



NICNAS matters.

Director's message

Overview of recent performance

It is now four years since NICNAS commenced operating in a full cost recovery environment. We have used this challenge to introduce significant changes to how we work, including shifting our operational focus from process to achievement.

During the last year, we have built on earlier initiatives to strengthen our corporate identity and the level of open and consistent service delivery.

A particular focus has been to ensure we are able to innovate and change the regulatory environment for our clients. This has involved change in the day-to-day operations of the organisation to a new focus on teams.

Over the past four years, we have implemented more than 23 reform initiatives. The uptake trends and cost impacts which we have evaluated are a measure of the effectiveness of these reforms.

Overall, NICNAS has delivered high level quality outputs across all operational areas in 2000-01.

Key achievements in 2000-01

Our key achievements include:

- Increase in outputs by 22 per cent for all assessment categories.
- Elimination of our assessment backlog (a major problem prior to moving to full cost recovery) with outputs keeping pace with inputs to avoid future backlogs.
- All quality and timeframe targets met across all assessment and permit categories and exceeded in many cases.
- Uptake by industry of reform initiatives leading to estimated savings to industry in the range of \$1.7 to \$6.3 million since July 1997.
- Our commitment to review 50 priority existing chemicals (PECs) in three years exceeded by 10 per cent (ending in April 2001), with the completion of 12 full assessments (target was 10) and 43 preliminary assessments (target was 40). This represents a tenfold increase in productivity, compared with results prior to 1997-98.
- A further 106 screening assessments completed for the PEC candidate list.
- Introduction of the practice of monitoring the uptake of recommendations made in PEC reports. This is to provide feedback to stakeholders on our review products and on the delivery of better outcomes for the safe use of chemicals.
- Enhanced usefulness of our assessment services both

in terms of a strategic broadening of the range of stakeholders and of tailoring a range of assessment outputs, e.g. the introduction of Safety Info Sheets for display in workplaces.

- A fivefold increase in the use of overseas reports within our PEC assessments and ongoing work to enhance access to overseas reports, resulting in 55 international assessments agreed to by Australia, available nationally.
- Introduction of an effective compliance strategy with 235 new cases over the past 4 years, compared with 2 in the previous 6 years to 1996-97.
- A redesign of our web site as the focal point of NICNAS information delivery, with nearly one million hits in its first 8 months.
- Increased access to better chemical safety information (more than 1000 chemical assessments now on the web site).
- *Chemical Gazette* published free online at a saving of about \$40,000 each year in subscription costs.
- *Handbook for Notifiers* available free online.

Importantly, our increase in productivity and outputs has been delivered with no increase in fees or charges to industry and reflects efficiency gains of about 10-15 per cent last year alone.



Dr Margaret Hartley
Director

Major milestone: NA/1000

It's arrived at last! We've reached four digits.

History was made in New Chemicals when notification NA/1000 burst through the door in early October 2001. After 11 years of operation, the 1,000th Standard or Limited Notification was received by NICNAS for assessment, a long way from the humble beginnings in 1990 when it took six months for the first notification NA/1 to be submitted.

New @ www.nicnas.gov.au

- The *NICNAS 2000-01 Annual Report* is now available in PDF for downloading at www.nicnas.gov.au/about/annualreport/index.htm
- The *NICNAS Handbook for Notifiers* has been amended and the latest version is now available in PDF for downloading from the Publications page.
- New Safety Info Sheets for: para-Dichlorobenzene; ortho-Dichlorobenzene; Triglycidylisocyanurate (TGIC); Short Chain Chlorinated Paraffins (SCCPs); Trisphosphates; and Ammonium, Potassium and Sodium Persulfate. Download them in PDF from the Publications page for display in your workplace.
- *Benzene - Priority Existing Chemical Secondary Notification Assessment Report No. 21* - is available for download in PDF at www.nicnas.gov.au/publications/CAR/PEC/PEC21/PEC21index.htm
- The *NICNAS 2001 Service Charter* is now available on the web site at www.nicnas.gov.au/about/servicecharter.htm
- The *Chemical Gazette* continues to be published online. The latest issue is available at www.nicnas.gov.au/publications/index.htm#gazette
- To assist users to find relevant information, the NICNAS web site now features a revised site map and search engine facilities.

Web site statistics 1 July-30 September 2001

Key outcomes:

- Average hits each day 7,363 (compared to 6,555 at the end of June 2001).
- Most requested pages – homepage, publications, and forms.
- Highest activity levels – continue to be on Tuesday and Wednesday.

