



## NICNAS signs authority and confidentiality commitment with US Food & Drug Administration

NICNAS's active involvement in international activities over many years has realised considerable benefits including a contribution to more effective and efficient decision-making, cost savings for government and industry and greater opportunities for trade. The value of such involvement has been

notable at multi-stakeholder consultations and is reflected in the [NICNAS Business Plan 2010-11](#).

On 8 March 2011, Dr. Murray Lumpkin, Deputy Commissioner for International Programs of the United States Food and Drug Administration (USFDA), and Dr. Marion Healy, Director, NICNAS (pictured) exchanged confidentiality commitments permitting them to exchange and receive non-public information covering Cosmetics.



The commitments were signed during Dr Healy's visit to attend the APEC Chemicals Dialogue (see page 12), and follows New Chemicals Head of Program Ms Hana Hamdan's discussions with the US FDA over several years. Completion and execution of the Agreement provides the two countries with a framework for sharing information on cosmetic-related matters. It does not legally bind NICNAS but is a clear expression of intent to cooperate with the US FDA.

The new agreement complements a similar agreement between NICNAS and the US Environmental Protection Agency (signed December 2008). Since the establishment of that Agreement there have been over 12 exchanges of new chemicals notifications under the bilateral arrangements. ■

Access the [FDA/NICNAS](#) agreement @:  
[www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/ucm247449.htm](http://www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/ucm247449.htm)

Access the [NICNAS/FDA](#) agreement @:  
[www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/ucm247450.htm](http://www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/ucm247450.htm)

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ISSN 1444-1209



a word from the Director ...

This edition of *NICNAS Matters* reports the recent signing of Confidentiality Agreements with the US Food and Drug Administration (FDA), which allows greater exchange of information and discussion of matters between the two agencies. This includes information and issues that are not yet in the public domain and enforcement activities related issues, with the main area of mutual interest and cooperation between NICNAS and the US FDA being the regulation of cosmetics and their ingredients.

Although the regulatory arrangements for cosmetics differ between the USA and Australia there is a common objective of ensuring that products in the marketplace are safe, fit for purpose and regulatory requirements harmonised to the extent appropriate in order to facilitate global trade. The differences in regulatory approach are illustrated by the management of the safety of new cosmetic ingredients – in Australia the introduction of ‘new chemicals’ are subject to a pre market notification and assessment framework, while in the USA, industry is responsible for substantiating the safety of products and ingredients and there is a greater emphasis on post market activities. In addition, in the USA, products claiming the presence of sun protection agents are considered to be drugs (therapeutic products) while in Australia certain cosmetic products can contain and claim the presence of sun protection factors.

The finalisation of the Confidentiality Agreements between NICNAS and the US FDA is another important step in NICNAS’s efforts strengthen and formalise bilateral agreements with our counterpart agencies in countries with comparable regulatory systems for industrial chemicals, including chemicals in cosmetics and personal care and household products. In addition, to this Agreement with the US FDA, NICNAS currently has formalised agreements in place with the Canadian authorities (new chemicals), the US EPA (new and existing chemicals) and New Zealand’s ERMA (information sharing and collaboration). In addition, NICNAS has informal relationships with agencies in Canada in relation to existing chemicals, Europe and Japan. These formal and informal arrangements are a key plank in NICNAS’s strategy to take advantage of assessment activities that have been undertaken in other countries and achieve further harmonisation of requirements.

An array of training opportunities for stakeholders is also highlighted in this edition of *NICNAS Matters*, to assist in meeting obligations under the *Industrial Chemical (Notification and Assessment) Act 1989*. These training opportunities continue NICNAS’s approach of assisting stakeholders know and understand their obligations under the legislation to facilitate compliance. Furthermore, as I noted in the December 2010 edition of *NICNAS Matters*, the stakeholder survey conducted in 2010 highlighted a strong request from stakeholders for further training and information sessions. I therefore encourage you to take advantage of the scheduled sessions as well to let us know of topics that you would like addressed in such workshops. ■



**NICNAS Matters 30 issues strong**

This is the 30<sup>th</sup> issue of **NICNAS Matters**. Issue No. 1 (pictured at left) – published in August 2000 – featured items on NICNAS’s 10<sup>th</sup> Birthday and the Trichloroethylene phase-out. See story page 12.



Dr Marion Healy



## NBPT Secondary notification assessment report now available

The final report on the existing chemical secondary notification assessment of N-(n-butyl) thiophosphoric triamide (NBPT) is now available on the [NICNAS website](http://www.nicnas.gov.au).

NBPT was assessed by NICNAS in 1997 as a new chemical (NA/467) and is now listed in the public section of the Australian Inventory of Chemical Substances (AICS). In June 2009, additional data on NBPT was provided that required secondary notification as an existing chemical.



### SECONDARY NOTIFICATION

A secondary notification is a mechanism whereby a chemical that has previously been assessed can be reassessed due to significant changes in circumstances which are deemed to warrant a reconsideration of its hazards and/or risks.

The main recommendation of the NBPT report relates to providing information on the adverse health effects of NBPT to workers by assigning an occupational classification for NBPT. The report recommends that NBPT be listed in Safe Work Australia's *Hazardous Substances Information System* (HSIS) as a hazardous substance indicating "Risk of serious eye damage (R41) and Possible risk of impaired fertility (Toxic to reproduction, Category 3) (R62)". The classification of NBPT as a hazardous substance ensures that there are provisions in place at workplaces to minimise exposure to NBPT to protect workers.

