



NICNAS matters.

NICNAS joins the Office of Chemical Safety

As part of the reform by Government to bring NICNAS to the Health and Ageing portfolio, all chemicals assessment and related public health control activities have been brought together in the Office of Chemical Safety.

Office of Chemical Safety

The Office, formed in January this year, provides advice on potential public health risks posed by chemicals used in the community. This is achieved by conducting risk assessments and providing toxicological advice to other regulatory authorities

on public health issues relating to agricultural, veterinary and industrial chemicals. It also provides technical policy advice on national and international chemicals negotiations and treaty matters, undertakes compliance and monitoring activities for the licit use of restricted and prohibited restricted substances and supports the scheduling of drugs and poisons for public health and safety.

The Office is led by Dr Margaret Hartley (Director, NICNAS) and is located in Sydney (NICNAS) and Canberra and forms part of the TGA Group of Regulators (with TGA and OGTR) in the Department of Health and Ageing.

Parliamentary Secretary announces Science Forum at meeting with Chemicals and Plastics Leadership Group

The Parliamentary Secretary for Health and Ageing, the Hon Trish Worth MP met with the Industry Minister, Ian Macfarlane and the Chemicals and Plastics Leadership Group (CPLG) at its second meeting in Melbourne on 19 February 2003.

Ms Worth outlined the good progress to date by Government agencies in implementing the nine regulatory initiatives contained in the Government's response to the Chemicals and Plastics Action Agenda.

Ms Worth announced the establishment of a Science Forum for regulators within the Health portfolio to identify best practice approaches to health risk assessment and management of chemicals. The Science Forum will be established under the auspices of the Office of Chemical Safety (OCS) and will include the Health portfolio regulatory agencies, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), the Therapeutic Goods Administration (TGA), the Office of the Gene Technology Regulator (OGTR) and Food Standards Australia and New Zealand (FSANZ). Agencies such as the Australian Pesticides and Veterinary Medicines Authority (APVMA), Environment Australia and the National Occupational Health and Safety Commission will also participate.

The establishment of the Science Forum is in response to Recommendation 3 of the Action Agenda that the APVMA, TGA and NICNAS compare their approaches to consultative/control mechanisms to identify a common efficient structure.

The findings of the Forum will inform the implementation of the Action Agenda's regulatory initiatives.

Dr Margaret Hartley, the Director of the OCS and NICNAS, will chair the Science Forum, which will hold its first meeting next month. The objective of the Forum is to bring regulatory scientists together to discuss common issues and innovations in risk assessment methods.

This collaborative approach between agencies will enhance the efficiency of chemicals regulation in Australia through comparison of current assessment approaches among participating agencies, consideration of international trends and harmonisation of best practice risk assessment methodology.

Science forum

Delivering best practice chemicals risk assessments
An initiative of the Department of Health and Ageing

For further information, please contact
Roshini Jayewardene
Phone: (02) 8577 8860
email: roshini.jayewardene@nicnas.gov.au

What's 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
- Reform of the Commercial Evaluation Permit (CEP) System Final Report – November 2002
- Draft Priority Existing Chemical (PEC) Report for Phosphorus-based Anti-valve Seat Recession (AVSR) Additive
- LRCC online questionnaire: www.nicnas.gov.au/news/lrcc-quiz01.asp

As at end March 2003, the NICNAS website was receiving some 13 000 hits each day.

NICNAS Reviews its Existing Chemicals Program

Following legislative changes introduced in 1997-98, an enhanced Existing Chemicals Program was established in April 1998 with a commitment to achieve 50 chemical assessments over the following 3 years.

This 3-year PEC Program was successfully completed in April 2001 and the same target outputs have been maintained for 2001-03. Given that the legislative changes would have been in operation for five years, it is timely to revisit the assessment program. Issues such as changes to overseas existing chemicals assessment programs currently underway or already in place, in particular the processes involved in nomination, prioritisation and assessment as well the effectiveness of overseas assessment outcomes will be considered.

