guide).

You should also provide details on any controls triggered by other legislation eg ACVM Act, Health and Safety in Employment Act, Land Transport Rules, Maritime Safety Rule, Resource Management Act, Ozone Layer Protection Act, Food Act, Health Act, and various district plans.

Section 3.5 of form—Comparative information on the life of the proposed substance(s) and the reference substance(s), from import/manufacture to intended uses and disposal

Similarity of use is not one of the criteria for rapid assessment but we still need comparative information. This is because if uses are significantly different, risks may differ even if hazardous properties are similar. In other words, there may be different exposure scenarios.

We also need information on other stages of the lifecycle of the substance although it is not so important for this to be comparative. We need information on disposal, for example, in its own right to make sure that disposal is appropriately managed.

The required information includes:

- transport and storage information
- the intended substance use(s)—consider the formation of potential by-products/metabolites/waste products during use
- other (reasonable) potential uses, recycling options
- who may use the substance (eg industrial or domestic users)
- how it is intended to be used (eg a two-pot paint requiring mixing by the user)
- any known adverse effects from unintentional use
- the disposal of the substance.

You should provide information covering the lifecycle from the stage at which the substance becomes hazardous through to when it is no longer hazardous (as defined by the HSNO Act and Regulations). The owner of the substance is responsible for the safe and effective disposal of the substance. However, you must provide information on the correct disposal methods. This should be appropriate to New Zealand, eg New Zealand does not have high temperature incineration facilities available for general industrial hazardous wastes.

Disposal information should also relate to products in which the substance is used where the hazardous properties of the substance persist in the product. Include options for re-use or recycling. Instructions on dealing with used containers as well as the substance itself should be included as appropriate. Disposal options should relate to the relevant performance requirements for disposal contained in the *Hazardous Substances (Disposal) Regulations 2001*.

Section four of application form—Identifying and assessing comparative variations in risk

Full risk assessments may not be required for ‘similar substance’ rapid assessment applications. However, there is still a requirement for the uses and risks (adverse effects) of the substance to be compared and contrasted with those of the reference substance. It’s not necessary to fully assess risks that are the same as those for the reference substance but you must provide enough information to confirm that the risks are similar. In identifying risks for comparison, you should refer to the matters set out in Part II of the Act, especially sections 5,6 and 8.

If the hazardous properties are similar (which they should be) then any differences in risk should arise from differences in exposure scenarios. That in turn is mainly a function of types and patterns of use. So, if both hazardous properties and usage are similar to the reference substance, risks should also be similar.

We suggest you consider whether any significant risks exist in any of the areas set out below. You can present the information in a variety of formats but it should be systematic. A simple table would be ideal. Information on the benefits of the substance is **not** required for rapid assessment applications. You need to consider the following:

- 1) The physical environment, including:
 - safeguarding the life-supporting capacity of air, water, soil and ecosystems
 - the sustainability of all native and valued introduced flora and fauna
 - the intrinsic value of ecosystems (those aspects of ecosystems that have value in their own right).
- 2) Effects on humans, including:
 - human health (including public exposure and occupational exposure)
 - the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.
- 3) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred place), valued flora and fauna and other taonga (sacred treasures, prized possessions, property, anything which is highly prized).
- 4) New Zealand’s international obligations, eg situations where the Rotterdam Treaty on Prior Informed Consent or the Basel Convention on the Control of Transboundary Movements of Hazardous Waste are relevant.

It's only necessary to assess in detail, any risks (adverse effects) that differ in nature, magnitude and likelihood of occurrence from those of the reference substance.

If you need to carry out a full assessment, then you should do it in the same way as a full (section 28) application. Details on this are in Part B of this guide.

Section five of application form—International considerations

Section 5.1 of form—Consideration by any other regulatory authority

We are interested in whether the substance (or any of its components) has been considered by any other regulatory authority in New Zealand or any other country. We'll take into account any decisions made if the details of the decision are provided. If you are aware that an assessment has been made on the substance by any other jurisdiction, you should provide this information or a reference to it, eg state the registry or inventory numbers. Include specific information about where, what and by whom the decision was made. Just stating 'approved by US EPA' is not enough. However, until regulations are enacted that prescribe countries and organisations for this section, provision of this information is not mandatory.

Section six of application form—Miscellaneous

Section 6.1 of form—Glossary

If you use terms from the interpretation in section 2 of the HSNO Act, you don't need to define those terms. However, we expect you to give definitions of all other technical terms used in your application.

Section 6.2 of form—Other relevant information

You should provide any other information that you consider relevant to the application but which does not fit clearly into any of the previous sections.

Section seven of application form—Summary of public information

Section 20 (1) of the HSNO Act requires the Authority to keep a public register of all applications. Summary information provided in section 7 of the application form may be used for the register. For this reason, you should make sure that your summary information does not contain any commercially sensitive material.

Section 7.1 of form—Name of the substance for the public register

Section 20 (2) (b) of the Act requires the public register of applications to contain a sufficient description to uniquely identify the substance. You should provide sufficient details of the name of the substance to meet this requirement (maximum of 80 characters).

If the identity of the new substance is commercially sensitive or if the application is for several similar (composition and property) substances, you may provide a generic chemical name or trade name, as long as this uniquely identifies the substance. The name should reveal the

chemical identity of the substance to the maximum extent possible without giving away commercially sensitive information.

ERMA New Zealand will check the adequacy of any generic chemical name and if the name does not uniquely identify the substance, we will contact you to develop another name.

Section 7.2 of form—Purpose of the application for the public register

Section 20 (2) (c) of the Act requires the public register to specify the purpose of the application. This should explain (in a maximum of 255 characters) the intended use of the substance and why an application is needed, based on the hazardous properties.

Section 7.3 of form—Use categories of the substance

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identifies various functional uses of substances. This information is relevant to the assessment of exposure scenarios and for determining risk. It's also useful for building up a profile of the substance. There are three types of use categories, some of which include a number of subcategories (see Appendix 2 of this guide). We ask that you state which categories (and subcategories) are relevant to all the intended uses of the substance(s).

Section 7.4 of form—Executive summary

In this section, you need to provide a summary of the significant parts of your application. It is stressed that this information will be available for public scrutiny and as such, should not contain any commercially sensitive or confidential material. You should include a summary of:

- the identification of the substance, its hazardous properties, intended uses and disposal
- information on the significant risks (adverse effects) of the substance
- the similarities and differences between this substance and the previously approved substance.

Appendix one of application form—Confidential information

Any information that is commercially sensitive should be attached as an appendix. The main application should be cross-referenced and should be able to be read as a stand-alone document.

Part E

Application for containment

Read this guide before filling in your application form (Form HS3) for approval to import of manufacture any hazardous substance in containment under section 31 of the HSNO Act.

We recommend you read this User Guide before filling out your application form. Further guidance is available in the *Sample Applications* (available on the ERMA New Zealand website or from our office). If you have any queries, please contact an ERMA New Zealand Applications Officer who will be able to help you.

You can apply for more than one hazardous substance on a single application form if the substances are related, eg a concentrated compound (active ingredient) and its related formulations or a range of substances for similar purposes to be tested in a field trial.

Level of information to be provided

The level of information you need to provide for a containment application is less than that required for a release application. This is because the limited quantities of substance involved and reduced level of exposure lead to a reduced level of risk. It is therefore critical in containment applications that you demonstrate the substance will be adequately contained.

You need to provide any information known to you about the adverse effects of the substance throughout its lifecycle, but this should be interpreted sensibly given that this is a containment application, ie focus on the particular scope of the work involved. You also need to consider the provisions set out in Part II of the Act, especially sections 5 and 6. However, you only need to refer to those matters that are specifically relevant to your application and you do **not** need to provide information relating to the benefits of the substance.

Note that all commercially sensitive material should be attached as an appendix.

Section one of application form—Applicant details

You must provide full contact details for the ‘applicant’. The ‘applicant’ may be the name of a company, organisation, or the name of an individual. If the applicant is not an individual, you should include a contact name (section 1.3). This should be a person available by telephone during normal business hours in New Zealand, and who has sufficient knowledge to respond to queries. This person should also have the authority to make decisions on behalf of the applicant, or be able to go to the appropriate source for a decision.

Section two of application form—Application type and related approvals

Section 2.1 of form—Purpose of application

The Authority may approve applications to manufacture or import hazardous substance(s) in containment for any one of the purposes listed below. You must state which purpose you are making your application under.

- use of small amounts of any hazardous substance as an analytical standard where approval to import or manufacture that substance has been declined (section 30(a))
- research on any hazardous substance to acquire information for use in assessing that substance for a HSNO approval (section 30(b))
- research and development on any hazardous substance (section 30 (ba))
- use in an emergency (section 30(c))
- other purposes as the Authority deems fit (section 30(d)).

