

A QUICK GUIDE TO

MAKING APPLICATIONS

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

THE APPLICATION PROCESS – AN OVERVIEW

This guide sets out in simple steps the process of making an application to ERMA New Zealand under the HSNO Act to introduce a hazardous substance or new organism. On the back page is a wiring diagram that takes you – step by step – through the process.

This guide sets out general requirements for applications. Two other Quick Guides are available which deal in more detail with new organisms and hazardous substance applications respectively.

The process usually begins before an application is even made. This reflects our wish for issues to be discussed informally as a first stage. Experience to date shows that liaison early on will pay dividends.

When an application is made, it is vital that all of the information for decision-making is provided. Otherwise the approval process is likely to be suspended while we wait for further information.

LET'S TALK: THE PRE-APPLICATION STAGE

Right from the start, we want to stress the importance of getting your application on the right track. The first thing to do is to confirm whether you need to make an application.

If you do, approvals can be streamlined by having a talk with one of our staff at the earliest opportunity. This helps us establish with you what supporting information is needed, and means we can discuss the process and timelines.

These first steps help us ensure that applications are sound and help applicants know what to expect from the approvals process. An early meeting will also pinpoint scientific, technical and risk management issues and promote efficient processing. We can also help identify people you should consult with.

IN THE DOOR: PREPARING AND SUBMITTING AN APPLICATION

To make decisions on applications, we need a range of information from applicants.

You will need to support your case with sound information. There needs to be an adequate description of the substance or organism and its possible risks, costs and benefits. That means its effects on the physical environment and on public health and safety, including social and cultural impacts. The information should reflect the significance of the issues.

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In general terms, the more significant the effects, the more information you will need to provide us with.

Our application forms contain a brief account of the sort of information needed for each type of application. To obtain more detail, you may also want to consult the relevant User Guide on making an application.

Once an application is lodged and provided it is accompanied by the correct payment, ERMA New Zealand will check it to make sure we have enough information to proceed. In accordance with the Act, we will then begin our decision-making process within 10 working days.

When we receive your application, we'll advise you of the next steps and we'll take you through the sequence and timing of events.

IDENTIFYING AND ASSESSING RISKS, COSTS AND BENEFITS

Making decisions under the HSNO Act is initially about weighing up risks, costs and benefits. In the text below, we just refer to risks. But you should read this to include costs and benefits as well.

You should note that there are some types of application (particularly 'rapid assessments' but some others as well) which do not require a full risk analysis. But for most applications you will need to show you have identified and assessed the relevant risks of your hazardous substance or new organism.

The types of risks you need to think about include:

- risks to the life supporting capacity of air, water, soil and ecosystems
- the ability of people and communities to provide for their economic well-being, their social and cultural well-being, and the reasonably foreseeable needs of future generations
- the sustainability of all native and valued introduced flora and fauna and the inherent value of ecosystems
- public health
- the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga
- the economic and other benefits and costs arising from the use of a particular hazardous substance or new organism
- New Zealand's international obligations.

Some types of applications will require additional risks or issues to be considered.

A note about consultation

Consultation may play an important role in putting together an application under the HSNO Act. The Authority's key requirement is for relevant information. This may require consultation but not always. Applicants need to apply the test of common sense.

How do I identify risks, costs and benefits?

Identifying the relevant risks, costs and benefits means looking at all the ways the substance or organism can affect people, communities, and the natural environment. ERMA New Zealand has published a Technical Guide on risk assessment that provides further guidance.

What do I do next?

Once you have pinpointed the relevant risks, costs and benefits, you need to think about what kind of broad category they fall into. This helps to work out how much more attention they need to be given. When putting risks into categories you need to think about all the ways the risks could be managed.

How do I assess each risk, cost and benefit?

It is your responsibility as an applicant to provide evidence that you have taken a structured and systematic approach to identifying risks, costs and benefits associated with your application.

The idea of risk identification is to minimise the impact of 'unknown risk', by adopting a systematic and transparent approach to identifying all of the risks that might be relevant.

Risk assessment is the process of analysing a wide range of possible outcomes (in this case resulting from the approval of an application) to determine what might happen and how sources of risk (or hazard) must be identified and described, and then the pathways investigated by which harm might occur. Each risk identified needs to be understood in terms of the combination of magnitude of effect or consequence and the likelihood of those consequences occurring.

The amount of detail required depends on how serious the risk is.

You also need to think about how best to gather the relevant information for the assessment. This may require research or consultation, as well as the use of immediately available data.

How much do I need to put in my application?

You need to show how you have identified the risks, and then list them. You need to show which risks were too small to need further analysis. If there is uncertainty associated with those risks you should comment on this. Give references for the information you use if they are available.

Sourcing your information

Whatever sources of information you use you must acknowledge them. You should also say how reliable you think they are. If any of the information conflicts, you need to say so and, if you can, explain why you gave more weight to certain information.