NBPT is a urease inhibitor which can reduce nitrogen loss by ammonia volatilisation from urea. It is used as a fertiliser additive in agricultural applications. It is not manufactured in Australia but is a component (20%) in an imported product, AGROTAIN®.

#### Risk

Potential occupational exposure to NBPT may occur during manual handling of AGROTAIN® at reformulation sites, and to a lesser extent during fertiliser application. Serious damage to the eyes is a concern for workers handling AGROTAIN® containing 20% NBPT. Risk of adverse systemic toxicity is considered to be low. NBPT adversely affects rat reproductive organs with a potential risk of effects on fertility with prolonged exposure to preparations containing ≥ 5% NBPT. The recommendations outlined in the report mitigate the risk.

The final fertiliser preparations contain very low amounts of NBPT and therefore the risk from the use of the fertiliser product is low.

No public exposure occurs during the reformulation or application processes and risk of adverse effects to the public is low. NBPT may be absorbed by crops grown on treated soil but residues of the chemical in food commodities are expected to be negligible.

No new data on environment were provided and the conclusion from the assessment as a new chemical (NA/467) applies. Leaching into groundwater from the soil is expected to be low. Aquatic hazard is expected to be low.

The [NBPT report](#) is available at:

[www.nicnas.gov.au/Publications/CAR/Other/NBPT\\_Final\\_Report\\_PDF.pdf](http://www.nicnas.gov.au/Publications/CAR/Other/NBPT_Final_Report_PDF.pdf) ■

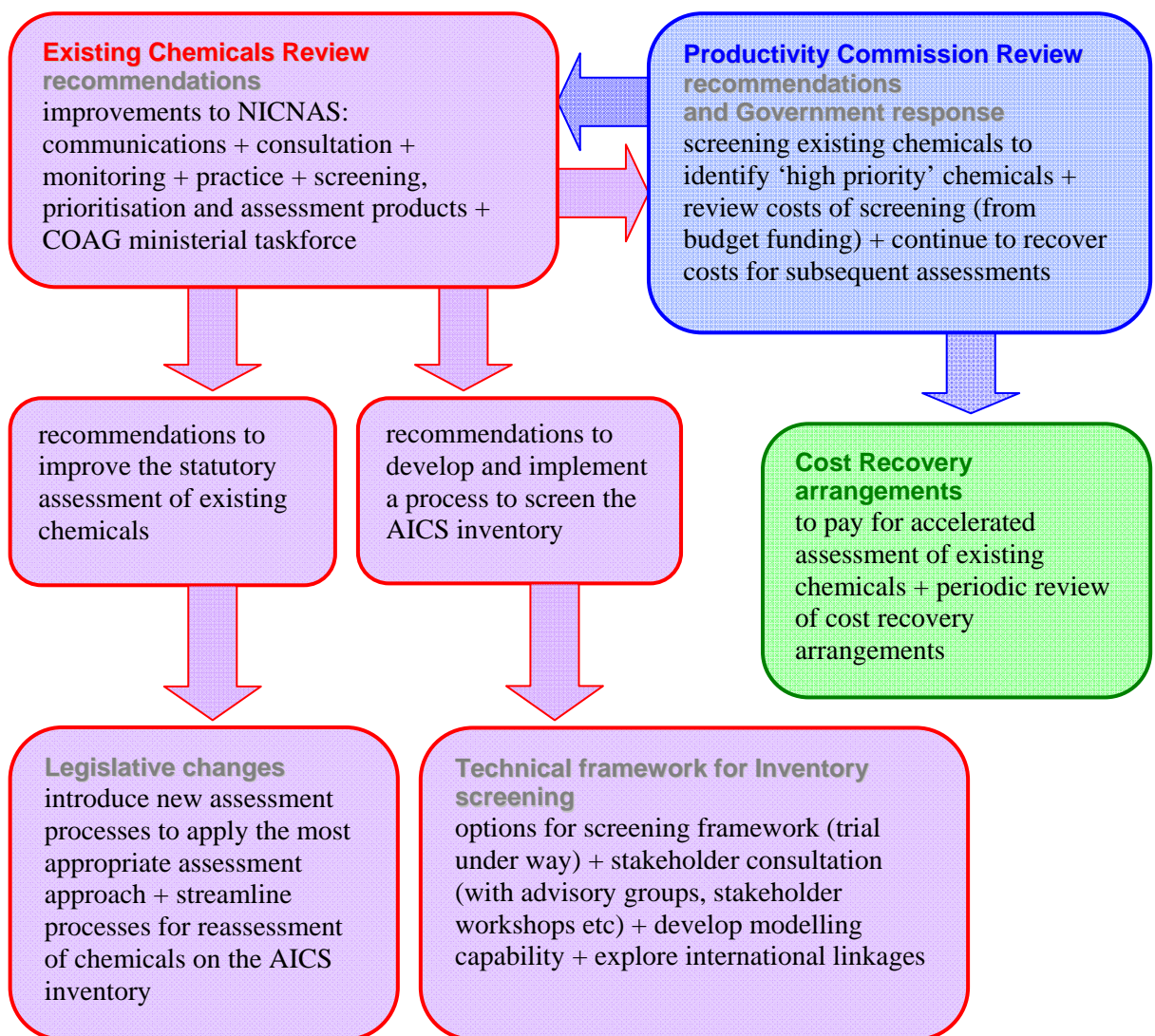




## NICNAS reform drivers and projects update

The Existing Chemicals Review and the Productivity Commission Review each presented challenges to NICNAS's work in the assessment and regulation of industrial chemicals.

