

ERMA NEW ZEALAND

# INFORMATION SHEET

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## Exemptions from the Provision of the HSNO Act for Small-Scale Research on Hazardous Substances

### Introduction

A central feature of the HSNO Act 1996 is the requirement for the import, manufacture and use of hazardous substances to be in accordance with an approval issued by the Authority. However, in recognition that there are a number of situations where the process of obtaining an approval for a hazardous substance is unreasonable, section 33 of the HSNO Act enables the use of hazardous substances in research and development or in teaching to be exempt from the provisions of the Act.

This information sheet outlines a number of the issues that arise from this provision of the HSNO Act.

**'33. Exemptions from the Act for small-scale research on hazardous substances** – Nothing in this Act shall apply to any small-scale use of hazardous substances in research and development or teaching if –

- (a) the use occurs in a laboratory that meets the prescribed requirements; and
- (b) the use does not create or involve a hazardous substance for which any application for approval has been declined under this Act; and
- (c) the importation, storage, and transportation of the hazardous substance each meets the prescribed requirements; and
- (d) no such hazardous substance, nor any substance created from that use, is sold as a substance or in a product containing or derived from that substance.'

The prescribed requirements indicated in section 33(a) of the HSNO Act are contained in the Hazardous Substances (Exempt Laboratories) Regulations 2001.

A laboratory is defined in the Act as:

'A vehicle, room building, or any other structure set aside and equipped for scientific experiments or research; or for teaching science; or for the development of chemical or medicinal products.'

Research and development, in relation to a hazardous substance, is defined in the Act as:

'Systematic investigation or experimentation activities that involve innovation or technology transfer for the purpose of gaining knowledge about the properties or uses of that substance.'

Institutions or companies that undertake research and development or teaching in laboratories are not compelled to invoke the s.33 exemption. There may be instances where the management of an organisation decides that compliance with the standard HSNO controls on substances are more applicable for the management of hazardous substances in the institution.

## Types of hazardous substances in the laboratory

There are three types of substances whose use may be covered by this exemption from the Act:

- (a) Authority approved hazardous substances
- (b) unapproved hazardous substances
- (c) *de novo* synthesis of substance whose hazardous nature is not defined.

Substances synthesised or prepared in research, development or teaching laboratories and which have, or may have hazardous properties are exempt from the requirement to make an application under the HSNO Act when the activity is being carried out in a laboratory that meets the requirement prescribed in the Hazardous Substances (Exempt Laboratories) Regulations 2001. It should be noted that this exemption does not apply to substances that have been declined by the Authority (s.33(b) of the HSNO Act).

An example of this is a toxic substance which is synthesised and used by a researcher in a university laboratory, that meets the prescribed requirements, as part of a study on the development of control agents for possums.

It should be noted that when development of a substance moves from synthesis to field trial evaluation then the s.33 exemption is no longer applicable. In these instances, the substance is now considered as being within s.31 research in containment to assist assessment for a Part V application.

## Small-scale use

There is no statutory interpretation of 'small-scale' use. The determination of limits of 'small-scale' will be a matter for the judgement of the Authority. When time permits, some more specific guidelines will be developed. In the meantime, applicants are referred to *AS2243:10 (1993) Safety in Laboratories: Storage of Chemicals* as one means of interpreting 'small-scale'. Sections 4.3 and 4.4 of this standard refer to the size of individual package and the total quantities for hazardous substances kept for *use* in a laboratory.

The s.33 exemption is also applicable to industrial laboratories recognising that a pilot laboratory may use volumes greater than that specified in AS2243:10. If you are in doubt as to whether the volumes used in an industrial laboratory can be covered by a s.33 exemption you should discuss this with ERMA New Zealand on a case-by-case basis.

Nevertheless, the intent of the law is clear, this exemption only applies to situations where the substance or products derived from the substance is not to be sold. Once a substance has been developed to the point where it could be sold or requires trial work outside the laboratory, an application for approval under Part V of the Act is required.

## Research and development or teaching

'Research and development' is interpreted in its broadest sense to mean investigations carried out according to scientific rules for performing observations and testing the soundness of conclusions, in a systematic, accurate manner assisted by expert knowledge. Such investigations need not be carried out only in scientific institutions but by other organisations and individuals provided they meet the definition above and are carried out in a laboratory which meets the prescribed requirements.

'Teaching' means, in its primary sense, the transfer of knowledge or understanding from one party to another by means of instruction, training or lessons. In addition, in a secondary sense, teaching can also have an application to include commercial activities where information on products and processes are transferred to staff, suppliers or clients.

The obvious examples of teaching are the activities of schools, universities, polytechnics and other institutions carrying out laboratory classes or workshops.

