




NICNAS matters.

NICNAS relocation to the Department of Health and Ageing



The Hon Trish Worth, MP

The Government announced on 26 November 2001, as part of its machinery of government changes, that the responsibility for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) would move to the Health and Ageing portfolio.

The *Therapeutic Goods and Other Legislation Amendment Bill 2002* was introduced into Parliament on 21 March 2002 to give effect to this administrative order.

The Hon Trish Worth, MP, Parliamentary Secretary to the Minister for Health and Ageing has executive responsibility for the Therapeutic Goods Administration (TGA), which now includes NICNAS.

The placement of NICNAS within the TGA group provides for an ongoing, consistent approach to the protection of human health from industrial chemicals.

NICNAS will continue to service all its stakeholders with provision of high quality independent chemical assessment advice. It will continue its strong links with the range of relevant Commonwealth and state/territory regulatory bodies, as this is necessary for the achievement of objectives.

Commitments have been given that NICNAS will maintain its service standards, and that the NICNAS Industry Government Consultative Committee (IGCC) will continue to be the primary consultative body for industry on NICNAS matters.



NICNAS contact details

NICNAS has settled into its new Marrickville office and our full contact details follow:

Street address:
334-336 Illawarra Road
Marrickville NSW 2204

Postal address:
GPO Box 58
Sydney NSW 2001
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New @ www.nicnas.gov.au

- The *Chemical Gazette* is published online. The latest issue is available at: www.nicnas.gov.au/publications/index.htm#gazette The New Chemicals Full Public and Summary Reports from the *Chemical Gazette* are also available for downloading.
- New Safety Info sheets for: Tetrachloroethylene, Hydrofluoric Acid, Benzene. Download them in PDF from the publications page for display in your workplace.
- New NICNAS information series – Chemical Info sheets. The first two of our new series of Chemical Info sheets for general use are now available:
 - Chemical Info sheet No. 1 What is Regulatory Toxicology?
 - Chemical Info sheet No. 2 What is an Industrial Chemical?
- To help us evaluate the quality and usefulness of the series, we'd welcome your feedback.
- Media releases on Formaldehyde and Sodium Cyanide.
- A new customer feedback form is available at: www.nicnas.gov.au/forms/feedback.htm
- The final Limonene and Acrylamide Priority Existing Chemical reports are available for downloading from the publications page.

Web site Statistics as at 31 March 2002

Key outcomes:

- Visitor sessions: average each day/average length; 402/13 minutes 15 seconds.
- Average hits each day: 8,449.
- Most requested pages: homepage, publications, forms, search, obligations, news.
- Most active day of the week: Wednesday.
- Most active day: 6 March 2002 (16,397 hits).

The value of your compliance

Any Australian company importing or manufacturing industrial chemicals should appreciate the value of compliance to their business.

In general, compliance is an integral part of a company's overall corporate goals and contributes to building and maintaining a company's status as a good corporate citizen.

The third issue of *NICNAS matters* contained a Due Diligence Checklist for NICNAS Compliance.

The benefits of compliance are many and can include:

- the potential benefits flowing from good corporate image, particularly from high profile triple bottom line accounting and environmental reporting;

- avoidance of damage to corporate image or brand of a breach, particularly if related to a significant adverse event;
- savings in legal and related costs flowing from failure to exercise due diligence and from avoidance of potential significant adverse events, and
- avoidance of personal liability relating to breaches of occupational health and safety requirements.

Although these reasons alone should be sufficient to encourage compliance, there is also the increasing prospect that offenders will be identified and subject to significant penalty.

The Industrial Chemicals (Notification and Assessment) Act 1989 includes extensive penalty provisions, currently as high as \$33,000. A summary of the main offences under the Act attracting penalties is provided below.

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Offences under the Act as at 26 February 2002

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All industrial chemical manufacturers and importers should be aware that NICNAS conducts investigations aimed at identifying non-compliance with the legislation and is placing greater emphasis on this compliance activity over the next few years. In deciding whether to prosecute a breach, NICNAS would take into account, among other things, whether the company had a compliance program in place.

Another significant consideration for chemical importers is the requirement of regulation 7A under the Act to keep a statement about each chemical imported that specifies:

- whether the chemical is, or contains, an industrial chemical;
- if an industrial chemical, whether that chemical is a new industrial chemical, and
- whether there is an assessment certificate or permit for the chemical.