The flow diagram (*below*) provides a general overview of how NICNAS is either currently meeting – or planning to meet – those challenges, through reform and other activities.



## Existing chemicals program reforms an update

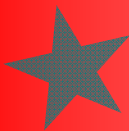
Readers of *NICNAS Matters* will be aware that a major current NICNAS project is to progress reforms resulting from recommendations from the Existing Chemicals program Review (ECR).

The reforms will enhance mechanisms to assess existing chemicals of concern and also provide greater access to information about chemicals in use in Australia. Recommendations from the review that are currently being implemented involve consultation, technical and legislative work.

Recommendations on which Implementation is currently focussed include:

- developing a risk based framework for the prioritisation and assessment of chemicals on the Australian Inventory of Chemical Substances (AICS), taking health and environmental criteria and indicators of exposure of the Australian community and environment into account
- finalising the framework for new assessment products and associated mandatory powers to gather information, and
- streamlined secondary notification conditions.

An update on NICNAS's ECR Reform developments will be posted on the NICNAS website at [www.nicnas.gov.au](http://www.nicnas.gov.au) (under *Reforming NICNAS's Existing Chemicals Program*) in early May.



All components of the project which relate to prioritising and assessing the 40K-odd chemicals on the AICS are now being 'packaged' as iMAP – the Inventory Multi-tiered Assessment and Prioritisation project.

### ECR stakeholder workshop – December 2010

NICNAS held a multi-stakeholder workshop to gain the views of stakeholders on options for the framework for the multi-tiered assessment and prioritisation of AICS in early December 2010. Representatives from industry, industry associations, scientific experts, community, state and territory governments, the Australian Government and NICNAS attended.

The workshop provided opportunities:

- to explore options for a risk-based framework for the prioritisation and assessment of chemicals on the AICS with a focus on efficient options for obtaining and using information to determine the potential for exposure of the Australian community and environment to the chemicals on AICS.
- to gain views from stakeholder groups
- for stakeholders to ask questions and understand each others views/positions – of those who attended the workshop.

Views from this workshop have been considered by NICNAS and its stakeholder advisory groups. They will be taken into consideration as the overall framework for the assessment and prioritisation of chemicals on the AICS is developed. A workshop report will be published on NICNAS's website shortly.

### More information



Further information about the Reforms to the Existing Chemicals Program may also be obtained from NICNAS's [Existing Chemicals Team](#) and Reform Team. ■



## NICNAS training and awareness – reaching out to industry

### Queensland (re-scheduled) and Victoria



NICNAS prefers to ensure industry complies with its legislation by working with industry representatives, providing advice to aid understanding of regulatory obligations, and assisting in finding the most practical ways to meet those obligations.

As part of our commitment to raising industry awareness, we conduct free training and awareness sessions each year. The sessions are open to all interested stakeholders: registered chemical introducers, regulatory consultants and others.

NICNAS officers will be in Melbourne and Brisbane in the coming months conducting stakeholders training sessions, and are seeking an expression of interest on attendance.

The training session dates and closing dates for expression of interest (EOI) are:

**Melbourne:** 5 & 6 May 2011 – *Expressions of Interest* are now closed

**Brisbane:** 15 June 2011 – *Expression of Interest* by 13 May 2011, please

Three sessions will be held on each day – approximate running times are given in the outlines (*below*).

#### Session 1 (09:15 to 11:30)

##### INTRODUCTION TO NICNAS

*Overview of regulatory obligations for all chemical introducers*

*NICNAS Registration*

*The Australian Inventory of Chemical Substances (AICS) and searching listed chemicals*

*New chemical notification and assessment, including exemptions*

*Annual reporting of chemicals to NICNAS*

*Existing Chemicals*

*Prior Informed Consent chemicals (PIC)*

*NICNAS Compliance and Enforcement functions*

#### Session 2 (12:00 – 13:45)

##### COSMETICS – YOUR REGULATORY OBLIGATIONS

*Overview of regulatory obligations for all chemical introducers*

*What is a cosmetic and why assess cosmetics?*

*NICNAS registration for imported or manufactured cosmetics*

*Cosmetics vs Therapeutic goods*

*Reporting requirements*

*Australian Inventory of Chemical Substances (AICS)*

*New industrial chemicals*

*The Cosmetics Standard 2007*

*The NICNAS Cosmetics Guidelines*

*Cosmetics and toiletries – ingredient labeling*

#### Session 3 (14:30 – 16:00)

##### INDUSTRIAL NANOMATERIALS

*What is an "industrial nanomaterial"?*

*How nanomaterials are currently regulated*

*Why is regulation needed?*

*NICNAS's consultation results on a proposal for regulatory reform of industrial nanomaterials*

*Administrative arrangement changes for nanoforms of new chemicals*

*How to get more information*

If you wish to attend please provide: your name; industry/company; number of attendees; preferred city and sessions, and email to:

[outreach@nicnas.gov.au](mailto:outreach@nicnas.gov.au)



If you have any further queries about industry training, please phone 02 8577 8800, or Freecall 1800 638 528 or Email [outreach@nicnas.gov.au](mailto:outreach@nicnas.gov.au)



## NICNAS NOTIFIERS UPDATE

New Chemicals Program staff are seeking expressions of interest in a **Notifiers Update** in Melbourne in May 2011, coinciding with the planned NICNAS Training and Awareness Outreach Sessions outlined on page 6. A similar update was held in Sydney in November, 2010.

