



## New assessment categories for new chemicals: LRCC reform initiatives finalised

NICNAS's Low Regulatory Concern Chemical (LRCC) reform initiatives are now complete.

The reforms to new chemicals streamline the efficiency and effectiveness of NICNAS's notifications scheme and encourage the use of safer chemicals. The final outcome has been a range of **LRCC assessment products** – with reduced fee incentives, reduced data requirements and shorter assessment timeframes – from which industry can choose.



Attendees at Sydney Notifiers' meeting, where participants learnt more about requirements for the new assessment categories.

Tables (at right and on page 3) provide a snapshot of the new chemicals framework 'PRE' and 'POST' LRCC reform – with assessment categories available 'PRE' (before) the reforms shaded teal and those 'POST' shaded mustard.

... continued page 3

PERMITS	Commercial Evaluation (CEC)
	Commercial Evaluation (CEC) renewal
	Low Volume Permit < 100 kg (LVC100)
	Low Volume Permit < 100 kg (LVC100) renewal
	Low Volume Permit < 1000 kg (LVC1000)
	Low Volume Permit < 1000 kg (LVC1000) renewal
	Controlled Use Permit
	Controlled Use Permit (Export only)
	Controlled Use Permit Renewal
	Early Introduction Permit – non-hazardous chemicals/polymers (fee)
Early Introduction Permit – non-hazardous chemicals/polymers (no fee)	
Early Introduction Permit – PLC (no fee)	
Early Introduction Permit – low hazard/risk	

ISSN 1444-1209

also  
in  
this  
issue:

- 2 A word from our Director; Training news
- 3 New assessment categories for New Chemicals (continued)
- 4 International Chemical Safety update; LRCC evaluation report
- 5 ECR: Prioritisation; Sodium Cyanide assessment
- 6 Disinfectant consultation and regulatory impact survey
- 7 Increase in New Chemicals fees and charges; Quiz
- 8 Stockholm Convention update
- 9 Acceptance of international assessments
- 10 Registration renewal 2009-10
- 11 Nanomaterials update
- 13 New publications; Upcoming events etc



## a word from the Director ...



Dr Marion Healy

**NICNAS**'s function to assess the human health and environmental risks posed by chemicals is underpinned by the strength of our scientific and technical expertise and we have been further developing our expertise in several key areas. In this edition of *NICNAS Matters*, we report on three major aspects of the development of our capability to conduct risk assessments of nanomaterials.

Firstly, we have been focussing on understanding the current state of scientific knowledge about the health and environmental impacts of nanomaterials, with particular emphasis on metal oxides, nano silver and the carbon nanotube and fullerene groups of chemicals. We have also been reviewing the data required to support assessments, taking into account our current understanding of the effects of the various nanoparticles. Finally, we have continued to be involved in the OECD program to generate some of the safety data for a representative set of 14 nanoparticles, including those of particular interest to NICNAS. Safety data is being generated for environmental fate and toxicology as well as for mammalian toxicology.

Our assessment work on nanoparticles is being assisted by a number of OECD documents that have been published in recent months. These include a review of the applicability of the OECD test guidelines to manufactured nanomaterials, which found that while many of the guidelines are applicable – with conditions in some cases – others are inadequate mainly because measuring, dosing, delivery and tracking of nanomaterials are not reliably accomplished at this stage. A second major focus has been workplace exposure with examinations of exposure assessment and exposure mitigation, including in relation to dermal and inhalation exposure.

A second area in which NICNAS has been building its scientific capability is the conduct of quantitative structure activity relationships, termed QSAR, which is a method for estimating properties of a chemical from its molecular structure. The approach aims to find relationships between chemical structure (or structural-related properties) and biological activity (or target property) of compounds of interest by utilising the assumption that activity of molecules is reflected in their structure and therefore structurally similar molecules have similar activities. While NICNAS has already been applying this assumption in relation to analogue chemicals, the approach has been strengthened with the development of predictive computer based modelling approaches. This approach is particularly valuable – in some cases – in addressing gaps in available test data.

NICNAS has purchased software necessary to conduct the QSAR modelling that is compatible with that of the OECD QSAR Toolbox. As reported in the [June 2009 edition of \*NICNAS Matters\*](#), several NICNAS staff,

together with colleagues from the Department of Environment, Water, Heritage and the Arts, have undertaken intensive specialised training in the use of the QSAR modelling software and we are currently utilising that training to broaden and further build expertise amongst our staff. I anticipate that we will apply this technique to our new chemicals assessment work as well as to the project to screen the chemicals on the national inventory to identify and prioritise those chemicals that warrant further assessment.

The addition of expertise to conduct assessments of nanomaterials – as well as incorporate the QSAR tool into our risk assessment methodology – are important and necessary steps in strengthening NICNAS's already considerable scientific expertise that ensures that our scientific approaches remains contemporary and robust. It also builds on recent initiatives to strengthen our capability in conducting quantitative exposure assessments and utilising the outputs of testing designed to replace animal testing protocols. ■

### NICNAS training and consultation schedule

Training and information sessions have been scheduled for the remainder of 2009 providing an opportunity for industry stakeholders to learn more about NICNAS and their obligations under the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Full details of the upcoming training sessions please go to the chart on page 3 and our [Training schedule](#), or to the [Workshop registration form](#) available from our website. To register your interest for any of these sessions please email [industry.training@nicnas.gov.au](mailto:industry.training@nicnas.gov.au).