NICNAS will be looking at how we determine national priorities for assessment, how better to utilise overseas testing and assessment program outputs and the needs of the community to have access to sound information on chemical hazards and risks.

A discussion paper will be released in June 2003, followed by wide consultation through seminars held in July/August 2003 in major cities.

For further information, please contact
Sneha Satya Phone: (02) 8577 8880
email: sneha.satya@nicnas.gov.au
Deborah Willcocks Phone: (02) 8577 8890
email: deborah.willcocks@nicnas.gov.au

what's inside...

- Reform Activities at NICNAS
- NICNAS out and about
- EU Visit
- LRCC Task Force
- AICS
- New staff

Low Regulatory Concern Chemicals (LRCC) Task Force

Low Regulatory Concern Chemicals (LRCC) Task Force meets for a second time

On 27 February 2003, the LRCC Task Force met to consider a range of options for progressing the LRCC reform initiative. The Task Force is required to provide a report on its findings by 30 June 2003.

The aim of the reforms is to introduce flexibility into the industrial chemicals assessment process to allow for fast tracking the introduction of previously assessed new chemicals onto the Australian market without compromising public health or the environment.

Chemicals could qualify for reduced regulatory input on the basis of a definition of low risk or where regulatory input from elsewhere is sufficient to meet Australian requirements.

Industry, government and the community are working in partnership to develop a range of options for public consultation. While there will be more flexibility introduced into the current regulatory system, the reform initiatives will not undermine the existing levels of public and worker safety or environmental standards.

Elsewhere in this edition of *NICNAS matters*, you will read progress reports from the NICNAS and industry technical Working Groups established by the Task Force to examine specific options.

An extensive consultation process has commenced with the engagement of industry and the community at each stage of the process. In general, there is overwhelming support from the industry sector for the reform process. The community is generally supportive provided that the existing levels of safety are maintained and that the public has improved access to information. Options for the implementation of an LRCC category may result in changes to the Act and Regulations and/or administrative changes within NICNAS, but these are not expected to fundamentally alter the intent and purpose of the Act.

For further information, please contact
Dusanka Sabic
Phone: (02) 8577 8870
email: dusanka.sabic@nicnas.gov.au



Industry, government and community working together on LRCC – LRCC Task Force meeting 27 February 2003

standing L to R: Mr Robert Ward (Dupont (Australia) Pty Ltd), Ms Dusanka Sabic (NICNAS), Mr John Hargrave (Dow Chemical (Australia) Ltd), Dr David Grantham (Queensland Division of Workplace Health and Safety), Ms Margaret Donnan (PACIA), Mr Joe Rundle (Clariant Australia Pty Ltd), Mr Geoff MacAlpine (ACSPA), Professor Neil Gunningham (ANU), Ms Megan Smith (NICNAS)

seated L to R: Ms Laurel Wolfram (BEREPA), Ms Sylvia Kidziak (IGCC, CPLG), Dr Margaret Hartley (NICNAS)

...Reform Activities at NICNAS...Reform Activities

Progress report from the NICNAS – Industry Technical Working Group

The NICNAS-Industry Technical Working Group comprises five members from the chemical industry with technical knowledge of NICNAS, and is chaired by Mr Geoff MacAlpine, Technical Manager Australian Consumer and Specialty Products Association.

The Group has established three project teams, each with industry and NICNAS project leads, with overall objectives to:

- align regulatory input from industry and Government to perceived risk; and
- enable sufficient knowledge and/or information of occupational health and safety, public health and environmental risks of the chemical.

Project 1 – Exclusion from NICNAS assessment of self-assessed non-hazardous chemicals using recognised classification and end-point criteria.

Objectives: To define parameters where industry can conduct self-assessment of risk, including the components of hazard, exposure and control mechanisms. The parameters are to satisfy regulators that industry can obtain and produce

information for the risk assessment, conduct the risk assessment and implement controls. NICNAS reporting and compliance aim to satisfy the community that industry self-assessment does not reduce safeguards below the current standard.