This free information session will provide notifiers with an update on the latest activities and initiatives within the New Chemicals Program. It is also an opportunity for notifiers to meet with NICNAS assessors and to ask questions on new chemicals notification matters.

Date: Friday 6 May 2011

Duration: approximately 1.5 hours

Cost: Free

Topics to be covered include:

1. How to submit new applications under the cooperative arrangements with the USA and Canada.
2. How the Low Volume Chemical (LVC)-1000 and LVC100 permit categories work.
3. The differences between free Early Introduction Permits (EIP) and other EIP types.
4. Submission tips.

If you are interested in attending the Notifiers Update, please contact Jacki Kitching on 02 8577 8832 or e-mail [new.chems.enquiries@nicnas.gov.au](mailto:new.chems.enquiries@nicnas.gov.au) or [jacki.kitching@nicnas.gov.au](mailto:jacki.kitching@nicnas.gov.au). Please advise expressions of interest as soon as possible – venue details will be given when you register.

Please also provide comment if there are topics that are not mentioned above that you would like covered in this information session. ■

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## CALLING ALL CUSTOMS BROKERS

### NICNAS offering tailored seminars on understanding NICNAS obligations

A series of training and awareness seminars – especially tailored for customs brokers – will be held at various locations around Australia during 2011. The seminars are part of NICNAS's program for raising industry awareness. If you are a customs broker responsible for processing your client's importation of industrial chemicals, it is crucial for you to understand your – and your client's – regulatory obligations in this area.

Sessions are free of charge and aim to equip participants with a greater understanding of the NICNAS legislation and how it impacts both you (the broker) and your clients.

Expressions of interest for these seminars is now open. However, as places are limited, please ensure you register as soon as possible.

The seminar session dates and closing dates for expression of interest (EOI) are:

**Brisbane:** 14 June 2011 – **EOI:** 13 May 2011

**Sydney:** 15 July 2011 – **EOI:** 17 June 2011


**Melbourne:** 23 September 2011 – **EOI:** 19 August 2011

**Darwin:** 28 October 2011 – **EOI:** 23 September 2011

**Perth:** 14 December 2011 – **EOI:** 16 November 2011

The seminar will run from 9:00 am -11:30 am and will cover the following topics:

- **NICNAS Legislation**
- **NICNAS Registration**
- **Cosmetics Introducers**
- **International Treaties and Conventions**
- **Exemptions and New Chemicals**
- **Industrial Nanomaterials**

 If you wish to attend please provide your name; industry/company; number of attendees; preferred city and sessions, and email to [outreach@nicnas.gov.au](mailto:outreach@nicnas.gov.au).

If you have any further queries about industry training, please phone 02 8577 8800 or Freecall 1800 638 528 or Email [outreach@nicnas.gov.au](mailto:outreach@nicnas.gov.au).



## NICNAS staff news

### Introducing our 2010 Year in Industry staff

NICNAS welcomes Year-in-industry student staff members Patrick Crisologo and Jennifer Veal (pictured at right). Patrick is working in the Existing Chemicals program, Jennifer in the Science Strategy and International program.



### NICNAS Australia Day Medal 2011

**Dr Sneha Satya** (left) was NICNAS's recipient of the 2011 Australia Day Medal – awarded to her for her contributions over many years to chemical regulation in Australia – notably in the management of Existing Chemicals.

### Three recipients of the NICNAS 2010 Award for Innovation

**Dr Kerry Nugent** (right) received the 2010 NICNAS Innovation Award in recognition of strategies he developed on exposure scenarios as part of the NICNAS prioritisation of the assessment of Existing Chemicals. His work in this area will greatly enhance the implementation of this critical project.



**STOP PRESS** Dr Kerry Nugent also won NICNAS's 2011 **Duleep Jayamanne Memorial Award for Fellowship**, which was presented during the staff **Harmony Day** luncheon on 23 March. The unique NICNAS award recognises loyalty and dedication to the organisation, camaraderie and fellowship amongst colleagues and a genuine love of life and positive attitude (see photo page nine).



**Dr Venky Krishnamurthy** (right, centre) and **Mr John Attard** (right, below) each received the NICNAS 2011 Innovation award in recognition of strategies they developed which directly increased the effectiveness of compliance activities targeted at unregistered industrial chemical introducers. These strategies were successful in increasing the proportion of companies registering with NICNAS as a result of auditing activities – and minimised the number of companies requiring repeat contact by NICNAS compliance officers. The innovation had the added benefit of enabling the Compliance team to apply resources to other compliance auditing activities and the efficient delivery of the NICNAS Registration Scheme.



### NICNAS employees of the month

*Congratulations to the following recent NICNAS employees of the month:*

**December 2010 Mr Ed O'Neil** (left, 2<sup>nd</sup> from top) – for the excellent work he did in preparing a draft Information Sheet on amorphous silicon oxide nanoparticles – with all available information effectively summarised for the sheet. This was carried out in addition to a high work load of his team.



**January 2011 Ms Sandie Sinclair** (left, 3<sup>rd</sup> from top)) – for her “top job” while acting as Executive Assistant to the Director, completed with a positive attitude and in a timely and thorough fashion.