**New assessment categories for new chemicals** (continued from page 1)

<b>REDUCED FEE CERTIFICATES</b>	<b>Foreign Scheme assessment</b>
	Self-assessment non-hazardous chemical
	Self-assessment non-hazardous polymer
	Modular assessment – similar to chemical previously assessed by NICNAS
	Modular assessment – secondary chemical
	Modular assessment – previously assessed by APVMA, FSANZ, TGA

Amendments to the *Industrial Chemicals (Notification and Assessment) Amendment Regulations 1990* giving effect to the outstanding LRCC recommendations commenced on 4 December 2008

The reform initiatives have resulted in the following changes to the **New Chemical Permit** categories (see table, page 1):

- increase in volume for low hazardous chemicals introduced under the Low Volume Chemical (LVC) Permit system
- introduction of a new Controlled Use Permit (CUP) for highly controlled low hazard/risk chemicals
- extension of the Early Introduction Permit (EIP) system to low hazardous and highly controlled low hazard/risk chemicals, and
- free EIP for non-hazardous chemicals and polymers, and polymers of low concern

and a reduction in the notification fees for **Certificate** applications in the following circumstances:

- the notified chemical is similar to a chemical which has been previously assessed by NICNAS
- the notified chemical is being notified at the same time as a chemical which is similar
- an assessment of the notified chemical by the Therapeutic Goods Administration (TGA) of the chemical under the *Therapeutic Goods Act 1989* is available
- an assessment of the notified chemical by the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the *Agricultural and Veterinary Chemicals Code Act 1994* is available, or
- an assessment of the notified chemical by Food Standards Australia New Zealand (FSANZ) under the *Food Standards Australia New Zealand Act 1991* is available.

<b>CERTIFICATES</b>	Standard (STD)
	Limited (LTD)
	Polymer of Low Concern (PLC)
	Extension of assessment certificate
	Polymer of Low Concern self-assessment

**Awareness raising and outreach activities about the reforms**

The *NICNAS Handbook for Notifiers* was updated with new guidance and new application forms published to help industry utilise the reforms. By 30 June, 27 permits and two assessment certificates had been issued under the LRCC reforms. As part of NICNAS's active engagement strategy to promote and raise awareness of the reforms, there were significant outreach activities with the Department of the Environment, Water, Heritage and Arts to effectively 'roll out' the reforms. The Notifier's update meeting in Sydney – attended by over 30 industry representatives and pictured on page 1 – focused on the new assessment categories, approved foreign scheme arrangements and other reforms. Targeted training was also held in Sydney (prior to Hazmat) and in Melbourne.

**NICNAS Training schedule** (from page 2)

<b>Melbourne</b>	New Chemicals Assessment Categories & Exemptions	7 October
	Introduction to NICNAS	8 October
<b>Sydney</b>	Introduction to NICNAS	16 October
	Introduction to NICNAS for Cosmetic Introducers	30 October
<b>Perth</b>	Introduction to NICNAS	18 November
<b>Adelaide</b>	Introduction to NICNAS	20 November
<b>Brisbane</b>	Introduction to NICNAS for Cosmetic Introducers	9 December
	Introduction to NICNAS	10 December

NICNAS sees these training programs as an ideal forum for networking and interacting with industry. This year the training was designed using workshop styles with examples of new chemicals assessments and handy hints on common assessment problems. Industry feedback supports these outreach activities (100% satisfaction!) and helps NICNAS in targeting its future training activities and selection of topics. ■



## International Chemical Safety update

### Rotterdam Convention

The Rotterdam Convention has decided that all tributyltin compounds should become subject to prior informed consent and be listed in Annex III (pesticides and industrial chemicals banned or severely restricted for health or environmental reasons) in the pesticide category. Reviews concluding that tributyltin compounds affect human health (immune system toxicity) and that they are highly toxic to aquatic organisms contributed to the recommendation.

### Mercury LBI

In February 2009, the Governing Council for the United Nations Environment Programme (UNEP) decided to commence negotiations on a global legally binding instrument (LBI) on mercury, beginning in 2010 with the goal of completing negotiations by February 2013. The LBI is likely to take the form of a multilateral environmental agreement similar to the Stockholm and Basel Conventions. Specific provisions within the LBI are subject to negotiations during the Intergovernmental Negotiating Committee (INC) process.

The Department of the Environment, Water, Heritage and the Arts (DEWHA) is coordinating Australia's participation in negotiations and NICNAS will provide technical advice on industrial uses during the negotiations. The decision on whether Australia enters into the LBI will be made after negotiations have been completed, and subject to a full Regulatory Impact Statement and National Interest Analysis.

### OECD Steering Committee for Perfluorinated Chemicals

The OECD survey on PFOS, PFAS, PFOA, perfluorocarboxylic acid (PFCA) and their related compounds and mixtures containing these substances has been finalised along with a global list of manufacturers of these compounds identified by BIAC (the Business and Industry Advisory Committee to the OECD).

NICNAS contributed to the development of the survey and is conducting the survey on behalf of the OECD.

