

Regulation Impact Statement for proposed amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989*



What is the problem requiring Government action?

The current notification and assessment requirements under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) can result in delays to the introduction into Australia of new chemicals with low hazard and/or low risk. The current arrangements under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) do not provide enough incentive to industry to encourage the introduction of safer, more environmentally friendly industrial chemicals on to the Australian marketplace. Current criteria are restrictive and may delay for several months the commercial introduction of an otherwise low risk chemical.

Industry concerns about the regulatory framework

Industry evidence found that in some instances, the total cost of introducing new chemicals including the cost of providing information to the government exceeded \$200,000. Industry is particularly concerned at the high cost of generating data because of some unique Australian requirements. In particular, in its report, industry cited the following examples as indicative of those generating a high cost for Australian data requirements:

- high cost of assessment for substances used in small quantities;
- degree of testing and assessment required for substances that are seen as of low concern in the US or Europe and, therefore not required to be assessed in those places;
- assessments by recognised overseas authorities not accepted in Australia. Similarly, non-recognition of chemicals approved for use by those authorities;
- under-estimation of the impact on new legislation and regulations at the time of drafting, and unanticipated consequences both in resources needed and costs required to implement them; and
- non-uniformity of regulations across jurisdictions. (p28-29)

Specifically, the Steering Group recommended that:

Relevant regulatory bodies be required to alter their assessment processes to ensure:

- I. Recognition of data from overseas sources that test to accepted international standards;*
- II. Recognition of chemical approvals from approved countries including substances “grandfathered” in those countries; and*
- III. Consistency of international definitions and/or classifications (pvii).*

In its response, the Government indicated that:

... via NICNAS, is committed to continuing to work with industry to ensure the most efficient regulatory system is in place for industrial chemicals, that is, a system that does not inhibit the introduction of new and safer chemicals. The Government will consider and develop options for access to adequately assessed and/or tested chemicals presenting low regulatory concern. (November 2002 p7)

In Australia, industrial chemicals are regulated by the Australian Government under the Act administered by NICNAS and located within the Health and Ageing portfolio. While the Government has agreed to examine options for flexibility in the assessment process for industrial chemicals, it indicated “...recognition of unassessed grandfathered chemicals is not acceptable on the grounds that it would impose Australia to unacceptable risks and lower our regulatory standards and hence inhibit our opportunity to harmonise with comparable regulators overseas” (p7). Grandfathered chemicals refer to those chemicals which were in

commercial use by industry in Australia between 1 January 1977 and 28 February 1990 at the time were placed onto the Australian Inventory of Chemical Substances (AICS). In general little is known about these chemicals, they have not been assessed or for some, limited assessment data is available.

Objectives of reform initiative

The aim of the reform process is to introduce flexibility into the current assessment process for industrial chemicals to enable the fast tracking of low regulatory concern chemicals (LRCC) while maintaining existing levels of worker safety, public health and environmental standards. Both industry and the Government support the need to pursue reform in this area and have given it a high priority.

The approach adopted during the reform process involved NICNAS identifying categories where low regulatory concern already existed based on experience over the range of new chemical assessments/applications processed over the past six years. A preliminary review by NICNAS identified a number of circumstances where reduced costs and/or data requirements are supported and/or where reduced assessment requirements may apply. These areas were explored with industry and the community with a view to defining LRCC to provide certainty to industry.

Due to the diverse nature of what constitutes “low regulatory concern”, there has always been difficulty in defining a single category or set of guidelines that readily capture the scope of possible reforms. A single definition of LRCC is not possible except in the most generic sense, as follows:

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

LRCC Reform Options

An LRCC Task Force made up of government and individuals from industry and the community was established to assist the reform process and provide expert input where needed. Technical working groups were established with members from industry, government and the community working together to explore options for LRCC and investigate the feasibility of implementation in Australia, thereby ensuring that the affected parties were involved in, and contributed to, the reform process.

In developing options for regulatory reform, the technical working groups undertook regulatory impact assessments on the range of options under consideration. These were published on NICNAS’s web site along with the Public Discussion Paper in May 2003. The impact assessments addressing specific options are attached, as follows:

- treatment of low hazard and/or low risk chemicals (Attachment A);
- treatment of chemicals assessed overseas, specifically the use of Overseas Assessments reports (Attachment B);
- polymers of low concern (Attachment C);
- modular Assessment - Analogue chemicals (Attachment D);
- other pathways for low regulatory concern chemicals (Attachment E);
- cosmetics and personal care chemicals (Attachment F); and
- mandatory registration for all chemical introducers (Attachment G).

Following extensive consultation and development of options the LRCC Task Force provided

its final report, *Final Report and Recommendations for NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative* to Government in June 2003. The Final Report made 12 key recommendations, the majority of which require legislative or regulatory amendment to the Act. The recommendations are as follows:

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| 1. <i>Audited self-assessment</i> | 8. <i>International cooperation</i> |
| 2. <i>Modular assessment</i> | 9. <i>Reducing the compliance burden</i> |
| 3. <i>Exemptions</i> | 10. <i>Safe use through compliance</i> |
| 4. <i>Polymer regulation</i> | 11. <i>Access to chemical safety information</i> |
| 5. <i>Cosmetic chemicals regulation</i> | 12. <i>Community participation</i> |
| 6. <i>Controlled use</i> | |
| 7. <i>Incentives for the introduction of new and safer technologies</i> | |

While provided as a reform package, some of the recommendations listed in the Final Report do not require legislative change as they refer to administrative processes such as improved consultation, better targeting of information or the development of compliance tools to assist industry with compliance. These recommendations have been accepted by Government but have not been included in this RIS since they are minor or administrative in nature and are principally designed to maintain public and industry confidence in the integrity of the Scheme.

In addition, new concepts such as automatic listing onto the Australian Inventory of Chemical Substances (AICS) and the establishment of a community Consultative Forum are administrative for NICNAS and as such, do not require an impact assessment. The distinction between significant changes requiring a RIS and those administrative activities and improvements within NICNAS are summarised below.

Recommendations requiring legislative and/or regulatory amendment for which a RIS was undertaken:

NEW CONCEPTS / ELEMENTS
<p>ASSESSMENT</p> <ul style="list-style-type: none"> • Audited self-assessment against NICNAS criteria/guidelines (Attachment A, option A, Attachment C) • Modular assessments (Attachment D) • Controlled/specified use (Attachment A, option b) <p>EXEMPTIONS</p> <ul style="list-style-type: none"> • Transshipment (Attachment E, option b) • Export Only (Attachment A, option b) • Non-hazardous Cosmetic Chemicals introduced in mixtures at concentrations of 1% or less. (Attachment F, option c) • Non hazardous chemicals up to 100kg (Attachment E, option c) <p>STAKEHOLDER</p> <ul style="list-style-type: none"> • Mandatory Company Registration for all chemical introducers (Attachment G)
MODIFICATIONS/ IMPROVEMENTS
<p>ASSESSMENT</p> <ul style="list-style-type: none"> • Streamline CEC, LVC renewals (unless new data)(Attachment E, option d) • increase bilateral agreements/foreign scheme recognition (Attachment B)

- identify and clarify any cosmetic /drug interface issues (Attachment F, option b)

EXEMPTIONS

- increase general <10kg exemption in volume for certain chemicals(Attachment E option c)
- increase R&D volume (Attachment E, option a)

DEFINITIONS

- harmonise definition of cosmetic chemical (Attachment F, option a)

Impact Analysis

The range of industries falling within the scope of the Act is diverse and can cover petrochemical manufacturers, specialty and refined chemicals, intermediate goods and components, consumer products and cosmetics. The Australian chemicals and plastics industry is a key contributor to the Australian economy and contributed \$6.87 billion in industry value added (Allen Consulting Group June 2003). This represented over 9.5% of manufacturing industry value added. The sectors' contribution to total manufacturing industry value has declined over the last few years falling from just over 10% in 1997-98 to 9.5% in 2000-01. This reflects the fact that from 1997-98 to 2000-01, industry value added for the chemicals and plastics industry was static while manufacturing as a whole recorded a growth rate of over 6% for the period (Allen Consulting Group p7-8).