Fulfilment of this requirement may be viewed as an early step towards compliance.

A company can only be confident of its position if its compliance strategy includes NICNAS requirements, either as a separate program or as part of a broader environmental and/or occupational health and safety compliance program. Companies that manufacture or import industrial chemicals and report on environmental compliance should also include NICNAS compliance issues in such reporting. In this way, not only will breaches and prosecution be avoided, but the company will reap the benefits of striving for best practice in all its activities.

- For further information, please contact **Phillip Lee**, Team Leader Innovation and Compliance on (02) 8577 8830 or email phillip.lee@nicnas.gov.au

ACT SECTION	DESCRIPTION	PENALTY
21	New Industrial Chemicals - Assessment Certificates A person must not introduce a new industrial chemical unless they hold an in force assessment certificate in relation to the chemical or a commercial evaluation, low volume, or introduction permit	\$33,000
21L(4)	Commercial Evaluation Permit A person commits an offence if the person is or was the holder, or any of the holders, of a commercial evaluation permit and contravenes a condition of the permit	\$33,000
21W(5)	Low Volume Chemical Permit System A person commits an offence if the person is or was the holder, or any of the holders, of a low volume permit and contravenes a condition to which the permit is subject	\$33,000
48	Priority Existing Chemicals (Chemicals already introduced but declared by Minister to require assessment) If the Director is considering making a recommendation under s50B for the declaration of an industrial chemical as a priority existing chemical, the Director may publish a notice in the Gazette requiring certain information. It is an offence to fail to comply with that notice	\$6,600
61(4) 61(5)	The Minister, by notice in the <i>Chemical Gazette</i> , may prohibit an activity while the chemical remains a priority existing chemical. An importer or manufacturer of industrial chemicals must not refuse or fail to comply with the notice and a person, other than an importer or manufacturer of industrial chemicals, must not refuse or fail to comply with the notice	\$33,000 for importer \$26,400 for a person
64(1)	Secondary Notification after Assessment Where an assessment report about an industrial chemical recommends secondary notification of the chemical in particular circumstances and the circumstances occur, the person must, within 28 days of the occurrence, notify the Director in writing that the circumstances have occurred	\$13,200
64(2)	Where a person who introduces an industrial chemical that has been assessed under the Act becomes aware of a number of circumstances (listed in the sub-section) that person must, within 28 days of becoming aware, notify the Director in writing	\$13,200

Information wanted SODIUM CYANIDE

Sodium cyanide was recently declared a priority existing chemical (PEC) for full environmental assessment (see the *Chemical Gazette* 7 May 2002).

The assessment will focus on determining the risk of adverse effects to the environment in Australia, by identifying the environmental hazards of sodium cyanide and the potential for exposure. Recommendations on ways to reduce any identified risks will be made.

Sodium cyanide is widely used in the mining industry in Australia for extraction of gold. Escape of the chemical into the environment can result in high acute toxicity to aquatic life, birds and animals. Consumption of contaminated tailings by birds has resulted in mass poisonings.

NICNAS is seeking assistance from anyone who may have information relevant to this assessment of sodium cyanide, such as uses of sodium cyanide and products containing sodium cyanide, concentrations of sodium cyanide in mixtures and information on environmental exposure.

Companies who wish to manufacture or import sodium cyanide during the period of the PEC review are required to apply to NICNAS for assessment. No application fee applies. Data requirements for importers/manufacturers and formulators of sodium cyanide and sodium cyanide products are stipulated in the Gazette notice

(www.nicnas.gov.au/publications/gazette/chemgazette2002.htm).

For further information or assistance, please contact

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Free call: 1800 638 528

For information on the NICNAS PEC program, please visit our web site at www.nicnas.gov.au

Information wanted FORMALDEHYDE

Formaldehyde was declared a priority existing chemical (PEC) for full assessment by a notice published in the *Chemical Gazette* of March 2002.

The assessment will determine the risk of adverse effects to the environment, workers and the public in Australia, by identifying the health and environmental hazards of formaldehyde and the potential for exposure. Recommendations on ways to reduce any identified risks will be made.

Formaldehyde is widely used in Australia, mainly in resins during furniture and textile manufacturing and to a lesser extent as a preservative in cleaning and cosmetic products. It is also emitted as a result of industrial processes.

