

How to use this handbook

This handbook aims to help manufacturers and importers of industrial chemicals comply with their obligations under *the Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth).

STEP 1

It is recommended that all users of the handbook start by reading Chapter 1, which outlines general information concerning the role of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in assessing industrial chemicals in Australia, and provides an overview of the legal obligations applying to importers and manufacturers.

STEP 2

Having decided which of the five key obligations outlined in Chapter 1 is relevant to you, the table below offers guidance as to which of the remaining Sections of the handbook you need to consult.

For information about:	Consult the following Sections of the handbook:						
	1	2	3	4	5	6	7
New Chemical Assessments	X	X		X			X
Priority Existing Chemical Assessments	X		X	X			X
Secondary Notifications	X			X			X
NICNAS Registration	X				X		X
Treaties	X					X	X

STEP 3

Complete any forms (a list of forms is available at Appendix 1) and prepare supporting documents for submission to NICNAS. Forms can be downloaded at <http://www.nicnas.gov.au/forms/>.

STAY UP TO DATE

The Handbook for Notifiers is updated from time to time with new and revised information.

HELP US HELP YOU

We are interested in your feedback on this handbook. Please send your comments and suggestions to:

National Industrial Chemicals Notification and Assessment Scheme
GPO Box 58
SYDNEY NSW 2001

Or email: info@nicnas.gov.au

SECTION I – Overview

1. Your Obligations Under NICNAS

This chapter provides general information about the role of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in assessing industrial chemicals in Australia and offers an overview of legal obligations applying to importers and manufacturers.

1.1 Why Assess Industrial Chemicals?

The goal of NICNAS is to aid in the protection of the Australian people and the environment by identifying the risks to occupational health, public health and the environment from industrial chemicals. These risks are minimised if potentially harmful effects are identified at the earliest possible time – prior to the chemical's importation and/or manufacture. Appropriate safe handling methods can then be devised and implemented.

NICNAS has established a comprehensive scientific program of international standards for assessing industrial chemicals in Australia. The availability of NICNAS assessment reports to State and Territory regulatory agencies, companies introducing chemicals, people in the workplace, other government agencies and to the public has contributed significantly to making workplaces safer and in protecting human health and the environment.

While the use of overseas hazard assessment reports is supported and encouraged, the actual risk posed by a chemical, and hence its management, must be determined by taking into account Australian conditions – that is, our demographics, unique environmental ecosystems and the patterns and conditions of the chemical's use in this country.

1.2 About NICNAS

In Australia, industrial chemicals are regulated by the Australian Government under the *Industrial Chemicals (Notification and Assessment) Act (1989)* (the Act), administered by NICNAS and located within the Health and Ageing portfolio.

NICNAS is the Australian Government's regulatory body for industrial chemicals. It was established in 1990 under the Act to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals.

NICNAS aims to ensure the safe use of industrial chemicals by making risk assessment and safety information on chemicals and their potential worker, public health and environmental risk widely available.

NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used and/or released to the environment. NICNAS also assesses those chemicals that are already in use in Australia known as

existing chemicals on a priority basis in response to specific concerns about potential health and/or environmental effects.

1.3 How Does NICNAS Define an ‘industrial chemical’?

Under the Act, an industrial chemical is any chemical that has an industrial use. This includes specialty chemicals, dyes, solvents, adhesives, plastics, laboratory chemicals, chemicals used in mineral and petroleum processing, refrigeration, printing and photocopying, paints and coatings, as well as chemicals used in the home, such as cleaning products, cosmetics and toiletries.

The Act specifically excludes articles (see Appendix 2 – Definitions and Appendix 9: Description of an article), radioactive chemicals and mixtures from notification and assessment requirements. Chemicals, which are used solely as therapeutic agents, agricultural, and/or veterinary chemicals, and/or food or food additives are also outside the scope of NICNAS. The definition of an industrial chemical is slightly different for NICNAS registration purposes.