The Government Response to the Chemicals and Plastics Action Agenda report indicated that the chemicals and plastics manufacturing industry has:

- an annual turnover for chemicals and plastics industry is around \$20 billion, or just under 10% of total manufacturing;
- it adds nearly \$7 billion in value to the Australian economy, about 10% of the total value added by the manufacturing sector; and
- the industry employs around 77,000 people or just over 8% of the total manufacturing industry workforce (p3).

NICNAS currently operates on a cost recovery basis. Cost recovery is achieved in two ways:

- assessment and administrative charges for new chemical assessments; and
- company registration charges.

Company registration monies fund the assessment of existing chemicals, client awareness and education activities, 50 per cent of the costs of compliance activities and the administration of the company registration itself. The remaining 50 per cent of compliance activities is funded by an appropriation from the Government. NICNAS recovers on an annual basis approximately \$4 million (0.018%) from the industrial chemical sector. For the registration year 2003-04, there are approximately 700 companies registered with NICNAS, that is, for the previous year's activity these companies imported and/or manufactured chemicals above the threshold level of \$500,000.

The overall aim in setting the fee structure for NICNAS is to meet stakeholders' needs as per the operations of the Act, by appropriately reflecting the cost of service provision to industry users, in accordance with Australian Government policies for cost recovered services. NICNAS uses an activity based costing (ABC) model to set its fees and charges and costs to the industry are kept to a minimum.

The cost structure design of NICNAS is such that new chemical activities for issuing permits and certificates should be 100% cost recovered. The funding is sourced directly from the users of the Scheme through fees and charges for assessment of new chemicals introduced to

Australia. Most small businesses are generally exempt from the company registration charges, but are still required to comply with the Act. It is the intention of NICNAS that no cross subsidisation between new chemical activities and other activities occurs. On the basis of Customs data, and NICNAS company registrations, it is estimated that approximately 5,700 small businesses are engaged in activities for which the Act would apply, but not the company registration requirements.

The expected changes to fast track the assessment processes will lead to significant savings to industry in both the cost of permits and certificates. For example with the introduction of:

- an audited self-assessment permit for polymers of low concern, industry could save up to \$1,000 in some instances while time to market could be reduced from 90 to 28 days; and
- administrative processes for permit renewals could save industry approximately \$2,000 and considerable saving in time as they will not be required to resubmit a data package for re-assessment.

Implementation of the LRCC reform initiatives will introduce a new range of exclusions, permits, and certificates and streamline some administrative processes. Determination of costs for new permits and certificates will be on the basis of NICNAS's current ABC model and will not result in the introduction of new policies in relation to cost recovery practices prior to the Government review of NICNAS's cost recovery policy due in 2004-05. As indicated above, these reform initiatives are expected to provide significant benefits to industry without compromising existing public health, worker safety and environment standards.

Additional measures to improve compliance, introduce mandatory registration for all chemical introducers, increase public access to chemical safety information and increased requirement for record keeping by the industry will maintain public confidence in the integrity of the Scheme. The exact costs and benefits to industry are hard to quantify, but the reform proposals have the support of all the affected parties. The additional burden on small business due to the introduction of a requirement for mandatory registration should not be significant. While small businesses may currently be exempt from paying an annual registration fee, they are not exempt from the operations of the Act and are expected to comply with it. Therefore, the additional impost on small business is expected to be an annual registration fee, currently estimated to be \$300 per annum.

In general, the reforms are expected to be widespread, delivering benefits to a high proportion of NICNAS notifiers. The impact on NICNAS's efficiency is expected to be moderate to high with a major time and cost saving to the industry through reduced assessment costs for permits and certificates costs based on NICNAS's ABC model. The community and industry will benefit through improved access to on line chemical safety information. In addition, the community and environment will benefit from an incentive for industry to introduce less hazardous chemicals.

Affected Parties

The affected parties will be Industry, Government Consumer/community and workers.

The expected benefits are, for:

- Government - more efficient use of limited resources, increased compliance, focussed regulatory activity on areas of highest risk, improve Government visibility in international forums as leader in innovation and reform.
- Community - improved access to information, increased participation through formal

- consultative mechanisms, introduction of safer newer technologies with better performance.
- Community sectors:
 - Workers – introduction of safer chemicals, reduced exposure to all chemicals, improved access to information;
 - Public research institutions – facilitate R&D investment, increase compliance and awareness.
 - Industry - lower compliance costs, chemicals onto market faster, more competitive industry, improved access to information, innovation, access to newer technology, better use of information gained from overseas experiences and harmonisation with international standards will reduce trade barriers.
 - Small business – better access to the broader industry through listing on Company Registration, better access to information through NICNAS’s compliance program, chemicals onto market faster, more competitive industry, innovation, access to newer technology, better use of information gained from overseas experiences and harmonisation with international standards will reduce trade barriers.
 - All sectors - a better understanding and management of the “total chemical load” and in the longer term reduce exposure to workers, the public and the environment.

Consultation

The LRCC Task Force operated in an open, consultative and transparent manner. In conducting the reform process, the LRCC Task Force and NICNAS consulted widely with a broad range of stakeholders including: the chemicals and plastics industry and its industry bodies; government and non-government organisations; and worker and community representatives. Two background papers were placed on the web site to provide information to interested parties. A quick response electronic questionnaire was developed to provide an opportunity for those wishing to engage in the reform process but unable to participate in detailed consultation due to time or other constraints.

Focussed consultations were conducted in Sydney, Melbourne and Brisbane with industry and the community. A detailed draft options paper was provided to all participants to assist in the decision-making process and to refine the reform options. The LRCC Task Force and NICNAS engaged with over 90 individuals of whom 30% were from the community or government agencies to seek additional feedback on the reform options prior to the release of the Public Discussion Paper in May 2003. This was in addition to the LRCC Task Force members and its various technical working groups.

Summary of public submissions received

Of the 34 submissions received: 27 were from industry members and or their associations; two were from community and worker representatives; four from federal and state government agencies; and one from the international body, the OECD New Chemicals Task Force on Aligning National Systems for New Chemical Notification and Assessment, sub-group Work Element V on Exemptions and Low Concern Chemicals.

In general, the industry submissions were highly supportive of the reform options presented in the Public Discussion Paper because of the perceived benefits they would bring to industry through a more efficient and effective regulatory system. Only one submission indicated that the proposed reform options were conservative, but nevertheless provided a good basis upon which to commence a reform program. While regarded as conservative, the submission nevertheless indicated that the initiative was critical to reducing regulatory cost barriers and improving the speed and quantity of new technology being created or entering Australia,

thereby addressing industry's concerns raised in the Action Agenda about the regulatory environment for industrial chemicals. There was overwhelming support for the reform process itself, in particular the open and consultative way the LRCC Task Force members and NICNAS conducted the review and engaged industry, government and the community from the beginning of the reform process. Overwhelmingly, industry saw the LRCC reform processes as part of NICNAS's continuous improvement process of which regulation reform was one component.

There was strong industry support for the LRCC reform aim which was to:

... introduce flexibility and optimise risk-resource allocation in the industrial chemicals assessment process to allow for fast tracking the introduction of chemicals of low risk (including chemicals of low hazard or low risk or controlled exposure) or previously assessed chemicals without compromising public health, worker safety or the environment.

Comments from the government and community were more circumspect, but never the less they provided in-principle support for the reform initiative. In general, it was felt that the Public Discussion Paper focussed on the benefits to be gained by industry in terms of time and cost savings and felt that there was little evidence or persuasive argument provided in the Paper that the introduction of the LRCC program would be an incentive to the introduction by industry of less hazardous chemicals. It was felt that, "therefore, any proposal to make it easier to introduce 'low regulatory concern chemicals' must be accompanied by a parallel strengthening at the other end of the regulation and control of use (including prohibition) of hazardous/dangerous chemicals of high concern."

The non-industry submissions did not support mechanisms to facilitate the introduction of more chemicals in the workplace, the community and/or the environment without assurances that the current system of public health, worker safety and environmental standards would be maintained. In order to be assured that LRCC did in fact trigger industry to shift towards the introduction of new safer technology, the community and government advised that monitoring of industry trends and other related information would need to be transparent and readily available. The jurisdictions sought reassurance that there be no additional compliance burden placed on them and that they, like industry, be kept fully informed of progress.