NICNAS is seeking information relevant to the assessment of formaldehyde, such as uses of formaldehyde and products containing formaldehyde, concentrations of formaldehyde in mixtures and information on human and environmental exposure.

Companies who wish to manufacture or import formaldehyde during the period of the PEC review are required to apply to NICNAS. No application fee applies. Data requirements for importers/manufacturers and formulators of formaldehyde and formaldehyde products are stipulated in the Gazette notice

(www.nicnas.gov.au/publications/gazette/pdf/2002mar_whole.pdf#page=56).

NICNAS asks end users of formaldehyde and formaldehyde products to contact us to discuss the assessment and the information we are seeking.

For information on the NICNAS PEC program, please visit our web site on www.nicnas.gov.au

For further information or assistance, please contact

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International Activities

Rome OECD New Chemicals Task Force workshop

In 1998, the OECD Joint Meeting of the Chemicals Committee established work on harmonising notification and assessment of new industrial chemicals among Member States. A Task Force was created to manage the work. The workplan, designed to proceed in an incremental manner with useful products and outcomes in the short, medium and long term, identifies seven key work elements, namely:

- Bilateral/Multilateral Arrangements;
- Standard Notification Form;
- Standardised Formats for Assessment Reports;
- Hazard Assessment – Promoting the Exchange of Common Elements;
- Minimal and No-Notification Requirements for Low Concern or Exempt Chemicals (Exclusions and Exemptions);
- Confidential Business Information – Information Protection,
- Inventories.

A recent workshop (held in Rome, April 2002) concentrated on Bilateral/Multilateral Arrangements; Standardised Notification Form and Minimal and No-Notification Requirements for Low Concern or Exempt Chemicals. For the moment, the other work elements are on hold. Attending for Australia were Megan Smith and Bob Graf (NICNAS) and Joe Rundle (industry). Ms Smith acted as rapporteur.

As a precursor to the workshop, NICNAS hosted a technical meeting the day before to learn in particular about each other's notification and assessment schemes. During this meeting Mr Graf made a presentation which highlighted the features of the Australian Notification and Assessment Scheme.

Australia has been most actively involved in work on Bilateral/Multilateral Arrangements and along with five other OECD countries (Canada, USA, Austria, Switzerland and the UK) compared assessment reports for four different chemicals. In Australia this comparative work was largely carried out by chemical assessors Bill Diver, Kerry Nugent and Nian Chen. Reports on these comparisons were presented at the workshop by each participating country (with Mr Graf presenting for Australia), and their findings were then discussed in smaller breakout groups.

The workshop resulted in significant outcomes in each of the work elements focussed on. For example, attendees gained much knowledge and insight from the multilateral sharing and comparing of assessment reports.

These multilateral comparisons indicated that there are a number of similarities to build upon in future work.

For instance, the comparisons indicated that the hazard assessment from one member country could be used as a source document for another country. On the other hand, the comparisons also indicated that the exposure and risk assessments were less sufficient as source documents, due to gaps in data requirements and the scope of assessment.

Lead Role for NICNAS Template

A key outcome was the recommendation that a standardised format be developed. It was also agreed that the NICNAS New Chemicals assessment report template (refer article *NICNAS matters, Issue Four*) should constitute the starting point from which an internationally agreed assessment reporting format will be developed. Dr Nugent will undertake the role of Project Officer for this work.

In addition, the workshop highlighted the need for some countries, including Australia, to become more familiar with quantitative structure activity analysis (QSAR) methodology in risk assessment, in order to fill assessment gaps without the need for additional animal testing. In light of the success of the comparison work, the work elements concerned with Standardised Formats for Assessment Reports and Hazard Assessment are to be reactivated, which will prove beneficial to Australian industry in terms of use of overseas reports.

Activity in the areas of the other work elements also proved fruitful. Work on development and use of a standardised electronic notification form resulted in the decision to conduct a pilot trial of the proposed form (an electronic checklist) which was suggested by industry. Australia has agreed to participate.

The workshop also dealt with the harmonisation of requirements for exclusions and exemptions, the list of exclusions (from notification) proposed by industry were generally agreed, however, it was also noted that better definition and guidance notes are required. All exclusions proposed are currently excluded under NICNAS.

The list of exemptions (low risk categories with reduced data requirements) was not fully discussed. However, Australia is well placed in this area with its low risk categories and work on chemicals of low regulatory concern.