Project 2 - Acceptance of chemicals assessed/approved overseas by a competent authority with comparable requirements and assessment rigour (for example EU, Japan, USA, Canada) through

- company declaration with CAS No. and Material Safety Data Sheet
- NICNAS approval within a prescribed timeframe unless valid reason to contrary.

Objectives: To define parameters whereby assessment information generated by a comparable overseas regulator or approved for use overseas can be utilised in the NICNAS assessment process. The parameters are to maintain scientific standards in the provision of assessment information, maintain relevance to Australian exposure scenarios, minimise assessment duplication by NICNAS, retain existing standards for

OHS, public health and environmental assessment, should not extend existing statutory timeframes and should be cost effective for NICNAS (that is, should not result in increased assessment hours, time at NICNAS or administration resources for NICNAS).

Project 3 – A specific pathway for chemicals of low regulatory concern based on previous ideas presented by industry to the IGCC.

Objectives: To develop a framework and criteria for identification of new substances as chemicals of low regulatory concern to assist the efficient introduction of the substances, while maintaining regulatory standards for OHS, public and environmental risk determination.

Each team provided an initial report on reform options to the LRCC Task Force on 27 February 2003.

For further information, please contact
Megan Smith
Phone: (03) 9665 8446
email: megan.smith@nicnas.gov.au

Progress report from the Cosmetics Working Group

The Cosmetics Working Group aims to develop a framework and criteria for identification of chemicals in cosmetic/personal care products as low regulatory concern and clarify the cosmetic/therapeutic interface, to assist the efficient introduction of these chemicals whilst maintaining regulatory standards for OHS, public and environmental risk determination.

The Cosmetics Working Group comprises representatives from industry, government and community interest groups. These include:

- industry representatives - Cosmetics, Toiletries and Fragrance Association (CTFA) Australia, Australian Consumer and Specialty Products Association (ACSPA) and the Australian Society of Cosmetic Chemists (ASCC) ;
- public interest representatives – Botany and Eastern Regional Environmental Protection Association (BEREPA); and
- Government regulatory agencies - NICNAS, TGA and Competition and Consumer Policy Division, Treasury.

To date the Working Group has identified the fundamental issues with regards to the regulation of cosmetics in Australia, defined the objectives of the cosmetics reform activity and identified several options for change.

Options specific to cosmetics include:

1. review of local and international definitions with the aim of identifying a preferred Australian definition;
2. reclassification of certain products as cosmetics, for example via TGA Excluded Goods Order;
3. recognition of assessments by local regulatory agencies to comparable standards, for example where the same chemical is used as an excipient in therapeutics or pesticides or as a food additive;
4. accelerated addition to the inventory of common cosmetic ingredients, for example from EU positive lists, US Cosmetic Ingredient Reviews; and
5. an increase in the volume thresholds for exemptions.

Options common to all industrial chemicals include:

1. recognition of ingredients assessed/permitted overseas to comparable standards;
2. accelerated Australian Inventory of Chemical Substances (AICS) listing of non-hazardous chemicals;
3. identification of criteria and specific pathways for chemicals of low regulatory concern, for example history of use, non-inclusion in EU negative lists, imported as mixtures in low concentrations, low volumes; and
4. timeliness and transparency of AICS listed chemicals.

The next steps are to progress the options specific to cosmetics, analyse the impact of each option on industry (including small business), Government and the community and identify a preferred option, where possible. The options and analyses will be included in the Draft Options Paper.

For further information, please contact
Roshini Jayewardene
Phone: (02) 8577 8860
email: roshini.jayewardene@nicnas.gov.au



NICNAS hosts LRCC Workshop

On Monday 10 March 2003, around 20 people met at NICNAS to discuss the LRCC initiative. The aim of the workshop was to build on the work of the second LRCC Task Force meeting, reported elsewhere in this edition, and to ensure that all possible options for notification and assessment of the LRCC category had been identified. It also provided an opportunity to begin discussions on identifying the minimum number of pathways into the NICNAS assessment process that would be user-friendly for industry.

