


NICNAS matters.

REDUCE BENZENE EXPOSURE RISK

SAYS DRAFT REPORT

NICNAS has recommended the revision of the occupational exposure standard and establishment of a national air standard for benzene in its draft assessment report on the carcinogen, which was released for public comment earlier this month.

"There is cause for concern about the risk for leukaemia in workers with repeated occupational exposure to benzene," said the Director of NICNAS, Dr Margaret Hartley.

"There is no known threshold for the carcinogenic effects of benzene, but since the risk for leukaemia increases with exposure, it can be reduced by controlling exposure to the highest practicable standard."

Benzene is produced predominantly in the steel industry, petroleum refining and in petrol vehicle emissions, where exposures are most likely to occur. Among workers who are exposed to benzene if the workplace environment is contaminated with petrol vapours or engine exhaust are vehicle mechanics and professional drivers.

The draft Priority Existing Chemical assessment report was released on 5 June for public comment until 3 July 2001. This was preceded by well-attended public seminars in most capital cities where the key findings of the report were presented.

"Occupational exposures should be minimised by improving workplace control measures and using the best available technology," Dr Hartley said.

The public are exposed to benzene through the inhalation of air contaminated with vehicle exhaust and petrol evaporation.

"The establishment of a national ambient air benzene level would help reduce the risk of public exposure to benzene," Dr Hartley said.



Left to right: Benzene seminar presenters Deborah Willcocks (NICNAS), Sheila Logan (TGA), Chris Lee-Steere (EA)

Public seminars

NICNAS conducted a series of public seminars on the draft report on benzene. These were held in Canberra, Sydney, Brisbane, Perth, Adelaide and Melbourne between 30 May and 7 June.

Topics covered by the seminars included:

- Human health and environmental hazards;
- Occupational, public health and environmental risk assessments; and
- Draft recommendations, such as recommendations to revise the occupational exposure standard and to set an ambient air level.

Major issues raised at the seminars were how the report estimated the Urban Model Environment for public exposure and the recommendations arising from the assessment.

Attendance at each exceeded expectations with 171 attendees overall, providing good representation from government, industry and public.

Distribution of Attendees	Number of Attendees Registered
Government - Federal	29
- State	75
Industry	47
Public	20
Total	171

New @ www.nicnas.gov.au

- The *NICNAS Handbook for Notifiers* has been updated and the new version is now available in PDF for downloading from the Publications page, using Acrobat.
- The Existing Chemicals page now includes the reasons why some chemicals nominated under this program are not selected for assessment. (See www.nicnas.gov.au/obligations/existing/index.htm)
- Go to the industry pages (Do you import or manufacture chemicals?) for the Company Registration Evaluation Reports. The latest report details the consultation undertaken in response to the consultant's final report. (See www.nicnas.gov.au/obligations/registration/index.htm)
- The *Chemical Gazette* continues to be published online. The latest issue is available from www.nicnas.gov.au/publications/index.htm#gazette

The NICNAS website is continually updated. Watch the news page for developments, latest media releases and final reports as well as those reports being released for public comment.

Six pack of PECs

On 5 June, NICNAS released six Priority Existing Chemicals (PEC) final reports on the following chemicals, summarised below. All the reports are available in full on our website at:

www.nicnas.gov.au/publications/car/pec/pecindex.htm

- **Hydrofluoric acid** was chosen for a preliminary assessment by NICNAS because of concern about the chemical's high toxicity and general availability.

Aqueous HF is used widely, especially in varied metal treatment and cleaning processes. Other important uses include wall and floor treatments, laboratory analysis, glass etching and cleaning, fabric rust removal, and etching silicon in the manufacture of semiconductors. Anhydrous HF is used as an alkylation catalyst at five petroleum refining sites in Australia.

Public exposure is most likely to occur from skin contact with consumer products containing HF. Skin contact can cause painful second and third degree burns, which heal slowly.

The assessment report found there were a number of actions for industry to take to improve safety, including using substitutes, but that compliance was poor. NICNAS will monitor industry's performance in improving safe use of this chemical over the next 12 to 18 months and have noted that if industry practices do not improve further regulatory action will be necessary.

what's inside...

- New PEC Reports
- Due Diligence
- CEC Permits survey results
- PIC procedures

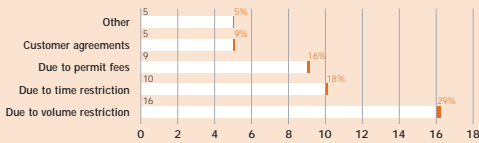
SURVEY LIFTS THE LID ON CEC PERMITS

A NICNAS survey of commercial evaluation permit users has found industry's main concerns about the CEC permits to be related to volume or time restrictions more than permit fees or customer agreements.