### APEC Chemical Dialogue and Regulators' Forum

The Chemical Dialogue (CD) and associated Regulators' Forum met on 31 July – 1 August in Singapore. It is a public-private sector forum for finding solutions to challenges facing the chemical industry in the Asia-Pacific region, and reflects APEC members' recognition of the importance of engaging with the private sector and building public-private sector dialogue and cooperation for mutual benefit.

The CD enables regulatory officials and industry representatives to discuss trade and economic challenges facing the chemical industry and users of chemicals. Issues addressed include chemical sector liberalisation, chemical trade facilitation and capacity building, improving regulatory policies and practices and seeking workable programs which ensure regulatory, safety, and environmental goals can be implemented by both governments and business.

The Regulators' Forum is focusing on facilitating risk reduction and the sound management of chemicals across the APEC region. It also seeks to share information and knowledge on chemicals management with increased and direct involvement of regulatory officials. Importantly, the Regulators' Forum seeks to bridge principles and practice through collaborative activities.

A workshop on *Good Regulatory Practices for Chemical Regulation* is being planned by the Regulators' Forum for February 2010. The aim is to foster exchange and uptake of good regulatory practices in industrial chemicals management in the region, promote enhanced economic and environmental sustainability and facilitate transparent, science-based processes. ■

Please also see the report on the **Stockholm Convention** on page 8.

### LRCC evaluation report

The [draft report for the first phase](http://www.nicnas.gov.au/About_NICNAS/Reforms/LRCC_Evaluation.asp) of the LRCC evaluation project is now available online at: [www.nicnas.gov.au/About\\_NICNAS/Reforms/LRCC\\_Evaluation.asp](http://www.nicnas.gov.au/About_NICNAS/Reforms/LRCC_Evaluation.asp). The period for public comment on the report finished on 26 August. In this first phase the impacts on industry have been evaluated by independent consultant Campbell Research through stakeholder interviews, case studies and an industry-wide online survey.

For more information please contact Dr Sarah Rumble on 02 8577 8832 or by email at [sarah.rumble@nicnas.gov.au](mailto:sarah.rumble@nicnas.gov.au).



*Existing Chemicals Review update:*

***Prioritisation of chemicals on the national inventory  
Australian Inventory of Chemical Substances***

NICNAS together with its advisory groups for this project have started developing the framework for undertaking the prioritisation process. The first step is to develop scientific criteria for hazard and exposure indicators. Towards this, two separate expert working groups are being established to develop draft criteria for environmental and health hazard endpoints.

The project's Environmental Expert Working Group will consist of members with expertise in the areas of bioaccumulation, ecotoxicology, environmental risk assessment and predictive modelling such as Quantitative Structure Activity Relationships (QSAR) modelling. The Human Health Expert Working Group will comprise of members with expertise in the areas of toxicology, risk assessment and predictive modelling. The Environmental Expert Working Group is expected to meet later this year to develop the environmental criteria and the Human Health Expert Working Group will undertake its work in the first half of 2010.

NICNAS is organising a workshop with the aim of obtaining industry views on collecting information for exposure indicators. The workshop is expected to be held in October 2009 and a discussion paper to inform potential workshop participants will be released soon on the NICNAS website.

**Sodium cyanide assessment**

The assessment of the Priority Existing Chemical sodium cyanide is an environmental risk assessment covering environmental exposure in Australia from the industrial uses of sodium cyanide and the potential risk of adverse environmental effects from its use. The assessment recommends risk minimisation measures.

Sodium cyanide was declared a priority existing chemical because of environmental concerns. These concerns related to:


- mass bird poisonings as a result of consumption of cyanide-contaminated water at tailings dams
- the potential release of toxic and flammable hydrogen cyanide gas when sodium cyanide comes in contact with water
- the high acute toxicity to aquatic life, birds and animals, and
- high chronic toxicity to aquatic life.

In Australia, sodium cyanide is mainly used in the mining industry to recover gold from ore. Sodium cyanide is also used for ore flotation of base metals, electroplating, metal (case) hardening and for analytical laboratory testing purposes. It is manufactured in Australia for local use and export. Sodium cyanide is also imported into Australia.

The statutory consultation process commenced in July 2009 with the release of the draft report to Applicants for 28 days. At that stage Applicants could advise the Director of any factual errors. NICNAS has revised the draft report to address any factual errors notified during the corrections period. The revised report was released for public comment on 11 September 2009, for 28 days – during which time requests to vary the report may be made.

Applications seeking variations should clearly outline any amendment or change(s) requested. All applications for variation must identify the exact words, sentence or paragraph in the report to be varied and then state replacement words, sentences or paragraphs. The rationale behind any request for variation must be clearly explained, with references where relevant. The public comment period will close on 9 October 2009.

Briefings on the findings of the assessment and recommendations will be held in Sydney, Melbourne and Perth during the public comment period in September. Please [click here](#) for details.

 An [information sheet](#) and additional documents and details have been posted under **Latest News** on the [NICNAS website](#). ■



## Second NICNAS Disinfectant consultation and regulatory impact survey

NICNAS – in conjunction with the Therapeutic Goods Administration (TGA) – is undertaking a second stakeholder consultation on proposed changes to the regulation of hospital, household and commercial grade hard surface disinfectant products. We expect to release the consultation document in October. Please contact NICNAS if you wish to receive the document.