Dr Bill Diver



In actual fact, NICNAS has received far more than 1,000 notifications. Together with the Standard and Limited Notifications, NICNAS has received more than 1,000 permits and over 270 notifications for polymers of low concern, making over 2,000 in total.

So who will assess NA/1000? None other than the doyen of new chemicals assessors, Dr Bill Diver. Dr Diver was a foundation assessor in New Chemicals in 1990 when the pace of submissions was somewhat slower than today. In today's cost recovery climate, it's usual for an assessor to have 20 assessments on their plate. These are now all completed within statutory timeframes! Dr Diver has been a tower of strength and great mentor in New Chemicals assessment over its lifetime and richly deserves the honour of assessing NA/1000.

what's inside...

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Australian High Volume Industrial Chemicals List

NICNAS is setting up a list of industrial chemicals that are manufactured and imported in Australia in large quantities. The list will contain information about volume (manufactured or imported), which industries use the chemical, and its general uses.

This list will be a useful source of information for NICNAS, industry and the community. It will improve the screening of chemicals nominated for assessment under the NICNAS Priority Existing Chemicals program, thus helping to ensure that assessments are carried out for the most warranted cases. Further, the list will enable NICNAS to support the international assessment of chemicals of particular importance to Australian industry, the community and the environment. The Australian High Volume Industrial Chemicals List (HVICL) is a reflection of NICNAS's commitment to addressing the increasing public demand for easily accessible information on chemicals.

The first stage of the process, collection of information on chemicals manufactured by a company in a quantity of 100 tonnes or more each year, has been completed. From this information, a list of those chemicals manufactured in aggregate volume of 1,000 tonnes or more was published in the May 2001 *Chemical Gazette*.

The second stage of the process now being undertaken involves collecting information on chemicals imported by companies in a quantity of 100 tonnes or more each year.

NICNAS conducted a pilot study to evaluate the practical issues faced by industry in providing import volume data. As a result, the original proposed reporting threshold for a company, has been increased to 100 tonnes each year for "pure" chemicals and ingredients, and a product screening threshold of 50 tonnes each year will apply.

A call for information on imported high volume industrial chemicals will be published in the December 2001 *Chemical Gazette*. **Companies will have until 30 April 2002 to supply this data.** Guidance documents will be provided to companies to help them determine the need to supply information and to assist in the reporting of chemicals imported in mixtures. Seminars will be conducted early next year to further explain the process.

- Importers wishing to register now for receipt of guidance material and a reporting package should contact Dr Meena Agrawal on (02) 8577 8839 or email meena.agrawal@nohsc.gov.au

Legislative changes update

Further to advice in the February 2001 issue of *NICNAS matters*, amendments to the *Industrial Chemicals Notification and Assessment (ICNA) Act* have recently been agreed to by Parliament.

The amendments were part of the *Safety, Rehabilitation, Compensation and Other Legislation Amendment Bill 2000 (SRCOLA Bill)*, which received royal assent on 1 October 2001 (Act No. 144 of 2001). It is anticipated that the changes to the Act will be proclaimed in November 2001.

The amendments aim to reduce red tape for introducers (manufacturers and importers) of industrial chemicals and minimise compliance costs to industry.

There have also been changes to the *Criminal Code* which will be applied to all Commonwealth criminal offences (including those stated in the *ICNA Act*) from 15 December 2001.

Changes to the ICNA Act

The main changes to the *ICNA Act* include:

1. Broadening the definition of synthetic polymers of low concern to include certain polyesters:

- This will enable polyesters of known low hazard to be assessed similarly to other low hazard polymers.
- This amendment is based on scientific experience both within NICNAS and overseas regulatory agencies, which has shown that certain polyesters are relatively benign, and in the past were over regulated compared to their potential risk.
- NICNAS will still carry out a risk assessment on these chemicals but can do so with reduced data requirements and hence reduced cost to industry.

2. Publishing a summary report only for synthetic polymers of low concern:

- This is an administrative change which reduces the cost of publishing a full report in the *Chemical Gazette*. The amendment will not affect the assessment or public access to chemical risk information. A full public report will still be available on the NICNAS website or free-of-charge on request from NICNAS.

3. Changes to the secondary notification process for Priority Existing Chemicals (PEC) – secondary notification is the

reassessment of a chemical as a result of new significant information becoming available after the publication of a PEC assessment:

- This will align the secondary notification to the more open assessment process, including public comment periods, as occurs when conducting PECs.
- Industry, the public and other interested parties will have access to draft reports and have the opportunity to request variations to reports before they are published (note: currently non-applicants cannot request variations until after a final report is published).

