

## A QUICK GUIDE TO

# APPLYING FOR A HAZARDOUS SUBSTANCE APPROVAL

*ERMA New Zealand's Quick Guides series is designed to give you a simplified and user friendly guide to our operations*

## INTRODUCTION

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This guide tells you what you need to do when making an application for approval to import or manufacture a hazardous substance.

It offers guidance on what information to present in an application, how applications are handled, and how to address important issues, including consultation with Māori and other interested parties.

Some definitions and other basic information are provided. To complement this guide we suggest that you read our Quick Guide on *Making an Application* which gives more general information on the application process.

## HAZARDOUS SUBSTANCES – WHAT ARE THEY?

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A hazardous substance is any substance that may be: explosive, flammable, able to oxidise, corrosive, toxic or ecotoxic.

Most of us use hazardous substances every day at home and at work. We are also broadly familiar with the most important risks they pose, for example:

- the flammability of methylated spirits or petrol
- the oxidising capacity of a common household bleach
- the ecotoxic nature of some garden chemicals.

In reality, most hazardous substances have more than one hazardous property, that is, they are hazardous in a number of ways. For example, methylated spirits and petrol are not only flammable but also toxic. Some common garden pesticides not only kill garden pests but also beneficial organisms, and may be toxic to humans.

Anyone who uses or is involved with hazardous substances needs good information on their potential risks and how to use them safely. The HSNO Act provides a platform for completely describing a hazardous substance so that it can be managed appropriately.

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## NEW LAWS ON HAZARDOUS SUBSTANCES – DO THEY AFFECT ME?

The law affects sectors that are involved with or use hazardous substances, such as:

- importers and manufacturers
- petroleum fuels industry
- the agriculture, horticulture and forestry sectors, and
- research and educational laboratories.

Anyone importing or manufacturing a new hazardous substance in New Zealand needs to be aware of the requirements under the HSNO Act. All new substances will need to go through the ERMA approval process if they have hazardous properties that exceed the thresholds established by regulations under the Act.

If you import or manufacture a hazardous substance that has been notified, licensed or permitted under previous laws, you can continue to do so, providing it is either covered by the transitional provisions or has been transferred to being an approved hazardous substance.

Included here are hazardous substances that have previously been:

- notified to, or scheduled by, the Ministry of Health under the Toxic Substances Act
- registered under the Pesticides Act
- authorised as an explosive, or
- covered by the Dangerous Goods Act.

ERMA New Zealand will transfer them to the new HSNO regulatory framework during a transitional period. Most hazardous substances will be covered in this way. More information on the transfer process is covered by *Quick Guide to the Transfer of Substances*.

### DO I NEED TO MAKE AN APPLICATION?

Only new substances, ie substances which are not covered by the transitional provisions or do not already have a HSNO approval, and that are hazardous under the HSNO Act, need an application for approval. Applicants themselves, in the first instance, are responsible for determining whether the substance is hazardous. If requested we can issue a formal determination on whether or not a substance is hazardous, but you should check to see how much this would cost.

An Information Sheet on *Determining the Status of a Hazardous Substance* is available from ERMA New Zealand provide more detail on this process.

The *User Guide to Thresholds and Classifications* gives a summary of how to decide whether or not a substance is hazardous, ie its explosiveness, flammability, ability to oxidise, corrosiveness, toxicity or ecotoxicity. Accompanying this is a substance evaluation sheet which is designed to guide you simply through the process of assessing whether an application is needed.

Exemptions from the Act may also apply in some circumstances, such as when the hazardous substance is being used in small-scale chemistry in scientific investigations or teaching being undertaken in laboratories that meet the requirements of the

HSNO regulations, some foods, and some medicines. For more information on exemptions see the Information Sheet on *Exemptions* and Information Sheet on *Manufactured Articles*.

If you **do** need to make an application to import or manufacture a hazardous substance, you need to fill out an ERMA application form. There are a number of application forms and you will need to make sure you have the right one.

### APPLICATION FORMS

There are six different application types and each requires a separate form. This is to make it easier for you to be informed about the requirements.