In response to a recommendation in the Australian Government's *Report of the Taskforce on Reducing Regulatory Burden on Business* (The Banks report, 31 January 2006), NICNAS and the TGA commissioned an independent review of the current Australian regulatory framework for disinfectant products and the regulation of disinfectants in comparable overseas countries to assist us to identify best practice models.

### The current position

Hard surface disinfectants are considered to be "other therapeutic goods". Under the TGA scheme, all therapeutic goods and devices, unless exempt, must be entered on the *Australian Register of Therapeutic Goods* (ARTG) before they can be supplied. Listing occurs under one of three categories: 'registered', 'listed', or 'included' goods – with the degree of regulation depending on the category.

### What is being proposed?

The report of the independent review – available on the [NICNAS](#) and [TGA](#) websites – makes five recommendations based on an analysis of the consequences of product failure. The consultant's preferred approach is to change the regulatory responsibility for hard surface disinfectants and sanitisers for use in low risk applications, such as household and commercial use. If the stakeholder consultation supports the consultant's proposal, regulatory responsibility for these products would be transferred from the TGA to NICNAS.

Under NICNAS, all chemicals in these products need


to be listed on the *Australian Inventory of Chemical Substances* (AICS) or the introducer must hold a NICNAS assessment certificate or permit which allows introduction. Some exemptions apply for low risk chemicals introduced in low volumes; introduction under exemptions (ie. without assessment) is balanced by post-market reporting and record-keeping obligations.

NICNAS will consider occupational health and safety and environmental risk – currently not part of TGA evaluation. Current health and safety standards would be maintained.

Assessment of the regulatory impact of the regulatory reform proposal is an Australian Government best practice regulatory requirement. NICNAS and the TGA released the consultant's report for public comment in early 2008, and this was followed by public meetings, a public comment period and a survey where information was sought on potential business compliance costs and impacts on business and individuals, including restrictions on competition. Unfortunately, data gathered from these past activities are insufficient to undertake regulatory impact analysis.

NICNAS and the TGA will therefore shortly release a second consultation document, combined with a more focused regulatory survey instrument, which together will comprise a consultation regulatory impact survey. In response to comments from some areas of industry, a preferred government position will be proposed, however interested parties are asked to comment on all the options proposed in the report of the independent review.

NICNAS and the TGA aim to have developed an appropriate framework by the end of 2009. The consultation/regulatory impact survey will be in an electronic format and distributed by e-mail in October.

 If you wish to receive the survey please contact Stephen Zaluzny on 02 8577 8883 or e-mail: [stephen.zaluzny@nicnas.gov.au](mailto:stephen.zaluzny@nicnas.gov.au) ■

**SUBSCRIBE TO [NICNAS MATTERS](#) or to the NICNAS CEF's [COMMUNITY ENGAGEMENT BULLETIN](#) (see also the [Community page](#))**

If you wish to sub-scribe to NICNAS Matters, please send an email to [the editor](#) marked "NM subscription" or "Community Engagement Bulletin subscription".

*Subscriptions are free of charge.*



## Increase in New Chemicals fees and charges


From 1 July 2009, a 4.15% increase applied to NICNAS New Chemicals fees and charges. Please note that all new chemicals applications submitted prior to 1 July 2009 – for which fees remained outstanding at that date – incur the increased fees.

For applications submitted under the *Submit Once Review Once* system, payment of the remainder of the assessment fees must be lodged within 7 days of starting the assessment clock and incur the 2009-10 schedule of fees.

The Schedule of New Chemical fees and charges can be found at:  
[http://www.nicnas.gov.au/Industry/New\\_Chemicals/Fees\\_and\\_Charges.asp](http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp).

## Increase in NICNAS Registration fees and charges

NICNAS Registration fees and charges for the registration cycle commencing 1 September 2009 have not been increased. For Registration fees and charges, please see:  
<http://www.nicnas.gov.au/Industry/Registration/Registration%20fees%20charges%202009-10.pdf>.

 For further information, please contact NICNAS on:

Free call: 1800 638 528

Phone: 02 8577 8800

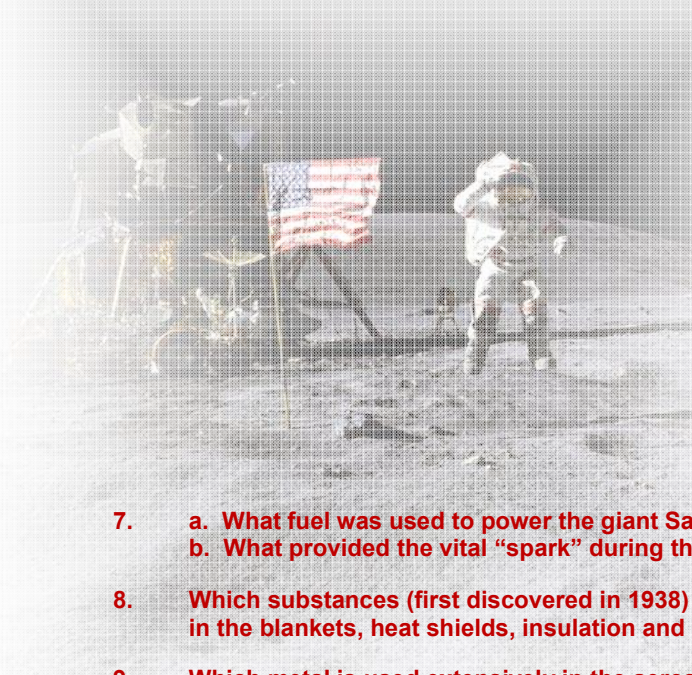
Fax: 02 8577 8888

Email: [info@nicnas.gov.au](mailto:info@nicnas.gov.au)

or visit our website at [www.nicnas.gov.au](http://www.nicnas.gov.au)

## September Chemical Quiz

20 July 2009 marked 40 years since the Moon landing, so the questions in this issue relate to our near neighbour – the Moon – and the regions beyond ...