Hailed as a much-needed insight into the commercialisation of industrial chemicals in Australia, the survey was finished by NICNAS in March this year and gathered information for the possible reform of the permit provisions.

Major concerns with the CEC permits were listed as volume restriction (from 29 per cent of respondents), time restriction (18 per cent), permit fees (16 per cent) and customer agreements (9 per cent).

Chart 1: Reasons preventing introduction



There was substantial commentary provided by survey respondents that the allowable volume of two tonnes was inadequate. The survey found the quantity of chemical required for commercial evaluation ranged from 25 kg to 10 tonnes, with the most frequent response being one to two tonnes.

The range of lead times to import or manufacture chemicals from obtaining a CEC permit to finalising the evaluation was typically reported as 21 months, with a range of lead times from four months to five years.

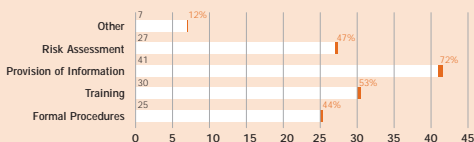
"While the number of companies who responded to the survey – 57 – was slightly less than the target of 63, the sample had coverage over the range of small, medium and large business, the range of chemicals manufactured and across industry sectors," said Ms Carol Jenkins, the NICNAS project officer handling the survey.

Selection bias

Ms Jenkins added that there was evidence of a selection bias operating. "The larger companies with a more progressive approach to health, environment and government regulatory issues were more likely to have the inclination and resources to participate," she said.

When asked how they ensured compliance with environmental health and safety (EHS) for chemicals that they were evaluating, less than half the companies surveyed indicated they had formal procedures in place. Around half of all companies reported they did not use risk assessment or training to meet EHS requirements.

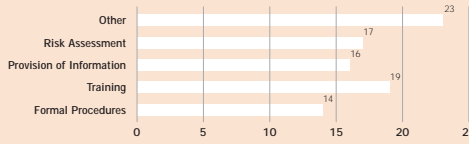
Chart 2: How companies ensure EHS compliance for new chemicals during commercial evaluation of new chemicals



Companies scored better at providing information, with nearly three quarters of the respondents providing information to ensure EHS compliance during commercial evaluation of a new chemical.

"This suggests that a move to promote stewardship for CEC chemicals, incorporating information, training and risk assessment tools, could be beneficial, and may facilitate higher customer acceptance," Ms Jenkins said. "With lack of customer acceptance the leading factor cited as preventing new chemicals from gaining commercial acceptance, this makes sense from a commercial and environmental perspective."

Chart 3: Factors preventing new chemicals gaining commercial acceptance



Compliance with conditions

While most companies (87 per cent) that had used CEC permits reported they ensured compliance with the permit conditions and advised customers of these, 13 per cent reported they did not comply with permit conditions, nor did they advise customers to do so.

Gaining an understanding of current practices was seen as a first step for NICNAS in its work towards reform of the commercial evaluation permit provisions.

"The survey collects statistics in relation to chemicals, which addresses one of the objectives of the NICNAS legislation," Ms Jenkins explained. "It also moves regulatory reform to a knowledge-based process rather than relying on anecdotal evidence."

"Here we actively sought out specific information to inform the change process, and with a bit of perseverance, have gained very useful data."

Ms Jenkins presented the report to the NICNAS Industry Government Consultative Committee (IGCC) at its meeting on 27 April.

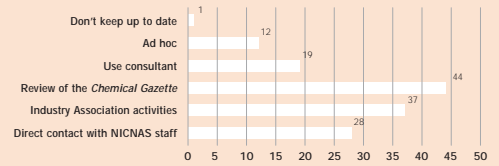
New ground for industry

Mr Ian Swann, of PACIA, an observer at the IGCC meetings, complimented the report. "This work really covers new ground for the chemical industry. The survey has turned up strategic data for companies introducing new industrial chemicals, from both a regulatory and a commercial perspective," Mr Swann said.

"I have asked NICNAS to present the survey finding to PACIA members as it provides important feedback and analysis for industry and government processes."

Ms Jenkins said an interesting indication in the survey was how "experienced regulatory players keep up to date by using a three-tiered approach. This combines review of the *Chemical Gazette*, industry association activities and direct contact with NICNAS staff to collect information and thus reduce the risk of critical information gaps."

