

1 Introduction to the Hazardous Substances and New Organisms Act 1996 and to Using this Guide

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1.1 Introduction to the HSNO Act

1.1.1 Purpose of the HSNO Act

The purpose of the Hazardous Substances and New Organisms Act 1996 (HSNO Act) is to protect the environment and the health and safety of people by preventing or managing the adverse effects of hazardous substances.

The HSNO Act replaced the Dangerous Goods Act 1974, Explosives Act 1957, Pesticides Act 1979, Toxic Substances Act 1979, and the regulations associated with these Acts.

Section 25(1)(a) of the HSNO Act states:

No hazardous substance shall be imported or manufactured ... otherwise than in accordance with an approval issued under this Act or in accordance with Parts XI to XVI of this Act.

Parts XI to XV of the HSNO Act were the transitional provisions of the Act for substances that had approvals under the predecessor legislation. That is, pesticides, toxic substances, dangerous goods, and explosives. These parts of the Act have now expired.

The HSNO Act provides for a series of regulations to be developed. These regulations enable hazardous substances to be defined, and for the level of hazard to be classified and then managed to minimise adverse effects.

When an application is made to the Authority to import or manufacture a hazardous substance, a classification for each hazardous property of the substance is determined. This classification triggers a set of controls (called default controls) from the controls regulations. The Authority may also, in some circumstances, vary the default controls.

1.1.2 Definition of a hazardous substance

Section 2 of the HSNO Act defines a ‘substance’ as:

- (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 of combinations of any of the above:
- (d) Any manufactured article containing, incorporating or including any hazardous substance with explosive properties:

A substance is considered a ‘hazardous substance’ when it has an effect more hazardous than any one or more of the regulated threshold levels for any of the intrinsic properties of:

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

1.1.3 What is a threshold?

A threshold is the amount or concentration of a substance that is likely to cause an adverse effect on people or the environment. It is a trigger level for an effect that the Authority may consider requires controls on the substance to meet the purpose of the HSNO Act.

The threshold level is the bottom ‘rung’ on the classification ‘ladder’. As you move up the ladder, the substance becomes more hazardous and requires greater controls to protect people and/or the environment.

The thresholds and classification categories reflect the international harmonisation of classification systems for hazardous substances and mixtures under the auspices of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (United Nations, 2007a).

1.1.4 Description of thresholds and classification systems

Thresholds for hazardous properties

The thresholds for the HSNO Act hazardous properties are set out in Schedules 1 to 6 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. Regulation 4 of those regulations states that a substance is not hazardous for the purposes of the HSNO Act unless data indicates it meets the minimum degrees of hazard for at least one of the intrinsic hazardous substance properties specified.

In those regulations, data includes ‘values that are directly measured, calculated, or estimated for any of the measures given’. This means it is not necessary to rely only on directly measured data to determine whether a substance exceeds any of the hazardous property threshold criteria. It may be possible to calculate a relevant parameter for a

substance based on the directly measured values available on its components by making use of ‘mixture rules’ (see the relevant chapters for details). Alternatively, a relevant parameter for a substance may be estimated based on the similarity of that substance to another substance for which the hazardous properties are known.

Classification criteria for hazardous properties

The classification criteria for the HSNO Act hazardous properties are set out in Schedules 1 to 6 of the Hazardous Substances (Classification) Regulations 2001.

The classification systems comprise:

- numbered classes (for example, class 6), indicating the intrinsic hazardous property;
- numbered subclasses (for example, subclass 6.1), indicating the type of hazard; and
- lettered categories (for example, category A) indicating the degree of hazard.

Exceptions to this are explosive substances, which are classified into a subclass (indicating the type of explosive hazard) and a category (indicating compatibility groupings) in the combinations permitted by the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations (United Nations, 2007b). Categories for explosive substances do not indicate the degree of hazard. Other exceptions are the two separate classifications for sensitisation, where a substance can be classified as both 6.5A (respiratory sensitisation) and 6.5B (contact sensitisation). Likewise, the 6.8C (causes developmental effects via lactation) category is independent of the other 6.8A and 6.8B categories. Further guidance is provided in the relevant chapters for these properties.

The combination of numbers and letters used in the classification system (eg, 6.1A) constitutes a hazard classification of a substance.