1. What is the name given to the INNER layer of the Moon, and what are the main substances/ elements in it?
2. What is the name given to the MIDDLE layer of the Moon, and what are the main substances / elements in it?
3. What is the name given to the OUTER layer of the Moon, and what are the main substances/ elements in it?
4. What GASES are contained in the Moon's atmosphere?
5. What is the origin of the word *Moon*?
6. The lunar module was a surprisingly flimsy, cramped vehicle. What chemical substance (in common use today) protected it?
7.
  - a. What fuel was used to power the giant Saturn V rockets of the Apollo program?
  - b. What provided the vital "spark" during the launch?
8. Which substances (first discovered in 1938) was in the weave of the astronauts' space suits and also used in the blankets, heat shields, insulation and cargo hold liners used in the Moon landing?
9. Which metal is used extensively in the aerospace industry to lighten air and spacecraft?
10. When the Mars Rovers bounced to their landings, they were protected by multi-balloon landing systems made of ...?

... answers on page 13.



## Stockholm Convention on Persistent Organic Pollutants

*update*

The Stockholm Convention on Persistent Organic Pollutants (POPs) provides for the elimination or restriction of the production and use of chemicals found to be toxic, persistent and bioaccumulative. The Convention came into force in May 2004 and covers 12 chemicals including DDT, hexachlorobenzene (HCB), PCBs, poly chlorinated dioxins and furans and eight other pesticides.

The fourth Conference of the Parties (COP) to the Convention met in Geneva from 4–8 May 2009 and agreed to add new chemicals to the Annexes of the Convention (Table 1).

Eight of the nine chemicals were listed in Annex A (elimination), while PFOS was listed in Annex B (restriction) as it has many uses where satisfactory alternatives have not yet been identified. Pentachlorobenzene was listed in Annex A (elimination) and Annex C (unintentional production). Each new chemical has been assessed through a rigorous scientific process in accordance with Article 8 of the Convention.

Only four of the nine listed chemicals are of significance to Australia, as follows.

Two of the chemicals (commercial pentabromodiphenyl – pentaBDE – and commercial octaBDE) have been used in Australia in the recent past. While octaBDE was removed from AICs in 2007, pentaBDE is still under assessment by NICNAS. Nevertheless, both are likely to be present as flame retardants in various articles still in use. A special limited time exemption was agreed by the Stockholm COP allowing the recycling of plastic from articles that might contain these BDEs because of the difficulty in identifying the listed BDEs in the waste stream. Article 6 of the Stockholm Convention has certain requirements regarding waste disposal that may have implications for the BDEs.

Only two of the nine chemicals are actively used in Australia at the present time: lindane and PFOS. Lindane is presently used under an Australian Pesticides and Veterinary Medicines Authority (APVMA) permit to control pests in pineapple production in Australia but this use is being phased out.

PFOS does not have proven alternatives for all uses as yet but the listing provides for its continued use for

... continued page 9

**Table 1: Chemicals Added to the Stockholm Convention**

Chemical	Annex A, B or C	Known historical use/production in Australia	Currently used in Australia
Chlordecone <sup>1</sup>	Annex A	No	No
Lindane <sup>1</sup>	Annex A	Yes	Yes
Alpha hexachlorocyclohexane (alpha HCH)*	Annex A	Yes	No
Beta hexachlorocyclohexane (beta HCH)*	Annex A	Yes	No
Perfluorooctane sulfonate (PFOS) <sup>2</sup>	Annex B	Yes	Yes
Hexabromobiphenyl (HBB) <sup>2</sup>	Annex A	No	No
Tetrabromodiphenyl ether and pentabromodiphenyl ether present in commercial pentabromodiphenyl ether (c-penta BDE) <sup>2</sup>	Annex A	Yes	No
Hexabromodiphenyl ether and heptabromodiphenyl ether present in commercial octabromodiphenyl ether (c-octa BDE) <sup>2</sup>	Annex A	Yes	No
Pentachlorobenzene <sup>1,2</sup>	Annex A & C	Yes	No

1 Pesticide chemical

2 Industrial chemical

\* By-product in the production of lindane (gamma HCH). The three isomers of HCH have been used as technical HCH, an insecticide used in the sugar cane industry prior to 1987.



## Acceptance of international assessments of new chemicals

Bilateral and multilateral international cooperation on new chemicals is a key to increasing the mutual understanding and acceptance of hazard assessments among countries with comparable standards. Australia (NICNAS) is one of the few countries in the world that recognises comparable international assessments under the industrial chemicals regulatory framework.