**February 2011 Dr Rebecca Janson** (left, 2<sup>nd</sup> from bottom) – for her work in coordinating the Year in Industry program. Her effective management and implementation of significant changes to the structure in 2010 resulted in a very successful program – and was carried out in addition to a high work load of her team.

**March 2011 Dr Harjit Deol** (left, bottom) – for his excellent effort and dedication to complete the hazard assessment report for Perfluorohexanoic acid. This assessment contained various toxicological studies and is a crucial step in the project pertaining to a review of NICNAS's position on the assessment of replacements of long chain perfluorinated chemicals. This assessment was undertaken while juggling other tasks, including new chemical assessments.



## NICNAS staff news *(continued)*

### **NICNAS's Principal Scientists**

**Dr Daniela Leonte** (*pictured at right*) has been appointed to the position of Principal Scientist in the NICNAS New Chemicals Program. Dr Leonte comes to NICNAS from the University of NSW where she held an academic position in the School of Risk and Safety Science. With academic training in engineering and statistics, Dr Leonte has a strong background in quantitative risk assessment in a range of circumstances, including human and environmental assessments.



**Dr Kerry Nugent** has been appointed Principal Scientist in the NICNAS Existing Chemicals Program. Dr Nugent has worked at NICNAS for many years and brings to the position a wealth of experience in chemistry, regulatory toxicology and the assessment of chemicals within the NICNAS framework.

Dr Nugent is pictured in the photo at left, holding the NICNAS 2011 *Duleep Jayamanne Memorial Award*, having received it from 2010 winner, Lewis Norman, Head of Program, Compliance & Enforcement – (see **STOP PRESS** page 8, for more information).

### **New staff member**

**Mr Michael Papahatzis** (*pictured at right*) has commenced at NICNAS and is working in the Compliance and Enforcement Program.



The NICNAS **Industry Engagement Group** met at NICNAS on Monday 7 February 2011 (*photo above*) –the sixth meeting of the group. Items discussed ranged across a number of topics including the NICNAS *Handbook for Notifiers*, the Exposure Scenarios project, the OECD New Chemicals Clearing House project on expansion of the approved polyester reactant list for polymers of low regulatory concern, ongoing operational improvements and the new administrative requirements for nanomaterials.



## Industrial Nanomaterials update

### *Introduction of new administrative arrangements for nanoforms of new industrial chemicals*

NICNAS has now introduced arrangements (effective from 1 January 2011) to ensure that all new chemicals that are industrial nanomaterials are assessed by NICNAS, pre-market.

The new arrangements include:

- restrictions on using exemption provisions, where human or environmental exposure can reasonably be anticipated
- restrictions on using the certificate notification category that allows industry to self-assess non-hazardous chemicals against certain criteria and guidelines
- requirement that reports of introduction under exemption provisions – and applications for assessment certificates or permits – include a declaration that chemicals are not nanomaterials, and
- requirement that notifications to NICNAS contain more specific information (such as particle size, shape and other specific information on properties) depending on the use.

Furthermore, NICNAS may stipulate permit conditions for conventional chemical notifications where it can be reasonably assumed that a nanoform may be introduced in the future.

Further information on these arrangements and guidance on data requirements for notifiers has been published on the NICNAS website at: [www.nicnas.gov.au/Current\\_Issues/Nanotechnology.asp](http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp)

### *Update*

- NICNAS has received no new notifications under these new arrangements to end March 2011.
- NICNAS has been providing advice to interested stakeholders – predominantly clarifying to industry that these new arrangements do not apply to nanoforms of existing chemicals.
- No concerns have been raised regarding the impact of these arrangements for nanomaterials that are new chemicals.
- General outreach sessions conducted in Perth, Adelaide and Sydney have included a nano-technology regulatory update strand, and more sessions are planned for Melbourne, Brisbane and Darwin (see pages 6 and 7).
- Compliance activities will begin from April 2011 to assess the extent to which business is complying with the new arrangements. Results of this assessment will inform the ongoing outreach sessions that will assist industry in understanding these changes.
- Businesses are encouraged to contact NICNAS to clarify whether the nanomaterials they are introducing are new or existing chemicals, and therefore whether or not they face new obligations under these changes.
- NICNAS is further developing options for notification and assessment of nanoforms of existing chemicals, including the concept of an integrated notification and assessment program for new and existing industrial nanomaterials. This option will be subject to future public consultation.

To register interest in the outreach sessions, please phone 02 8577 8800, Freecall 1800 638 528 or Email [outreach@nicnas.gov.au](mailto:outreach@nicnas.gov.au).



For more information on Nanotechnology regulation, contact [nicola.hall@nicnas.gov.au](mailto:nicola.hall@nicnas.gov.au) or phone +61 2 8577 8871.

### *Recent NICNAS publications*

**COSMETIC GUIDELINES** - New version with changes to Part F (on Prohibited or Restricted Cosmetic Chemicals in Australia) with links to sources of information on chemicals that, by law, must not be used in cosmetics in Australia, or may be used with restrictions + links to information on cosmetic ingredients that are prohibited or restricted in countries other than Australia. See: [www.nicnas.gov.au/Current\\_Issues/Cosmetics/Cosmetic\\_Guidelines\\_revised\\_PDF.pdf](http://www.nicnas.gov.au/Current_Issues/Cosmetics/Cosmetic_Guidelines_revised_PDF.pdf)

**CHEMICAL ASSESSMENT REPORTS** [Secondary Notification Assessment Report on N-\(n-butyl\) thiophosphoric triamide \(NBPT\)](#)

**CHEMICAL GAZETTES** [January 2011](#) [February 2011](#) [March 2011](#)

**INFORMATION SHEETS** [Multiple Chemical Sensitivity](#)



## Chemical Safety update

### ASBESTOS MANAGEMENT REVIEW ESTABLISHED

The establishment of a national review into the management of asbestos was announced in October 2010 by Minister for Workplace Relations, Senator Chris Evans. The Asbestos Management Review will assess current activities in the area of asbestos management and research and make recommendations for the development of a national strategic plan to improve asbestos awareness, management and removal.