Examples of acceptable applications

Section 30(a): An example would be the use of polychlorinated biphenyls (PCBs) as analytical reference standards in testing laboratories (PCBs are prohibited substances).

Section 30(b): Examples include:

- further characterisation of the substance and its formulations
- testing for the effects of the substance (positive and negative)
- evaluating different methods of managing risk
- evaluating methods and options for disposal of the substance.

Section 30(ba): An example would be product development.

Applications with purposes under section 30(a), (b) and (ba) may qualify for exemption under section 33. You can contact us at any time to check this out.

Section 30(d): The Authority will consider the following characteristics in determining the suitability of “other” purposes:

- that the substance will be used for a purpose that is inherently consistent with the application of containment
- that the use of the substance for the purpose is time limited, and after that period of time, all quantities of the substance will be either destroyed or held in secure containment until an application for release is approved.

An example of an acceptable purpose under section 30(d) would be field-testing a new pesticide. However, this type of application requires more supporting information than other

containment applications because the risks are larger and containment will require careful attention.

It is stressed that containment applications do not apply to work that is part of directly producing material for commercial sale or release, eg using a raw material in a (contained) process. In these cases, you must apply under section 28 or section 28A.

Section 2.2 of form—Additional information on application purpose

You need to provide supporting information for the particular purpose identified above. Even if the Authority accepts the purpose, the Authority must still be satisfied that that the substance can be adequately contained (see section 4 of the application form).

Section 2.3 of form—Import or manufacture

You must identify whether the information in your application form covers import only, manufacture only, or import and manufacture. This is so we can decide what extra information might be required, given that any resulting approval would cover import and manufacture, and would, in principle, cover all manufacturing processes. If you think the substance is not ever likely to be manufactured in New Zealand, it would be useful to say this and explain why.

Section 2.4 of form—Information on manufacturing process

If you are applying to manufacture a hazardous substance, describe the manufacturing process. You should provide enough information to show whether the manufacturing process itself is likely to create adverse effects, eg whether there are any hazardous by-products of the process.

It would also be useful to say whether other processes exist, are likely to be used, and what the risk characteristics are.

Section 2.5 of form—Other approvals required

Although not essential, it would be useful if you could indicate whether the hazardous substance(s) is subject to other New Zealand legislation requirements. This may include the Agricultural Compounds and Veterinary Medicines Act 1997, the Food Act 1981, the Medicines Act 1981, the Chemical Weapons (Prohibition) Act 1996, the Radiation Protection Act 1965, the Biosecurity Act 1993, the Resource Management Act 1991, or any other Act.

This allows us to do any sensible cross-checking with other agencies so that we can keep bureaucracy and cost to a minimum.

Section three of application form—Information on the substance

All commercially sensitive information must be attached as an appendix. The application form should be cross-referenced to the appendix but must be a stand-alone document that will be publicly available.

If you are applying for more than one hazardous substance, you need to complete this section separately for each hazardous substance.

For mixtures, if you are not privy to the formulation composition, you will need to arrange for the third party to supply the information directly to ERMA New Zealand. You will need this clearly indicated in this section.

Section 3.1 of form—The unequivocal identification of the substance(s)

In this section, you should provide information on the identification of the hazardous substance(s). The information may be supplied in any suitable format but may best be expressed in tabular form.

You should provide enough information to unequivocally identify the substance. Listed below is an indication of the type of information required. It is not a comprehensive list, but shows the type of information needed. Provide any chemical names, synonyms, and relevant trade names whether or not they are registered brands/trade names.

- chemical name (eg the Chemical Abstracts Preferred Index name (CA name) or International Union of Pure and Applied Chemistry (IUPAC))
- common name (where relevant)
- synonyms (where relevant)
- trade names (where relevant)
- CAS registry number (where it is available)
- molecular formula (where relevant)
- structural formula (where relevant)
- information on impurities/contaminants. In most cases, you don't need to specify components present at levels less than 0.1% unless there are hazardous property reasons for including them. For example, any dioxin contaminants present, even in trace amounts, should be included if they are known to exist in the substance. If the substance contains a polymer, you should identify any unreacted monomers that may be present and the relevant percentages.

Mixtures—provide information on each component

As well as providing the above information on the actual mixture, you should provide the following information on the composition of the mixture for **each** component, including non-hazardous components and impurities. This information may be best expressed in tabular form (see Table 3.1).

- the name of each component
- the CAS number of each component (where relevant)
- the function (eg active ingredient, emulsifier, surfactant, solvent, filler) of each component
- the percent contribution of each component, ie the complete composition of the product/mixture. The total percentage should add up to 100 %.

Table 3.1 Example of composition information required for a mixture eg pesticide formulation

Name of component	CAS Number	Function	Composition (%)
<i>Glyphosate</i>	1071-83-6	<i>Pesticide</i>	50%
<i>Aluminium silicate</i>	12141-46-7	<i>Dispersant</i>	30%
<i>Silicon dioxide</i>	7631-86-9	<i>Anti-caking agent</i>	10%
<i>Nonyl phenol</i>	25154-52-3	<i>Surfactant</i>	10%

Application for a product range

The interpretation of ‘substance’ in the HSNO Act includes ‘defined mixture of elements’ or ‘defined mixture of compounds’. Section 2(2) of the Act elaborates that ‘the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance’.

Correspondingly, you can make a single application covering a group of products, for example a range of pesticide formulations for use in a field trial, that have similar compositions and similar hazards, may be submitted in one application.

The information may be best expressed in tabular form (see Table 3.2). The percentages of the components can be given in ranges with the total percentage adding up to 100 % or more. The percentage ranges should generally not be so wide as to allow significant variation in the hazardous properties of the products covered by the application.

Table 3.2 Example of composition information required for a product range eg range of pesticide formulations for field trial

Name of component	CAS Number	Function	Composition (%)
<i>Glyphosate</i>	1071-83-6	<i>Pesticide</i>	40-60%
<i>Aluminium silicate</i>	12141-46-7	<i>Dispersant</i>	15-25%
<i>Silicon dioxide</i>	7631-86-9	<i>Anti-caking agent</i>	10-25%
<i>Nonyl phenol</i>	25154-52-3	<i>Surfactant</i>	5-15%

If the composition of a similar substance falls outside the range of the approved substance group, then it would be considered a new substance and would need a separate application.

Section 3.2 of form—The chemical and physical properties of the substance(s)

In this section you should provide as much information as possible on the chemical and physical properties of the substance(s). This information may be relevant to the unequivocal identification of the substance(s) but is also relevant to the determination of specific hazard property endpoints (eg water solubility is relevant to aquatic toxicity, boiling point is relevant to flammability, and viscosity and physical form are relevant to aspiration hazard (toxicity)).

Where possible, these properties should be those evident at 20°C and 101.3 kPa, but if this information is unavailable, you must specify the relevant temperature and pressure conditions of the data provided. Where appropriate, you should include the relevant units for each test. This information may best be expressed in tabular form.

For mixtures, we would ideally like information on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of **each** hazardous component of the mixture.

Examples of properties we would like information about include:

- appearance (colour, odour, physical state or form)
- pH
- density
- vapour pressure
- boiling/melting point
- solubility in water
- water-octanol partitioning coefficient.

Section 3.3 of form—Hazardous property information

Although it's not necessary for containment applications to determine the specific hazard classifications of the substance(s), it is nevertheless necessary to obtain data on the hazardous properties of the substance(s). Information on the type and degree of hazard is central to assessing any potential adverse effects of the substance(s) and is also important for applying containment controls as specified in Part III of the Third Schedule to the Act.

You should therefore consider **each** of the six hazardous properties listed below, and if possible determine which of those hazardous properties trigger any threshold level.

For mixtures, we would ideally like information on the hazardous properties of the mixture itself. However, if this information is not available, you should provide as much information as possible on the hazardous properties of **each** hazardous component of the mixture.

The six hazardous properties are:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

You should also consider whether any one or more of the hazardous properties above would be generated if the substance comes into contact with air or water (excluding situations where the temperature or pressure has been artificially increased or decreased).

We recognise that in many cases information on the hazardous properties may not exist eg if the substance(s) are test samples. In other situations, it may not be feasible to obtain full information on the properties, eg for some imports. In such cases, we would suggest the following:

- Make as much comment as possible. If no information is available, then say so rather than not writing anything at all.
- If the material was sourced from overseas, for example, identify the name and location of the supplier and say what response you have had from the supplier in trying to obtain information.
- In some cases, it might be helpful to provide comparative information eg identify other substances which can be demonstrated to be more or less hazardous and about which more is known.