NICNAS continually strives to increase the effectiveness and efficiency of the new chemicals scheme. This is achieved through establishment of bi- and multi-national agreements for sharing of assessments.

NICNAS's strong track record in sharing new chemicals assessments under the cooperative arrangements, with Canada, since 1998, continues to deliver mutual benefits and opportunities to reduce regulatory burden, minimise duplication of effort including reduced fee incentives, and protect public health and the environment.



### Canada-Australia – bilateral notifications

Under these arrangements where a new chemical, previously assessed in Canada, is notified to NICNAS the health and environmental hazard assessment of the Canadian assessment reports is considered and where appropriate is used in the NICNAS assessment report. See [December 2008 Chemical Gazette](#) Notice for guidance on how to participate in the arrangements with Canada.



### US-Australia – bilateral notifications

Recently a new Cooperative Arrangement was signed with the United States Environmental Protection Authority Office of Pollution Prevention and Toxics. The Agreement sets a framework for sharing information and cooperative efforts for notification of new chemicals between US and Australia.



### OECD Parallel Process – multilateral notifications

In the parallel process a company notifies a new chemical to multiple jurisdictions (of their choice), providing an agreed set of data to all participating countries: a lead country and secondary countries. In principle, the lead country conducts the hazard assessment, secondary countries provide input into the process, and then – once the hazard assessment is accepted by the notifier – each participating country utilises the hazard assessment in its own risk assessment. This process is viewed as a useful tool to facilitate cooperation and make progress towards the ultimate vision of **mutual acceptance of notifications**. Australia (NICNAS) as the Chair of the OECD Clearing House on New Chemicals is an active participant of the parallel process as both a lead and a secondary country.

If you are interested in utilising the cooperative arrangements, please contact the Notification and Assessment Team at NICNAS on 02 8577 8800. ■

## Stockholm Convention on persistent organic pollutants *(continued from page 8)*

specified acceptable purposes (not time limited) and specific exemptions (time limited). These include:

**Acceptable purposes** (only those that may be relevant to Australia listed):

- photo-imaging
- photo-resist and anti-reflective coatings for semi-conductors
- aviation hydraulic fluids
- hard metal plating in closed loop systems
- fire fighting foam

The COP will review the continued need for the various acceptable purposes and specific exemptions in 2015 and every four years thereafter. For these acceptable purposes, PFOS can continue to be used unless a future Conference of the Parties decides that suitable alternatives are available.

**Specific exemptions** (only those that may be relevant to Australia listed):

- photo masks in semi-conductors
- hard metal plating other than closed loop systems
- metal plating (decorative plating)

Specific exemptions last for five years only and an extension for up to a further five years would require the COP's agreement.

The addition of the nine chemicals to the convention will only apply in Australia if and when the treaty amendment progresses through the domestic treaty-making process and is ratified by the Australian Government. Relevant regulations would also need to be proclaimed. The treaty-making process will involve consultation with affected parties, including potentially affected industries. ■



## NICNAS registration renewal 2009-10

All importers and manufacturers of relevant industrial chemicals for commercial purposes must be registered with NICNAS prior to introducing these chemicals regardless of the amount of industrial chemicals imported and / or manufactured.

The NICNAS registration year runs from 1 September to 31 August annually. The following information relates to NICNAS registration renewals for 2009-10.

**The renewal deadline** was 31 August 2009, the date on which your current registration expires. You must renew your registration before it expires.

### Renewal schedule

In July 2009, NICNAS mailed Renewal Tax Invoice and Application form for renewal of registration/ non-renewal to all registrants. If you have not yet received an invoice, please contact NICNAS on 1800 638 528.

Registrants are required to advise NICNAS of any changes to contact details contained in the Application form for renewal of registration/ non-renewal, where applicable.

A [copy of this form](#) is available on the NICNAS website at: [www.nicnas.gov.au/Forms/Registration.asp](http://www.nicnas.gov.au/Forms/Registration.asp)

### NICNAS Registration fees and charges

Level	Description – total value of chemicals introduced	2009-10 price <sup>1</sup>
Tier 1	\$1 - \$499,999	\$381
Tier 2	\$500,000 - \$4,999,999	\$1,522
Tier 3	\$5,000,000 or more	\$8,881

1. All NICNAS fees and charges are in Australian Dollars and are GST free.

### Reminder: penalties for late renewal

NICNAS registration for a company lapses if it was not renewed by the 31 August 2009 deadline. Applications received after this date are considered late renewal applications, and subject to a late renewal penalty. The late renewal penalty is calculated at 15% of the total registration cost.

This penalty is mandatory, and payment is required in addition to the registration renewal fee before NICNAS can re-instate a registration.


A late renewal application can only be processed when both the appropriate registration fee (Tiers 1, 2 & 3) and charge (Tiers 2 & 3 only), and the appropriate late renewal penalty, have been paid.

The following table shows the costs for late renewals for 2009-10 registration year.


Level	Late renewal penalty (rounded to nearest whole dollar)
Tier 1	\$57
Tier 2	\$228
Tier 3	\$1,332

Non renewals (ie, non-registrations) carry a risk.

It is an offence for a person to introduce (import and/or manufacture) relevant industrial chemicals without a NICNAS registration in force. The legislation provides for severe penalties for a person who introduces relevant industrial chemicals without a current registration in place.