4. Broadening the scope of collecting information for secondary notification.

- The Act currently limits the collection of information for secondary notifications to introducers (manufacturers and importers) of a chemical. The amendments will enable information on a chemical to be sought from a wider group of interested persons. This acknowledges that users and other industry sectors may have relevant information on chemical safety.

New regulations

There are several new regulations, including regulations to support the above amendments to the Act. It is anticipated that these regulations will come into effect in December 2001. The main regulations are:

- New criteria for synthetic polymers of low concern (the criteria will define which polyesters can be considered as synthetic polymers of low concern – see amendment to the Act above).
- Amend Regulation 11B to reflect the name of the voluntary Prior Informed Consent (PIC) procedure and its derivation.
- Omit obsolete Regulation 16 (waiver of fees for 1,4-dioxane).
- Amend Regulation 17 to allow for review by the AAT of decisions made under regulations made in 1999 (subRegulation 15(6) and Regulation 16A).
- For further information on these significant changes, please contact Bob Graf, Team Leader New Chemicals, on phone (08) 8577 8850, email bob.graf@nicnas.gov.au or Deborah Willcocks, Team Leader Existing Chemicals, on phone (08) 8577 8890, email deborah.willcocks@nicnas.gov.au

Japan/Australia talks

In August 2001, NICNAS staff met with Dr Teruyoshi Hayamizu, who was visiting Australia for a series of Japan/Australia High Level Environment Consultations. Dr Hayamizu is Head of the Chemicals Evaluation Office in the Environmental Health Department in Japan. The focus of these discussions was the architecture of the chemical assessment programs in each country, and exploration of the differences and similarities.

Dr Hayamizu was particularly interested in how environment assessments are conducted in Australia, as Japan is considering introducing environment assessment into their system, which currently focuses on human health. Systems for sharing work among government agencies for environment - and public and occupational health - were also discussed, as Japan also has a "multi-department" model. Differences in how each country handles confidentiality were identified. A major difference is that the identity of assessed new chemicals in Japan cannot be kept confidential. At the risk management end, there are also significant differences due to Japan's ability to regulate

specific chemicals at the national level, while in Australia this occurs at the State/Territory level.

In Japan, the main way a need for risk management of a chemical is identified is through assessment for biodegradability, bioaccumulation and long-term toxicity.

The meeting was very successful in developing mutual understanding, enabling exchange of information, and strengthening contacts for the future.



Dr Hayamizu with (from left) NICNAS staff Dr Sneha Satya, Director Dr Margaret Hartley and Ms Carolyn Vickers.

International Harmonisation of Risk Assessment Approaches

The International Program on Chemical Safety (IPCS), in its Project on Harmonisation of Approaches to the Assessment of Risk from Exposure to Chemicals (Harmonisation Project), is leading the way towards improving the science of risk assessment on a global basis. The Harmonisation Project, in developing a common language for risk assessment methods and approaches, is making international sharing of data and risk assessment approaches a reality.

Participating countries, including Australia, have shared information and collaborated to improve our understanding of risk assessment. Much has been learned and there is much more to learn and share with our international colleagues. Risk assessment methods are now evolving to take account of scientific advances. Revised and new tools provide the means to incorporate new information into risk assessments. Improving methods and developing innovative approaches mean better estimates of risk can be made and ensure greater safe chemical use. Harmonisation plays an important role in this process.

What is harmonisation?

In the context of chemical risk assessment, harmonisation is about compatibility. The goal is to bring assessment methods and approaches together on a global level. This will result in a number of benefits, including increased confidence in the assessment process.

The foundation of harmonisation is sound science. Scientific discussions will result in the development of common assessment tools and increased understanding, improving our ability to interpret scientific data and incorporate it into the risk assessment process. However, until recently, a common risk assessment language did not exist to facilitate such discussions.

In 1994, the IPCS, World Health Organisation, initiated a process to promote discussions about the application of scientific data and information into chemical risk assessment.

Australian scientists including those from NICNAS made effective contributions to a number of key activities including promoting the use of common data sets, clarification and use of terminology, and development of frameworks for assessing toxicity endpoints.