**Importation or manufacture of a hazardous substance for release (rapid assessment).** An application of this type must meet either of two criteria (There are separate forms for these criteria). The first criterion is that it must have a similar composition and similar hazardous properties to a substance that already has a HSNO approval. For more information on what similar means see our publication *User Guide to making an Application for a Hazardous Substance Approval*.

The other criterion is that all its hazardous properties must not be above certain thresholds. Again this is dealt in more detail in our publication *User Guide to making an Application for a Hazardous Substance Approval*.

**Importation or manufacture of a hazardous substance for release.** This is for all applications for the release of a new hazardous substance that don't meet the rapid assessment criteria above. The majority of applications are expected to be of this type. Because the substances will cover a wide range eg from a specialty industry chemical at one extreme, to a new agricultural pesticide at the other extreme, information requirements will vary widely. This is commented on in the next section. See our publication, *User Guide to making an Application for a Hazardous Substance Approval*.

**Importation or manufacture of a hazardous substance in containment.** This is for applications where the substance is not for commercial release and will be used in containment. It applies only to specified purposes. Examples include the use of a chemical as a test standard, and field trials of a pesticide.

**Importation or manufacture of a hazardous substance for use in an emergency.** An emergency in this context means a foreseeable event. An example would be for a dispersing agent to combat a particular type of oil spill. An approval would mean that this substance (which may not meet approval requirements under other sections) could be used but only for this particular emergency.

**Transshipment of a hazardous substance.** Transshipment approvals are required for any hazardous substance entering New Zealand which is imported solely for the purpose of export within 20 working days and does not already have an approval from the Authority.

## WHAT INFORMATION DO I NEED TO SUPPLY WITH MY APPLICATION?

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### General requirements

ERMA New Zealand has prepared a detailed document, *User Guide to making an Application for a Hazardous Substance Approval*, to help with the process of making an application.

The level of information that you are required to submit will depend on the level of risk. The onus is on you to provide this information. Applications with inadequate or insufficient information may be declined, or may take a lot longer to process and cost you more.

For full release applications, your application needs to include information on the identification of the substance, its properties and intended uses, and the identification, assessment and management of possible adverse effects or risks. Sufficient information needs to be provided to enable all the hazardous properties of the substance to be classified. The management of risks is achieved by the imposition of controls. Appropriate controls are assigned to each hazard classification. Further information on controls and their relationships to the hazard classification system is contained in the *User Guide to the HSNO Control Regulations*. You will also need to provide information on costs and benefits.

For applications made under the rapid assessment route, you will not need to supply full information but compare and contrast with the 'similar' substance. For a low hazard rapid assessment application, the information required will also be even less.

For a containment application, you will need to supply information on the identification of the substance, its properties and intended uses and the quantities involved. Information on the proposed containment and management system is important. You should also discuss the identification, assessment and management of possible adverse effects or risks.

An application for use in an emergency will require information on why the substance is necessary, the identification of the substance, its properties, the proposed management plan for the substance, and an identification and assessment of risks.

### Information from other jurisdictions

Overseas approvals will not directly translate into an ERMA approval because of the specific requirements of the HSNO Act. However, assessment information from other jurisdictions will often be very useful. When referring to decisions by other jurisdictions, you need to include specific information about where, what, how, and by whom the decision was made. It is the assessment information from the other jurisdictions that is important, not the approval itself.

The main criteria for acceptability of information from other processes and agencies will be that the data:

- meet the requirements of a reputable international process
- are recognised by a reputable international agency
- can be verified by ERMA New Zealand
- meet the requirements of the HSNO Act, and
- are applicable to the New Zealand social, cultural, institutional and natural environment.

This type of information will be considered on a case-by-case basis.

### Māori perspectives

The HSNO Act identifies risks to Māori culture and taonga as matters to be considered in making decisions on applications. Our *Quick Guide to Making Applications* gives more detail on what to do and where to get advice.

We do not expect most straightforward 'low risk' applications to raise issues of concern to Māori, although major applications very often may. If in doubt ask our advice.