Dr Hartley, Director of NICNAS and Chair of the LRCC Task Force discussed the importance of balancing the needs of government, industry and the public in developing the reform proposals. Dr Hartley outlined the Task Force's goal, assessment criteria, principles and risk spectrum to be taken into account when developing reform proposals. The risk spectrum could be used to focus regulatory activity on the areas of greatest risk, as well as allowing for the introduction of a tiered approach to safety assessment.

The Task Force's goal for the reform process is:

- the safe and sustainable use of industrial chemicals in Australia.

The criteria against which each proposal will be assessed to ensure it meets the Task Force's goal are:

- does the proposal provide protection of Australian workers, public and the environment from risks posed by industrial chemicals?
- will adequate information be provided by introducers, that is, industry?
- is the reform measure effective, efficient, transparent, consistent and proportionate to the risk?
- will NICNAS be able to meet its mandatory reporting requirements to the public, states and territories and other regulatory agencies?
- do the proposals comply with the Council of Australian Governments Principles and Guidelines and the Office of Regulation Review's Guide to Regulation?
- has trust between the sectors been established – is there a balanced approach between the community's 'right to know' and industry's needs including consideration of a range of options such as industry codes of conduct/practice?

The workshop provided an opportunity for industry, government and the community to gain an understanding of the bigger picture and where their particular projects fitted into the overall



reform process. The working groups are on track to develop an options paper for public consultation in May 2003.

For regular updates on the LRCC Task Force please regularly check: www.nicnas.gov.au

For further information, please contact
Dusanka Sabic
Phone: (02) 8577 8870
email: dusanka.sabic@nicnas.gov.au

ies at NICNAS...Reform Activities at NICNAS...

Progress report from the Analogue Working Group

Analogue chemicals have been identified by the LRCC Task Force as an area where a lower level of regulatory input may be justified.

The Analogue Working Group has been looking at the various types of analogue chemicals expected to be introduced into Australia, as well as other similar scenarios where the assessment of a new chemical may be treated as an extension of the assessment of a previously notified chemical.

The Group has proposed the following options for the fast-tracked assessment of chemicals analogous to those previously assessed by NICNAS:

- **minimum testing packages**

Where the analogy has been demonstrated and accepted by NICNAS as meeting the requirements of predetermined criteria. Furthermore, the mode of use of the chemical and expected public exposure is such that data beyond the minimum dataset is not considered necessary

- **case-by-case assessment**

Where the chemical is not considered to meet the criteria for a minimum data package, testing requirements will be determined on a case-by-case basis

- **extensions of assessment certificates for inseparable analogue mixtures**

Where a manufactured chemical consists of two or more inseparable analogues, each additional chemical becomes the subject of an extension to the assessment certificate for the primary analogue.

All three options are expected to result in reduced timeframes and fees compared with those of current standard notifications.

In forthcoming weeks, the Group will be working closely with the Polymer Technical Working Group, as significant overlap between the Groups has been identified. The requirement of specific criteria for polymer analogues has been identified as a major concern.

For further information, please contact
Lewis Norman
Phone: (02) 8577 8854
email: lewis.norman@nicnas.gov.au

Progress report from the LRCC Polymer Technical Working Group

NICNAS has assessed low hazard polymers since March 1993, with reduced data requirements and fees available for polymers that satisfy the criteria for these polymers of low concern (PLCs). The criteria for PLCs are based on the US exemption criteria for low hazard polymers and have also been adopted by Canada.

Polymers have been identified as a class of chemicals where further reform is possible, as in most cases, the costs of notification and assessment of polymers under NICNAS do not match the level of hazard and risk. A joint Industry-Government Polymer Technical Working Group has been working to identify options for simplifying the current PLC category and to develop options for other polymers identified as LRCC polymers. These include:

Polymers of Low Concern (PLC)

Option 1

Provided the polymer meets the PLC criteria, no additional risk assessment beyond screening against the criteria would be conducted. No change to the PLC criteria is envisaged.

Option 2

As for Option 1, except that if a potential risk is identified in the two week pre-screening phase, a reduced risk assessment would be conducted (current experience flags a potential risk identified in approximately 5-10% of cases).