1.4 The Australian Inventory of Chemical Substances (AICS)

The Australian Inventory of Chemical Substances (AICS) is a key tool that lists the chemicals that are available for use in Australia. Some chemicals may only be available for specified/conditional use. It is important that you are aware of any conditions or restrictions that may apply to chemicals you import and/or manufacture or plan to export. Failure to comply with the conditions could lead to unsafe use.

The AICS is a listing of industrial chemicals in use in Australia between 1 January 1977 and 28 February 1990. In addition, it includes new assessed chemicals and corrections as required.

The AICS is maintained under NICNAS and contains over 38,000 chemicals. The AICS is a list of chemical identity data; it does not contain information on toxicity, manufacturers or importers.

Any chemical not included in AICS or any listed chemical whose importation and/or manufacture is subject to a condition of use, is regarded as a new industrial chemical unless it is outside the scope of the Act. New industrial chemicals must be notified and assessed before being manufactured or imported into Australia unless they qualify for an exemption.

1.4.1 Compilation of AICS

The first edition of the AICS was a listing of industrial chemicals already in commercial use in Australia over the period 1 January 1977 to 28 February 1990 (‘grandfathered chemicals’). It included approximately 36,000 non-confidential chemicals, with a further 2,500 in the Trade Name section and another 1,000 in the confidential section. Additional chemicals (Eligible Chemicals) were added during a two-year amnesty from 1993 to 1995. As these chemicals were added to AICS (or

later taken as eligible to be on AICS) before the advent of NICNAS, the vast majority have not been assessed in Australia for health and environmental effects.

Since 1995 any addition to AICS has been principally through the new chemical assessment process. This accounts for about 1,200 chemicals in the AICS database.

The chemical details for some chemicals on AICS have been amended where there has been a change to the CAS number or chemical nomenclature or where an error occurred during the AICS compilation period.

1.4.2 Components of AICS

AICS is composed of two sections: **Non-confidential** and **Confidential**. Each section contains the following chemical details only:

CAS Number: The CAS Number is a unique number assigned to a substance when it is entered into the Chemical Abstracts Service (CAS) Registry database. The general format is XXX-XX-X.

Chemical Name: Chemicals are listed under their CAS approved name.

Molecular Formula: Molecular formula for some chemicals is listed on AICS.

Associated names (if any): Chemicals are more commonly known by names other than their CAS approved name. Some of these associated names or synonyms are also included on AICS.

The only difference between these two sections is the availability of these sections. The confidential section of AICS is not available to the public. Chemicals listed on the confidential section are up for renewal every five years.

1.4.3 Listing of 'New' Chemicals on AICS

Five year listing

All certificate-assessed chemicals are included on AICS five years of the certificate date. For the interim five years, chemicals are not listed on AICS.

At the end of five years, the company, which is the holder of the certificate for the assessed chemical is given the opportunity to put the chemical on the confidential section of AICS.

For a chemical to be listed on the confidential section, an application to NICNAS is required. There are some minimum data requirements for the application and these are specified in the "Guidelines for Confidential Listing". The Director, NICNAS makes the decision after taking into consideration the public and commercial interest.

Immediate listing

Under Section 13B, an assessed chemical can be listed on the non-confidential section of AICS prior to the five year period.

If the holder of certificate makes an application within 28 days of the issue of assessment certificate no fees apply. However if any application is made after 28 days fees apply.

Chemicals are added to non-confidential AICS through gazetting in the *Chemical Gazette*.

1.4.4 Searching of AICS

To find out if a chemical is listed on AICS, you may need to check both the confidential and non-confidential sections. The non-confidential section of AICS is available on the NICNAS web site (www.nicnas.gov.au/obligations/aics). Please refer to Appendix 13 – AICS Online Training – for more information.

You can also request NICNAS to do the search for you. For searches of the non-confidential section, please complete the AICS Search Form 4 (Appendix 1). The fees for this service (excluding GST) are as follows:

- Administrative fee: \$ 30 per search
- Chemical search fee: \$ 35 per chemical

All fees are payable before the search commences. Requests from the public to search the non-confidential section of AICS are free.

For searches of the confidential section please complete AICS Search Form 5 (Appendix 1). This service is free. A statement of *bona fide* intent to introduce the chemical into Australia must accompany the search request.