- For further information, please contact **Bob Graf**, Team Leader New Chemicals, Phone: (02) 8577 8850 Email: bob.graf@nicnas.gov.au

Increase surveillance of worker exposure to Acrylamide, report says

Revision of the hazard classification for acrylamide has been recommended by NICNAS in its latest Priority Existing Chemical assessment report published on 7 May 2002. The possible risk of impaired fertility and the designation of the chemical as being harmful in contact with the skin are among the changes.

"Airborne levels of acrylamide are greater in processes using the crystal form of the chemical as opposed to liquid or gel forms. NICNAS recommends the use of liquid or gel forms instead of crystalline acrylamide where possible," said the Director of NICNAS, Dr Margaret Hartley.

"There is cause for concern about the risk of nerve damage in workers with repeated occupational exposure to acrylamide. Routine air monitoring by industry would help reduce this exposure. Establishment of formal health surveillance guidelines and setting of a biological exposure standard by NOHSC would assist in early identification of symptoms and help in prevention of acrylamide-induced nerve damage," Dr Hartley said.

Acrylamide is not manufactured in Australia, but is imported in large volumes and used to make polyacrylamides which have a wide spectrum of use in a number of diverse applications, including water and sewerage treatment, paper manufacture, surface coatings, textile processing, cosmetics and oil exploration. The chemical may be released to the environment, with 99 per cent finding its way into water. It is slightly toxic to aquatic plants and organisms and to terrestrial plants and micro-organisms.

Publication of the PEC report revokes the declaration of acrylamide as a priority existing chemical under section 62 of the Act.

The report is available from the NICNAS web site at: www.nicnas.gov.au/publications/car/pec/pecindex.htm

Hard copies are also available (free) on request to:
NICNAS
GPO Box 58
Sydney NSW 2001
Australia

Free call: 1800 638 528

NICNAS – Canada cooperation a step closer

During 19 - 26 February this year, NICNAS hosted an eight-day visit from representatives of Environment Canada and Health Canada and from Canadian industry involved in new industrial chemicals notification and assessment in Canada. The purpose of the visit was to complete negotiations for the Australia-Canada Bilateral Arrangement between NICNAS and Environment Canada/Health Canada and to provide an opportunity for the Canadians to visit other Commonwealth chemical regulators and industry in Australia.

Mr David McBain, Director New Substances Branch, Environment Canada and Ms Jacqueline Sitwell, Acting New Substances Assessment and Control Bureau, Health Canada led the visiting Canadian Government team. Very productive discussions were held with NICNAS concerning information sharing on the respective regulatory schemes, new activities under the Bilateral Arrangement work plan, outcomes of the comparisons of assessment reports undertaken by Australia and Canada under the OECD New Chemicals Program and future directions in international chemicals' policy.

The group met with other regulators including the chemical assessment sections at the Therapeutic Goods Administration and Environment Australia, Australia and New Zealand Food Authority, National Registration Authority and Office of the Gene Technology Regulator.

Mr Jack Soule (DuPont Canada) and Mr Allan Jones (Canadian Industry Coordinating Group) discussed the Bilateral Arrangement with Australian industry, NICNAS and the Canadian regulators, to help ensure that the arrangement incorporates tangible benefits to industry in both countries. The Plastics and Chemicals Industries Association (PACIA) in Melbourne hosted a very beneficial industry day on 22 February.

Both Canada and Australia are committed to a closer working relationship that will enable work and information sharing to enhance new chemical assessments and reduce regulatory burden for governments and industry. All parties found the face-to-face meetings very successful and good working relationships between the two regulators are firmly established.

NICNAS hopes to further the relationship by visiting Canadian Government regulators and industry later in the year.



Representatives from the Canadian Government and NICNAS at Marrickville

Left to right
Standing Nick Miller (NICNAS) Bob Graf (NICNAS) Martin Sirois (Environment Canada) Berhanu Idris (Health Canada) Roshini Jayewardene (NICNAS) Megan Smith (NICNAS)
Seated Jacqueline Sitwell (Health Canada) Margaret Hartley (Director NICNAS) David McBain (Environment Canada) Shaunalea Savard (Health Canada)

Introducing new **NICNAS** staff



Trang Pham



Janet Cumming



Warwick Shaw



Jane Weder



Griffin D'Costa



Phillip Lee



Cecelia Loi



Nigel Bruce

NICNAS would like to introduce eight new staff members

Trang Pham and **Janet Cumming** recently joined the New Chemicals team to research and assess new industrial chemicals for potential risks prior to their importation or manufacture in Australia.