Option 3

A reduced risk assessment would be conducted for all PLCs. This option would include a reduced set of data requirements.

Summary

There is general agreement that a reduction in the costs and time of notification and assessment is warranted for polymers that meet the PLC criteria, as PLCs are generally of low risk. For approximately 5-10% of polymers notified as PLCs, the criteria do not completely obviate the risk, as some hazard and/or risk is identified, usually during the initial two week pre-screening period. The PLC criteria, which are based on the US EPA criteria and also adopted by Canada, are well understood by industry, reflected in the current 90-95% accuracy in self-assessing the polymer against the criteria.

Other Polymers (LRCC polymers)

LRCC polymers have been defined as those polymers that do not meet the PLC criteria but, for one reason or another, do not warrant a complete assessment. LRCC polymers include other classes of low hazard polymers, analogues, polymers already assessed by NICNAS or assessed overseas and polymers with standard use/exposure profiles. More work is required to develop the LRCC polymer criteria. Options include:

Option 1

Provided the polymer meets the LRCC criteria, no risk assessment would be conducted.

Option 2

Provided the polymer meets the LRCC criteria, no risk assessment would be conducted. However, the polymer would be subject to post-introduction reporting and/or auditing.

Option 3

A reduced risk assessment would be conducted for all LRCC polymers. This option would include a reduced set of data requirements.

Option 4

NICNAS could introduce a tiered approach to notification and assessment proportional to the level of regulatory concern. This is a flexible approach to assessment, where the level of assessment required for the LRCC polymer would be determined during the two week pre-screening phase and would depend upon factors such as volume of introduction, hazard status and use pattern (exposure profile).

Option 5

NICNAS could introduce a modular approach to assessment for LRCC polymers, where the level of assessment would be determined prior to application.

Summary

There is general agreement that a number of polymers currently notified do not warrant a complete assessment, for example other low hazard polymer classes, analogues and polymers assessed overseas. Therefore LRCC polymers provide an opportunity to substantially reduce the costs of notification and assessment of many polymers and, at the same time, enhance the flexibility of the Scheme. The criteria for identifying LRCC polymers need to be more fully developed, although considerable discussion on this issue has taken place in the Polymer Technical Working Group.

The opportunity to develop standard use/exposure profiles is being developed, where a reduction in notification and assessment costs can be realised without impacting upon OHS, public health or the environment. Industry will work with NICNAS in developing the profiles. To allay concerns regarding polymers with a potential risk, safeguards will be built into the criteria and assessment process.

For further information, please contact
Bob Graf
Phone: (02) 8577 8850
email: bob.graf@nicnas.gov.au

Introducing new NICNAS staff

NICNAS has welcomed three new staff members since the last issue of *NICNAS matters*.

Julie Thé joined NICNAS in November 2002 to assist with administration over the Christmas/New Year period. Currently Julie is assistant to the New Chemicals team and her valuable contribution to NICNAS was recognised with a Staff member of the month award in February 2003 (joint winner with Dr Margaret Hartley, Director, NICNAS).

Before her commencement in January 2003, **Anita Wai** had worked for many years in quality assurance/control in the pharmaceutical industry. She has an MSc in analytical chemistry from the UK. In the New Chemicals team, Anita researches



Julie Thé



Anita Wai



Claire Pakalns

and assesses new industrial chemicals for potential risks prior to importation or manufacture in Australia.

Like her predecessors in the Year-in-Industry Program, student **Claire Pakalns** will gain valuable experience with rotations through four NICNAS teams. Since arriving in February this year, Claire has completed a placement with the Innovation and Compliance team, where she compiled a list of chemical manufacturers and importers, and is now with the New Chemicals team. NICNAS appealed to Claire, because the opportunity for both scientific and administrative work complemented her University of Sydney Bachelor of Science/Commerce degree majoring in chemistry.

On Harmony Day 21 March 2003, **Deanna Kettle** was awarded the inaugural:

Duleep Jayemanne Memorial Award for Fellowship.