The LRCC Task Force also took advice provided by NICNAS's Technical Advisory Group (TAG) on confidentiality and access to information as a result of industry and community consultations on the current NICNAS guidelines on procedures for establishing a case for confidential listing on the AICS. The TAG consultations identified a range of issues beyond confidentiality and AICS listing. Community concerns were focussed on access to chemical safety information, community right to know issues and community consultation. Industry concerns were more focussed on the issue in hand, confidentiality but did take the opportunity to raise concerns about the efficiency of NICNAS processes and the cost and effort of assessment processes.

The TAG, while appointed to advise the Director of NICNAS on public interest tests associated with confidential listing on the AICS, has general expertise in a broader range of public interest and community right to know issues. As a result of their consultations with community and industry, they have offered "expertise and assistance to NICNAS in other matters where the public interest is involved. These include other situations in the NICNAS legislation that call for decisions based on the public interest, acting as an informal public

interest sounding board and participating in regular and ongoing public consultation meetings and workshops with NICNAS stakeholders.”

Regulatory Best Practice

The LRCC initiative has followed best practice principles in the design and execution of the reform process. The affected parties, ie. government, industry and the community were involved from the beginning of the review through to the final report and are expected to play a significant role in the implementation phase. The reform options have been designed to minimise the compliance burden and decrease industry time to market. In Australia the regulation of industrial chemicals is “light touch” scientific assessment to identify potential risks but does not include product registration processes. The LRCC reform options are consistent with international trends and the concept is being explored within the OECD New Chemicals Task Force and by the EU as it introduces its new regulatory regime, Registration Evaluation Assessment of Chemicals (REACH) with a view towards harmonisation and streamlining assessment throughput. The overall aim of global (new chemicals) chemical assessment harmonisation is to have the notification and assessment process in one country facilitate the notification and assessment process in another country.

Implementation

While legislation is required to amend the Act to enable the majority of reforms to be implemented, further work will still be required by industry, government and the community to develop guidelines and criteria for areas such as low hazard, controlled use and modular assessment. The majority of submissions indicated their willingness to work with NICNAS during the implementation phase.

Treatment of low hazard and/or low risk chemicals

a) Early Introduction Permit for Low Hazard and/or Low Risk Chemicals

The Problem

The current notification and assessment requirements under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) can result in delays to the introduction into Australia of chemicals with low hazard or low risk.

The current legislation enables introduction of some new chemicals prior to assessment being completed by NICNAS. An Early Introduction Permit (EIP) may be used for introduction of chemicals which are not classified as hazardous substances or dangerous goods, which comply with specified environmental criteria and meet other prescribed matters. An Early Introduction Permit is granted essentially on the basis that the chemical concerned is of low hazard to health and the environment, or is contained to the extent that environmental impact is negligible. These criteria are restrictive and may delay for several months the commercial introduction of an otherwise low risk chemical.

Under current legislation, chemicals that may be of higher hazard but are of overall low risk to workers, the public and the environment and are supported by a complete and sound data package and effective exposure controls cannot qualify for an EIP and cannot be introduced until the assessment certificate is issued. The only other alternative for early introduction requires Ministerial approval. This option is reserved for chemicals that are needed in the national interest and is not a routine option for most chemical introductions.

It is appropriate that the existing EIP be expanded to enable early introduction of chemicals for which hazards are defined and the risks can be controlled when introduced in the workplace, public domain and the environment.

EIPs are available for chemicals (including polymers) which are not hazardous to human health or the environment. For human health, the chemical must not be a hazardous substance according to the NOHSC Approved Criteria. For the environment, the chemical must satisfy certain criteria, for example, low toxicity to fish, daphnia and algae. Once an EIP is granted, the applicant for assessment can introduce the chemical according to the permit conditions before the full assessment is completed. Factors taken into account include reasonable protection of occupational health and safety, public health and the environment. Synthetic polymers of low concern (PLC) automatically qualify for an EIP as long as they are composed mainly of carbon or silicon.

Objectives

To outline a framework and criteria that can be used by NICNAS to permit early and efficient introduction of low hazard and/or low risk substances, while maintaining regulatory standards for OHS, public and environmental risk determination.

Options

Option 1a – No change to existing provisions. Chemicals may be introduced under a Section 30A Early Introduction Permit if not classified as hazardous substances or dangerous goods and comply with specified environmental and other criteria. Chemicals not meeting these criteria may seek introduction with Ministerial approval under a Section 30 Permit. The Permits must be issued by NICNAS before introduction takes place.

Option 2a – Retain existing Section 30 and 30A Permits. Expand Section 30A criteria to also enable low risk chemicals that do not meet the current Section 30A criteria to be introduced under permit conditions. Low hazard and/or low risk chemicals may be defined in accordance with currently available criteria and by requirements of existing States' OHS legislation. The expanded criteria would include the requirement that the chemical has a complete and sound data package, and the exposure controls ensure low risk for workers, the public and environment. This option will enable introduction (prior to completion of assessment) of substances for which hazards can be determined by reference to a detailed data package and risks can be determined and controlled by use of exposure and control scenarios.

Impact Analysis

Parties affected include industry, the workforce, the Government (NICNAS) and the community.

Option 1a – Maintains the current situation, whereby chemicals meeting low hazard and environmental and other prescribed criteria may be introduced under an EIP before the NICNAS assessment certificate is issued. An adverse impact on timing of chemical introduction is imposed on industry because chemicals with a defined hazard do not qualify for early introduction even if exposure is well controlled and the overall risk is low. These chemicals cannot be introduced for at least 3 months after chemicals are notified to NICNAS, compared with introduction after 28 days for chemicals under EIP.

Option 2a – Broadens the Section 30A EIP criteria to enable substances with specified hazard and risk controls to be introduced prior to completion of assessment by NICNAS whilst maintaining occupational health and safety, public safety and environmental safety standards. This will enable the introducer to obtain early commercial access to the new substance in annual quantities as detailed in the notification statement. In turn, early introduction will enable downstream users of the chemical to gain earlier access and commercial benefit from the new substance. The new chemical will potentially be introduced earlier (say 28 days) than if it was required to undergo complete assessment before being able to be introduced.

Members of the workforce will not be adversely affected by the earlier introduction of the new chemical because information on its potential hazards, risk control measures and the permit status will be detailed on product Material Safety Data Sheets (MSDS). This information will enable employers to conduct risk analyses as required under current States' OHS legislation. If an EIP is granted, the hazard and risk information conveyed to end-users will not differ from the information that will be available when NICNAS assessment has been completed. This option will only be available to chemicals with a complete data package that can be used by introducers together with exposure scenarios to implement appropriate risk control measures. The data package will also be used by NICNAS to determine that the risk is appropriate to allow early introduction of the chemical under permit.

The permits would require an assessment fee to cover NICNAS activity in assessment and administration. NICNAS will be required to review the permit application, hazard data and risk control recommendations and issue the permit. The option should be available for NICNAS to include further specific use conditions. Introduction of the chemical after issue of an EIP or after complete assessment is expected to occur with the same control measures. Hence, it is not expected that the community will be affected adversely.

b) Controlled Use Permit for Low Risk Chemicals

Problem

Some new chemicals are not introduced to Australia because the notification and assessment costs may not be recoverable, the chemical may have limited available data or the quantity necessary for Australian introduction may exceed the current permit or exemption allowances. Such chemicals are not available to Australian manufacturing industry although they may be able to be used in a controlled way in low risk situations and may be of benefit to the Australian economy.

Objectives

The objective is to outline a framework and criteria that can be used by NICNAS to permit introduction of commercial quantities of low hazard and/or low risk substances for which notification and assessment in an existing certificate or permit category is not suitable. Regulatory standards for OHS, public and environmental risk determinations are to be maintained.

Options

Option 1b – No change to existing ICNA provisions. Commercial quantities of new chemicals may only be introduced after issue by NICNAS of an Assessment Certificate, a Low Volume Chemical Permit, a Commercial Evaluation Permit or if exempted under the 10kg per annum exemption category.