Dr Pham previously provided support to several expert medical committees whilst with the Department of Health and Ageing in Canberra.

After completing her BSc Hons in environmental chemistry at Griffith University in Brisbane, Ms Cumming worked with NRCET (National Research Centre for Environmental Toxicology) before joining NICNAS.

The Existing Chemicals team welcomes three new staff members, who are involved in collecting and reporting data on the use

of chemicals and in the assessment of industrial chemicals. After completing his BSc Hons in toxicology at Lincoln University in Canterbury, New Zealand, **Warwick Shaw** worked on the Transfer of Substances Group of the Environmental Risk Management Authority New Zealand for two years.

Dr **Jane Weder** joined NICNAS following an Industry Research Fellowship with the University of Sydney School of Chemistry.

In addition to his background in toxicology, **Griffin D'Costa** brings to NICNAS corporate experience in problem management, service level agreement management and customer service.

During his 12 months with NICNAS, **Phillip Lee** will lead the Compliance team. Mr Lee has extensive policy and regulation experience relating to the energy industry from a lengthy career in the NSW Ministry of Energy and Utilities.

Over the years, NICNAS has been fortunate to host a number of Year-In-Industry Program students. Like her predecessors, **Cecelia Loi** will gain valuable experience from placements in four NICNAS teams and in Agricultural and Veterinary Chemicals OHS Assessment at NOHSC. At the end of her placement, Ms Loi will return to the University of Sydney to complete her BSc, majoring in chemistry.

NICNAS has been fortunate in recently obtaining the services of accountant **Nigel Bruce**, who for six months will assist with NICNAS finances, notably with the transfer to the Department of Health and Ageing.

Widely used citrus solvent reviewed

On 7 May 2002, NICNAS released a final report on the chemical limonene. The report assessed the health, safety and environmental risks of limonene and made a number of recommendations for safe use.

Limonene is manufactured in Australia from orange oils by extraction through distillation. It is also imported both as raw material and as an ingredient in products.

Limonene is used widely as a fragrance additive in household and cosmetic products. It is also present in most of the essential oils that are commonly used in Australia, particularly citrus oils. Most limonene-containing consumer products contain less than 1 per cent limonene. In the workplace, it is used mainly in hand cleaners, industrial cleaning and degreasing products, removers and strippers.

The report finds that limonene causes skin irritation and that contact with oxidised products of limonene (formed by exposure of limonene to light and air) can cause skin sensitisation.

The report recommends limonene be classified as a skin sensitiser and further recommends a number of measures to prevent the formation of oxidation products.

The publication of this report revokes the declaration of limonene as a priority existing chemical under section 62 of the Act.

The report is available from the NICNAS web site at: www.nicnas.gov.au/publications/car/pec/pecindex.htm

Hard copies are also available (free) on request to:
NICNAS
GPO Box 58
Sydney NSW 2001
Australia

Free call: 1800 638 528

Australian Inventory of Chemical Substances on CD-ROM

NICNAS advises that the new version of the Australian Inventory of Chemical Substances (AICS) on CD-ROM is now in production and will be released shortly. An announcement will be made on our web site when the CD is available for sale.

In the meantime, clients can find most chemicals on public AICS by searching the AICS CD-ROM 1999 version 2 and checking the *Chemical Gazette* for chemicals added to AICS from November 1999. This can be done electronically for issues published on our web site since February 2001.

In addition, NICNAS still offers a free AICS search service. The AICS Search Form is available on our web site www.nicnas.gov.au or from NICNAS on fax (02) 8577 8888.

AICS is also available on the CAS National Chemical Inventories disk.

Requests to search confidential AICS must be made in writing to the Director
NICNAS
GPO Box 58
Sydney NSW 2001
Australia



AAT Update

In March 2001, four companies made application to the Administrative Appeals Tribunal for review of the Director, NICNAS's decisions relating to their 1999-2000 company registration charges. All four applicants were cosmetic introducers, who were joined by their governing industry body as an interested party.

The applications were subsequently withdrawn in December 2001 and the Director's assessments on the applicants' registration charges were taken to stand.

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 **NICNAS**

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