INCLUDING MĀORI PERSPECTIVES

The HSNO Act identifies risks to Māori culture and taonga as matters to be considered in making decision on applications.

Applicants may need to further identify issues through consultation with iwi and hapū.

If you believe that your application raises issues of significance to Māori, contact us at the pre-application phase.

The role of Ngā Kaihautū Tikanga Taiao

A special committee has been set up to provide input to the Authority on Māori perspectives. The role of Ngā Kaihautū Tikanga Taiao is to provide input on issues of particular concern to Māori, the adequacy of consultation with Māori, and integrating Māori issues into the decision making process.

Identifying and assessing risks to Māori interests

The Authority wants to help applicants make a distinction between applications that involve issues significant to Māori, and those that do not.

If no significant issues exist, there will be no need to make an assessment or carry out any consultation.

Significant effects for Māori are especially likely with new organism applications. They are likely to be applications that impact on natural resources of all kinds, including waahi tapu, as well as on Māori spiritual values attached to valued natural resources.

Many Māori are likely to have particular concerns about genetically modified organisms (GMOs) and applications to release or field-test GMOs should include information about how genetic engineering could impact on Māori interests.

We have published a User Guide, *Working with Māori under the HSNO Act 1996*, that gives guidance on how to incorporate Māori perspectives. If you need further advice, talk to the Senior Māori Advisor on our staff.

INTERNATIONAL OBLIGATIONS

You will also need to provide information on meeting international obligations. There may be cases where applications are affected by international agreements between governments, for example the Montreal Protocol, and Basel Convention. You will need to provide information about any such agreements that might be relevant to your application.

CONFIDENTIALITY AND THE APPLICATION PROCESS

Commercially sensitive information will not be publicly released. We have procedures for handling commercially sensitive information. Applicants who supply us with commercially sensitive information need to clearly identify it as such, so that it can be handled securely.

BOTTOM LINES: FEES AND CHARGES

From 1 December 2003 we will have a range of fixed prices for processing applications. Our pricing schedule gives the prices for different types of application. For the more complex applications we will establish the price on a case by case basis prior to the application being lodged.

Though prices are fixed, there may be additional charges where

we need to obtain additional information or advice that the applicant has not provided in the application.

A RANGE OF PATHWAYS: HOW APPLICATIONS ARE HANDLED

All applications will generally follow one of four set processing paths. They are:

1 Notified applications, including release and conditional release of new organisms, release of hazardous substances and applications for emergency use and new organism field trials.

In general, applications for substances or organisms that can affect the environment must be publicly notified. Anybody can make a submission. A hearing will be held if the parties want one, or if the Authority thinks it is necessary. The timeframes are shown in the diagram at the back of this guide.

2 Non-notified applications, including transshipment, and hazardous substances, GMO development and new organisms in containment.

Applications for substances or organisms that are for secure containment may not need to be notified. So there is no opportunity for public submissions and the process is shorter.

The Authority may notify applications to develop a GMO or import a new organism into containment if it considers that there is likely to be significant public interest. These applications would then be processed following the notified pathway.

3 Rapid assessment

Where proposals to import a new organism or to develop a genetically modified organism in secure containment meets low risk criteria, a rapid assessment process may handle it. Rapid assessment procedures can also apply for certain medicines and veterinary medicines that include GMOs, and for some special emergency purposes. To further speed up the process, we will delegate this function to other agencies or to the Chief Executive of ERMA New Zealand where appropriate.

4 Ministerial call-in

The Minister for the Environment can call in an application for their decision if the Minister thinks it will have significant effects. If a call-in does occur, the Authority will continue to process the application, but instead of making a decision, will make a report and recommendation to the Minister.

All of our decisions on applications will follow one of these paths to ensure the relevant considerations are applied – and in the right order. This is to help ensure the approaches taken remain consistent, to help build up a series of precedents, and to give you a degree of certainty about how your applications will be treated.

REASSESSMENTS

A reassessment is where the risks and benefits associated with an approved substance or organism are reconsidered. As a result of that reconsideration the Authority may decide to change the conditions placed on the approval, or in extreme cases withdraw the approval altogether.

The possibility of reassessment is a vital part of the HSNO Act. Among other things it reflects the ‘cradle to grave’ approach to dealing with risks.

Who can ask for a reassessment?

Anyone may request a reassessment, and the Act especially empowers the Chief Executive of ERMA New Zealand to ask for one. Chief Executive initiated reassessments are important because they are paid for by the Authority, and because they recognise the need for ERMA New Zealand to take the initiative in dealing with problems rather than waiting for someone else to point out a difficulty.

The reassessment priority list

ERMA New Zealand maintains a priority list of potential reassessments. There will periodically be the opportunity for public consultation on this. A priority list has been established to make sure that reassessments don’t get forgotten.

When can you ask for a reassessment?

A reassessment can’t be done just because someone disagrees with an existing approval. There are set grounds that must be met.