The *Summary User Guide to HSNO Thresholds and Classifications* has been prepared to assist you in determining whether a substance is hazardous. The *Substance Evaluation Sheet* within the guide leads you through a process of assessing whether a substance is hazardous or not by considering each of the six hazardous properties listed above.

You should provide as much information as you can on each of the six hazardous properties. If no studies are available you should note this, and not leave it blank, eg 'we have not been able to find any information on the flammable properties of the substance'. However, bear in mind if information about a hazardous property is not available, the containment controls placed on the substance (see Section 4) should allow for this uncertainty.

If you say that a particular hazardous property does not exceed any threshold, you should give appropriate supporting information, clearly referenced. In many cases a simple statement will do, eg 'the substance is not covered by the UN book so is not considered flammable'. However, in other cases, more comprehensive information will be necessary eg 'the substance is not an acute oral toxic as the LD50 in all species tested was greater than 5000 mg/kg body weight'. When citing reference sources, you should, if possible, provide the primary reference for the data rather than a secondary reference, ie give the full citation of a paper rather than referencing the Hazardous Substance Database (HSDB).

For those hazardous properties that trigger any threshold level, you should provide all relevant information, ie give a description of, or reference to, the test methods used, as well as citing the data sources and any appropriate references. Remember to include all relevant units. It's unlikely that an MSDS (Material Safety Data Sheet) alone will satisfy the data requirements, unless it is comprehensive and fully referenced. You can find information on preferred test methods in our *User Guide to HSNO Thresholds and Classifications*.

A summary table should be included at either the beginning or end of section 3.3, listing each of the six hazardous properties and whether each has triggered any threshold levels. It would also be helpful to indicate the level of hazard, either by reference to the hazard classifications

set out in the HSNO regulations or by referring to the *User Guide to HSNO Thresholds and Classifications*.

Table 3.3 Example of summary table of hazardous property and threshold data of Substance X

Hazardous property	Threshold	Threshold “Trigger” Data
Explosive	Not triggered	
Flammable <ul style="list-style-type: none"> Liquid 	Triggered	Closed cup flashpoint 50 °C
Oxidising	Not triggered	
Corrosive	Not triggered	
Toxic <ul style="list-style-type: none"> Acute oral Acute dermal Acute inhalation Skin irritation Eye irritation Sensitisation Mutagenic Carcinogenic Reproductive/developmental Target organ/systemic 	<ul style="list-style-type: none"> Triggered Triggered Triggered Triggered Triggered Not triggered Not triggered Not triggered Triggered Triggered 	<ul style="list-style-type: none"> LD₅₀ rat 2800 mg/kg LD₅₀ rat 3400 mg/kg LC₅₀ mice 3130 ppm Draize Grade 4 Draize Grade 2 for corneal opacity reversed within 21 days of exposure Reproductive toxicant (foetal effects) Liver effects
Ecotoxic <ul style="list-style-type: none"> Aquatic Soil Terrestrial vertebrate Terrestrial invertebrate 	<ul style="list-style-type: none"> Triggered Not triggered Not triggered Not triggered 	<ul style="list-style-type: none"> LC₅₀ fish 80 mg/L (acute)

Section 3.4 of form—Information on the life of the substance, from import/manufacture to intended uses and disposal

We need information on the lifecycle of the substance for the development of exposure scenarios and the assessment of risks, which, in turn, determine the containment conditions that will be required. The information should be derived in a systematic and comprehensive manner and may be presented in a variety of ways, eg a flow diagram. The information you provide needs to reflect the containment nature of the application but should include details about the following:

- transport and storage information
- the intended use(s) of the substance—include consideration of the potential formation of by-products/metabolites/waste products during use
- the disposal of the substance. Disposal methods should be appropriate to the New Zealand situation. Include instructions on dealing with used containers as well as the substance

itself, as appropriate. Disposal options should relate to the relevant performance requirements for disposal contained in the *Hazardous Substances (Disposal) Regulations 2001*.

Section 3.5 of form—Quantity of substance(s)

Section 31(2)(c) of the Act, requires you to provide information on the quantity of the substance(s) to be manufactured/imported. This information is useful for developing exposure scenarios and assessing risks.

Section four of application form—Containment system

Section 4.1 of form—Information on the containment system

A major consideration with containment applications is that the Authority must be satisfied that the substance is adequately contained by the containment system, thus reducing the likelihood of risk to either people or the environment. It is essential that you provide good information in this section because the adequacy of containment in conjunction with the hazardous properties of the substance will have a major impact on whether or not your application is approved. However, it's also important that the amount of information sensibly matches the circumstances. For example:

- a small quantity of moderately hazardous chemical used as an analytical standard in a laboratory will require little supporting information
- a proposal to test samples of pesticides in the field will require comprehensive supporting information.

In some cases, the containment system may be a facility that provides physical boundaries such as a room or a building. In other cases, the containment facility may have non-structural boundaries such as in the case of field trials on pesticides. In both cases, you must describe the actual containment system, as well as providing information on the control measures (physical and procedural) that are in place to maintain the security of containment and to deal with any potential risks posed by the substance. You may want to present this information as a management plan attached as an appendix.

Specific containment control matters that you should address are set out in Part III of the Third Schedule to the Act. These are:

1. To limit the likelihood of escape of any contained hazardous substances or contamination of the facility by hazardous substances, the controls imposed by an approval shall specify:
 - (a) Requirements for treatment and decontamination to prevent escape by way of expelled air, discharge of water or liquid waste, removal of solid waste, or breaches in facility boundary
 - (b) Equipment and requirements for facility construction to enable the requirements for treatment and decontamination to be readily met
 - (c) Requirements to be complied with for the access of persons to the facility
 - (d) Procedures and requirements for transport, identification, and packaging of the substance to and from the facility and within the facility

- (e) Requirements for the disposal of any hazardous substance
 - (f) Requirements for facility construction
 - (g) Requirements to secure the facility and openings, including securing against failure in the event of foreseeable hazards.
2. To exclude organisms from a facility or to control organisms within a facility, the controls shall specify:
 - (a) Phytosanitary requirements
 - (b) Requirements to secure the facility and openings against likely unwanted organisms
 - (c) Monitoring requirements to establish the presence of organisms.
 3. To exclude unauthorised people from the facility, controls imposed by an approval shall specify:
 - (a) Means of identification of all entrances to the facility
 - (b) The numbers of entrances and access to the facility
 - (c) Security requirements for the entrance and the facility.
 4. To prevent unintended release of the substance by experimenters working with the substance, the controls shall specify:
 - (a) Requirements to prevent the contamination of work surfaces, equipment, clothing, and the facility generally
 - (b) Procedures to ensure that no person in the facility is exposed to a sufficient level of the substance to cause harm to that person.
 5. To control the effects of any accidental release of the substance, controls imposed by an approval shall specify:
 - (a) Procedures to recover and dispose of any hazardous substance
 - (b) Procedures to minimise the effects of such a release on people and the environment.
 6. Controls imposed by an approval shall specify inspection and monitoring requirements for containment facilities.
 7. Controls imposed by an approval may specify:
 - (a) The qualifications required of the person responsible for implementing the controls imposed by an approval
 - (b) The provisions of a management plan specifying procedures for implementing controls imposed by an approval.

Section five of application form—Identifying and assessing risks

This part of the application form requires you to identify and assess the risks (adverse effects) of the substance. You should provide all the information you are aware of relating to the adverse effects of the substance throughout its lifecycle. You should also provide a brief description on where the information was sourced.

In completing this section, it is important that you take account of the proposed containment system and the control measures (physical and procedural) described in Section 4, which may significantly reduce the likelihood or the consequence of any adverse effects. We are particularly interested in knowing about those risks that remain with the containment system in place. You should also take account of the quantity of material involved and the number of different locations that may be involved.

We recognise that containment applications can cover a wide range of situations, from laboratories to the field-testing of an agrichemical. Clearly, there will be different levels of risks associated with different types of applications primarily due to the different exposure scenarios involved. As such, the level of detail you need to provide in the risk assessment section depends on the nature of the application. For example, a field trial of an agrichemical will require a more in-depth investigation of the risks compared to a situation where the substance is kept in a secure laboratory.

Information on the benefits of the substance is **not** required for containment applications.

Section 5.1 of form—Identifying risks

When identifying risks, you should take into account the matters set out in Part II of the Act, specifically sections 5 and 6 (outlined below) and consider whether there are any significant risks that might exist in any of these areas. The information can be presented in a variety of formats but should be systematic. A simple table would be ideal (see Table 5.1).

- 1) The physical environment, including:
 - safeguarding the life-supporting capacity of air, water, soil and ecosystems
 - the sustainability of all native and valued introduced flora and fauna
 - the intrinsic value of ecosystems (those aspects of ecosystems that have value in their own right).