Chart 4: How companies keep up to date with NICNAS



Findings

The NICNAS Commercial Evaluation Survey found:

- The lead times to import or manufacture chemicals from obtaining a NICNAS Commercial Evaluation Category (CEC) permit to finalising the evaluation was typically reported as 21 months with a range of lead times from 4 months to 5 years.

- The quantity of chemical required for commercial evaluation varied across industry sector and production process, with a range from 25 kg up to 10 tonnes, with the most frequent response being 1-2 tonnes, reflecting current practice. There was substantial commentary provided by survey respondents that the 2 tonne volume limit was not adequate. There was a clear indication, from 29% of companies, that the current volume restriction of 2 tonnes was too low. The volume restriction was the most frequently cited reason preventing introduction of a chemical under a CEC Permit.

- The total and lapsed time taken to test technical capacity, production and the market was typically stated as 12 months but ranged from 3 months to 3 years.

- The results indicated that while 44% of companies considered their forecast of quantities very reliable or better, 37% rated their forecasts for quantity in this area as poorly reliable.

- The reliability of market planning is dependant in part upon accurate forecasts of quantities, (see previous point) which is reported as done either well or badly. This may reflect the lack of systematic planning for new products shown with only 45% of companies indicating that they did plan for new chemical materials.

- The four most frequently given reasons for a company to introduce a new chemical are, in order: new product line (68%), overseas parent organisation recommendation (61%), new technology (60%) and express request by customer (56%). Most companies had established customers before starting commercial evaluation with 70% of companies indicating they ran technical trials at customers' plant. Commentary and case studies show a trend to work with existing customers, with only 26% of companies indicating market research as a driving factor in new chemical introductions.

- In reporting how they ensured compliance with environmental health and safety (EHS) for new chemicals being commercially evaluated, less than half of the companies (44%) indicated they had formal procedures in place, with around half of all companies reporting they did not use risk assessment or training to meet EHS. Nearly three quarters (72%) of companies provided information to ensure EHS compliance.

- 67% of the companies were aware of CEC permits and 35% had practical experience in submitting CEC applications. There was a range of experience in NICNAS submissions with 33% of companies introducing between 0-5 new chemicals in the last 5 years and 36% of



DILIGENCE IN COMPANY MERGERS AND ACQUISITIONS

Transmission of a business, through sale or merger, is a time when all parties need to assess their liabilities and legal obligations, and watch out for traps. While due diligence in the transmission of business presents a number of areas for investigation, traditionally the focus has been on finance records, property and capital title, valuation of assets, and the general question as to whether there are any existing liabilities which have the potential to disrupt the operation of the company, incur costs, or penalties. NICNAS has found a number of companies that have discovered significant compliance problems in NICNAS notification and assessment requirements after acquisition of a business.

In one case the purchaser found that 14 chemicals in their new business were chemicals new to Australia, which had been imported in breach of the *Industrial Chemicals (Notification and Assessment) Act 1989*. The acquisition of this business brought an inherent risk of prosecution for failing to comply with the Act. In this case the company was able to enter in to a partner agreement with NICNAS, with a timetable and conditions to meet the notification and assessment requirements. This entailed preparation of notification packages, applications for assessment and early introductions permits, extra costs including payment of application fees, consultants' fees and staff time, as well as the loss of income from the disruption to trade. If identified before acquisition under due diligence, this compliance shortfall could have been addressed in the terms of transmission or sale.

In any acquisition or merger with a company that imports or manufactures industrial chemicals the due diligence process needs to consider NICNAS requirements. The first step will be to establish if a company's business falls within the scope of NICNAS i.e. do they import or manufacture – "introduce" – industrial chemicals as defined in the Act. If the company does introduce industrial chemicals then the NICNAS Company Registration status should be verified.

The next part of the checking process will audit a company's compliance with NICNAS for individual chemicals. An in-house chemical inventory for the

company identifying the names and quantities of the chemicals that the company imports or manufactures will need to be established. An accurate and unambiguous identifying name will be needed for each chemical, including each of the constituent chemicals in formulated products. The chemical name will need to include the Chemical Abstract Service (CAS) number. The marketing or trade name for the chemical will also be a useful reference in the inventory. It will also be useful to include an estimate of the volume of the chemical imported or manufactured in this in-house chemical inventory. An example of an audit checklist for NICNAS is attached.

Once an in-house chemical inventory is prepared a search on status for a number of NICNAS indices will be needed. This will identify any chemicals that do not comply with NICNAS obligations and may also flag any current or future obligations. The due diligence process should also check if systems are in place to ensure ongoing compliance with NICNAS.