The Review will build on work already being undertaken at the Commonwealth, state and territory levels, and will report by 30 June 2012. It will complement the development of harmonised workplace health and safety laws which include regulations and codes of practice relating to asbestos management and removal in the workplace as well as the Tasmanian Government's response to the 2010 report *Improving Asbestos Management in Tasmania*.

Senator Evans also announced the Government's intention to pursue ratification of three International Labour Organisation treaties, including the *Asbestos Convention, 1986* (Convention 162) and the optional Protocol to the *Occupational Health and Safety Convention, 1981* (Protocol 155).

[CLICK HERE](#) for more information.

### STOCKHOLM CONVENTION CONSULTATIONS

In the December 2010 NICNAS Matters we reported that nine new chemicals had been added to the Stockholm Convention's annexes – the first chemicals to be added to the annexes since Australia signed up to the Convention in 2004. For Australia, an amendment to the annexes takes effect upon ratification of that amendment. Accordingly, Australia is now considering ratification, and to do so must undertake a domestic treaty-making process.

In order to understand the implications of the ratification, the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) is preparing a regulatory impact analysis and a national interest analysis. Consultations began in December 2010, with a meeting of the Stockholm Reference Group. DSEWPaC is continuing consultation with other Australian and state and territory government agencies – and affected industry, environment and public health groups – to gather information to support this work.

Email feedback to: [chemicals@environment.gov.au](mailto:chemicals@environment.gov.au)  
... to page 14

## Cosmetic Reforms updates

*Here's a quick snapshot of the latest Cosmetic reform activities, carried out in consultation with NICNAS's Cosmetic Advisory Group.*

### Request for information on cosmetic ingredients

A big 'thank you' to all those who provided a response following the notice in the [December 2010 Chemical Gazette](#) – submissions closed on 7 March.

The information gathered has been used in the final phase of the *Stage Two* process: verifying that the chemicals nominated in the Call for Information (see [NICNAS Matters March 2010](#)) meet the eligibility criteria for listing on AICS.

Our team is now making progress on *Stage Three*: legislative amendments to create a mechanism for the listing of chemicals on AICS.

### Amendment to Cosmetic Guidelines

NICNAS has revised Part F of the [NICNAS Cosmetic Guidelines](#) – the section which deals with Prohibited or Restricted Cosmetic Chemicals in Australia. Changes include replacing the list of chemicals with links to sources of information on cosmetic ingredients that are prohibited or restricted in Australia – a change designed to assist introducers by providing access to up-to-date information on these chemicals.

NICNAS is currently working on a *List of Sunscreening Agents for use in Cosmetic Products*, which will be included as a new section to the Cosmetic Guidelines.



## APEC Chemical Dialogue Regulators' Forum

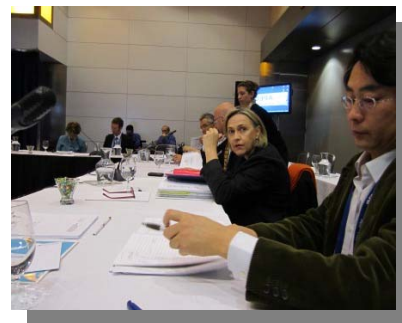


Australia actively participated in the first technical training workshop on chemicals inventories as tools for chemicals management held under the APEC Chemical Dialogue's Regulators Forum.

The workshop – hosted by the US and organised with the assistance of Australia, Chinese Taipei and New Zealand and held in Washington DC from 28 February to 1 March 2011 – exchanged views with a range of stakeholders, especially regulators, on approaches for the sound management of industrial chemicals across the APEC economies with the aim of training economies so as to facilitate efficient regulation, and thereby promote trade and investment, in the chemicals sector.

Specifically, NICNAS:

- presented a paper on behalf of the OECD Clearing House for New Chemical's Parallel Process and Mutual Acceptance of Notifications (presented by the NICNAS Director in her role as chair of the OECD CHNC) illustrating the role of multilateral organisations in promoting innovation, competitiveness, and decreasing regulatory burden, as part of a session on the linkages between chemical regulation and economic development
- moderated a session on reporting data, maintaining and updating inventories, at which Australia, Japan and the US presented – NICNAS's presentation reviewed the creation and management of the 20-year old Australian Inventory of Chemical Substances, and
- moderated a planning session on future workshop topics and formats, at which it was recognised that in order to meet the needs of interested economies and enable their full-participation, the mode of technical training will need to range from general through to in-depth, and will need to be held both in conjunction with APEC Chemical Dialogue meetings as well in local economies.



Australian industry also presented at the workshop through PACIA's presentation of Australia as a case study in the session on chemical regulation and links to economic development. ■

## NICNAS Matters now thirty issues strong

This is the thirtieth issue of NICNAS's newsletter for stakeholders!