Australian involvement

These activities have led to greater transparency in decision-making in chemical risk assessment and greater opportunity to share risk assessments to support chemical safety management activities globally. For example, within the IPCS Harmonisation Project, scientists from NICNAS and the Therapeutic Goods Administration have participated in expert workshops to discuss the incorporation of mechanistic data into cancer risk assessments. An internationally accepted framework for evaluating a mode of action for chemical carcinogenesis was developed. This framework has been incorporated into a number of regulatory agencies' assessment approaches including the US EPA's proposal to revise its Cancer Risk Assessment Guidelines. It is also used routinely in NICNAS Priority Existing Chemicals assessments.

A lead role for NICNAS

Currently the NICNAS Director, Dr Margaret Hartley, is the Chair of the IPCS Harmonisation Project Steering Committee, a group comprised of national and organisational representatives. The Committee provides advice and guidance to the IPCS on project directions, priorities and implementation strategies.

Further, Dr Roshini Jayewardene, a Team Leader in New Chemicals Assessment in NICNAS serves on the Planning Work Group working to harmonise exposure assessment methodology. The Exposure Assessment activity commenced in 1999 and aims to work towards the understanding of a range of exposure assessment issues confronting risk assessors, specifically the incorporation of exposure assessment

information into risk assessments. Two projects are currently underway, namely, *Harmonisation of Chemical Exposure Assessment Terminology* and *Principles of Characterising and Applying Exposure Models*. Two important products will be made available through the Terminology Activity: *A Glossary of Key Exposure Assessment Terms* and *Exposure Assessment: A Compilation of Glossaries*. The Modelling Activity will develop a *Set of Characteristics of a Model* for use by model developers and users.

These and other Harmonisation Project activities will be incorporated into the risk assessment methodology here at NICNAS to ensure our risk assessments remain at world best practice and are open to exchange programs with other regulatory agencies overseas.

Harmonisation delivers benefits

The importance of harmonisation is not only that it provides a forum for scientific exchange, but that it also promotes greater sharing of assessment burden between countries and has the capacity to increase the number and availability of chemical risk assessments worldwide, thus supporting better risk management decisions and actions.

Harmonisation is about incorporating scientific advances into risk assessment and creating credible future approaches by working together for the benefit of all. To achieve success, it is incumbent upon risk assessment scientists from academia, government, industry and the NGOs community to participate in harmonisation activities. NICNAS continues to support this international effort towards harmonisation of chemical risk assessment.

- For more information on the Harmonisation Project see www.ipcsharmonize.org or contact Dr Hartley on phone (02) 8577 8808; email Margaret.Hartley@nicnas.gov.au

New Template for Notifier Submission of Draft Reports

NICNAS has provision for a 15 per cent rebate for notifiers who provide their own draft report in electronic format. While this provision has been used a number of times in the past, general availability of the NICNAS template and guidance material about how to fill out the template is expected to make the procedure simpler for notifiers in future.

As the preparation of a notification statement entails the preparation of a document which includes the information which NICNAS then uses to prepare a report, significant time savings may be possible if the notifiers prepare the document in an electronic form thereby saving double entry of information. This also has advantages in identification of confidential business information. NICNAS has therefore prepared a revised notification template for use by notifiers and NICNAS staff alike. Full guidance material has also been prepared.

The new process is similar to that practiced in Europe. A draft report will be submitted by the notifier and the contents of the draft will be checked and edited by NICNAS and its partner agencies. Additional sections containing the risk assessment of the new chemical will also be added by NICNAS, Environment Australia and the Therapeutic Goods Administration. The finished report will be forwarded to the notifier and published upon receipt of approval.

The revised template is similar to that used for European notifications. This will have advantages for the notifier where a chemical previously notified in Europe is then submitted to NICNAS.

The revised template will initially be used for Standard and Limited notifications; this will be extended to Synthetic Polymers of Low Concern (PLC) at a later date.

Implementation of the change will occur in three phases:

1. Use of the revised template by NICNAS to prepare reports.

2. A pilot program where a small group of notifiers trial the new template and provide comments to NICNAS.
3. General availability of the template to all notifiers.

The first phase will allow NICNAS to develop expertise in the using the template and to produce reports in the revised template, which may be useful as examples when the second and third phases commence. The first phase began in September 2001 with the adoption of part of the new template for preparation of the toxicology sections in all NICNAS assessment reports and is proceeding to adoption of the full new template.

The second phase will allow problems that may be associated with notifier submissions in the template to be identified and corrected prior to general release of the template. Details of the pilot program are given in the *Chemical Gazette* of 2 October 2001.