### Forwarding an application

You should submit one typed copy of the application well in advance of the actual need to import or manufacture the substance. You will also need to enclose the appropriate fee (see *Quick Guide to Fees and Charges*). You will receive written notice that your application has been received and, possibly, a request for additional information or clarification. You may withdraw an application at any time, but you will be liable for any costs incurred by ERMA New Zealand up to that time.

## DO I NEED OTHER APPROVALS?

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HSNO is the principal law for managing the import or manufacture of hazardous substances, but parallel approvals may also be needed under a number of other pieces of legislation. For example, in the case of substances used for agriculture, you may need to make an application under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.

## A NOTE ABOUT CONFIDENTIALITY

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Commercially sensitive information can be protected. If you send us commercially sensitive information, you need to send it as a completely separate document and clearly identify it as confidential, so that it can be handled securely.

ERMA New Zealand considers that information such as trade name, name of manufacturer and applicant, physicochemical data, summary of toxic and ecotoxic properties/test results, disposal information for rendering the substance harmless etc, may not be treated as confidential without good justification.

It is important that there is a clear understanding of confidentiality **before** the application is lodged and the commercially sensitive information is supplied. The Authority needs to be able to release sufficient information so that, where appropriate, the public notification and register requirements of the Act can be met, and the decision and any residual risks posed by the substance can be adequately explained.

## WHAT WILL AN APPLICATION COST?

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We are obliged to operate on a cost recovery basis, though the Crown currently makes a contribution to ERMA New Zealand's costs associated with public participation. The actual costs in each instance will vary considerably according to the nature and complexity of the issues.

We have published a list of fees and charges, and will provide an estimate of likely costs in specific instances on request.

## **HOW WILL MY APPLICATION BE HANDLED?**

All hazardous substance applications will generally follow one of two main processing paths. These are:

### **Publicly notified application (for approval to import or manufacture a hazardous substance for release)**

In this case, hazardous substance importers or manufacturers have to provide a non-confidential summary of the information provided with the application. You must expect that this summary will be made readily available to the public. It will also be the basis of any public notice relating to the application.

The application needs to be publicly notified so that people who may wish to make submissions are aware of it. You need to consider the prospect of a hearing.

Under the Act, the Authority has up to 85 working days to process a notified application. Processing can take longer if further information is required, or if there are complex issues for the Authority to consider.

### **Non-publicly notified application (for rapid assessment, containment, emergency, and transshipment)**

There is no opportunity for public submissions and the approval process is shorter.

## **PUBLIC NOTIFICATION, SUBMISSIONS AND HEARINGS**

Formal public notice of receipt of an application will be made by placing an alert in the major newspaper, by posting it on our website and in our monthly Bulletin. We will also advise those who have indicated that they have an interest in that type of application.

Anyone may make a submission to the Authority on any publicly notified application. The submission must be in writing and should include any decision sought, reasons, and whether a hearing is requested.

We may suggest an informal meeting at the pre-hearing stage, involving both the applicant and submitters. Identifying and discussing relevant information at this stage may help clarify areas of dispute.

We will arrange a public hearing for a notified application if you or any submitters request it, or if we consider it necessary.

## **NEED MORE INFORMATION?**

Please do not hesitate to get in touch with the ERMA New Zealand if you have any more questions. Our contact details are on the front of this Quick Guide.

### **Other relevant publications include:**

*User Guide to Thresholds and Classifications*

*User Guide to Making an Application for a Hazardous Substance Approval*

*User Guide to Working with Māori under the HSNO Act 1996*

*User Guide to the HSNO Control Regulations*

*Information Sheet on Section 33 – Exemptions*

*Information Sheet on Estimated Prices for Hazardous Substance Applications*

*Quick Guide to Making Applications*

*Quick Guide to Fees and Charges*

*Protocol, Information Requirements for Hazardous Substance Applications No 4, Series 2*

*Ministry for the Environment HSNO Guide*

HSNO Website, [www.hsno.govt.nz](http://www.hsno.govt.nz)