Classes for the hazardous properties

The nine classes for the hazardous properties are:

- class 1: explosiveness (see [chapter 2](#));
- class 2: flammability, gases (see [chapters 3](#) and [4](#));
- class 3: flammability, liquids (see [chapters 3](#) and [5](#));
- class 4: flammability, solids (see [chapters 3](#) and [6](#));
- class 5: oxidising capacity (see [chapter 7](#));
- class 6: toxicity (see [chapters 9–17](#));
- class 8: corrosiveness (see [chapter 8](#) for metal corrosivity and [chapter 11](#) for corrosion of biological tissues); and
- class 9: ecotoxicity (see [chapters 18–23](#)).

Class 7 is unallocated in the HSNO Act classification system, because it is reserved for radioactivity, which is outside the scope of the HSNO Act. Class 7 is used in the United Nations classification system for the transport of dangerous goods for radioactive materials. In New Zealand, these substances are covered by the Radiation Protection

Act 1965, which is administered by the National Radiation Laboratory of the Ministry of Health.

Similarly, subclass 6.2 is unallocated in the HSNO Act classification system for toxicity, because it is reserved in the United Nations classification system for the transport of dangerous goods for infectious substances. These are also outside the scope of the hazardous substances part of the HSNO Act.

1.1.5 Exemptions from the HSNO Act

Some human medicines and food are categories of substance that are exempt from requiring approval under the HSNO Act even if they have properties that exceed the hazardous property thresholds. These exemptions are set out in sections 5 and 6 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001.

Human medicines

Human medicines in their finished dose form are excluded from the HSNO Act unless the substance is a gas contained at a pressure greater than 170 kPa in a container larger than 100 mL, before the gas is administered to a person for a therapeutic purpose.

However, new medicines (as defined in the Medicines Act 1981) are not excluded from the HSNO Act if they meet any of the threshold criteria and are either a substance to which section 3(1)(b) of the Medicines Act 1981 applies (that is, they are an ingredient of a medicine) or the substance is registered as a veterinary medicine under the Agricultural Compounds and Veterinary Medicines Act 1997.

Food

Food in a ready-to-consume form, which may meet the hazardous property thresholds, is excluded from the HSNO Act.

Food additives are not excluded from the HSNO Act if they meet any of the threshold criteria and if they have not been mixed with or added to any other food or drink that is in a ready-to-consume form.

1.1.6 Manufactured articles

Manufactured articles containing or incorporating hazardous substances with properties other than explosiveness are *not* substances under the HSNO Act.

Manufactured articles with explosive properties (such as flares or detonators) *are* hazardous substances under the HSNO Act.

Other manufactured articles containing, incorporating, or including a hazardous substance may be regulated under the HSNO Act through the provisions for Group Standards (Part 6A of the HSNO Act). However, in these instances, the article itself would not be subject to hazard classification.

Manufactured products such as glues, paints, and pesticides are also considered substances under the HSNO Act.

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

A manufactured article is something for which its intended use is primarily to do with its physical shape, rather than its chemical composition.

However, because this distinction is not always clear, we have expanded the 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.
- 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 fluid.

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. That is, 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.

More detailed information on manufactured articles is provided in the information sheet *Manufactured Articles* (ERMA New Zealand, 2001).

1.1.7 Definitions

The chapters on each hazardous property list the key definitions relevant to that property.

1.1.8 Application forms and related publications

If a substance is assessed as having properties that are above one or more of the hazardous property thresholds discussed in this document, then an approval for the substance is required under the HSNO Act.

Several ERMA New Zealand publications and application forms will help applicants with their application for an approval. For more information on the HSNO Act and ERMA New Zealand procedures, see our website (<http://www.ermanz.govt.nz>).

1.2 How to use this guide

1.2.1 Aim of this guide

This guide is to help you to interpret the:

- threshold regulations, which determine whether a substance is hazardous and subject to the requirements of the HSNO Act; and
- classification regulations, which assign levels of hazard to hazardous substances.

1.2.2 Responsibility for deciding whether a substance is ‘hazardous’

The initial responsibility for deciding whether a substance is ‘hazardous’ rests with the importer or manufacturer of the substance.

1.2.3 Hazardous properties

Each substance must be assessed for each of six hazardous properties before a conclusion can be reached.

The threshold regulations set the level of hazard below which a substance is not considered hazardous.