 For further information, please contact NICNAS on:

- Free call: 1800 638 528
- Phone: 02 8577 8800
- Fax: 02 8577 8888
- Email: [registration@nicnas.gov.au](mailto:registration@nicnas.gov.au)

or visit our website at [www.nicnas.gov.au](http://www.nicnas.gov.au) 

### Contacting NICNAS

Do you have an industrial chemicals issue or matter you would like to raise with us? Please feel free to call or write to us. Our contact points are: **Freecall:** 1800 638 528 **Email:** [info@nicnas.gov.au](mailto:info@nicnas.gov.au)

**Post:** GPO Box 58, SYDNEY, NSW 2001 AUSTRALIA



## Nanomaterials – a comprehensive update ...

*In pace with worldwide impetus, NICNAS is stepping up its activities to ensure the safe and sustainable use of industrial nanomaterials. NICNAS is continuing to ensure that an effective risk-based, best practice regulatory approach to industrial nanomaterials is implemented in Australia.*

**Previous activities** have provided a sound basis for a coherent, strategic approach with which to move forward. These include:

- review of the NICNAS regulatory framework in response to findings from [A Review of Possible Impacts of Nanotechnology on Australian Regulatory Framework](#) (The Monash Report)
- stakeholder engagement through the establishment of the NICNAS Nanotechnology Advisory Group (NAG) which includes members drawn from industry, community, academia and from NICNAS, to advise NICNAS's Director on strategies to address regulatory and safety impacts of industrial nanomaterials
- undertaking calls for information in 2007-08 and 2008-09 to ascertain the extent of introduction of nanomaterials into Australia
- investigation of reports in relation to possible non-compliance, when introducing nanomaterials
- publishing advice to industry that introducers of nanomaterials should contact NICNAS to ensure that any nanomaterial they wish to introduce is either on the (AICS) Inventory, or (if a new chemical that they wish to introduce under exemption categories) that the new chemical poses 'no unreasonable risk to health and safety and the environment'
- building technical capacity within NICNAS by providing assessors with in-depth knowledge through training and reviewing scientific literature relating to nanomaterials of specific relevance to NICNAS, and
- participating in international initiatives such as the Organisation for Economic Co-Operation and Development (OECD) *Working Party on Manufactured Nanomaterials* and International Standards Organisation (ISO) *Technical Committee for Nanotechnologies (TC229)*, both aimed at gathering data on health, safety and environmental issues, setting definitions and standards for these materials and developing appropriate risk assessment methodologies and guidelines.

**Current activities** intend to 'ramp-up' and build on previous work, to ensure the industrial chemical framework remains an appropriate mechanism for the effective assessment and management of nanomaterials. This work is occurring in two parallel streams;

### *Regulatory Reform:*

- developing a draft NICNAS regulatory strategy, in conjunction with the Nanotechnology Advisory Group, that takes into consideration the appropriateness of the current regulatory framework for managing risks posed by nanomaterials
- ensuring any proposed changes in NICNAS processes arising from the strategy will involve further stakeholder input including public consultation, and
- regulatory impact analysis on this strategy is likely to be conducted in 2009-10.

### *Building technical capacity:*

- developing risk assessment and modelling capabilities for NICNAS staff
- commissioning a Literature Review of new toxicological data, to fill gaps in knowledge between existing reviews for the nanomaterials of particular interest
- reviewing data requirements for NICNAS assessments and benchmarking risk assessment methodology for nanomaterials that meet international best practice
- leveraging built up linkages between national and international agencies that are doing work in the same area to maximise efficiency of research
- continuing to lead the OECD WPMN project on a database of environment, health and safety (EHS) research into manufactured nanomaterials that is a global resource which:
  - identifies research projects (completed, current and planned) that address EHS issues associated with manufactured nanomaterials

... continued page 12



## Nanomaterials *(continued from page 11)*

- assists scientists planning research to identify research needs and avoid duplication
- provides support for scientists working in similar fields leading to collaboration and networking
- provides critical information and support for other WPMN projects by acting as an inventory on research programs world-wide
- continuing to facilitate the work of an Australian consortium, led by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) that is participating in the safety testing of zinc oxide, cerium oxide, and silver nanoparticles. The project will generate data on the human and environmental health impacts of specific nanomaterials using standardised samples, which can be used as a reference point for the prediction of the hazards of related nanomaterials
- continuing participation in ISO TC229, through the Standards Australia Nanotechnology Committee (NT-001) to develop standards through which reliable

nomenclature, characterisation of nanomaterials can be established, and

- developing information products for use by industry and community on nanomaterials and to keep an open dialogue about potential changes and implications of regulatory processes.

*Updates on these activities will be provided in future editions of NICNAS Matters*

### In short:

***NICNAS is gearing up to be very busy in this area! NICNAS aims to maintain its priority role – of ensuring that the Australian public and environment are protected from undue risk – while facilitating the successful adoption of this emerging technology by industry and the community.***

To progress these goals NICNAS seeks industry, community and research sector cooperation to ensure continued health, safety and environmental protection.

We welcome feedback from all stakeholders. ■

 For more information, please contact NICNAS's Ms Nicola Hall on 02 8755 8873, or email [nicola.hall@nicnas.gov.au](mailto:nicola.hall@nicnas.gov.au)

Further information on NICNAS activities, NAG and NETS can be found at our [Nanotechnology webpage](#).