Our website at www.nicnas.gov.au provides information for industry on its Do you import or manufacture chemicals? page. As well, the *NICNAS Handbook for Notifiers* provides more detail about the procedures and can be downloaded from our website's publications page. It is worth keeping up to date with the monthly *Chemical Gazette* for new assessment reports and legislative changes. This gazette is published on our website.

Due Diligence Checklist for NICNAS Compliance

In-house inventory check

Product or Trade Name:
Chemical Name:
CAS Number:
AICS – open:
AICS – confidential:
Assessment Certificate or Permit Status:
Priority Existing Chemical or Data Call:
Assessment Report

Procedures Check

Does the company have written procedures to check NICNAS compliance for possible new products?

Can the company identify all the chemical constituents in the products it supplies?

Does the company review the *Chemical Gazette* to see if any new NICNAS obligations arise?

Does the company hold copies of NICNAS assessment reports for chemicals it supplies?

Does the company track volume and time limits for any NICNAS permits or assessment certificates it holds?

companies assessing more than 15 new chemicals in the same period. Up to 1999 there were 59 companies that had submitted one CEC application and 14 companies submitted a total of 352 CEC applications.

- 36% of companies reported that the CEC provisions were too restrictive and they prevented the company from using this category to introduce chemicals for commercial evaluation. 40% reported they had used another NICNAS category to commercially evaluate chemicals. Roughly equal numbers – 39% reported that CEC did not prevent commercial evaluation of a new chemical.

- While most companies (87%) that had experience with CEC permits reported that they ensured compliance with permits conditions and advising customers of permit conditions, 13% reported they did not comply with permits or advise customers of permits.

- The major concerns with the CEC permits were volume restriction (29%), time restriction (18%), permit fees (16%) and customer agreements (9%).

THANK YOU

NICNAS staff would like to thank the 57 companies who participated in the survey for their help. We appreciate that this added to an already very full workload.

< page 1

- The NICNAS assessment of **ammonium, potassium and sodium persulfate** was carried out after concerns were raised about their widespread use in the hairdressing industry and the prevalence of skin disease and asthma in that profession.

There was also concern as to whether the information included on the hazard warnings was adequate.

Exposure effects of these chemicals in humans include contact hypersensitivity, contact urticaria, rhinitis, bronchitis and early and late onset asthma. Current labels for salon products lack warnings about respiratory sensitisation. The report recommends the phasing out of those products that release dust at work.

- A preliminary assessment of **polybrominated flame retardants (PBFRs)** was undertaken after concerns were raised about their health and environmental effects.

PBFRs are not manufactured in Australia but imported as pure chemicals or mixtures, or in polymer resins or extruded polystyrene foam boards.

The primary health concerns revolve around the potential of some PBFRs to act as carcinogens, endocrine disruptors and neurodevelopmental toxicants.

There is a potential for exposure among workers who are involved in the formulation of flame retarded resins and polymers, particularly where weighing and mixing are carried out in manual and open systems, and where minimal personal protective equipment is used.

The report recommends that a full risk assessment be considered for this group of chemicals, following completion of testing overseas under an OECD chemical safety program.

- **Short chain chlorinated paraffins (SCCPs)** were found to have a high potential for damage to the aquatic environment. The preliminary assessment was carried out after concern about SCCPs' long term health and environmental effects.

In Australia, they are used in the manufacture of metalworking fluids, and in a range of products used in the building industry such as fillers, adhesives and coating materials. Other uses include the manufacture of pigment dispersants, rubber, and leather treatment products. Some of the final products containing SCCPs such as adhesives, paints and sealants may be available to the general public.

PIC procedures begin

In the first issue of *NICNAS matters*, we described the Prior Informed Consent procedures (PIC), which had recently been negotiated internationally. Australia is a signatory to this agreement, also known as the Rotterdam Convention, and is among the countries now implementing its procedures on a voluntary basis.

Australia is still to decide whether to ratify the Convention, pending widespread consultation and the preparation of a National Interest Analysis.

One of the responsibilities entailed under the voluntary interim procedure is that the Australian government notifies the Convention secretariat of any chemicals that have been banned or severely restricted in Australian territory.

Australia has already notified the Convention Secretariat that amphibole asbestos is severely restricted, based on the legislation of States and Territories. This form of asbestos comprises crocidolite (already PIC-listed), amosite, tremolite, anthophyllite and actinolite.

Rome meeting

This notification was discussed informally at the second meeting of the PIC technical group, known as the Interim Chemical Review Committee (ICRC), held in March in Rome. NICNAS was represented in the Australian delegation.