1.2.4 How to determine whether a substance is ‘hazardous’

The determination as to whether a substance is ‘hazardous’ is not only a technical determination but also a legal one. The manufacture or importation of a hazardous substance without an approval is an offence.

[Figure 1.1](#) overviews the process for determining whether a substance is hazardous and requires a HSNO Act approval to be imported or manufactured.

This guide has separate sections for each hazardous property (see ‘[Classes for the hazardous properties](#)’ in section [1.1.4](#)). While many substances trigger only one threshold, other substances trigger more than one. Therefore, it is necessary to evaluate each substance against the thresholds in each section. This evaluation is a moderately complex technical task.

We have developed this guide assuming you have sufficient scientific and technical knowledge and experience to determine whether a substance is hazardous. If you do not have the ability to address the technical issues, seek advice from people who do. To evaluate a substance collect as much relevant information about the characteristics of the substance as you reasonably can. Then compare this information with the criteria within each property that may trigger the threshold.

For advice about evaluating the quality of data, see section [1.3](#).

Note that an inability to access the information does not necessarily mean there is no information. If you do not have adequate information, use your technical judgement, including answering the following questions.

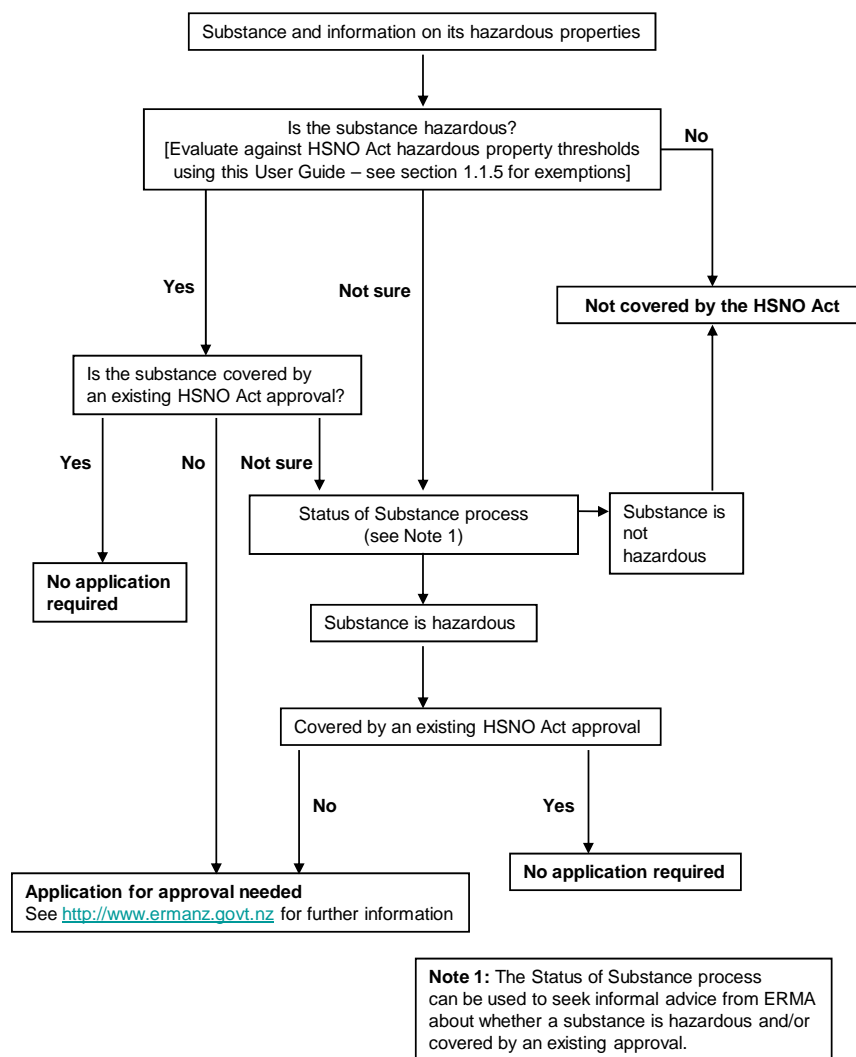
- Do similar substances have properties that would give reliable guidance?
- Is it plainly unreasonable to expect the substance to have such a property?
- Should this gap be referred to an expert in the field?