Assistance for notifiers will include a comprehensive guidance document, which details (with examples) the information to be provided at each point. NICNAS will also hold a series of workshops at the time of general release on submitting information in the template. Additionally, there will be an example of a submission (for a fictitious chemical) showing what would be expected in a notifier's draft report. Finally, by the time the pilot program commences, a number of reports completed entirely in the new template will have been published and may serve as examples for use of the template. Many more published reports will exist by the time the template is generally released.

- For more information on the new template, please contact Dr Kerry Nugent on phone (02) 8577 8861 or email kerry.nugent@nicnas.gov.au

Australian Inventory of Chemical Substances on CD-ROM

NICNAS advises that the Australian Inventory of Chemical Substances (AICS) on CD-ROM is temporarily unavailable. Current stocks of the AICS CD-ROM have run out and the next version is not yet ready for release.

Unfortunately, in compiling the next version of the AICS CD-ROM, we have experienced technical and contractual difficulties resulting in project delays. We are working to overcome these as soon as possible and will advise clients when the new version is released. We apologise for any inconvenience this delay may cause.

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 maintains a free AICS search service. The AICS Search Form is available on our web site www.nicnas.gov.au or from NICNAS on fax (08) 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



Customer survey results

In June 2001, a customer survey was conducted on performance against service standards as defined in the NICNAS Service Charter. The telephone survey canvassed the 65 companies that various sections of NICNAS most often deal with and the 22 companies with whom NICNAS has the least contact. In all, 87 companies were contacted with 70 interviewed, a response rate of 82 per cent. Last year's response rate was 21 per cent. The sampling methods and conduct of the survey differed between the two surveys.

Figure 1

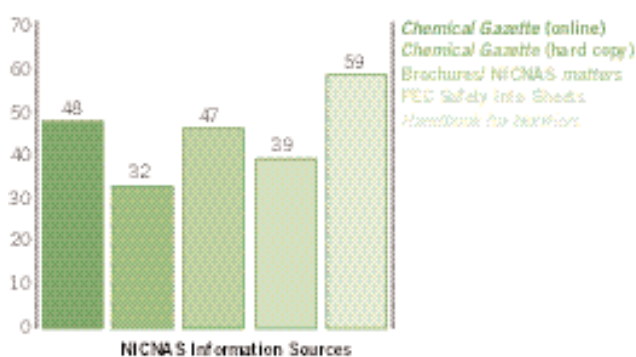


Figure 1 indicates the NICNAS information material most used by industry respondents. The online *Handbook for Notifiers* and *Chemical Gazette* constitute a major information source for industry.

None of the companies surveyed this year made any complaints in relation to our service. The survey showed that:

- 93 per cent found staff to be always helpful and courteous (80 per cent last year).
- 83 per cent found their questions and enquiries always answered promptly (63 per cent last year).
- 71 per cent found written explanations always clear (79 per cent last year).
- 93 per cent of companies surveyed are aware of the NICNAS web site. Of these, 82 per cent found the web site easy to navigate.

NICNAS would like to thank those companies which took the time to give us feedback on how successfully we are servicing your needs.

A number of suggested improvements were made by companies and NICNAS is working to incorporate these into our day to day practice. For example, navigation of our web site has been improved with the recent redesign of our site map - a direct result of feedback from the survey.

NICNAS Publications

All NICNAS publications are available to download free of charge from our web site at www.nicnas.gov.au

In addition, a hard copy of the *Handbook for Notifiers* can be ordered from NICNAS for AUD\$55 each (including GST).