1.5 The Five Key Obligations

The Act sets out five key obligations for manufacturers and importers of industrial chemicals. These obligations relate to:

1. New chemicals assessments – the notification and assessment of chemicals determined as ‘new industrial chemicals’
2. Existing chemicals assessments – assessment of chemicals declared ‘priority existing chemicals’
3. Secondary Notifications – the notification and assessment of chemicals previously assessed by NICNAS including chemicals assessed under the self assessment category

4. NICNAS Registration – registration of anyone importing and/or manufacturing relevant industrial chemicals of any value for commercial purposes.
5. Treaties – certain regulatory requirements apply to chemicals subject to an international agreement to which Australia is a Party.

An overview of each of these obligations follows.

1.5.1 New Chemical Assessments

All new industrial chemicals must be notified to NICNAS and assessed prior to their import or manufacture in Australia. For detailed information about what constitutes a ‘new industrial chemical’, refer to [Chapter 2 – Do You Need to Notify?](#). Certain new industrial chemicals are exempt from notification provided they meet certain criteria including use; volume; concentration and risk to human health or the environment. For most exempt categories no further action is required prior to the introduction of the new chemical. However, in some cases, information about exempt category chemicals still needs to be provided to the Director justifying the exemption. All exemption categories have an annual reporting obligation. For further information on Exemptions, see [Section 2.5](#) in this handbook.

It is the responsibility of the importer and/or manufacturer of the new industrial chemical to notify NICNAS through the preparation of a notification statement. The notification statement must contain an application for an assessment certificate or permit and a technical dossier containing all the information required for the assessment.

Several assessment categories exist which require different levels of assessment to be undertaken. In general, the amount of information, which is required in the notification statement, increases in accordance with the proposed introduction volume of the new chemical and the associated hazards, use, handling and disposal of the notified chemical. The volume of a chemical to be introduced and the hazards of the chemical are considered to be significant factors in determining the risk posed to human health and the environment.

There are fee reductions if those notifying NICNAS are able to supply an acceptable written draft assessment report or a report of a chemical assessed under an approved foreign scheme. In some circumstances, importers or manufacturers can apply for permits allowing chemicals to be introduced before the assessment process has been complete. There is also provision for companies to apply to have their names added to assessment certificates already issued to another company importing or manufacturing the same chemical. For further information on new chemicals assessments, refer to Chapters 2-8 Section II of this handbook.

1.5.2 Existing Chemical Assessments

Existing chemical assessment activities have an important role to play in reducing risks from chemicals currently in use. Whereas each new industrial chemical undergoes an assessment before being imported or manufactured in Australia, most of

the 38,000 already present in Australia (i.e. existing chemicals) have never had an independent assessment of their potential risks. Declaration as a priority existing chemical (PEC) ensures the closer examination and detailed assessment of those chemicals that are seen to pose a potential risk to human health and/or the environment, enabling recommendations to be made regarding their control and risk reduction.

An industrial chemical is declared a PEC by notice in the *Chemical Gazette*. Once declared, all those who wish to continue import and/or manufacture of the chemical must apply for assessment of the chemical. In all but exceptional cases, applicants can continue to import and/or manufacture the chemical while it is a PEC. Relevant available information on the human health and environmental effects of the chemical is collected for the assessment, as well as data on human and environmental exposure and control measures.

Any interested person can nominate a chemical of potential concern for declaration as a PEC by completing the “Priority existing chemicals nomination form”. Nominated chemicals are ranked according to published selection criteria. Recommendations are then made by the Director to the Minister for Health and Ageing for the declaration of PEC.

For detailed information about Priority Existing Chemical assessments, refer to Chapter 9 – Priority Existing Chemical Assessments in Section III of this handbook.

The Director may publish notices in the *Chemical Gazette* under section 48 of the Act, requiring information to be provided about a chemical that is being considered for recommendation as a PEC. Persons to whom the notice is directed must respond to the notice.