Given the restricted use of substances in containment applications, it's clear that the risks to the environment will not be as great as with a substance in widespread use. However, you still need to consider the possibility of any potential adverse effects if the substance enters the environment unintentionally, eg if the containment system fails, or if there is an accident during storage or transportation.

- 2) Effects on humans, including:
 - human health (including public exposure and occupational exposure)
 - the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.

As the substance will not be for general public use, the most likely risk to humans will be occupational exposure. However, you should consider the possibility of the substance escaping from containment and causing an adverse effect on public health or and the economic, social and cultural well being of the community.

- 3) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred place), valued flora and fauna and other taonga (sacred treasures, prized possessions, property, anything which is highly prized). Section 5.2 below has information on this, but for containment applications such matters will only be relevant if the substance escapes from containment.
- 4) New Zealand’s international obligations, eg situations where the Rotterdam Treaty on Prior Informed Consent or the Basel Convention on the Control of Transboundary Movements of Hazardous Waste are relevant.

Deciding whether a risk is potentially significant or not should be based on your knowledge of the substance and its uses throughout its lifecycle, and what you consider the likelihood to be of the substance escaping from containment. If you aren’t sure whether a risk is significant, you should include it. If you decide that a risk is not significant, you should explain why. If relevant, provide references to sources of data used. A detailed risk assessment is only necessary for those risks that have been identified as significant. If there are **no** significant risks, there is no need to carry out a risk assessment in section 5.2 below.

Table 5.1 Summary of risk identification of Substance X.

Source of Risk Event/Incident	Haz. Property	Possible reasons for event (including lifecycle)	Effect/Impact	Exposure Pathway
Release/spillage of substance (either onto land, in or near water, or into the air via vapours or aerosols)	Toxic Ecotoxic	<ul style="list-style-type: none"> • Transport accident (Import, transport) • Accident during use (Use) • Natural hazard eg earthquake (any stage) • Sabotage (any stage) • Damaged packaging (import, storage, transport, use) • Incorrect disposal (disposal) 	1. Adverse (acute) effect on human health – nausea, headache	Inhalation
			2. Adverse effect on aquatic environment - fish die	Substance enters waterway

Section 5.2 of form—Assessing significant risks

You should provide an assessment of the risks identified in section 5.1 as significant. Your assessment should include whether the substance can be adequately contained by the proposed containment system and whether the (significant) risks identified above can be adequately managed by the containment controls detailed in section 4.

The risk assessment process integrates what the hazards are, the magnitude and likelihood of them occurring, how and when they are likely to occur and who or what is likely to be affected. In carrying out your risk assessment, you should consider the following:

- What is the nature of the hazardous substance and how serious are the risks, ie what are the potential consequences from the hazard, eg burns, fatal poisoning?
- What is the likelihood/probability of the adverse effect occurring?
- What is the magnitude of the effect? In estimating the magnitude, you should consider whether the risks will be localised geographically or distributed more widely, whether particular groups in the community may be more affected than others, whether the risk will persist over time and whether any potential adverse effects are irreversible or reversible?
- What are the uncertainty bounds of the information used in the assessment (ie how reliable is it)?

For significant risks, assessments can be quite involved and are best done by experienced risk assessors. However, if you wish to work through this section yourself, ERMA New Zealand has produced the following Technical Guides to assist you:

- *Identifying Risks*
- *Preparing Information on Risks, Costs and Benefits*
- *Assessment of Effects of Hazardous Substances and New Organisms on Human Health.*

Assessing risk to Maori

It is emphasised that for containment applications risk to Maori is unlikely to be an issue and will only be relevant if the substance escapes from containment. However, if you have identified that there may be potentially significant risks in this area, you should provide an assessment of the likelihood (probability) of the adverse impact on Maori and estimate how severe that impact may be. The magnitude of risks may be influenced by whether the risk is limited to a geographical region or will affect Maori generally. To help you identify issues of significance to Maori, we have prepared the following documents:

- *User Guide to Working with Maori under the HSNO Act 1996*
- *Protocol 1 Series 2 Taking Account of Maori Perspectives.*

You should also take into account the principles of the Treaty of Waitangi. In assessing the significance of Treaty issues, you should consider whether your application will impact on the ability of Maori to control their natural resources (including indigenous flora and fauna, waterways, and land), language or culture. You can find more information on Treaty of Waitangi considerations in the two documents mentioned above.

If you aren't sure how to fill out this section, contact an ERMA New Zealand Applications Officer who can tell you the kind of information required and whether or not it is likely to be necessary to consult with Maori. If you do consult with Maori, give details of that consultation in this section.

Section six of application form—International considerations

Section 6.1 of form—Consideration by any other regulatory authority

We are interested in whether the substance (or any of its components) has been considered by any other regulatory authority in New Zealand or any other country. We'll take into account any decisions made if the details of the decision are provided. If you are aware that an assessment has been made on the substance by any other jurisdiction, you should provide this information or a reference to it, eg state the registry or inventory numbers. Include specific information about where, what and by whom the decision was made. Just stating 'approved by US EPA' is not enough. However, until regulations are enacted that prescribe countries and organisations for this section, provision of this information is not mandatory.

Section seven of application form—Miscellaneous

Section 7.1 of form—Glossary

If you use terms from the interpretation in section 2 of the HSNO Act, you don't need to define those terms. However, we expect you to give definitions of all other technical terms used in your application.

Section 7.2 of form—Other relevant information

You should provide any other information that you consider relevant to the application but which does not fit clearly into any of the previous sections.

Section eight of application form—Summary of public information

Section 20 (1) of the HSNO Act requires the Authority to keep a public register of all applications. Summary information provided in section 8 of the application form may be used for the register. For this reason, you should ensure that this summary information does not contain any commercially sensitive material.

Section 8.1 of form—Name of the substance for the public register

Section 20 (2) (b) of the Act requires the public register of applications to contain a sufficient description to uniquely identify the substance. You should provide sufficient details of the name of the substance to meet this requirement (maximum of 80 characters).

If the identity of the new substance is commercially sensitive or if the application is for several similar (composition and property) substances, you may provide a generic chemical name or trade name, as long as this uniquely identifies the substance. The name should reveal the chemical identity of the substance to the maximum extent possible without giving away commercially sensitive information.

ERMA New Zealand will check the adequacy of any generic chemical name and if the name does not uniquely identify the substance, we will contact you to develop another name.

Section 8.2 of form—Purpose of the application for the public register

Section 20 (2) (c) of the Act requires the public register to specify the purpose of the application. This should explain (in a maximum of 255 characters) the intended use of the substance and why an application is needed, based on the hazardous properties.

Section 8.3 of form—Use categories of the substance

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identifies various functional uses of substances. This information is relevant to the assessment of exposure scenarios and for determining risk. It's also useful for building up a profile of the substance. There are three types of use categories, some of which include a number of subcategories (see Appendix 2 of this guide). We ask that you state which categories (and subcategories) are relevant to all the intended uses of the substance(s).

Section 8.4 of form—Executive summary

In this section, you need to provide a summary of the significant parts of your application. It is stressed that this information will be available for public scrutiny and as such, should not contain any commercially sensitive or confidential material. You should include a summary of:

- the identification of the substance, its hazardous properties, intended uses and disposal
- an assessment of the adverse effects of the substance
- information on the proposed containment.

Appendix one of application form—Confidential information

Any information that is commercially sensitive should be attached as an appendix. The main application should be cross-referenced and should be able to be read as a stand-alone document.

Part F

Application for emergency

Read this guide before filling in your application form (Form HS4) for approval to import, release from containment, or use any hazardous substance in an emergency under section 47 of the HSNO Act.

We recommend you read this User Guide before filling out your application form. If you have any queries, please contact an ERMA New Zealand Applications Officer who will be able to help you.

You can apply for more than one hazardous substance on one application form if the substances are related, eg a concentrated compound (active ingredient) and its related formulations.

Level of information to be provided

This type of application covers plans for the using substances in an emergency, and only in an emergency. The level of information you need to provide for an emergency application is less than that required for a full release application as the reduced level of exposure leads to a reduced level of risk. However, you must demonstrate to the Authority that the substance is necessary to deal with the emergency and you have developed a plan for using the substance in the emergency that will adequately control any adverse effects. If these criteria are met, then the Authority must approve the substance—the application cannot be declined.

In order to test the adequacy of the proposed management plan, you must provide all information relating to the adverse effects of the substance. You also need to consider the provisions set out in Part II of the Act, especially sections 5 and 6. However, you only need to refer to those matters that are specifically relevant to your application. You do **not** need to provide information relating to the benefits of the substance in order to show that that benefits outweigh the risks and costs. The Authority assumes that the use of the substance in managing the emergency is benefit enough.