## Suppliers of specialist hazardous substances

Many research, development and teaching activities require the use of specialist laboratory chemicals that are hazardous substances. These are not usually manufactured in New Zealand and must be imported, often in quite small quantities. Where the import is made directly by the laboratory or institution carrying out the investigation or teaching activity the exemption from the provisions of the Act apply. Importation may be made without an approval to import from the Authority provided the laboratory meets the prescribed requirements.

However, few institutions undertake such importation directly and most order these substances from specialist suppliers.

The Hazardous Substance (Exempt Laboratories) Regulation is silent on how a laboratory proves to a specialist supplier that they meet the prescribed requirements. Therefore the onus is on the laboratory to ensure that all the performance requirements are met and that the information they supply to the supplier on their status is sufficient to confirm this status. One means to achieve this could be via independent certification that the laboratory meets the performance requirements.

Where a specialist supplier is in receipt of a purchase order for a hazardous substance from an institution or laboratory that meets the prescribed requirements, the supplier can import that substance (in the amount specified in the purchase order) without having to obtain an approval to import from the Authority. The supplier, through the purchase order, is regarded as being an agent of the laboratory.

Specialist suppliers are also able to import and hold stocks of laboratory chemicals, that they expect will be requested by laboratories that meet the prescribed requirements, without an approval from the Authority.

In both cases, the suppliers must meet the requirements of the standard HSNO Control Regulations for storage and handling of the chemicals. The key regulations here are the Identification, Emergency Management, Packaging, Tracking and Class 1-5 Control Regulations. Requirements relating to Identification, Emergency Management and Packaging may be met by meeting the international transport requirements discussed below.

It should be noted that importation of a hazardous substance for uses other than those that qualify for exemption requires an approval from the Authority prior to the importation of that hazardous substance. For example, a specialist supplier may import several containers of the same hazardous substance but only one of these containers may be for a s.33 laboratory.

## Importation, storage and transportation to the laboratory

No hazardous substance, including substances that have not been approved by the Authority, can enter New Zealand without transport controls assigned to it under the United Nations Recommendations for the Transport of Dangerous Goods (UNRTDG) Model Regulations, International Air Transport Association (IATA) or International Maritime Dangerous Goods (IMDG) Code. Therefore ERMA New Zealand regards these transport controls as sufficient to control the potential hazard of the substance during its importation and its storage at the port of entry. Transportation requirements for the substance from the border to the laboratory should be as per those required under the Land Transport Rule: Dangerous Goods 1999 (Rule 45001).

If an approved substance is used in a s.33 laboratory and is sourced from within New Zealand, the controls on that substance up until it enters the laboratory, will be those assigned to it by the Authority during the Part V approval process. If the substance is an existing substance awaiting transfer, then the existing controls for explosives, pesticides, toxic substances and dangerous goods, as detailed in Part XI-XV of the HSNO Act, will apply.

# Prescribed laboratory requirements

The Hazardous Substances (Exempt Laboratories) Regulations 2001 list the performance based requirements that a laboratory and its personnel must meet to be considered for a s.33 exemption.

In general this covers:

- laboratory design requirements, including signage at entrances to the laboratory;
- recording of hazardous substances present in the laboratory;
- handling and storage of approved hazardous substances and unapproved hazardous substances, including information that must be provided on a container holding the substance;
- the designation of a laboratory manager, and the knowledge and skills that person must have;
- the knowledge that a person handling a hazardous substance in a laboratory must have; and
- emergency response plan requirements.

In general, the best way of meeting many of the regulation requirements will be to follow the control regulations for that particular requirement.

## ***Laboratory Design Requirements***

The laboratory design requirements are intended to ensure that people working inside the s.33 laboratory, the environment outside the s.33 laboratory and people outside the laboratory, are protected from the adverse effects of any hazardous or potentially hazardous substance contained inside the laboratory.

This includes requirements for disposal of the substance. Disposal of approved substances will reflect the disposal controls on the substances under the Hazardous Substances (Disposal) Regulations 2001. Unapproved substances must be stored within the laboratory until it is approved by the Authority and disposal controls assigned to it, or treated so it is no longer hazardous, or it is lawfully exported from New Zealand.

Signage is required on all entry points to the laboratory that warns non-authorised persons that they are not permitted in the laboratory unless under the direct supervision of an authorised person. Signage must meet the comprehensibility, durability and clarity requirements of the Hazardous Substances (Identification) Regulations 2001.

When no authorised person is present, the laboratory must be secured against entry, such that an authorised person can only enter the laboratory by using a tool, a key, or any other device used to operate a lock. This securing must be able to prevent entry through manual force (such as kicking the door in).

It should be noted that an authorised person includes a person who in the normal course of his or her work is required to enter the laboratory. Therefore cleaners and maintenance staff may be deemed to be authorised persons.

ERMA New Zealand is currently considering AS/NZS 2982.1 (1997) as one means of meeting the design/construction requirements and AS 2243.10 (1993) for storage of chemicals in the laboratory.