These grounds for reassessment are set out in section 62 of the HSNO Act. There needs to be a change in circumstances before a reassessment can be triggered. This could include new information about risks, or the availability of a new substitute substance that is less risky, or a significant change in the quantity of the substance being used or how it is being used.

As a first step the Authority must agree there are grounds for a reassessment.

Someone has to then ask for the reassessment to be done. Sometimes there may be grounds for a reassessment but, for some reason, no one is prepared to take the next step.

Withdrawing an existing approval

There may be occasions when new information not only suggests a reassessment is justified, but indicates that allowing the existing approval to continue is very risky. Under those circumstances the Act allows the Authority to suspend the existing approval while the reassessment is carried out.

How do you ask for a reassessment?

If you wish to ask the Authority to decide whether there are grounds for a reassessment you need to make an application on our application form called *Application to consider whether there are grounds for a reassessment*. Forms are available from ERMA New Zealand. The application form asks for information to support your request. If this information is not sufficient to enable the request to be accepted, it will be declined.

If the Authority agrees that grounds exist, but the Chief Executive is not prepared to become the ‘sponsor’ for a reassessment, then anyone else can make an application. At this point an application for a reassessment becomes the same as an application for a new approval, so applicants use exactly the same forms.

Who pays?

ERMA New Zealand pays for Chief Executive initiated reassessments – this includes deciding whether there are grounds for a reassessment and then carrying out the reassessment if grounds exist.

If the Authority agrees there are grounds for reassessment, the Chief Executive may decide that he or she should sponsor the application and pay the further costs. In all other cases the person requesting the reassessment effectively becomes the applicant and is liable for the same fees and charges as if the reassessment was a normal application for approval. But the Authority may agree to waive a part of these charges if it considers there is some degree of public interest in carrying out the reassessment.

In the short to medium term we expect most Chief Executive initiated reassessments will come from the process of transferring existing approvals to the HSNO Act. This is because new approvals will still be small in number and very recent.

PROCESSING NOTIFIED APPLICATIONS: A NOTE ABOUT TIMING

Under the Act, we’ve got up to 100 days to process a notified application. But we hope to do better than this. It largely depends on how good a job you do with your application. On the other hand, extended time may be needed if more information or special evaluation is required.

PUBLIC NOTICES: NOTIFICATION AND SUBMISSIONS

In general, applications for substances or organisms that can affect the environment must be publicly notified. An exception is applications to import or develop substances and organisms in containment, and rapid assessment applications.

Public notification involves posting the application on our website, specific notification to people that have indicated an interest in that type of application, and publishing in *The Bulletin*. We also place an alert in the major newspapers.

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

MEETING FOR A CHAT: PRE-HEARINGS

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. One possible outcome is that either the applicant or submitter may withdraw a request to be heard at the formal hearing.

WHAT ABOUT HEARINGS?

We will arrange a public hearing for a notified application if the applicant or any submitters request it, or if we consider it necessary. An evaluation and review report will be presented to the hearing committee. This may include a review by external consultants or an advisory committee in addition to our staff. Parties will receive this report in advance.

We ask that parties pre-circulate their information to ERMA New Zealand and to each other so that it can be read before the hearing. Hearings will have sufficient formality to be fair and allow for all relevant information to be put before us. They will, however, be relaxed enough so as to be accessible by all parties – and not too intimidating.

For more information refer to our *Quick Guide to Making Submissions*.

EVALUATION AND REVIEW REPORT

An evaluation and review report of the application is produced by ERMA New Zealand. This may include a review by external consultants or advisory committee in addition to our staff. This report determines whether the information provided is sufficient, evaluates associated risks and identifies controls. The evaluation and review report will be presented to the hearing committee, although parties will receive this report in advance.

ASKING FOR ADDITIONAL INFORMATION

Having the best possible information available is crucial for robust decision making. The Authority can formally request additional information (s52 and 58 of the Act) and when it does so effectively the ‘clock stops’ so delays can occur.

We especially put emphasis on getting relevant information from the application, and this could on occasion delay public notification.

BRINGING IN A VERDICT: DECISIONS

How decisions are made

In its consideration the Authority will look at the adverse effects of the application after the controls have been applied. Then they will weigh up the risks, costs, and benefits to make their decision. The Authority may also vary the controls assigned to the application.

How decisions are announced

Our decision, including reasons, on each application will be given in writing and notified to all parties. All decisions will be added to our registers and be publicly available.

CAN DECISIONS BE APPEALED

Decisions cannot be directly appealed. The Environment Court for example has no jurisdiction. However it is possible to appeal on ‘points of law’ or to seek a judicial review.

PLAYING BY THE RULES: ENFORCEMENT

Inspection and enforcement under HSNO involves seven government departments and all territorial local authorities. ERMA New Zealand is not a primary enforcement agency, but has a supervisory role in enforcement.

For more information on enforcement, refer to our *Quick Guide to Enforcement and Compliance for New Organisms* or our *Quick Guide to Enforcements and Compliance for Hazardous Substances*.