Note that all commercially sensitive material should be attached as an appendix.

Section one of application form—Applicant details

You must provide full contact details for the ‘applicant’. The ‘applicant’ may be the name of a company, organisation, or the name of an individual. If the applicant is not an individual, you should include a contact name (section 1.3). This should be a person available by telephone during normal business hours in New Zealand, and who has sufficient knowledge to respond to queries. This person should also have the authority to make decisions on behalf of the applicant, or be able to go to the appropriate source for a decision.

Section two of application form—Application type and related approvals

Section 2.1 of form—Import, release or use

You must identify whether the application is for import to use in an emergency, release from containment to use in an emergency, or import **and** release from containment to use in an emergency. If the use of the substance in an emergency is in a manner that would otherwise contravene the provisions of the HSNO Act, you should say this. An example might be using a neutralising agent in the open environment in a way that would not be permissible if normal controls were applied.

Section 2.2 of form—Information on why substance is necessary

You must provide information to show why the specified hazardous substance is necessary to deal with the emergency. Include information such as:

- the type(s) of emergency situations that require the use of the substance
- the efficacy of the substance(s)
- why alternative means cannot be used—give reasons.

‘Need’ is one of the key criteria for justifying the use of section 47 to gain an approval. It is important that you provide enough information so that the need is clear to the Authority.

Section 2.3 of form—Other approvals required

Although not essential, it would be useful if you could indicate whether the hazardous substance(s) is subject to other New Zealand legislation requirements. This may include the Agricultural Compounds and Veterinary Medicines Act 1997, the Food Act 1981, the Medicines Act 1981, the Chemical Weapons (Prohibition) Act 1996, the Radiation Protection Act 1965, the Biosecurity Act 1993, the Resource Management Act 1991, or any other Act.

This allows us to do any sensible cross-checking with other agencies so that we can keep bureaucracy and cost to a minimum.

Section three of application form—Information on the substance

All commercially sensitive information must be attached as an appendix. The application form should be cross-referenced to the appendix but must be a stand-alone document that will be publicly available.

If you are applying for more than one hazardous substance, you need to complete this section separately for each hazardous substance.

For mixtures, if you are not privy to the formulation composition, you will need to arrange for the third party to supply the information directly to ERMA New Zealand. You will need this clearly indicated in this section.

Section 3.1 of form—The unequivocal identification of the substance(s)

This section must contain information to unequivocally identify the hazardous substance(s). If the substance(s) is not unequivocally identified, the application will not meet the statutory

requirements and will not be processed. The information may be supplied in any suitable format but may best be expressed in tabular form.

Where relevant, information identifying the substance in data packages provided for equivalent USA, EU and Australian processes is considered acceptable. You should provide the data package to ERMA New Zealand but if you can't, we may be able to source it on your behalf. However, we will charge for this service.

Listed below is an indication of the type of information required. It is not a comprehensive list, but shows the type of information needed. Provide any chemical names, synonyms, and relevant trade names whether or not they are registered brands/trade names.

- chemical name (eg the Chemical Abstracts Preferred Index name (CA name) or International Union of Pure and Applied Chemistry (IUPAC))
- common name (where relevant)
- synonyms (where relevant)
- trade names (where relevant)
- CAS registry number (where it is available)
- molecular formula (where relevant)
- structural formula (where relevant)
- information on impurities/contaminants. In most cases, you don't need to specify components present at levels less than 0.1% unless there are hazardous property reasons for including them. For example, any dioxin contaminants present, even in trace amounts, should be included if they are known to exist in the substance. If the substance contains a polymer, you should identify any unreacted monomers that may be present and the relevant percentages.

Mixtures—provide information on each component

As well as providing the above information on the actual mixture, you must provide the following information on the composition of the mixture for **each** component, including non-hazardous components and impurities. This information may be best expressed in tabular form (see Table 3.1).

- the name of each component
- the CAS number of each component (where relevant)
- the function (eg active ingredient, emulsifier, surfactant, solvent, filler) of each component
- the percent contribution of each component, ie the complete composition of the product/mixture. The total percentage should add up to 100 %.

Table 3.1 Example of composition information required for a mixture eg pesticide formulation

Name of component	CAS Number	Function	Composition (%)
<i>Glyphosate</i>	<i>1071-83-6</i>	<i>Pesticide</i>	<i>50%</i>
<i>Aluminium silicate</i>	<i>12141-46-7</i>	<i>Dispersant</i>	<i>30%</i>

<i>Silicon dioxide</i>	<i>7631-86-9</i>	<i>Anti-caking agent</i>	<i>10%</i>
<i>Nonyl phenol</i>	<i>25154-52-3</i>	<i>Surfactant</i>	<i>10%</i>

Applying for a range of substances

The interpretation of ‘substance’ in the HSNO Act includes ‘defined mixture of elements’ or ‘defined mixture of compounds’. Section 2(2) of the Act elaborates that ‘the definition of any mixture of elements or mixture of compounds may include a range of percentages of the elements or compounds making up the substance’.

Correspondingly, you can make a single application covering a group of substances, for example a series of products containing differing levels of key ingredients for dealing with different types of emergencies.

The maximum concentrations of all the components listed will generally be used when assessing the hazardous properties of the substance. Therefore you should ensure that the management plan you have in place for using the substance (see Section 4) will be suitable for all members of the group covered by the application. The percentages of the components can be given in ranges with the total percentage adding up to 100 % or more. This information may be best expressed in tabular form.

Section 3.2 of form—The chemical and physical properties of the substance(s)

In this section you should provide as much information as possible on the chemical and physical properties of the substance(s). This information may be relevant to the unequivocal identification of the substance(s) but is also relevant to the determination of specific hazard property endpoints (eg water solubility is relevant to aquatic toxicity, boiling point is relevant to flammability, and viscosity and physical form are relevant to aspiration hazard (toxicity)).

Where possible, these properties should be those evident at 20°C and 101.3 kPa, but if this information is unavailable, you must specify the relevant temperature and pressure conditions of the data provided. Where appropriate, you should include the relevant units for each test. This information may best be expressed in tabular form.

For mixtures, we would ideally like information on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of **each** hazardous component of the mixture.

Examples of properties we would like information about include:

- appearance (colour, odour, physical state or form)
- pH
- density
- vapour pressure
- boiling/melting point
- solubility in water
- water-octanol partitioning coefficient.

Section 3.3 of form—Hazardous property information

Information in section should be provided on the hazardous properties of the substance(s). You should consider **each** of the six hazardous properties listed below. It would be helpful for you to determine which of those hazardous properties trigger any threshold level because it won't generally be necessary to actively manage any hazardous properties below these thresholds.

For emergency applications, hazardous property information is required only to identify and assess the risks (adverse effects) so the adequacy of the management plan can be considered. It is not necessary to assign hazard classifications.

For mixtures, we would ideally like information on the hazardous properties of the mixture itself. However, if this information is not available, you should provide information on the hazardous properties of **each** hazardous component of the mixture.

The six hazardous properties are:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

You should also consider whether any one or more of the hazardous properties above would be generated if the substance came into contact with air or water (excluding situations where the temperature or pressure has been artificially increased or decreased).

In some cases, it may not be feasible for you to provide full information on the hazardous properties and we recognise that this will be the case for some imports. In these cases, we would suggest the following:

- Make as much comment as possible. If no information is available, then say so rather than not writing anything at all.
- If the material was sourced from overseas, for example, identify the name and location of the supplier and say what response you have had from the supplier in trying to obtain information.
- In some cases, it might be helpful to provide comparative information eg identify other substances which can be demonstrated to be more or less hazardous and about which more is known.

The *Summary User Guide to HSNO Thresholds and Classifications* has been prepared to assist you in determining whether a substance is hazardous. The *Substance Evaluation Sheet* in the guide leads you through a process of assessing whether a substance is hazardous or not by considering each of the six hazardous properties listed above.

You should provide as much information as you can on each of the six hazardous properties. If no studies are available you should note this, and not leave it blank, eg 'we have not been able to find any information on the flammable properties of the substance'. However, bear in mind where information about a hazardous property is not available, you must factor in this uncertainty when preparing your management plan, which must be capable of managing any adverse effects of the substance (see Section 4).

If you say that a particular hazardous property does not exceed any threshold, you should give appropriate supporting information, clearly referenced. In many cases a simple statement will do, eg 'the substance is not covered by the UN book so is not considered flammable'. However, in other cases, more comprehensive information will be necessary eg 'the substance is not an acute oral toxic as the LD50 in all species tested was greater than 5000 mg/kg body weight'. When citing reference sources, you should, if possible, provide the primary reference for the data rather than a secondary reference, ie give the full citation of a paper rather than referencing the Hazardous Substance Database (HSDB).