The first issue of *NICNAS Matters* (see front cover) was published almost eleven years ago, in August 2000.

At that time, hard copies were sent to a comparatively small mailing list of subscribers who represented industry, the community and other interested groups and individuals.

That list has now grown considerably, and *NICNAS Matters* is published in electronic format on the NICNAS website. This (March 2011) issue is the thirteenth of the electronic series of *NICNAS Matters* – there were seventeen issues of the original hard-copy publication.

Today, a notice of the release of each issue is sent to a long list of close to 6,000 subscribers at the time of publication.

To revisit all twenty-nine past copies of NICNAS matters (and the 12 issues of the *NICNAS e-newsletter* which complemented *NICNAS Matters* in 2006-08) please [CLICK HERE](http://www.nicnas.gov.au/Publications/NICNAS_Matters.asp) or see: [www.nicnas.gov.au/Publications/NICNAS\\_Matters.asp](http://www.nicnas.gov.au/Publications/NICNAS_Matters.asp). ■



## International chemical safety update

### REACH Substances of Very High Concern

The European Chemicals Agency has invited comment on proposals to identify eight chemicals as Substances of Very High Concern (SVHC). Defined in Article 57 of the REACH regulation, SVHC include substances that may be carcinogenic, mutagenic or toxic to reproduction; persistent, bioaccumulative and toxic; or cause probable serious effects equivalent in concern. Identification of a substance as a SVHC leads to inclusion on a Candidate List for eventual listing in Annex IX of the REACH legislation. Listing on Annex IX makes introduction on to the market or use of the chemical subject to Authorisation procedures under REACH. The eight chemicals for which dossiers have been prepared for comment are: Cobalt dichloride; 2-ethoxyethyl acetate; Strontium chromate; 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters; Hydrazine; 1-methyl-2-pyrrolidone; 1,2,3-trichloropropane; and 1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7 rich. Deadline for comments: 7 April 2011. Further information: [CLICK HERE](#)

On 17 February, six chemicals from the Candidate List of SVHC became the **first substances to be included on Annex IX of the REACH regulation**. Substances listed in Annex IX cannot be placed on the market or used unless authorisation has been

granted for a specific use. A 'sunset date' ranging from 2014-15 has been provided for these six chemicals, after which authorisation is required. There are no lower limits in terms of volume of chemical for the authorisation requirements. The measure aims to provide for the control of the risks posed by these substances and for their progressive replacement by economically and technically viable alternatives. The six chemicals are: 5-ter-butyl-2,4,6-trinito-m-xylene (musk xylene); 4,4'-diaminodiphenylmethane (MDA); Hexabromocyclododecane (HBCDD); Bis(2-ethylhexyl) phthalate (DEHP); Benzyl butyl phthalate (BBP); and Dibutyl phthalate (DBP). More information at: [CLICK HERE](#)

Eight other SVHC have been recommended to the European Commission for inclusion on to Annex IX: Diisobutyl phthalate; Diarsenic trioxide; Diarsenic pentaoxide; Lead chromate; Lead sulfochromate yellow (C.I Pigment Yellow 34); Lead chromate molybdate sulphate red (C.I Pigment Red 104); Tris (2-chloroethyl) phosphate (TCEP); and 2,4-dinitrotoluene (2,4-DNT). Further information on Authorisation recommendations: [CLICK HERE](#) ■

### Regulation of Mercury

Progress toward the international regulation of mercury occurred January 24-28 with the holding of the second meeting of the Intergovernmental Negotiating Committee to Prepare a Global Legally Binding Instrument on Mercury (INC2) in Chiba, Japan. The International Negotiating Committee was convened under the United Nations Environment Program and commenced work in 2010. This was the second of five planned meetings due to conclude in 2013, at which time a diplomatic conference is planned in Japan to host the signing of the instrument. For submissions, technical briefing documents, meeting documents, and a report of the meeting [CLICK HERE](#)

Meanwhile, in Canada, Proposed *Regulations Respecting Products Containing Certain Substances Listed in Schedule 1 to the Canadian Environmental Protection Act, 1999*, were published on 26 February 2011 in the *Canada Gazette*, Part I, for a 75-day comment period. This is the start of the start of a regulatory process to prohibit the manufacture, import, and sale of most mercury-containing products in Canada. [CLICK HERE](#) for details. ■

### Survey of Perfluorinated Chemicals

In January, a report prepared by Australia on the outcomes of a 2009 OECD survey on the production, use and release of PFOS, PFAS, PFOA, PFCA, their related substances and products/mixtures containing these substances was published by the OECD. These chemicals are being monitored as they are known to be persistent in the environment and some have adverse health and environmental effects. The survey was prepared and conducted with the assistance of the Business and Industry Advisory Committee to the OECD (BIAC), and targeted manufacturers of the chemicals in OECD and also non-OECD countries, although no responses were received from manufacturers in non-OECD countries. The survey covered environmental releases of the chemicals at the production site and from off-site transfers; uses of products manufactured using the chemicals; concentrations of the chemicals in products. [CLICK HERE](#) to access the report. ■



## International chemical safety update *(continued from p13)*

### ***Burden of disease attributable to chemicals***

The World Health Organisation has undertaken a systematic review of the literature for global burden of disease estimates for chemicals. The review found that 8.3% of deaths and 5.7% of disability-adjusted life years (DALYs) were attributable to environmental exposure and management of selected chemicals in 2004. These figures represent only a number of chemicals for which data are available, and are therefore likely to underestimate the actual burden.