If a substance does not trigger a threshold, then it is not ‘hazardous’ and does not need an approval under the HSNO Act. However, if a substance does trigger a threshold, it cannot be imported or manufactured in New Zealand without an approval.

If the substance is not covered by an existing approval, including Group Standards, then you need to make an application before importing or manufacturing it (see [Figure 1.1](#)).

ERMA New Zealand provides a Status of Substance service if you wish to obtain informal advice about whether a substance is hazardous and/or covered by an existing approval.

Figure 1.1: Process for determining whether a substance is hazardous and requires a HSNO Act approval



1.3 Evaluating the quality of data

1.3.1 Reliability, relevance, and adequacy

In general, the three aspects to assessing the quality of data from studies are reliability, relevance, and adequacy. Klimisch et al (1997) defined these terms in the following way.

- *Reliability* – the inherent quality of a test report or publication evaluated in relation to a standard test methodology. This includes considering the clarity in how experimental procedures are described and the plausibility of the results.
- *Relevance* – the extent to which data and tests are appropriate for a particular hazard identification or risk characterisation.
- *Adequacy* – the usefulness of data for hazard or risk assessment purposes. Studies may be undertaken for many purposes, and while the research may be scientifically valid, it may not always be adequate for use in a hazard assessment. When there is more than one study for each element, attach the greatest weight to the study that is the most reliable and relevant.

Evaluate carefully the quality of the study, its method, the report of the results, and the conclusions drawn.

Data may vary in quality because studies:

- use outdated test guidelines;
- fail to characterise the test substance properly (for example, in terms of purity and physical characteristics);
- use techniques and procedures that have since been refined; or
- have not recorded or measured certain endpoint information that is now recognised as important.

Determine whether a study is reliable, before determining its relevance and adequacy.

1.3.2 Reliability considerations

Undertake an initial, quick assessment to filter out unreliable studies, and then focus further resources on the most reliable studies. It is critical you know how the study was carried out, because without this information, all other considerations are likely to be irrelevant.

Klimisch et al (1997) developed a scoring system for reliability, particularly for ecotoxicology and health studies, that may be extended to physicochemical and environmental fate and pathway studies.

- *1 = reliable without restrictions:*
studies or data ... generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to Good Laboratory Practice (GLP)) or in which the test parameters documented are based on a specific (national) testing guideline ... or in which all parameters described are closely related/comparable to a guideline method.
- *2 = reliable with restrictions*
studies or data ... (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.
- *3 = not reliable*
studies or data ... in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.
- *4 = not assignable*
studies or data ... which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).

Klimisch codes are a useful tool for discarding unreliable studies, organising studies for further review, focusing on the most reliable studies, and allowing additional time to be devoted to considerations of relevance and adequacy of only reliable studies.

The best studies are those that give a precise description of the nature of the effect, the number of subjects or the percentage of animals affected by the observed effects, and the exposure conditions (duration and concentration).

Evaluate reliability using international standard test guidelines as references. The classification should not exclude all unreliable data from further consideration by experts. In general, data with lower reliability may be used as supporting data.

Use the criteria listed in [Table 1.1](#) to screen test results for reliability. These criteria address the overall scientific integrity and validity of the information in a study; that is, reliability. Any study not meeting the criteria in the table would be assigned a Klimisch score of 4 (not assignable). Such studies could provide only supplementary information.

Table 1.1: Key reliability criteria for screening data

Criteria	Required for specific tests		
	Physical and/or chemical properties	Environmental fate	Toxicity and ecotoxicity
Test substance identification (adequate description of test substance, including chemical purity and identification or quantification of impurities to the extent available]	x	x	x
Temperature	x ¹	x	x
Controls ²		x	x
Species, strain, number, gender, and age of organisms			x
Dose or concentration levels		x	x
Route or type of exposure ³			x
Duration of exposure		x	x
Statistics (with some exceptions, eg, the <i>Salmonella</i> /Ames assays)			x
Full citation or reference	x	x	x

Notes

- 1 For vapour pressure, octanol or water partition coefficient, and water solubility values.
- 2 All studies must have negative controls and some studies (eg, biodegradation, *Salmonella*/Ames assay) must also have positive controls. If a vehicle is used in the administration of the test substance, vehicle controls must also be established and reported. Exceptions may be allowed for acute mammalian toxicity studies.
- 3 The route or type of exposure (eg, oral or inhalation for mammalian studies) or test system (eg, static, flow-through for ecotoxicity) must be reported.