Option 2b – Establish a new category and criteria for a Controlled Use Permit. The category should consist of chemicals which either alone, or in a mixture, or because of the way they are transported, handled, used and/or disposed, qualify as LRCC. The following parameters are proposed for assessing these chemicals and establishing that they present a low risk to human health and the environment – one or more of the following may apply:

- controlled transport and storage;
- specialised uses;
- low public, workplace & environmental exposure;
- containment in closed systems;
- imported as part of a specific formulation;
- low concentration in formulation; and
- intended for export only.

Other parameters can be considered. The implication for this category is that no special risk management controls (other than established good work practices, responsible disposal and compliance with all relevant chemicals regulations) are required. The proposal is that NICNAS would issue a LRCC Controlled Use Permit. An Assessment Certificate would not

be issued and the chemical would not ultimately be listed on the AICS.

Impact Analysis

Parties affected include industry, the workforce, the Government (NICNAS) and the community.

Option 1b – Maintains the current situation. Currently, a gap exists in NICNAS permit options for chemicals of low risk, to be introduced at volumes exceeding 100kg per year and which do not qualify for a commercial evaluation permit. Chemicals in these situations are obliged to be notified in either the standard or limited notification categories, which are costly and may require a full data set. Industry is hampered from introduction of many new substances that are used in other countries due to lack of required notification data, due to the cost of notification or because insufficient permit or exemption quantities are allowed. End-user companies and/or the community are prevented from access to the benefits of new chemical technology and the economic benefits accruing from the ability to use the chemistry in a competitive manner internationally.

Option 2b – Establishing a new category and criteria for a Controlled Use Permit for chemicals to be introduced, handled and used in low risk situations would broaden the range of new chemicals potentially available to the Australian industry at a lower regulatory cost. This will enable industry to bring chemicals quickly to market and capitalise on business opportunities. For NICNAS, the new category should result in a greater number of new chemicals being notified under the new permit. However, the new permit assessment fee would support the screening/ review processes. Specific criteria are to be developed to clarify which chemical types, uses or situations will be included in this category. Establishment of the category will result in the potential for the workforce to be exposed to a greater number of new chemicals. It will be necessary for criteria for the category to be established such that introducers of chemicals ensure that all hazards and risks are understood and controlled. The guidelines for the category should also ensure that risks to the public and to the environment are controlled.

Conclusion and Preferred Options

Taking into account the views on the options received from the public submissions, the focus groups and the views of the LRCC Task Force, the following options are preferred.

a) Early Introduction Permit for Low Hazard and/or Low Risk Chemicals

The LRCC Task Force believes that the most innovative reform which has received the greatest support is the proposal to introduce audited self-assessment by industry for those chemicals which are considered to be of low regulatory concern against NICNAS criteria. The range of options identified below result in a simplified process for the issue of NICNAS permits and certificates and introduces a new LRCC Assessment Category for defined low risk circumstances. In each case, benefits result from audited self-assessment of chemicals by the introducer in accordance with specific low risk criteria based on hazard and exposure. The reduced compliance burden is a positive incentive for industry to focus on the introduction of non-hazardous and/or low risk chemicals thus providing benefits in terms of incentives for introduction of safer and more environmentally friendly chemicals.

An audited self-assessment for LRCC categories would involve:

- introducer/notifier self-assesses a chemical against specified criteria and guidelines issued by NICNAS;

- introducer/notifier to provide information to NICNAS, as specified;
- introducer/notifier to keep records to validate the self-assessment for audit purposes;
- NICNAS to undertake a screening assessment of the industry self-assessment;
- NICNAS to conduct post-market audits to ensure robustness and integrity of the process; and
- progress in implementation, with stakeholder involvement in the development of necessary criteria and/or guidelines and processes.

In addition, an audited self-assessment permit for low hazard chemicals and low risk chemicals (introduced at low volumes 100-1000kg) against NICNAS criteria and/or guidelines developed by NICNAS, industry and the community should also be introduced.

The impact on industry is expected to be widespread benefits for a high proportion of NICNAS notifiers with savings in time and money to industry (ie.>that 30%). In some instances, time to market for audited self-assessment of low risk/low hazard chemicals could be reduced from 90 to 28 days. While savings in permits and certificate costs are expected, it is difficult to estimate these costs until the proposals are implemented. The proposed changes will not undermine existing levels of public health, worker safety or environmental standards.

b) Controlled Use Permit for Low Risk Chemicals

Given the concerns raised and the specific requirements for such a permit, the preferred option is to examine the introduction of a controlled use /specified use assessment (permit and/or certificate) category based on history of use, limited exposure and/or use in controlled environments. In addition, it is also recommended that an examination of the feasibility for an Export Only Permit also be considered.

Treatment of overseas assessment reports

Problem

Globalisation of trade means that many new chemicals notified to NICNAS may have been notified to and assessed by other overseas or even other Australian regulatory agencies. Presently, for these chemicals, industry duplicates effort in preparing notifications for each country or agency and NICNAS duplicates effort in re-assessing these chemicals.

Objectives

The overall objective of the following options is to provide opportunities for the notification and assessment of industrial chemicals that utilise information from overseas or other local assessment schemes (referred to here collectively as foreign schemes), enabling or maintaining:

- optimal regulatory input from industry and Government; and
- sufficient information regarding OHS, public health and environmental risks of the chemical.

The options should:

- maintain scientific standards in the provision of assessment information and be flexible;
- maintain relevance to Australian exposure scenarios;
- minimise assessment duplication by NICNAS;
- minimise unnecessary detail and further validation of data;
- retain existing standards for the OHS, public health and environmental assessments;
- should not extend existing statutory timeframes;
- be cost-effective for NICNAS and all other parties; and
- assist public access to chemical information.

Considerations With Respect to Foreign Assessment Information

There are important differences in data requirements and assessment processes between NICNAS and foreign regulatory agencies responsible for industrial chemicals. For example, NICNAS publishes assessment reports whilst the majority of regulatory agencies overseas do not. This has implications for the free sharing of information as this is often provided to the overseas regulatory agency on a confidential basis. Moreover, many overseas regulatory agencies rely on third party data ie. information provided by another source (such as another company) to fill data gaps for a particular chemical. Clearly, if NICNAS is to use (and publish) reports containing such information, appropriate administrative policies and procedures must be established to deal with obvious issues of proprietary rights.

Therefore, the following issues are relevant to considering overseas or other local agency assessment information or reports:

Firstly, sufficient information must be provided to determine the:

- chemical in question and the use (if any) of analogue data;
- extent to which different assessment scenarios eg OHS, public health, environment are

- covered;
- methodology for the conduct of risk assessments and their relevance to Australian exposure scenarios; and
- transparency of the assessment process or evidence of an agreed standard or recognised status of authority through access to the original data submitted for the foreign assessment.

Secondly, if a foreign assessment report is submitted, it should be accompanied by validation from the foreign authority that the report is the full and final report issued for that chemical. In this way, if the chemical is subject to an ongoing assessment, this will be noted.

Lastly, NICNAS requires a mechanism to allow information from the foreign assessment report to be published, especially for information that is handled as confidential by the foreign regulatory agency.

Options

Option 1 – Use of Modified NICNAS Transitional Arrangements to Allow Submission of Foreign Assessment Reports Accompanied by the Original Foreign Notification Data

NICNAS presently allows overseas assessment reports to be submitted through Transitional Arrangements Towards Approval of Approved Foreign Schemes (Chemical Gazette C11 6 November 2001). This option proposes the following criteria for a foreign assessment report acceptable to NICNAS and attracting up to 40% rebate in notification fee:

- report to date from post-1994;
- originate from national authority of an OECD Member country, preferably Canada or any other EU state;
- include confidential information eg. chemical identity. Sanitised documents are not acceptable;
- include a summary and assessment of physicochemical properties;
- include a summary and assessment of toxicological and environmental effects data, as appropriate;
- include a health and environmental risk assessment; and
- be accompanied by a letter of validation from the overseas authority that the report is the full and final report issued for that chemical.

With the conditions that:

- NICNAS notification procedures are followed and Schedule information is also submitted;
- where not covered by the foreign notification statement, details of the overseas authority and when and where notified are submitted;
- copy of all data submitted to the foreign scheme are submitted to NICNAS also; and
- any other assessment information about the chemical available to the applicant and *relevant to the Australian notification* is submitted.