Sometimes, after consideration of information gathered on a chemical, a PEC assessment is not considered necessary or appropriate. Other types of assessments may be considered for a chemical. More information on existing chemical assessments other than PEC assessments can be found in Chapter 10, in Section III.

1.5.3 Secondary Notification

The initial assessment under NICNAS of the occupational health and safety, public health and environmental aspects of a chemical is based on information available at the time of notification. For some chemicals, changes in circumstances may occur which necessitate a reassessment of the chemical – that is, a secondary notification and assessment. The onus is on the importer or manufacturer to inform the Director when a change in circumstance occurs. The Director may then decide to initiate a secondary notification by placing a notice in the *Chemical Gazette*. This may apply to all manufacturers and importers of the chemical or only to those specified in the notice. The notice will specify the information to be provided in the notification.

For further information about secondary notifications refer to Chapter 11 – Secondary Notifications in Section IV of this Handbook.

1.5.4 NICNAS Registration

All importers and/or manufacturers of industrial chemicals for commercial purposes must register with NICNAS regardless of the amount of industrial chemicals imported and/or manufactured in that registration year. A registration year runs from 1 September to 31 August in the following year. The Registration Tier that applies to you depends on the value of the industrial chemicals you import and/or manufacture.

The Register of Industrial Chemical Introducers is a maintained list of all registered importers and/or manufacturers. The register allows NICNAS to keep its industry clients fully informed of their obligations under the Act and any changes as they take place.

For further information on NICNAS Registration refer to Chapter 13 of this Handbook.

1.5.5 Treaties

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (The Rotterdam Convention).

The Rotterdam Convention is an international procedure that:

- a) helps participating countries learn more about the characteristics of certain potentially hazardous chemicals and certain severely hazardous pesticide formulations that may be exported to them;
- b) initiates a decision making process on the future import of these chemicals and formulations by the countries themselves and facilitates the dissemination of these decisions to other countries; and
- c) requires exporting countries to comply with the decisions.

The Convention covers industrial chemicals and pesticides (including in specific circumstances, severely hazardous pesticide formulations). The Convention does not involve international bans or restrictions. Decision-making on the future import of a chemical included in the Convention lies with each Party participating in the Convention.

The Convention provides that, if a chemical is banned or severely restricted in a country that exports this chemical, the exporting country must provide information to the importing country about why the chemical is banned or severely restricted.

Annex III of the Convention lists chemicals that have been banned or severely restricted on the basis of a risk assessment in the jurisdictions of the parties to the Convention. To be listed on Annex III, a chemical must be nominated by two countries from different PIC regions.

For further information on the Rotterdam Convention, refer to Chapter 14 of this handbook.

1.6 Compliance

The Act provides the broad parameters or framework in which the NICNAS compliance operates. All importers, manufacturers and exporters of industrial chemicals must comply with the legislation.

Although there are many good business reasons to pursue regulatory compliance, there is also the prospect that offenders will be identified and subject to significant penalty. The Act includes extensive penalty provisions, currently as high as \$165,000.

NICNAS is committed to developing and maintaining an effective compliance strategy to ensure the safe use of industrial chemicals in Australia. Its current strategy is to maintain the public's trust in chemical safety through compliance actions that ensure the integrity of the scheme. All industrial chemical manufacturers, importers and exporters should be aware that NICNAS conducts investigations aimed at identifying non-compliance with the legislation.

For further information, refer to Chapter 15 of this handbook.

1.7 Publication and Further Notification

Copies of the Act can be accessed through the SCALEplus website of the Australian Attorney General's Department at scaleplus.law.gov.au.

Information about industrial chemicals and NICNAS activities is available to the public through NICNAS assessment reports and the *Chemical Gazette* (see Appendix 5: *Chemical Gazette*), as well as at our web site: www.nicnas.gov.au/publications/gazette

Assessment reports are available on our web site or by contacting NICNAS on Free Call 1800 638 528. The *Chemical Gazette* is published on the first Tuesday of every month. It is available on the NICNAS web site.

Further information about NICNAS operations can be found in our annual report, which can be obtained directly from NICNAS or from the Publications page on our web site.