## ***Record-keeping of hazardous substances present in the laboratory***

Substances that are highly hazardous to humans or the environment require tracking controls for the lifetime of the substance. If an approved substance is subject to tracking requirements outside the s.33 laboratory, or an unapproved substance is likely to be subject to tracking requirements if approval from the Authority is sought, then a record of use must be kept for at least 12 months after the substance is totally consumed or removed from the laboratory.

Tracking requirements are identified in the Hazardous Substances (Tracking) Regulations 2001 and include the following:

- the identity of the authorised person using the substance;
- the unequivocal identification of the substance;
- the total amount the authorised person is in control of at any one time;
- the location of the substance;
- if the substance is transferred to another location, identification of the new authorised person and the date the transfer occurs;
- how the substance was disposed of.

### ***Handling and storage of hazardous substances***

Approved substances are required to be handled and stored as per the 'normal' HSNO controls unless they are being used in a s.33 experimentation. When being used in the laboratory, or stored in a small container (such as a storage flask or beaker), the substance requires the following information to be readily available (for example, written on the container):

- it needs to be identified;
- the concentration present;
- a warning of the hazardous property (eg Explosive, Oxidiser, Flammable, Toxic, or Ecotoxic) if it is highly hazardous.

The information also needs to be readable for another person who may come in contact with the undiluted or diluted substance.

Unapproved substances that are likely to be hazardous under the HSNO Act should be handled and stored in a manner equivalent to that required for a comparable approved hazardous substance.

Containers used to hold approved and unapproved hazardous substances should be compatible with the hazardous substance, contain the substance at the temperature and conditions in which it is used in the laboratory and prevent entry by any organism capable of transporting the substance out of the laboratory. The definition of an organism excludes humans. This refers to organisms such as ants, cockroaches and vermin not being able to carry an amount of the substance with them on exit from the laboratory.

### ***Personnel Requirements***

More than one manager may be appointed to the laboratory, or multiple laboratories within a research area, or designated parts of the laboratory. Only one person may be in charge of a laboratory or part thereof and the hazardous substances (approved and unapproved) contained there at any given time. Responsibilities may be delegated such that a management plan or procedure would identify the 'pecking order' in the laboratory, in the absence of the laboratory manager.

The laboratory manager is required to have the skill and knowledge to ensure the safety of those using the laboratory and to protect the environment and people outside the laboratory from the effects of hazardous substances. The laboratory manager must ensure that authorised people in the laboratory receive information on procedures for safe use of equipment, clothing and the laboratory and requirements for managing and using substances in a s.33 laboratory, including the emergency response plan.

If a hazardous substance has a tolerable exposure limit (TEL) or a workplace exposure standard (WES) attached to its approval, then no person outside the laboratory (for the TEL) or in the laboratory (for the WES) can be exposed to a level greater than those set in the approval.

If highly hazardous substances are to be used in the laboratory that would, outside a laboratory, trigger the competency requirements to become an approved handler of the hazardous substance, then in this instance, the laboratory manager should still meet the knowledge and skill requirements necessary to become an approved handler although certification is not required.

### ***Emergency Response Plans***

The s.33 laboratory is required to have an emergency response plan that meets the requirements of Part 4 of the Hazardous Substances (Emergency Management) Regulations 2001, regardless of the quantity of substance used in the laboratory. The emergency response plan can be for the individual laboratory or the overall research/teaching facility. It is expected that an emergency response plan meeting the more general requirements of the Health and Safety in Employment (HSE) Act 1992 would also meet this requirements.

## **Overlap with other legislation**

Laboratories are deemed 'places of work' and therefore there is some overlap with requirements under the HSE. It should be noted that the Department of Labour, Occupational Safety and Health staff, will probably have the prime responsibility for enforcing this part of the Act.

There is also overlap with the Resource Management Act 1991. Some structural or procedural aspects of laboratories may require resource consents, such as land use requirements in a district plan or discharge consents for emissions from fume cupboards.

If the laboratory 'entity' is contained within a 'building' as defined in the Building Act 1991, any significant modification to its structure will be subject to the requirements of that Act. This also applies for construction of new laboratories. The Building Act is not retrospective so laboratories constructed or modified before 1991 are not covered by the Building Act.

## **ERMA NEW ZEALAND INFORMATION SHEETS:**

*ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issues or proposals being dealt with by the Authority.*

*Please feel free to photocopy this material. Acknowledgement of ERMA New Zealand would be appreciated.*

*The information sheets are available from*

ERMA New Zealand, PO Box 131 Wellington. Phone: 64 4 473 8426. Fax: 64 4 473 8433. Email: [info@ermanız.govt.nz](mailto:info@ermanız.govt.nz)

*The information sheets can also be viewed and downloaded on our website at [www.ermanız.govt.nz](http://www.ermanız.govt.nz)*