This last point in italics is clarified from the original conditions for Transitional Arrangements so as only to require data relevant to the Australian notification.

Impact Analysis

NICNAS

This is a minor modification of an existing mechanism of notification and would be of no negative impact to NICNAS. However, contact with overseas assessment reports would enable NICNAS (and industry) to determine commonalities between the assessment processes and outputs of NICNAS and overseas jurisdictions and allow movement towards the mutual acceptance of assessments.

Industry

For global chemical companies who notify overseas, the ability to submit an overseas assessment report with the data originally submitted for the overseas notification will enable time and cost savings for industry. However, advantages for small industry participants are uncertain.

On the one hand, the submission of information to local importers from global suppliers may be encouraged by the option of global suppliers to submit data in the form of an overseas assessment report and the data for the original overseas notification rather than in a form required by a NICNAS notification. On the other hand, any reluctance to share information, especially with small local notifiers because of concerns with confidentiality, would not be relieved by this measure.

For this measure to be effective in the larger companies, sufficient communication is required between the overseas parent and the local company office so that the local office is aware of the notification history of a particular chemical and whether an overseas assessment report is available.

Community

Given no compromise of the existing NICNAS Schedule of Data Requirements, the use of overseas assessment reports *per se* is likely to have minimal impact on the quality and extent of regulation of chemicals in Australia. Therefore, the use of overseas assessments according to this option is unlikely to impact the community.

Option 2 – Submission of Foreign Assessment Reports without Resubmission of Original Notification Data

A foreign assessment report would be submitted in the absence of the original notification data with a statement of validation of the assessment report, accompanied by Australian exposure data and an Australian MSDS/label.

Without the original data for validation of the assessment report, how can NICNAS and Industry have confidence in the assessment report? The concept of “assessment competence” of the foreign regulatory agency becomes relevant. By this, it is meant that the outputs of the overseas assessment process are of sufficient scientific robustness, relevance and applicability with regards to the Australian use of the chemical for the requirements of NICNAS. Similarly, the “competence” of NICNAS (with regards to the assessment processes as well as matters such as the handling of foreign data) is relevant for the overseas (or other local) agency.

Given the duty of care of NICNAS as a National Regulator, “competence” involves addressing the list of considerations identified above. Given likely particular local use and exposure patterns, but recognising agreed standards in hazard testing of chemicals (eg. OECD

Guidelines for Testing of Chemicals) mutual recognition of the methodology and results from the hazard assessments from overseas reports is a logical starting point with respect to using overseas information.

Ultimately, if sufficient experience with assessment procedures and outputs from particular foreign agencies is achieved, this option will allow acceptance of an individual foreign assessment or parts thereof (such as the hazard assessment) through an expedited audit of the foreign report by NICNAS for internal consistency and coverage of essential information as required by the Act.

There are noteworthy processes presently under development for encouraging and facilitating the mutual acceptance of overseas assessment reports. This option encourages their advancement:

OECD New Chemicals Taskforce

Communicating between jurisdictions, determining “assessment competence”, determining mechanisms of sharing assessment data including confidential business information and ultimately the mutual acceptance of notifications are the aims of the work of the current OECD New Chemicals Taskforce. NICNAS is a participant in this work.

Work Element IV of the OECD New Chemicals Taskforce specifically aims to identify opportunities for the sharing of hazard assessment information.

Bilateral Agreements e.g. Australia-Canada Cooperative Arrangement

NICNAS is currently facilitating the sharing of information with Canada through an Australia-Canada Bilateral agreement. The aims of the current Australia-Canada Cooperative Arrangement Work plan include the comparative analysis of assessment methodologies, identifying opportunities for work sharing such as co-notifications and electronic filing of co-notifications and staff exchanges.

Bilateral Agreements are likely the most effective mechanism in the short to medium term to facilitate sharing of detailed information between particular overseas jurisdictions and NICNAS to ultimately allow legislative recognition of foreign schemes.

Impact Analysis

NICNAS

As stated, the concept of “assessment competence” of the foreign authority, ie. that for the purposes of NICNAS, outputs of the assessment process are of sufficient scientific robustness and applicability for the local use of the chemical, would need to be established by NICNAS. Similarly, the competence of NICNAS (with regards to the assessment processes as well as routine matters such as the handling of overseas data) would need to be established for foreign jurisdictions. This work is ongoing through present OECD New Chemicals Taskforce activities and Bilateral Cooperative Arrangements.

The development of OECD and bilateral arrangements require additional resources from NICNAS. However, the requirements only for expedited audits of submitted foreign assessment reports are likely to produce resource savings for new chemicals notifications.

Industry

For global chemical companies, the acceptance of overseas assessment reports by NICNAS would represent a significant time and cost saving. However, as for Option 1, advantages for small industry participants are uncertain.

On the one hand, the submission of information to local importers may be encouraged by the option of global suppliers to submit data in the form of an overseas assessment report rather than original notification data in a form required by NICNAS. On the other hand, any reluctance on the part of global chemical companies to share information, especially with small local notifiers because of concerns with confidentiality would not be relieved by this measure.

Similarly to Option 1, for this measure to be effective in the larger companies, sufficient communication is required between the overseas parent and the local company office so that the local office is aware of the notification history of a particular chemical and whether an overseas assessment report is available. It is possible also that multinational companies can aid Bilateral arrangements by assisting foreign regulatory agencies with mechanisms to share confidential business information between the overseas regulator and NICNAS.

Community

Given the recency of activities with regards to bilateral and multilateral new chemicals work sharing, the impact to the community is difficult to determine at this time.

Depending on the extent to which data are available in assessment reports, the use of overseas assessment reports *per se* may have a positive effect on the community (if additional relevant data are available to assist the assessment process), no effect (if the current or a revised version of the Schedule of Data Requirements and Variation of Data Requirements provisions are satisfied) or may have a negative effect (if certain critical data are not available).

It is envisaged that maintaining the present NICNAS Schedule of Data Requirements, using mutually accepted hazard assessment methodologies and risk assessment/management based on Australian exposure data, there would be minimal community impact with the use of foreign assessment reports.

Option 3 – Submission of Foreign Notification Statements

For a new chemicals notification, this option allows industry to submit an overseas notification statement plus an Australian MSDS and label. This would be accompanied by a checklist indicating how data on the overseas notification statement correspond to the NICNAS Schedule of Data Requirements.

Impact Analysis

NICNAS

Provided that all data required by the Schedule and that relevant supportive data eg. test reports are submitted, the impact on daily NICNAS operations would be minimal. However, to standardise the notification process and to provide opportunity for industry involvement, NICNAS is encouraging the submission of data on the New Chemicals notification template. The use of overseas notification statements would work against the ready adoption of this template and the associated administrative efficiencies.

Industry

Access to overseas notification statements is possible for the larger industry participants who notify chemicals overseas. However, as for Option 1, advantages for small industry participants are uncertain. On the one hand, the submission of information from global suppliers to local importers may be encouraged by the option of global suppliers to submit data in the form of an overseas notification statement and the data for the submission rather than in a form required by a NICNAS notification. On the other hand, any reluctance to share information, especially with small local notifiers because of concerns with confidentiality would not be relieved by this measure.

The use of overseas assessments is likely to decrease costs for notifiers with access to overseas notification statements.

Community

Given no compromise of the present NICNAS Schedule of Data Requirements, the use of overseas assessment reports *per se* is likely to have minimal impact on the quality and extent of regulation of chemicals in Australia. Therefore, the use of overseas notification statements is unlikely to impact the community.

Conclusion and Preferred Option

A number of submissions commented favourably on the current Australia-Canada bilateral arrangements. This arrangement presented a good model on which to base further bilateral arrangements. Industry has indicated its keenness for Australia to commence negotiations with a number of other countries. Therefore, the recommended option is that industry and NICNAS further cooperate to identify and pursue agreement with countries of similar regulatory standards where bilateral arrangements may present opportunities for cost-effective progress with bilateral agreements.