More detail on each of the above topics can be found in:

- [NICNAS Information Sheet: Nanomaterials September 2006](#)
- [NICNAS information Sheet: Summary of Call for Information on the use of Nanomaterials January 2007](#)
- [NICNAS Matters: NICNAS nano-related activities - an update, December 2008](#)
- [Chemical Gazette: Introduction of new nanomaterials, February 2009](#)

In addition, three new NICNAS information sheets are in preparation:

- Nanomaterials – summary of 2008 Call for Information
- Nanomaterials – NICNAS regulatory activities
- Nanomaterials – NICNAS's current activities, 2009

### Recent OECD publications in the series on the Safety of Manufactured Nanomaterials:

#### Topics

[Current Developments/ Activities on the Safety of Manufactured Nanomaterials](#)

[Preliminary Analysis Of Exposure Measurement And Exposure Mitigation In Occupational Settings: Manufactured Nanomaterials](#)



## Upcoming events

### AT HOME

#### October

- 7-9** International Federation of Societies of Cosmetic Chemists (IFSCC 2009), Melbourne  
**15** Industry Engagement Group (IEG) 2, NICNAS  
**20-23** [ACCORD National Conference and Asia Oceania Soap and Detergents Assoc. Conference](#), Melbourne  
**27** Collecting Exposure Information for the NICNAS Prioritisation Project, Sydney  
**28-29** [Fire Protection: The Great Debate](#), Hobart

#### November

- 17** CEF 21, NICNAS  
**25** IGCC 35, NICNAS  
**29 - 2 Dec** Australasian Society of Clinical & Experimental Pharmacologists & Toxicologists ([ASCEPT Annual Scientific Meeting](#)), Sydney

#### December

- 6-10** Pacific Polymer Conference, Cairns

#### February 2010

- 18** Cosmetic Advisory Group 2, NICNAS  
**22-26** [International Conference on Nanoscience and Nanotechnology](#) (ICONN) Sydney

### ABROAD

#### September

- 13-16** 46<sup>th</sup> Congress, [European Societies of Toxicology](#), Dresden Germany  
**16-18** OECD workshop on Risk Assessment in a Regulatory Context, Washington USA  
**20-25** ICAM 2009 - 11th [International Conference on Advanced Materials](#), Rio de Janeiro, Brazil  
**28-30** [Nanotech Europe 2009](#), Berlin, Germany

#### October

- 11 - 16** [Stockholm Convention](#), Geneva, Switzerland  
**12-15** [Second World Materials Summit on Advanced Materials in Energy Applications & Sustainable Society Development](#) Suzhou, China  
**13-15** 29<sup>th</sup> SIDS Initial Assessments, Hague, Netherlands  
**28-30** OECD WPMN 6<sup>th</sup> meeting, Paris France

#### November

- 30 - 1 Dec** OECD Exposure Task Force, Paris, France

#### December

- 9 - 11** UN 18<sup>th</sup> Subcommittee of Experts on the [GHS of Classification and Labelling of Chemicals](#) Geneva, Switzerland

## Answers:

### September Chemical Quiz (questions on page 7)

- The lunar core (20%) partly molten, is made up of metallic iron, sulphur and nickel.
- The mantle – which starts 50km below the surface – comprises the minerals olivine, orthopyroxene and clinopyroxene, plus some iron.
- The crust (from the surface to a depth of 50km) comprises oxygen (42%), silicon (21%), iron (13%), calcium (8%), aluminium (7%) and magnesium (6%). There are also trace elements like titanium, uranium, thorium, potassium and hydrogen. There is no water on the moon's surface.
- The moon has little or no atmosphere. If the moon ever did have a surrounding layer of gases, it would have leaked away into space because of the moon's weak gravity. The moon has no weather, no clouds, no rain, and no wind.
- Moon* is a Germanic word related to the Latin *mensis* (month). It is ultimately a derivative of the Proto-indo-European root *me-*, also represented in *measure* (*time*).
- It was protected with polyethylene terephthalate (PET) film.
- a. Hydrogen; b. Oxygen
- Teflon* (polytetrafluoroethylene)
- Titanium metal (produced from ore using chlorine chemistry).
- Specially formulated polymer plastics

## New NICNAS publications

### REPORTS

[Complex Soap TH17 Secondary Notification Report \(draft\)](#)

[Complex Soap TH17 Secondary Notification Report \(draft overview and recommendations\)](#)

[Methyldibromo glutaronitrile \(MBDG\) Hazard Assessment Report](#)

[LRCC Evaluation Report \(draft for first phase\)](#)

### INFORMATION SHEETS AND ALERTS

[Methyldibromo glutaronitrile \(MBDG\) information sheet](#)

[Sodium Cyanide information sheet](#)

### CHEMICAL GAZETTES

[July 2009](#) - [August 2009](#) - [September 2009](#)

[Special Chemical Gazette \(on release of draft Sodium Cyanide report for public comment\)](#)

© Commonwealth of Australia 2009. This work is copyright. Apart from educational or training purposes and any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth. Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra ACT 2600 or posted at: <http://www.ag.gov.au/cca>