The review is published in *Environmental Health*, 10: 9 (2011) and is available at: [www.ehjournal.net/content/10/1/9](http://www.ehjournal.net/content/10/1/9).

## Chemical safety update *(continued from page 11)*

### ***Decisions to implement recommendations from NICNAS's assessments of two Priority Existing Chemicals have been finalised recently:***

#### ***Triclosan***

Triclosan is used in many consumer products, including cosmetics, due to its antimicrobial activity. NICNAS's assessment report recommended that triclosan be considered for scheduling in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with a cut off for cosmetics and personal care products.

The delegate for deciding amendments to the SUSMP has announced a schedule 6 entry for triclosan when for cosmetic use in humans containing 0.3% triclosan. This scheduling decision comes into effect on 1 May 2012. Further information is available at:

[www.tga.gov.au/regulation/scheduling-decisions-1103.htm](http://www.tga.gov.au/regulation/scheduling-decisions-1103.htm)

#### ***Diethylhexyl phthalate (DEHP)***

DEHP is mainly used as a plastic softener in a range of consumer products, including children's toys and childcare articles. NICNAS's assessment report recommended that the Australian Competition and Consumer Commission take action to limit exposure to DEHP in toys and child care article.

The Consumer Protection Notice No. 11 of 2011 introduces a permanent ban on the children's plastics toys with more than 1% DEHP. The ban prohibits the supply of plastic products that are intended for use by children up to and including 36 months of age; contain or have an accessible component containing more than 1% weight of DEHP; and are products that children can readily chew and/or suck. The ban applies to toys, childcare articles and eating vessels and utensils that meet these criteria and was introduced on 1 February 2011. Further information is available at

[www.productsafety.gov.au](http://www.productsafety.gov.au)

#### ***Interim decision: Diethylhexyl phthalate (DEHP) in cosmetics***

DEHP is also imported as a component of cosmetics – mainly perfumery products. The NICNAS assessment report recommended that scheduling the cosmetic use of DEHP in Appendix C of the SUSMP should be considered in order to limit the potential exposure of the public to DEHP. Appendix C lists those chemicals prohibited for sale, supply and use in specific applications.

An interim decision on the scheduling for DEHP has been announced following consideration by the delegate of advice from the Expert Advisory Committee on Chemical Scheduling. The delegate's interim decision is to include DEHP in cosmetic products in Appendix C, with a six month implementation period. Further information is available from [www.tga.gov.au/pdf/scheduling-decisions-1104.pdf](http://www.tga.gov.au/pdf/scheduling-decisions-1104.pdf)



## Upcoming events

### AT HOME

#### May

- 5 NICNAS Training and Awareness session, Melbourne (see p.6)
- 6 Community Engagement Forum – CEF 25 (at NICNAS)
- 10 NICNAS Nanotechnology Advisory Group (at NICNAS)
- 11-12 [HAZMAT 2011](#), Olympic Pk, Sydney
- 17 NICNAS Cosmetic Advisory Group (at NICNAS)

#### June

- 7-9 [Plastics and Chemicals Industries Association \(PACIA\)](#) national conference: "The business of chemistry", Melbourne

#### August

- 18 IGCC 40
- 19 Community Engagement Forum – CEF 26

#### September

- 7-15 [CleanUp 2011](#) including workshop on Chemical Bioavailability in Terrestrial Environment, Contaminated Site Remediation Conference and National (Firefighting) Foam Forum and Workshop, Adelaide
- 26-27 EnHealth face-to-face meetings, Darwin NT
- 26-28 [Society of Risk Analysis Australia and New Zealand](#), Brisbane

#### October

- 17 Industry Engagement Group (at NICNAS)
- 26-28 [AELERT Conference](#), Darwin NT
- 23-29 [National Safe Work Australia Week](#), Nationwide
- 27-29 [ACCORD National Conference](#)
- 27-28 [Australian College of Toxicology and Risk Assessment \(ACTRA\)](#) annual scientific meeting, Melbourne

#### November

- 22 Industry Government Consultative Committee (IGCC) meeting 41 (at NICNAS)

#### December

- 2 CEF 27
- 3-7 [AIOH \(Australian Institute of Occupational Hygienists Inc\) Conference](#), Brisbane
- 5-7 [Third Asian-Oceanian Conference on Green and Sustainable Chemistry \(AOC-3\)](#), Melbourne

### ABROAD

#### April

- 25-29 [Conference of parties to Stockholm Convention COP-5](#), Geneva, Switzerland

#### May

- 16-24 64<sup>th</sup> World Health Assembly, Geneva, Switzerland
- 19-20 [Helsinki Chemicals Forum](#), Helsinki, Finland
- 30-31 OECD Hazard Assessment Task Force, Paris, France

#### June

- 13-17 OECD Joint Meeting, Paris, France
- 20-24 Rotterdam Convention COP-5, Geneva, Switzerland

#### Throughout the year

The UN declared 2011 International Year of Chemistry (IYC 2011). The theme: Our life, our future.

The aims:  
to increase public appreciation of chemistry in meeting world needs; to increase the interest of young people in chemistry; to generate enthusiasm for the creative future of chemistry; and to celebrate the 100<sup>th</sup> anniversary of Mme Marie Curie's Nobel Prize for Chemistry and the founding of the International Association of Chemical Societies.

In Australia, there is [a full program of IYC 2011 events](#).

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