For those hazardous properties that trigger any threshold level, you should provide all relevant information, ie give a description of, or reference to, the test methods used, as well as citing the data sources and any appropriate references. Remember to include all relevant units. It's unlikely that an MSDS (Material Safety Data Sheet) alone will satisfy the data requirements, unless it is comprehensive and fully referenced. You can find information on preferred test methods in our *User Guide to HSNO Thresholds and Classifications*.

A summary table should be included at either the beginning or end of section 3.3, listing each of the six hazardous properties and whether each has triggered any threshold levels. It would also be helpful to indicate the level of hazard, either by reference to the hazard classifications set out in the HSNO regulations or by referring to the *User Guide to HSNO Thresholds and Classifications*.

Table 3.2 Example of summary table of hazardous property and threshold data of Substance X

Hazardous property	Threshold	Threshold ‘Trigger’ Data
Explosive	Not triggered	
Flammable <ul style="list-style-type: none"> • Liquid 	Triggered	Closed cup flashpoint 50 °C
Oxidising	Not triggered	
Corrosive	Not triggered	
Toxic <ul style="list-style-type: none"> • Acute oral • Acute dermal • Acute inhalation • Skin irritation • Eye irritation • Sensitisation • Mutagenic • Carcinogenic • Reproductive/developmental • Target organ/systemic 	Triggered Triggered Triggered Triggered Triggered Not triggered Not triggered Not triggered Triggered Triggered	LD ₅₀ rat 2800 mg/kg LD ₅₀ rat 3400 mg/kg LC ₅₀ mice 3130 ppm Draize Grade 4 Draize Grade 2 for corneal opacity reversed within 21 days of exposure Reproductive toxicant (foetal effects) Liver effects
Ecotoxic <ul style="list-style-type: none"> • Aquatic • Soil • Terrestrial vertebrate • Terrestrial invertebrate 	Triggered Not triggered Not triggered Not triggered	LC ₅₀ fish 80 mg/L (acute)

Section four of application form—Management of the substance

Section 4.1 of form—Providing management plan

The Authority needs to be assured that any risks (adverse effects) created by using the substance in an emergency will be properly controlled or managed. You must therefore provide a management plan for using the substance(s) in the emergency. Your management plan should include:

- what types of emergency the substance will be used to deal with, including other substances likely to be involved
- who will be using the substance(s)
- details on packaging, labelling, storage and transportation
- measures that will be taken to avoid, remedy or mitigate any actual or potential adverse effects arising from the use of the substance
- disposing of the substance and any waste products.

You should provide as much information as you can on each of these matters. It is emphasised that the effectiveness of your management plan is critical to your application being approved.

Section five of application form—Identifying and assessing risks

This part of the application form require you to identify and assess any risks (adverse effects) of the substance and determine whether or not your management plan (described in section 4) will be effective in managing the risks. You should refer to the control measures detailed in your management plan that will reduce the likelihood or the consequence of specific adverse effects. We are particularly interested in knowing whether there are any risks (residual risks) that can't be effectively managed by the management plan.

You should focus on providing information relating to the adverse effects of the substance in the circumstances in which it will be used, ie dealing with the emergency, but also consider potential risks that may arise when the substance is stored and transported to the site of the emergency. You should also provide a brief description on where the information was sourced.

If the Authority is satisfied that the proposed plan will adequately control the adverse effects of the substance, and it has been established that the substance is necessary to deal with the emergency, the application will be approved. Therefore you must provide comprehensive information in this section.

Information on the benefits of the substance is **not** required for emergency applications.

Section 5.1 of form—Identifying risks

When identifying risks, you should take into account the matters set out in Part II of the Act, specifically sections 5 and 6 (outlined below) and consider whether there are any significant risks that might exist in any of these areas. The information can be presented in a variety of formats but should be systematic. A simple table would be ideal (see Table 5.1).

- 1) The physical environment, including:
 - safeguarding the life-supporting capacity of air, water, soil and ecosystems
 - the sustainability of all native and valued introduced flora and fauna
 - the intrinsic value of ecosystems (those aspects of ecosystems that have value in their own right).

For emergency applications, the focus should be on whether there are any potential adverse effects in the environment that the substance is being used in eg if it's to be used in the marine environment to treat oil spills, consider whether there are any ecotoxic effects on marine organisms. You should also consider situations where the substance may enter the environment unintentionally, eg if there is an accident during storage or transportation.

- 2) Effects on humans, including:
 - human health (including public exposure and occupational exposure)
 - the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations.

As the substance will only be used in very specific circumstances (in an emergency), the most likely risk to humans will be to people dispensing the substance or to people in the immediate vicinity. However, you should also take into account the possibility that the substance may enter the wider environment either accidentally or as a result of intended use, and cause adverse effects on either public health or the economic, social and cultural well being of the community.

- 3) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu (sacred place), valued flora and fauna and other taonga (sacred treasures, prized possessions, property, anything which is highly prized). Section 5.2 below has guidance on this, but it's unlikely that such matters will be relevant given that the substance will only be used in very specific situations.
- 4) New Zealand's international obligations, eg situations where the Rotterdam Treaty on Prior Informed Consent or the Basel Convention on the Control of Transboundary Movements of Hazardous Waste are relevant.

Deciding whether a risk is potentially significant or not should be based on your knowledge of the substance and your view on how effective the management plan will be in preventing and managing any risks. If you aren't sure whether a risk is significant, you should include it. If you decide that a risk is not significant, you should explain why. If relevant, provide references to sources of data used. A detailed risk assessment is only necessary for those risks that have been identified as significant. If there are **no** significant risks, there is no need to carry out a risk assessment in section 5.2 below.

Table 5.1 Summary of risk identification of Substance X.

Source of Risk Event/Incident	Haz. Property	Possible reasons for event (including lifecycle)	Effect/Impact	Exposure Pathway
Release/spillage of substance (either onto land, in or near water, or into the air via vapours or aerosols)	Toxic Ecotoxic	<ul style="list-style-type: none"> • Transport accident (Import, transport) • Accident during use (Use) • Natural hazard eg earthquake (any stage) • Sabotage (any stage) • Damaged packaging (import, storage, transport, use) • Incorrect disposal (disposal) 	1. Adverse (acute) effect on human health – nausea, headache	Inhalation
			2. Adverse effect on aquatic environment - fish die	Substance enters waterway

Section 5.2 of form—Assessing significant risks

You should provide an assessment of the risks identified in section 5.1 as significant. Your assessment should include whether the (significant) risks identified can be adequately managed by the management plan described in section 4. If it is evident that significant risks remain despite the management plan, ie that the plan does not adequately control the adverse effects of the substance, the Authority may decline the application.

The risk assessment process integrates what the hazards are, the magnitude and likelihood of them occurring, how and when they are likely to occur and who or what is likely to be affected. In carrying out your risk assessment, you should consider the following:

- What is the nature of the hazardous substance and how serious are the risks, ie what are the potential consequences from the hazard, eg burns, fatal poisoning?
- What is the likelihood/probability of the adverse effect occurring?
- What is the magnitude of the effect? In estimating the magnitude, you should consider whether the risks will be localised geographically or distributed more widely, whether particular groups in the community may be more affected than others, whether the risk will persist over time and whether any potential adverse effects are irreversible or reversible?
- What are the uncertainty bounds of the information used in the assessment (ie how reliable is it)?

For significant risks, assessments can be quite involved and are best done by experienced risk assessors. However, if you wish to work through this section yourself, ERMA New Zealand has produced the following Technical Guides to assist you:

- *Identifying Risks*
- *Preparing Information on Risks, Costs and Benefits*
- *Assessment of Effects of Hazardous Substances and New Organisms on Human Health.*

Assessing risk to Maori.

It is emphasised that for emergency applications, risk to Maori is unlikely to be an issue given that the substance will only be used in limited circumstances. However, if you have identified that there may be potentially significant risks in this area, you should provide an assessment of the likelihood (probability) of the adverse impact on Maori and estimate how severe that impact may be. The magnitude of risks may be influenced by whether the risk is limited to a geographical region or will affect Maori generally. To help you identify issues of significance to Maori, we have prepared the following documents:

- *User Guide to Working with Maori under the HSNO Act 1996*
- *Protocol 1 Series 2 Taking Account of Maori Perspectives.*

You should also take into account the principles of the Treaty of Waitangi. In assessing the significance of Treaty issues, you should consider whether your application will impact on the ability of Maori to control their natural resources (including indigenous flora and fauna, waterways, and land), language or culture. You can find more information on Treaty of Waitangi considerations in the two documents mentioned above.