Additional bi-lateral arrangements can improved the efficiencies of the schemes co-operating in bi-lateral arrangements and reduce duplication in data generation requirements on industry. NICNAS presently allows overseas assessment reports to be submitted and this should be encouraged. The NICNAS document, Transitional Arrangements Towards Approval of Approved Foreign Schemes (Chemical Gazette C11 6 November 2001) outlines criteria for a foreign assessment report acceptable to NICNAS and attracting up to 40% rebate in notification fee. Extending bi-lateral arrangements could have widespread benefits for a high proportion of NICNAS notifiers (ie. >30%) with savings in time and costs, although these savings are difficult to quantify at present but could include at least the 40% rebate in current notification fees.

Polymers of low concern (PLC) and low regulatory concern polymers (LRCP)

Problem

Certain polymers are exempt from notification and assessment in overseas regulatory schemes. Under NICNAS, all new polymers must be notified and assessed, although the scheme provides for an abbreviated assessment for synthetic polymers of low concern (PLC). Therefore, under the current arrangement, the costs incurred by industry in compiling a notification package, and assessment by NICNAS, do not match the level of hazard or risk of the polymers assessed.

In addition, other polymers which may not satisfy the PLC criteria are subject to notification and assessment at a level which may also not match their level of regulatory concern or risk. This is due partly to a lack of flexibility in the scheme.

Objectives

The overall objective is to develop feasible options for notification and assessment of industrial chemicals of low regulatory concern, which would enable:

- alignment of regulatory input from industry and government to perceived risk; and
- sufficient knowledge and/or information of occupational health and safety, public health and environmental risks of the chemical, while maintaining regulatory standards for OHS, public health and environmental risk assessment.

The specific objectives of the Polymer Technical Working Group are to:

- simplify the polymer notification and assessment process, including the PLC category;
- identify low hazard/low risk scenarios that may be applicable to self-assessment by the introducer or streamlined assessment by NICNAS;
- identify certain classes of polymers that may be considered as LRCC; and
- maximise use of overseas assessments for polymers.

PLC and other polymers

The Project has been divided into two parts, PLC and Other Polymers (Low Regulatory Concern Polymers, abbreviated as LRCPs), with options developed for each. LRCPs have been defined by the technical group as those polymers which do not meet the PLC criteria but, for one reason or another, do not warrant a complete assessment. LRCPs would include other classes of low hazard polymers, analogues, polymers assessed overseas and polymers with standard use/exposure profiles (see list below). Work is required to develop the LRCP criteria.

The technical group is of the view that the PLC criteria have served the scheme well as they are scientifically based and have worked well in identifying low risk polymers. Approximately 5-10% of PLCs have some degree of health or environmental risk associated with their introduction, however, this risk is usually detected during the pre-screening phase before assessment by NICNAS.

Also, approximately 5-10% of polymers notified as PLCs do not meet the criteria. Conversely, approximately 5-10% of polymers notified as a Limited or Standard Notification meet the PLC criteria. This reflects a 90-95% success rate by notifiers in self-assessing their polymers against the PLC criteria.

Typical LRCs, as defined above, will include the following:

- polymers of certain classes which are of low hazard and risk;
- polymers chemically similar to polymers already assessed by NICNAS (analogues);
- polymers composed of similar reactants;
- consolidated notification, where more than one polymer can be notified and assessed together;
- polymers used in accordance with standard use profiles, developed by industry and NICNAS;
- polymers used in a controlled environment;
- polymers manufactured, formulated or used on certain approved sites;
- low concern polymers which are hazardous substances due to residual monomer content (currently polymers cannot be PLCs if the residual content of a hazardous monomer is above the concentration cut-off); and
- polymers assessed in overseas regulatory schemes.

PLC Options

Option PLC1a – Provided the polymer meets the PLC criteria*, which are intended to remain essentially unaltered, no risk assessment conducted. Polymer added to AICS.

Option PLC1b – As for Option PLC1a, but polymer not added to AICS.

Option PLC2 – As above, but if a potential risk was identified in the 2-week pre-screening phase, a reduced risk assessment conducted [currently a potential risk is identified in 5-10% of cases]. The risk assessment would be conducted using a tiered or modular approach, proportional to the level of regulatory concern (see notes below). Polymer added to AICS.

Option PLC3 – A reduced risk assessment conducted for all PLC. This option would include a reduced set of data requirements. Polymer added to AICS.

The PLC criteria already in use by NICNAS have proved to be robust and predictive after some 6 years of use. The criteria details are listed for information:

LRC Options

Option LRCP1 – Provided the polymer meets the LRCP criteria, no risk assessment conducted. Polymer added to AICS.

Option LRCP2 – As above, but if a potential risk was identified in the pre-screening phase, a reduced risk assessment conducted. The risk assessment would be conducted using a tiered or modular approach, proportional to the level of regulatory concern (see notes below). Polymer added to AICS.

Option LRCP3 – A reduced risk assessment conducted for all polymers identified as LRCPs according to criteria. This option would include a reduced set of data requirements. Polymer

added to AICS.

Notes on Risk Assessment Options

The first option is a tiered approach to notification and assessment, proportional to the level of regulatory concern, for example, based on volume, hazard and/or use pattern. It is a flexible approach to assessment where the level of assessment required for the LRCP (and PLC in a small number of cases) would be determined during the two-week pre-screening phase and would depend upon factors such as volume of introduction, hazard status and use pattern (exposure profile). Polymer added to AICS.

The second option is a modular approach to notification and assessment where only those aspects of the risk assessment causing concern, for example, OHS or environment, would be assessed. It is another flexible approach to assessment where the scope of assessment required for the LRCP (and PLC in a small number of cases) would be determined during the pre-screening phase. Polymer added to AICS.

Combined PLC/LRCP Options

The combined low concern polymer option consists of a number of parts, as listed below. The option is a special case of those options presented above for PLC and LRCP and is dependent on the hazards of polymer classes.

Part A: Total exemption from assessment, notification only (experience built on 10 or more past assessments, foreign scheme information and other available reference material), 10% audit of notifications, AICS listing

Certain classes of PLC, all with number-average molecular weight (NAMW) > 1000

Information to be provided: identity [CAS, chemical name, chosen broad generic chemical name], use, volume, signed statement that MW, FGEW and charge density meet PLC criteria

Part B: Self assessment and notification only (experience built on 10 or more past assessments, foreign scheme information and other available reference material), 10% audit of notifications, AICS listing

Classes of polymer in Part A but NAMW < 1000 or 500-1000, and other classes of PLC with NAMW > 1000

Information to be provided: identity [CAS, chemical name], use, volume, signed statement of conformity to PLC criteria, GPC of MW. Analogues may be used to substitute data for notified polymer.

Part C: Full assessment as per current PLC practice with potential to request further information, no audit, AICS listing

Other classes of PLC in Part B but NAMW < 1000, and non-PLC classes of polymer with NAMW > 1000 [these are polymers which would currently be Limited or Standard notifications]

Information to be provided: as per current PLC data requirements, or less; overseas

notification if applicable. Analogues may be used to substitute data for notified polymer and justify immediate introduction.

Impact Analysis

Affected Parties

Parties directly affected by the polymer reforms are:

- industry, in particular, the chemical industry and including small business; and
- government.

Parties indirectly affected are workers and the public at large. Also indirectly affected is the environment.

Effect on Existing Regulation

The *Industrial Chemicals (Notification and Assessment) Act 1989* and associated regulations will require amendment.

Cost/Benefit Analysis

In all cases, the level of assessment proposed is less than under current arrangements.

Option PLC1 (1a and 1b)

Costs

No additional costs to industry or government. The only indirect costs are to workers and/or the public where a polymer with some risk to human health and/or the environment is either added to AICS without a risk assessment, or is not added to AICS. Approximately 5-10% of PLC have an identifiable risk, for example, a cosmetic polymer with eye irritant properties.

Benefits

Reduction in costs to industry and government through reduction in fees and notification costs (industry, including small business) and reduction in assessment costs (government). In addition, industry would benefit from earlier introduction of the polymer. Industry also claim that more new polymers would be introduced, that is, easier access to new technological developments.

Option PLC2

Costs

As for PLC1, except that no indirect costs to workers and/or the public would be expected as PLC with an identifiable risk would be assessed by NICNAS, albeit at a reduced level. If the PLC was assessed, costs would vary dependent on level of assessment determined at the pre-screening stage

Benefits

As for PLC1.