1.3.3 Relevance and adequacy considerations

The use of sound scientific judgment is the most important principle in considering relevance and adequacy. The chapters on specific hazard properties provide more information on which studies are considered relevant and adequate for assessing each property.

ERMA New Zealand assigns Klimisch scores to the data used to classify substances. It uses a weight-of-evidence approach (see section 1.3.4) to evaluate all the available data for a particular hazard classification, including bridging principles from the GHS (United Nations, 2007a).

Each hazardous property chapter states the data required for classification purposes. The quality and type of additional data required vary with different types of substance and different HSNO Act approval categories.

Further information is included in the user guide for each application form, and see the ERMA New Zealand website (<http://www.ermanz.govt.nz>).

1.3.4 Weight of evidence

In the GHS a weight-of-evidence approach is given prominence for classification (United Nations, 2007a). All available information that bears on the determination of classification for an endpoint is considered together. Include information such as epidemiological studies and case reports in humans and specific studies along with subchronic, chronic and special study results in animals that provide relevant information. You may also include evaluations of substances chemically related to the material under study, particularly when information on the material is scarce.

The weight given to the available evidence is influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for inter-group differences, number of endpoints affected, relevance of route of administration to humans, and freedom from bias. Collate both positive and negative results into a weight-of-evidence determination. However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results may justify classification.

Each hazardous property chapter contains further information on specific approaches that may be used in reaching a classification decision based on the weight of evidence.

1.3.5 Data sources

Data sources are highly variable in terms of quality, reliability, accuracy, extent of peer review, the time spans covered, the number of chemicals addressed, and the extent of detail. Experienced searchers will know which sources have been most useful to them in the past.

There are a large number of other potentially useful data sources, and many require specific searching skills in order to ensure all relevant information is retrieved. The person classifying a substance should be looking to optimise the value of the searches carried out. As is the case for many specialised activities, possibly the most efficient mechanism is to use the services of people who have expertise in searching the data sources. While it might be possible in the future to define a stepwise approach to data searching (or a minimal acceptable search strategy), it is not considered appropriate at present to recommend any specific strategy as being sufficient for purpose. A critical aspect is that the search strategy is clearly recorded to allow transparency in relation to the depth and width of searching that has been undertaken, the dates on which searches were carried out, and details of the coverage (for example, topics, relevance, size, and years) of the data sources that are examined.

When no data are found, other types of information (such as Quantitative Structure Activity Relationships (QSARs)) might be valuable. When validated, QSARs are available for specific endpoints. This is indicated in the relevant chapters (for example, [chapter 19](#) on aquatic toxicity).

1.3.6 Examples of information sources

Information sources include the following.

- *Company files* may include studies generated in-house, commissioned studies carried out on contract, information about experience with using the material, reports from downstream companies and customers, purchased reports from other companies, collections of published papers, and reviews of published data. This information is likely to cover the company's product range and requires expertise to interpret.
- *Published literature* includes papers reporting original findings (primary papers), review papers, books, monographs, and reports of proceedings, meetings, and conferences. It covers many more chemicals than does the product range of any company. It requires expertise in identifying and interpreting information.
- *Databases and databanks* may include relevant information depending on the objectives of the hosts or providers (which may change). Databases generally direct searchers to original sources, while databanks generally contain limited information from original sources, and give little insight into the quality of test information. Databases and databanks are only routes to the original sources, rather than sources themselves. They cover many more chemicals than does the product range of any company. They require expertise in searching numerous systems and interpreting information.
- *QSAR and SAR models* are sometimes freely and sometimes commercially available. In theory, they may be applied to any untested chemical, but domain applicability is a potential problem. Specialised expertise is needed to run models and interpret results.
- *The internet* has search engines that identify electronic versions of a diverse range of data sources. In addition, the websites of various expert organisations and regulatory bodies contain useful information. Much 'grey' (that is, not formally published) literature is available via this route.

Individual chapters in this user guide contain links to electronic data sources. These links were current at the time of publication.

1.3.7 Acceptable test methodologies

Acceptable test methods for assessing each hazardous property are identified in the relevant hazardous property chapters.

References

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