If you aren't sure how to fill out this section, contact an ERMA New Zealand Applications Officer who can tell you the kind of information required and whether or not it is likely to be necessary to consult with Maori. If you do consult with Maori, give details of that consultation in this section.

Section six of application form—International considerations

Section 6.1 of form—Consideration by any other regulatory authority

We are interested in whether the substance (or any of its components) has been considered by any other regulatory authority in New Zealand or any other country. We'll take into account any decisions made if the details of the decision are provided. If you are aware that an assessment has been made on the substance by any other jurisdiction, you should provide this information or a reference to it, eg state the registry or inventory numbers. Include specific information about where, what and by whom the decision was made. Just stating 'approved by US EPA' is not enough. However, until regulations are enacted that prescribe countries and organisations for this section, provision of this information is not mandatory.

Section seven of application form—Miscellaneous

Section 7.1 of form—Glossary

If you use terms from the interpretation in section 2 of the HSNO Act, you don't need to define those terms. However, we expect you to give definitions of all other technical terms used in your application.

Section 7.2 of form—Other relevant information

You should provide any other information that you consider relevant to the application but which does not fit clearly into any of the previous sections.

Section eight of application form—Summary of public information

Section 20 (1) of the HSNO Act requires the Authority to keep a public register of all applications. Summary information provided in section 8 of the application form may be used for the register.

We also use this summary information to inform those people and agencies (eg Ministry for the Environment, Department of Conservation, Department of Labour, Ministry of Health, etc), who may be notified of the application. It's also sent to potential submitters who are interested in the application. Summary information will also be used to prepare the public notice of the application.

For these reasons, you should make sure that your summary information does not contain any commercially sensitive material.

Section 8.1 of form—Name of the substance for the public register

Section 20 (2) (b) of the Act requires the public register of applications to contain a sufficient description to uniquely identify the substance. You should provide sufficient details of the name of the substance to meet this requirement (maximum of 80 characters).

If the identity of the new substance is commercially sensitive or if the application is for several similar (composition and property) substances, you may provide a generic chemical name or trade name, as long as this uniquely identifies the substance. The name should reveal the

chemical identity of the substance to the maximum extent possible without giving away commercially sensitive information.

ERMA New Zealand will check the adequacy of any generic chemical name and if the name does not uniquely identify the substance, we will contact you to develop another name.

Section 8.2 of form—Purpose of the application for the public register

Section 20 (2) (c) of the Act requires the public register to specify the purpose of the application. This should explain (in a maximum of 255 characters) the intended use of the substance and why an application is needed, based on the hazardous properties.

Section 8.3 of form—Use categories of the substance

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identifies various functional uses of substances. This information is relevant to the assessment of exposure scenarios and for determining risk. It's also useful for building up a profile of the substance. There are three types of use categories, some of which include a number of subcategories (see Appendix 2 of this guide). We ask that you state which categories (and subcategories) are relevant to all the intended uses of the substance(s).

Section 8.4 of form—Executive summary

In this section, you need to provide a summary of the significant parts of your application. It is stressed that this information will be available for public scrutiny and as such, should not contain any commercially sensitive or confidential material. You should include a summary of:

- the identification of the substance, its hazardous properties and intended uses
- information showing why the substance is necessary to deal with the emergency
- an assessment of the adverse effects of the substance
- information on the proposed management plan for dealing with the use of the substance in an emergency.

Appendix one of application form—Confidential information

Any information that is commercially sensitive should be attached as an appendix. The main application should be cross-referenced and should be able to be read as a stand-alone document.

Appendix 1

Definitions used in the Act

Substance means:

- (a) any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof
- (b) any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which has been declared by the Authority, by notice in the *Gazette*, to be a different substance from that element or compound
- (c) any mixtures or combinations of any of the above
- (d) any manufactured article containing, incorporating, or including any hazardous substance with explosive properties.

Hazardous substance means any substance:

- (a) with one or more of the following intrinsic properties:
 - (i) explosiveness
 - (ii) flammability
 - (iii) a capacity to oxidise
 - (iv) corrosiveness
 - (v) toxicity (including chronic toxicity)
 - (vi) ecotoxicity, with or without bioaccumulation; or
- (b) which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (a) of this definition.

Containment is defined by the Act as ‘restricting a substance to a secure location or facility to prevent escape’. [This is usually achieved through the establishment of barriers (physical and procedural) to prevent release of the substance to the uncontrolled environment].

Environment includes:

- ecosystems and their constituent parts, including people and communities
- all natural and physical resources
- amenity values
- the social, economic, aesthetic, and cultural conditions which affect the matters stated in paragraphs (a) to (c) of this definition or which are affected by those matters.

Importation, in relation to hazardous substances, means the arrival of the goods in New Zealand in any manner whatever, whether lawfully or unlawfully, from a point outside New Zealand; and to ‘import’ and ‘imported’ have corresponding meanings. (This includes goods in

transit that remain on a craft or vessel, as well as goods which are removed for short-term storage prior to re-export).

Manufacture is not specifically defined by the Act which simply states that ‘manufacture, in relation to a hazardous substance, **includes** the mining or extraction of any hazardous substance’. Therefore the dictionary definition prevails which defines manufacture as ‘the process by which something is made into a form suitable for use or sale’. In the context of hazardous substance applications, manufacture also includes the preparation of formulations.

Appendix 2

Use categories

The three categories developed by the European Union and adopted by ERMA New Zealand are:

- main category
- industry category
- function/use category.

Main Category:

There are four main categories, which are relevant to potential exposure scenarios throughout the life of the substance. These are

1. **Use in closed systems.** A substance should be assigned to this category if it remains within a reactor or is transferred from a vessel through closed pipe-work and therefore accidental spillage is the only likely cause for human exposure or environmental contamination. Intermediates are restricted to the reaction vessel and its dedicated equipment. Isolated products are stored on-site or are transported under controlled conditions. Where substances are used in closed systems but might be released into the environment after production, or where significant discharges to the environment cannot be excluded during production, the use pattern should be assigned to the 'non-dispersive use' or the 'wide dispersive use' categories. The substances should be assigned to one of the following sub-categories:
 - 1A non-isolated intermediates; for substances restricted to the reaction vessel and its dedicated equipment
 - 1B isolated intermediates; for intermediates stored on-site
 - 1C isolated intermediates with controlled transport.
2. **Use resulting in inclusion into or onto a matrix.** Use consisting of inclusion into or onto a matrix means all processes where substances are incorporated into products or articles from which release into the environment would not take place (environment) or is substantially curtailed (workplace). Examples relevant for environmental exposure: inclusion of plasticisers in plastics; additives such as pigments or dyes in plastic or fibres; catalysts in coating materials. Examples relevant for occupational exposure: dispersion of solids in water; use of raw materials in pellet form; use of elastomer master batches.
3. **Non-dispersive use.** Non-dispersive use refers to processes in which substances are used in such a way that only certain groups of workers with knowledge of the processes come into contact with these substances. These substances may also be discharged into the environment from point sources. Quantities discharged will be limited due to protective measures such as waste water treatment or filtration of air.
4. **Wide dispersive use.** Wide dispersive use refers to activities which deliver uncontrolled exposure. Examples relevant for occupational exposure: painting with paints; spraying of

pesticides. Examples relevant for environmental/consumer exposure: use of detergents, cosmetics, disinfectants, household paints.

Industry category: There are 16 industrial categories, which represent industrial uses of the substance. Some substances will be used in more than one industrial category.

0. Others. Category for substances used in industries not covered by those listed below.
1. Agricultural industry. eg plant protection products; fertilizers.
2. Chemical industry: basic chemicals. eg solvents; pH regulating agents (acids, alkalis).
3. Chemical industry: chemicals used in synthesis. eg intermediates (including monomers); process regulators.
4. Electrical/electronic engineering industry. eg electrolytes; semiconductors but **NOT** galvanics; electroplating agents.
5. Personal/domestic. eg consumer products such as detergents (including additives); cosmetics; agricultural pesticides for domestic use.
6. Public domain. eg professional products used in public areas as non-agricultural pesticides, cleaning agents, products used in offices such as correction fluids, printing inks.
7. Leather processing industry. eg dyestuffs, tanning auxiliaries.
8. Metal extraction industry, refining and processing industry. eg heat transferring agents.
9. Mineral oil and fuel industry. eg gasoline; motor oil; gear oil; hydraulic fluid; colouring agents; fuel additives; antiknock agents; waste oil detoxification agents.
10. Photographic industry. eg antifogging agents; sensitisers.
11. Polymers industry. eg stabilisers; softeners; antistatic agents; dyestuffs.
12. Pulp, paper and board industry. eg dyestuffs; toners.
13. Textile processing industry. eg dyestuffs; flame retardants.
14. Paints, lacquers and varnishes industry. eg solvents; viscosity adjusters; dyestuffs; pigments.
15. Engineering industry: civil and mechanical. eg agents used in construction work; agents used in automobile, aircraft and ship building.