This award is for:

- loyalty and dedication to the organisation;
- camaraderie and fellowship among colleagues;
- a genuine love of life and a positive attitude.



Deanna Kettle

Visit by EU cosmetics expert

An expert in the field of cosmetics, Dr Gerhard J Nohynek visited NICNAS on 26 February 2003. Dr Nohynek is a senior toxicologist with L'Oreal, Europe with special interest and expertise in the field of sunscreens. Dr Nohynek met with NICNAS staff and discussed cosmetics regulation in the EU, the impact of the EU White Paper and other related topics.



L to R: Dr Jayewardene (NICNAS), Mr Chris Mejean (L'Oreal Australia), Dr Nohynek and Dr Hartley (NICNAS)

New Guidelines in development for Confidentiality Listing on the AICS

The document *Guidelines for Establishing a Case for Confidential Listing of Chemicals on the Australian Inventory of Chemical Substances* was first published in July 2000 after extensive industry and public consultation. The Guidelines document included a recommendation that a review of appropriateness and efficiency take place after a suitable period of operation, suggested as two years, and the Guidelines revised as necessary. NICNAS, with the assistance of a Technical Advisory Group (TAG), has considered over 75 applications for confidential listing on AICS under the new Guidelines, with about 50% achieving confidential listing.

Experience has shown that some companies have difficulty addressing the commercial and public interest criteria needed in making an application for confidential listing. It is therefore timely to revisit the Guidelines. The review seeks feedback on implementation from industry, as well as comment from industry and the public on the current criteria NICNAS uses for defining commercial and public interest. Comment is also sought on how to improve the efficiency of the confidential listing process. Following the review, NICNAS will clarify and/or amend the Guidelines to improve industry understanding of the issues taken into account by NICNAS when considering applications. Ultimately this should result in focussed applications, a higher percentage of which satisfy the criteria for confidential listing.

This review does not include review of the confidential listing provisions of the Act or the application fee.

To date, consultations have been held with industry applicants in Melbourne (March 2002) and Sydney (May 2002) and with community representatives with experience in chemicals and public right-to-know matters in Melbourne (August 2002) and Sydney (October 2002).

NICNAS is compiling the outcomes from industry and the community, and plans to release the draft revised Guidelines for broad public comment on www.nicnas.gov.au by June this year. Following consideration of any comments, NICNAS will revise the Guidelines and seek endorsement from the NICNAS Industry Government Consultative Committee.

For further information, please contact
Megan Smith
Phone: (03) 9665 8446
email: megan.smith@nicnas.gov.au

NICNAS matters is published by the National Industrial Chemicals Notification and Assessment Scheme
334-336 Illawarra Rd, Marrickville NSW 2204

Editorial Team: Nick Miller, Fiona de Mestre

Contact

NICNAS matters
GPO Box 58
Sydney NSW 2001

Inquiries

Phone: (02) 8577 8800
Email: info@nicnas.gov.au

ISSN 1444-1209

www.nicnas.gov.au

NICNAS – out and about Site Visit: Malabar Sewage Treatment Plant

NICNAS staff were 'treated' to a visit to Sydney Water's Malabar Sewage Treatment Plant in March. Community Liaison Officer Mr Ross Law provided a one-hour visual presentation on the fate of Sydney's wastewater and sewage, followed by a tour of the plant four storeys below ground.

With a capacity to treat up to 1 200 million litres of wastewater, Malabar is the largest sewage treatment plant in Sydney. Deepwater outfalls 3.6 km offshore and at a depth of 80 m utilise the natural ability of the ocean for final treatment of pre-treated effluent. Additionally, methane generated during the treatment process is utilised in a co-generation facility to generate electricity for use on site.

The visit was in part prompted by an interest in the environmental fate of many of the new chemicals assessed by NICNAS, which end up going to sewer.

NICNAS would like to thank Mr Law and the Malabar team for their hospitality.



Mr Ross Law guides NICNAS staff through the plant

 **NICNAS**
Assessing chemicals for your protection