Option PLC3

Costs

Costs less than current, however, still some costs to industry and government due to NICNAS

fees and costs associated with compiling a notification package.

Benefits

Costs less than current and therefore overall reduction in costs to industry and government. No effect on workers and public as risk assessment of all PLC would still be conducted.

Option LRCP1

Costs

No additional costs to industry or government. The only indirect costs are to workers and/or the public where a polymer with some risk to human health and/or the environment is added to AICS without a risk assessment. As for PLC, it would be expected that some LRCPs would have an identifiable risk.

Benefits

Reduction in costs to industry and government through reduction in fees and notification costs (industry, including small business) and reduction in assessment costs (government). In addition, industry would benefit from earlier introduction of the polymer. Industry also claim that more new polymers would be introduced, that is, easier access to new technological developments.

Option LRCP2

Costs

As for LRCP1, except that no indirect costs to workers and/or the public would be expected as LRCPs with an identifiable risk would be assessed by NICNAS, albeit at a reduced level. Costs would vary dependent on level of assessment determined at the pre-screening stage. Indirect effect on workers and public expected to be minor as level of risk assessment determined during pre-screening stage, however, in most cases, risk assessment would be less detailed than under current arrangements.

Benefits

As for LRCP1. Costs substantially less than under current arrangements and therefore overall reduction in costs to industry and government.

Option LRCP3

Costs

Costs substantially less than current, however, still some costs to industry and government due to NICNAS fees and costs associated with compiling a notification package.

Benefits

Costs substantially less than current and therefore overall reduction in costs to industry and government. No effect on workers and public as risk assessment of all LRCPs would still be conducted.

Combined PLC/LRCP Option

Costs

No additional costs to industry or government. The only indirect costs are to workers and/or the public where a polymer with some risk to human health and/or the environment is added

to AICS without a risk assessment. For example, approximately 5-10% of PLC have an identifiable risk, for example, a cosmetic polymer with eye irritant properties, and some LRCPs would also be expected to have some identifiable risk.

Benefits

Reduction in costs to industry and government through reduction in fees and notification costs (industry, including small business) and reduction in assessment costs (government). In addition, industry would benefit from earlier introduction of the polymer. Industry also claim that more new polymers would be introduced, that is, easier access to new technological developments.

Conclusion and Preferred Option

There is general agreement that the level of notification and assessment for polymers should be proportional to the level of risk, and that there is ample scope for considerable simplification of the polymer process without compromising the risks to workers, the public or the environment. All the options proposed result in reduction of costs to industry and government.

For PLCs, a much-simplified process is desirable, with little or no assessment required, and the polymer added to AICS. However, as a risk is identified in approximately 5-10% of cases, a risk assessment when necessary is required to provide a safeguard to workers, the public and the environment. Therefore Option PLC2 is the preferred option for PLC as it will deliver substantial benefits to industry and government while upholding the objectives of the scheme. One option (PLC1b) was not to add PLCs to AICS, however, many companies have search mechanisms and systems which rely on the listing of the substance on AICS before a product can be released for sale (Table 3 -1a).

For polymers which do not meet the PLC criteria, a flexible approach is required to cater for other low hazard polymers and polymers which do not warrant a full risk assessment (LRCPs), for example, analogues of assessed polymers and polymers used in accordance with a standard controlled use profile. Therefore the preferred option for these polymers is Option LRCP2, where the level of risk assessment is determined during a 2-week pre-screening phase. For some low hazard classes of polymer, no risk assessment may be required, that is, as proposed for most PLCs. For other polymers, a lower level of assessment will be required, using the tiered or modular approaches described. The benefits of this option are substantial, as it will deliver reduced costs to industry and government while providing a safeguard for human health and the environment. Criteria will be required for other low hazard polymers and guidelines to cater for analogues and controlled use scenarios.

Options PLC1 and LRCP1 are not preferred as chemicals would be added to AICS without assessment (or not added to AICS at all) and without providing a safeguard for the proportion of polymers, albeit small for PLC, that warrants some level of risk assessment.

Options PLC3 and LRCP3 are not preferred as they would require a risk assessment for all polymers and, due to the fixed set of data requirements, would not provide a flexible approach to polymer notification and assessment. Costs would be highest and benefits least for these two options.

The Combined PLC/LRCP Option is not preferred as, with its focus on polymer classes, it covers a subset only of the PLC2/LRCP2 Options, but without the provision of safeguards

warranted for some PLC/LRCPs.

In summary, the overall benefits to industry from the preferred options are a streamlining of the notification and assessment process, earlier introduction of new polymers and encouragement to introduce more low hazard polymers. Of particular benefit to small business would be the reduction in data requirements, due to the difficulty small business has in accessing data generated overseas.

Government would benefit by the reduction in assessment costs as its resources could be directed towards chemicals of greater hazard and risk.

The impact of the preferred options on workers is expected to be minimal, due to the provision of safeguards to cater for polymers where some risk to workers is identified. Similarly, the impact of the preferred options on the community is expected to be minimal. PLCs and LRCPs are generally of low risk to the public at large, however, where potential exposure of the public is possible, for example, cosmetics, safeguards will allow the assessment of public health risk where necessary. It is expected that some form of published report or information will still be available on the NICNAS web site for polymers identified as PLCs or LRCPs.

In addition, safeguards provided for in the preferred options should allay concerns for polymers where some risk to the environment is identified.

Analogue chemicals

Problem

In Australia, new chemicals require a full standard notification package regardless of their similarity or analogy to other chemicals previously assessed by NICNAS since its inception in 1990.

Industry has claimed that in many cases such analogue chemicals represent no greater risk to human health and the environment than an analogue already assessed by NICNAS. However, manufacturers or importers are required to submit similar notification packages with similar fees to those required for a standard new chemical notification. As well as the assessment periods and the financial costs involved for analogues, there are also potential issues such as additional animal testing and use of regulatory resources that could be better utilised in the evaluation of non-analogue chemicals. Additionally, industry has also raised concerns about the lack of documentation and consistency of one-off decisions that have been made by concerning analogues in the past.

The problem therefore facing NICNAS and industry is to develop a mechanism to demonstrate that a notified chemical has a similar “pattern of activity” to an analogous chemical already assessed, thus fast-tracking the assessment process without compromising human health and the environment. To address this problem, the LRCC Task Force has initiated the NICNAS Analogue Working Group (AWG) to explore and develop initiatives in this area.

Objectives

The overall objective is to develop feasible options for notification and assessment of industrial chemicals of low regulatory concern that would enable:

- alignment of regulatory input from industry and government to perceived risk; and
- sufficient knowledge and/or information of occupational health and safety, public health and environmental risks of the chemical while maintaining regulatory standards for OHS, public health and environmental risk assessment.

Therefore, the objectives of the AWG as a project group under the Low Regulatory Concern Chemical task force is as follows:

- define chemical “analogue”;
- describe the different types of analogues that may be expected to be notified, and their suitability for a lower degree of regulatory input (for example stereoisomers and salts of a chemical);
- suggest other likely or known scenarios where a reduced level of regulatory scrutiny may be warranted for defined analogues;
- suggest alternatives to current assessment procedures which may allow for reduced regulatory input from both industry and government;
- provide an overview of the regulatory impact that suggested changes to NICNAS policies or the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) may produce; and
- propose preferred option(s) that maintain current high regard for occupational health,

public health and environmental protection.

Present Status

There currently exists no mechanism to fast track the assessment of analogue chemicals via reduced testing requirements, even though, both in Australia, and overseas, a standard notification may often rely on analogue data for determination of their toxicological and environmental endpoints. Other countries such as New Zealand and the United States make allowance for chemical analogy in the assessment of new chemicals and in some circumstances provide a specific notification pathway for such chemicals.

Analogues Defined

In chemistry, an analogue can be defined as a compound similar in structure to another compound but differing in some slight structural detail. It is important to note however that while the differences in structure may be slight, a chemical compound with a structure similar to that of another but differing from it with respect to a certain component may have a similar or opposite action metabolically.