Function/Use category: There are 55 categories, which represent various functional uses of the substance. Some are divided up into sub-categories where appropriate. For clarity, exclusions are indicated in some cases.

0. Others. Substances whose technical functions are not described by any other category.
1. Absorbents and adsorbents. Materials used to absorb or adsorb gases or liquids; filter material/media; molecular sieves; silica gel etc.
2. Adhesives, binding agents. Materials which are applied to two surfaces causing them to adhere: dispersion based adhesives, hotmelt, resins for polymer-based hardening adhesives, solvent based adhesives.
3. Aerosol propellants. Compressed or liquefied gases within which substances are dissolved or suspended and expelled from a container upon discharge of the internal pressure through expansion of the gas.
4. Anti-condensation agents. Substances used to avoid condensation on surfaces and in the atmosphere: anti-dim agents, condensation removers.

5. Anti-freezing agents. Substances used to prevent and remove ice formation: anti-freeze liquids, de-icing agents.
6. Anti-set-off and anti-adhesive agents. Substances used to prevent set-off and adhesion: spraying powder and anti-set-off additives for printing; oils and waxes for lathes and shuttering; casting slip etc.
7. Anti-static agents. Substances used to prevent or reduce the tendency to accumulate electrostatic charges: anti-static additives; substances for surface treatment against static electricity.
8. Bleaching agents. Substances used to whiten or decolourise materials but **NOT** cosmetics; photographic bleaches; optical brighteners.
9. Cleaning/washing agents and additives. Substances used to remove dirt or impurities from surfaces. **Subcategories:** detergents; soaps; dry cleaning solvents; optical brighteners in detergents.
10. Colouring agents. Substances used to impart their colour to other materials. **Subcategories:** dyestuffs; pigments (including toners); colour forming agents; fluorescent brighteners (but note the following exclusion regarding detergents) **NOT** cosmetics; food colours; photo-chemicals; optical brighteners used exclusively in detergents; reprographic agents.
11. Complexing agents. Substances used to combine with other substances (mainly metal ions) to form complexes.
12. Conductive agents. Substances used to conduct electrical current. **Subcategories:** electrolytes, electrode materials.
13. Construction materials additives. Substances used in building materials and constructional articles: wall construction materials; road surface materials, ceramic, metal, plastic and wooden construction materials.
14. Corrosion inhibitors. Substances used to prevent corrosion: corrosion inhibiting additives; rust preventives.
15. Cosmetics. Substances used as components of cosmetic and toiletry formulations.
16. Dust binding agents. Substances used to control finely divided solid particles of powdered or ground materials to reduce their discharge to air.
17. Electroplating agents. Substances used as a source for a layer of metal deposited on another surface; or that aid such a deposition.
18. Explosives. Substances or mixtures that are characterised by chemical stability but that may be made to undergo chemical change, rapidly producing a large quantity of energy and gas accompanied by bursting or expansion. **Subcategories:** blasting agents; detonators; incendiaries.
19. Fertilisers. Substances used to supply chemical elements needed for plant nutrition.
20. Fillers. Relatively inert and normally non-fibrous finely divided substances added to elastomers, plastics, paints, ceramics etc., usually to extend volume which may improve desired properties such as whiteness, lubricity, density or tensile strength.
21. Fixing agents. Substances used to interact with a dye on fibres to improve fastness.
22. Flame retardants and fire preventing agents. Substances incorporated into, or applied to the surface of, materials to slow down or prevent combustion.
23. Flotation agents. Substances used to concentrate and obtain minerals from ores: flotation oil; flotation depressants.
24. Flux agents for casting. Substances used to promote the fusing of minerals or prevent oxide formation.

25. Foaming agents. Substances used to form a foam or cellular structure in a plastic or rubber material: physically by expansion of compressed gases or vaporisation of liquid, or chemically by decomposition evolving a gas. **Subcategories:** chemical or physical blowing agents; frothers.
26. Food/feedstuff additives. Substances used in food or animal feedstuffs to produce or enhance taste, odour or colour or to improve conservation.
27. Fuels. Substances used to evolve energy in a controlled combustion reaction.
Subcategories: gasoline; kerosene; gas oil; fuel oil; petroleum gas; non-mineral oil.
28. Fuel additives. Substances added to fuels. **Subcategories:** antifouling agents; anti-knock agents; deposit modifiers; fuel oxidisers.
29. Heat transferring agents. Substances used to transmit or to remove heat from a material.
Subcategories: cooling agents; heating agents.
30. Hydraulic fluids and additives. Fluids used for transmitting pressure.
31. Impregnation agents. Substances used to admix with solid materials, which retain their original form: impregnating agents for leather, paper, textile and wood but **NOT** flame retardants, conserving agents, biocides.
32. Insulating agents. Agents used to prevent or inhibit the flow of electrical current, heat or light or the transmission of sound.
33. Intermediates. Substances used for synthesis of other chemicals **Subcategories:** monomers; pre-polymers.
34. Laboratory chemicals. Substances used in laboratories for analytical purposes.
35. Lubricants and additives. Substances entrained between two surfaces and thereby used to reduce friction: oils; fats; waxes; friction reducing additives.
36. Odour agents. Substances used to produce, enhance or mask odour but **NOT** food additives; cosmetics.
37. Oxidising agents. Substances that give up oxygen easily, remove hydrogen from other substances, or accept electrons in chemical reactions, and are used for such purposes.
38. Pesticides. Active ingredients and preparations containing one or more active ingredients, intended to protect plants or plant products against harmful organisms or prevent the action of such organisms, influence the life processes of plants, preserve plant products, destroy undesirable plants or destroy parts of plants but **NOT** nutrients, fertilisers.
39. Pesticides, non-agricultural. Active substances and preparations containing one or more active substances, intended to destroy, deter, render harmless, prevent the action of or otherwise exert a controlling effect on any organism which has an unwanted presence for man, or a detrimental effect for man, his activities or the products he uses or produces; or for animals or for the environment. **Subcategories:** disinfectants, preservative products, pest control products, specialist biocides **NOT** plant protection products; veterinary products.
40. pH regulating agents. Substances used to alter or stabilise the hydrogen ion concentration (pH): acids; alkalis; buffers.
41. Pharmaceuticals. Substances used as active ingredients in medicinal preparations.
Subcategories: veterinary medicines.
42. Photo-chemicals. Substances used to create a permanent photographic image.
Subcategories: desensitisers; developers; fixing agents; photosensitive agents; sensitisers; anti-fogging agents; light stabilisers; intensifiers.
43. Process regulators. Substances used to regulate the speed of a (chemical) process.
Subcategories: accelerators; activators; catalysts; inhibitors; siccatives; anti-siccatives; cross-linking agents; initiators; photo-initiators etc

44. Reducing agents. Substances used to remove oxygen, hydrogenate, or in general, act as electron donors in chemical reactions.
45. Reprographic agents. Substances used to reproduce a permanent image. **Subcategories:** toner for photocopying machines, toner additives.
46. Semiconductors. Substances having resistivities that are between those of insulators and metals, and are usually changeable by light, heat or electrical or magnetic field, or generate electromotive force upon the incidence of radiant energy. **Subcategories:** semi-conductors, photovoltaic agents.
47. Softeners. Substances used for softening materials to improve feel, to facilitate finishing processes or to impart flexibility or workability. **Subcategories:** coalescing agents; bates (leather technology); devulcanising agents; emollients; swelling agents; water softeners, plasticisers.
48. Solvents. Substances used to dissolve, thin, dilute and extract: extraction agents; solvents and thinners for paints, lacquers, adhesives and other materials.
49. Stabilisers. Substances used to prevent or slow down spontaneous changes in, and ageing of, materials. **Subcategories:** anti-oxidants; heat stabilisers; light stabilisers; scavengers; charge stabilisers.
50. Surface-active agents. Substances used to lower the surface and/or interfacial tension of liquids and promote cleaning, wetting, dispersion etc.
51. Tanning agents. Substances used for treating hides and skins.
52. Viscosity adjusters. Substances used to modify the flow characteristics of other substances, or mixtures, to which they are added. **Subcategories:** pour point depressants; thickeners; thixotropic agents; turbulence suppressors; viscosity index improvers.
53. Vulcanising agents. Substances added to rubber to aid and hasten vulcanisation: vulcanisation accelerators and vulcanising assistants.
54. Welding and soldering agents. Materials used for welding and soldering; electrodes; flux; powdered metal; wire etc.