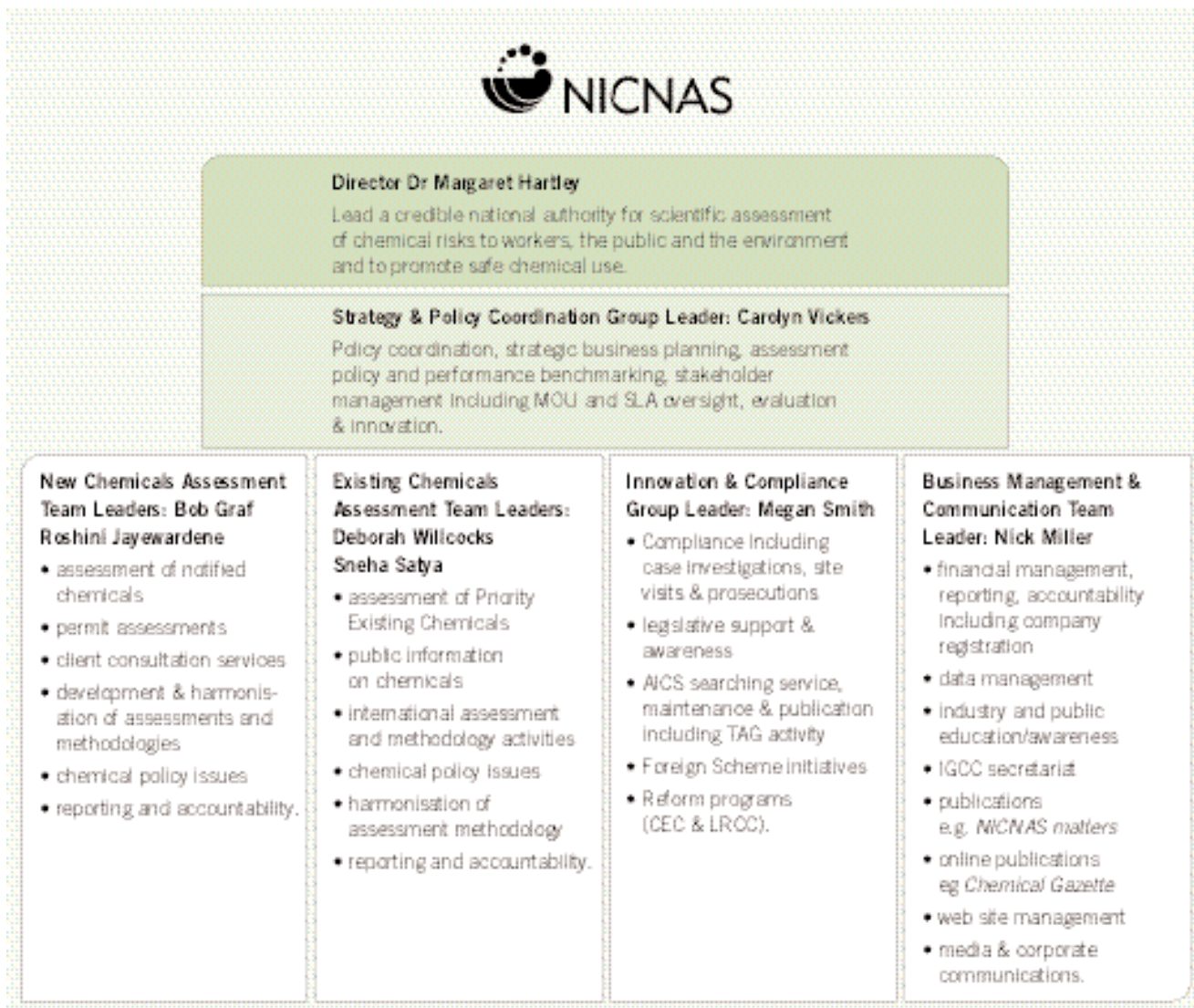
- For further information on obtaining copies of NICNAS publications, please phone free call 1800 638 528 or email info@nicnas.gov.au

Changes at NICNAS

Working in teams

The current business focus at NICNAS is on the successful transition to working in teams.

Our new team-based structure is detailed below. We hope the changes will ensure NICNAS continues to improve its outputs across all operational areas.



NICNAS Innovation Award

Dr Kerry Nugent



Innovation is one of NICNAS's four key organisational values - along with excellence, cooperation and achievement. By innovation we seek to embrace our creativity in all aspects of work and be flexible in our approach with unique and independent ideas.

NICNAS has introduced an Innovation Award to recognise staff who have made a substantial contribution to the organisation. Each quarter, candidates are nominated by staff and judged by a staff panel. The recipient of the inaugural Innovation Award for 2001-02 is Dr Kerry Nugent.

The win recognises Dr Nugent's special contribution to NICNAS electronic activities, including implementing the New Chemicals template as detailed on page 3 and developing a single NICNAS resource allocation sheet. The resource allocation sheet has streamlined reporting, promotes accountability by tracking staff activity against outputs and allows improved activity-based costing data to be collected to ensure tracking of expenditure across the Scheme.

NICNAS Moves New Contact Details

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) moved from Camperdown to Marrickville on 5 November 2001.

Our new contact details follow - please note that our GPO Box and freecall numbers, as well as our web site and email addresses, remain unchanged.

Street address:
334-336 Illawarra Road
Marrickville NSW 2204

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