

EXISTING CHEMICALS REVIEW

UNDERSTANDING THE NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

This paper provides general information about NICNAS's role in assessing industrial chemicals in Australia and offers an overview of legal obligations applying to importers and manufacturers.

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 for assessing industrial chemicals in Australia which meets international best practice standards. The availability of NICNAS assessment reports to State and Territory regulatory agencies, to companies introducing chemicals, to people in the workplace, to 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, our unique environmental ecosystems and the patterns and conditions of the chemical's use in this country.

ABOUT NICNAS

NICNAS was established with the enactment of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) on 18 July 1990. It is a Commonwealth Government scheme located within the Office of Chemical Safety (OCS), within the Regulation Group of the Commonwealth Department of Health and Ageing and forms an integral part of the Commonwealth regulatory framework for chemicals. The Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth MP, has responsibility for industrial chemicals regulation.

As well as ensuring industrial chemicals are assessed, the Scheme disseminates information through the release of public assessment reports and the *Chemical Gazette*.

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 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 company registration purposes.

THE FOUR KEY OBLIGATIONS

The Act sets out four 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
4. Company Registration - registration of any company importing and/or manufacturing chemicals above a prescribed value.

An overview of each of these obligations follows, along with details of penalties for those who do not comply.

NEW CHEMICALS ASSESSMENTS

All new industrial chemicals must be notified to NICNAS and assessed prior to their import or manufacture in Australia. There are certain exemptions, for example, reaction intermediates, incidentally-produced chemicals, industrial chemicals introduced solely for research, development or analysis in quantities of less than 50 kg in any 12 month period, and chemicals which are produced in a fixture (site limited) in the course of a program of research, development or analysis. Exemptions for larger quantities are available, but criteria must be met. New industrial chemicals introduced in quantities of less than 10 kg per annum no longer need to be assessed, provided that they pose no appreciable risk to human health and the environment.

It is the responsibility of the importer 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.

A range of assessment categories exists 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.

EXISTING CHEMICALS 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 40,000 already present in Australia (ie 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 to manufacture or import the chemical must apply for assessment of the chemical. In all but exceptional cases, applicants can continue to import 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. Nominated chemicals are ranked according to published selection criteria. Recommendations are then made by the Director of NICNAS (the Director) to the Parliamentary Secretary for Health and Ageing for the declaration of PECs.

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.

OTHER ASSESSMENT CATEGORIES

While PEC assessments are the most well known of the NICNAS existing chemicals assessment activities, tailored / focussed assessments are also undertaken.

These other / 'preliminary' assessments address specific aspects of an existing chemical such as properties, use or uses, intrinsic adverse effects, and or the extent to which people or the environment will be exposed to the chemical. As such assessments are more targeted in their focus than PEC assessments (which a full hazard and risk assessments), they are faster to produce and allow greater flexibility in addressing specific concerns about an existing chemical.

In addition, NICNAS produces a number of chemical information products about chemicals of concern and matters of specific interest. These address particular concerns about a chemical for which there is a need for information (but not

necessarily an in-depth evaluation), specific topics of interest or summarise the outcome of PEC and preliminary assessments.

These chemical information products are in addition to the public assessment reports and are designed for the general public, workers and any others interested in the matters. These information products include:

- Chemical Information Sheets;
- Safety Information Sheets;
- NICNAS Alerts;
- Existing Chemicals Information Sheets, and
- High Volume Industrial Chemicals List.

COMPANY REGISTRATION

Companies which import and/or manufacture ‘relevant industrial chemicals’ above the prescribed threshold value are required to register annually with NICNAS. An annual application fee and registration charge is payable. The registration charge is based on the total value of relevant industrial chemicals imported and/or manufactured by the company. The Register of Industrial Chemical Introducers is kept, containing the name and registration number of the companies registered. The register allows NICNAS to keep its industry clients fully informed of their obligations under the Act and any changes as they take place.

Fees obtained from company registration are used to fund NICNAS's Existing Chemicals Assessment Program, compliance activities, and education and awareness-raising activities.

COMPLIANCE

NICNAS aims to uphold the integrity of the Scheme and enhance public confidence in the safe use of industrial chemicals by ensuring compliance with the Act. We are committed to protecting the business interests of importers and manufacturers who comply with their legal obligations. We aim to minimise instances of non-compliance with the Act through education and awareness-raising activities, but where compliance issues are identified, we work in partnership with companies to rectify them. In the extreme case where importers or manufacturers are unwilling to rectify compliance issues with us and the matter is brought before the Courts, there are penalties under the Act for failing to comply with assessment, information provision and company registration requirements. The amount of these penalties vary according to the offence and range from \$16,500 to \$165,000 for a company.

Powers to Monitor Compliance

There is a range of powers under the Act to assist us in monitoring compliance, including search powers to enter premises. The Federal Court may also grant an injunction to restrain a person or company from importing or manufacturing industrial chemicals where the requirements of the Act are not being met.

It should be noted that if an injunction is granted with respect to a particular chemical in the process of being imported (i.e. currently being shipped to Australia, though not

yet cleared through the Australian Customs Service), the importer would be required to make arrangements for Customs to hold the goods (at the importers cost) or return the goods to their place of origin. This would be necessary to avoid breaching the injunction.

Interacting with NICNAS in Compliance Matters

Aside from undertaking our own compliance activities, we are very committed to promptly following up compliance matters which are brought to our attention by other regulatory agencies, members of the chemical industry and the wider community. Complete confidentiality is ensured in all cases.

We encourage industry or the public to bring compliance matters to NICNAS. You may wish to bring a compliance matter involving your own company or another company's activities to our attention.

You may remain anonymous if you wish, however we would prefer your contact details in case we need to seek clarification or further information.

For more information about our compliance activities, visit our web site at www.nicnas.gov.au

PUBLICATIONS AND FURTHER INFORMATION

Copies of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) can be accessed through the Australasian Legal Information Institute's Internet site at www.austlii.edu.au or may be purchased in hard copy from any AusInfo bookshop.

Information about industrial chemicals and NICNAS activities is available to the public through NICNAS assessment reports and the *Chemical Gazette* as well as at our web site: www.nicnas.gov.au

Assessment reports are freely available either 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 and is provided free of charge to NICNAS registrants or by subscription to the Government publishing service, AusInfo.

Further information about NICNAS can be found in its annual report and Service Charter 2002-05, which can be obtained from NICNAS or from our web site or *NICNAS matters*, a regular newsletter providing up to date information on industrial chemicals regulatory activities at www.nicnas.gov.au/news.