The major work of the ICRC is to recommend chemicals for inclusion in the PIC procedure, and to prepare the information that is circulated to participating countries when a chemical is PIC-listed.

The European Union has also notified the Secretariat of asbestos in the industrial category, triggering its formal consideration at the 2002 meeting of the ICRC.

To assist the ICRC, Australia will supply information on the risk evaluations carried out at the time restrictions were put in place. NICNAS will consult State and Territory authorities to obtain this information.

Other chemicals already PIC-listed in the industrial category are polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polybrominated biphenyls (PBBs) and tris(2,3-dibromopropyl) phosphate. It is expected that extra chemicals will be added to the list through the process outlined in the breakout box on this page.

NICNAS contributes to PIC

The recent NICNAS assessment of polybrominated flame retardants (PBFs) as priority existing chemicals has useful benefits for PIC (see separate article on p1 on the latest PEC assessments). This assessment included the PIC chemicals PBBs and tris (2,3-dibromopropyl) phosphate, and found that they are not currently

imported or manufactured in Australia.

These chemicals were found to have significant adverse health effects, with evidence of carcinogenicity, endocrine disruption and reproductive effects.

Should Australia ratify the Rotterdam Convention, the findings of the assessment on use, exposure and effects will allow Australia to make an informed decision on future imports of these chemicals.

For further details on PIC, contact **Rosemary Sager** on (ph) 02 9577 9476 or email sagerr@nohsc.gov.au

The contact for pesticides is **André Mayne** at the Department of Agriculture, Fisheries and Forestry – Australia on (ph) 02 6272 5391 or email andre.mayne@affa.gov.au

An Australian information paper on PIC can be accessed on the NICNAS website at www.nicnas.gov.au/foreign/ or in hard copy from NICNAS. International information is available at www.pic.int and its links.

The Rotterdam Convention

The focus of the Rotterdam Convention is on the exchange of information about chemicals. The core procedure covers inclusion or "listing" of certain pesticides and industrial chemicals under the Convention and circulation of information on these chemicals to all participating countries. Each country then advises whether they will accept future imports of each listed chemical, and exporting countries are to respect these decisions. The Secretariat coordinates these procedures, and publicises the import decisions of countries in its twice-yearly circular. The Internet site at www.pic.int and its links are also an important source of information.

How is a chemical chosen to be on the PIC list? This is done on the basis of bans or severe restrictions on the chemical in individual countries. When two notifications that the chemical is banned or severely restricted are received from different regions of the world, the chemical is considered for inclusion under the Convention. Notifications are made separately for the use categories of pesticide and industrial. For example the chemicals ethylene oxide and ethylene dichloride have been listed under the Convention in the pesticide category but their industrial uses are not affected.

There is the potential for workers to be exposed to SCCPs in the formulation of these products, although the report considers this potential to be low.

NICNAS recommends a full environmental risk assessment be conducted on the use of SCCPs in metal working fluids.

• **Chlorinated trisphosphates** were assessed after concerns were raised about their possible bioaccumulation in humans and the environment.

Trisphosphates are imported into Australia for use as flame retardants or plasticisers in the production of flexible and rigid foams, elastomers and specialist rubber materials, fibreglass resins, industrial paints, surface coatings and sealants.

The chemicals are absorbed through the skin or via inhalation but the report found there is little evidence that these compounds are likely to accumulate in animal tissues. They are not expected to be persistent in the environment and overall environmental hazards are assessed as low.

The NICNAS report recommends a full risk assessment be carried out because of the identified effects on human health with some trisphosphates and lack of adequate data on others. There is also the potential for workers and the public to be exposed to trisphosphates.

• **Tetrachloroethylene**, which is an animal carcinogen and mainly used in dry cleaning, was assessed for its health and environmental risks.

High exposure levels can result in harm to the central nervous system and in respiratory irritation in humans. Subtle effects on the liver have been observed in humans following repeated exposure.

Although occupational exposure levels are generally low, NICNAS recommends that industry strive to improve their process and engineering controls to ensure workers are not exposed to the chemical. Environmental risk is considered to be minimal in Australia.

STOP PRESS

The National Occupational Health and Safety Commission (NOHSC) has relocated from Sydney and is now based in Canberra. NICNAS and the Agricultural and Veterinary Chemicals unit remain in Sydney. NOHSC's new contact details are:

Visiting address:
Level 6, 25 Constitution Avenue, Canberra ACT 2600

Mailing address:
GPO BOX 1577, Canberra ACT 2601
Ph: 02 6279 1000 Fax: 02 6279 1199
Email: info@nohsc.gov.au

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