Determination of Analogy

The following elements are basic requirements for a chemical to be considered an analogue of another:

- similar molecular size and structure;
- contains some substructure that may play a critical functional role;
- similar molecular property eg. lipophilicity, electronic or steric parameters; and
- is related through some precursor, metabolite or breakdown product.

Options

As to what constitutes an analogue (for the purposes of notification) has yet to be determined, it is impossible to provide an all-encompassing solution to the problem of fast tracking the assessment process for such chemicals. However, regardless of how close the structural relationship is between a notified chemical and one listed on AICS list, a minimum data package would still be required.

For physico-chemical, toxicological and environmental endpoints, the minimum data requirements are yet to be finalised. However, it may be that for toxicological endpoints, it is envisaged that in determining what data is required consideration is given to animal welfare issues.

Option 1 – Tier 1 Analogue Assessment (Minimum Testing Packages). This would represent the most streamlined analogue assessment process available. For such chemicals the analogy has been demonstrated and accepted by the regulator as meeting the requirements for a predetermined (as yet undetermined) minimum data package. Furthermore, the mode of use of the chemical and expected public exposure is such that data beyond the minimum dataset is not considered necessary. It is envisaged that such an assessment strategy would allow for completion of assessment within a similar time frame to that of Early Introduction Permits (28 days) and Low Volume Chemical Permits (20 days).

If the notified chemical is deemed to be unsuitable for assessment as an analogue the notifier will be required to notify under one of the existing notification categories. It has been suggested that Self-assessment may be an alternative to this option, however it is agreed by the AWG that at least some degree of review by NICNAS should be preserved.

Option 2 – Tier 2 Analogue Assessment. In cases where the chemical is not considered to meet the (as yet undetermined) criteria for a minimum data package, then testing requirements will be determined following an initial screening of the available data. It is envisaged that testing beyond a minimum data set would be requested when: the scientific justification for analogy between two chemicals does not demonstrate beyond doubt that the chemicals would be expected to have similar physico-chemical, toxicological and environmental properties, or; the uses and/or exposure population are significantly greater for the notified chemical to warrant further data. For such chemicals NICNAS will determine what data is required in addition to the minimum data package. However, it should be noted that the results of these requested tests would determine whether further testing is required.

In the case where a new chemical and several analogues are notified together the notifier will be required to nominate the primary analogue which will be assessed as a new chemical for which a certificate will be issued. It is proposed at this stage that each additional analogue will be treated as an “extension” to the original assessment certificate however the most appropriate method of administering such a scenario is yet to be determined.

Option 3 – Extensions of Assessment Certificates for Inseparable Analogue Mixtures. Where a manufactured chemical consists of two or more inseparable analogues the chemical may be assessed in the following manner:

- (i) the chemical of the highest concentration is the primary analogue and is the chemical which appears on the assessment certificate. The notification for the primary analogue is treated as a Standard or Limited Notification based on existing criteria with regard to fees and timeframes;
- (ii) each additional chemical becomes the subject of an extension to the assessment certificate for the primary analogue with appropriately reduced timeframes and modular fees.

Regardless of the option/s utilised by NICNAS, it should be noted that “umbrella-ing” of several chemicals will be possible. For example, a notifier submitting a sodium-salt may nominate other salts such as the potassium and ammonium salt which may also be expected to be imported/manufactured in the future.

It is not within the scope of this paper to develop specific criteria which may be applied to a chemical to determine whether or not it is suitable for a reduced level of regulatory scrutiny

Impact Analysis

Option 1 – Analogue Assessment

Industry

Reduced assessment timeframes and fees in comparison to a standard notification.

Reduced cost of notification package due to reduced toxicological/ecotoxicological testing

Community, workers and the environment

As these chemicals will have an analogy to chemicals already being imported, produced and used in Australia, no additional impact is anticipated.

NICNAS

Appropriate use of assessment resources based on activity based costing model.

Overseas counterparts such as the US EPA use data generated by SAR software in the pre manufacture process. NICNAS may need to consider the acquisition of SAR (or QSAR) software as part of a hierarchal approach, where there are concerns that the notified chemicals may not have the same “pattern of activity” to the analogous assessed chemical (eg as a screening exercise to ensure that the notified and assessed chemical both have the same QSAR/SAR profile). Acquisition of SAR or QSAR software by NICNAS could be used as an additional (confirmatory) tool in analogue assessment. Cost of such software is in the order of up to \$100,000. Considerable resources may be required in the development of scientific criteria to be used in Tier 1 analogue assessment.

Option 2 – Analogue Assessment

Industry

Reduced assessment timeframes and fees in comparison to a standard notification.
Reduced cost of notification package due to reduced toxicological/ecotoxicological testing

Community, workers and the environment

Though these chemicals may have an analogy to chemicals already being imported, produced and used in Australia, NICNAS may request additional information on uses of the chemical and public exposure. This will ensure the ongoing protection of the public health.

NICNAS

The determination the suitability of a chemical for analogue assessment will require a combined high level of chemical and toxicological expertise. NICNAS will need to ensure the acquisition and development of staff so that intellectual resources are maintained.

Overseas counterparts such as the US EPA use data generated by SAR software in the pre manufacture process. NICNAS may need to consider the acquisition of SAR (or QSAR) software as part of a hierarchal approach, where there are concerns that the notified chemicals may not have the same “pattern of activity” to the analogous assessed chemical (eg as a screening exercise to ensure that the notified and assessed chemical both have the same QSAR/SAR profile). Acquisition of SAR or QSAR software by NICNAS could be used as an additional (confirmatory) tool in analogue assessment. Cost of such software is in the order of up to \$100,000.

Option 3 – Extensions of Assessment Certificates for Inseparable Analogue Mixtures

Industry

Reduced assessment timeframes and fees in comparison to a standard notification

Community, workers and the environment

As these chemicals will have an analogy to chemicals already being imported, produced and used in Australia, no additional impact is anticipated.

NICNAS

Appropriate use of assessment resources based on activity based costing model.

Conclusion & Preferred Option

The option allowing for minimum regulatory input would be in developing criteria that provide a reduced (minimum) test package for defined analogues – Tier 1 Analogue

Assessment. However, developing such criteria may prove difficult, and may not provide the level of robustness required to adequately deal with a variety of analogue chemical scenarios. Nevertheless, in the meantime, this should not prevent implementation of changes to current practices which could reduce the level of regulatory input in the assessment of chemicals analogous to previously assessed chemicals such as Tier 2 Analogue Assessment by NICNAS. In the absence of a defined reduced test package NICNAS could still evaluate available analogue data and determine what toxicity tests (if any) are initially required. It should be noted, that the results of these requested tests would determine whether further testing is required. Regardless of the amount of analogue data available there will always be a level of uncertainty associated with a chemical on which a complete suite of toxicological tests have not been performed. A conservative approach to assessment of analogue chemicals is necessary to minimise these risks.

The systematic evaluation of analogue chemicals and the documentation of decisions made concerning analogue notifications would ensure consistency regardless of the type of analogue or situation. Decisions made and knowledge gained from Tier 2 assessments could be used in the development and refinement of Tier 1 Analogue Assessment criteria, which could be implemented in the future.

The application of a case-by-case option should not exclude the future development of other options. Once established on a case-by-case basis, analogue chemicals would then be subject to modular assessment which would significantly reduce notification costs, reduced data preparation costs and reduce the timeframe for assessments and permits. The changes are expected to have widespread benefits to a high proportion of NICNAS notifiers (ie.>30%) and could result in a high costs savings. Exact figures cannot be quantified at this time.

Other Alternative Pathways for LRCC

Background

NICNAS currently allows situations where new industrial chemicals are exempt from notification and assessment. Other Alternative Pathways for LRCC identifies low risk situations for the introduction of new industrial chemicals under exemption or by administrative processes that are not effectively covered by the other Options for Change identified in this document.

Problem

Certain situations for the introduction and use of new industrial chemicals do not achieve a balance between notification and assessment requirements under the Act and the anticipated low risk of introduction and handling of chemicals in such situations in Australia. These situations can be clearly defined. There is a need to redress the balance between regulatory input and risk for these defined situations to better utilise regulatory resources.

Four situations have been identified with scope for redressing the current regulatory resource imbalance.

These are:

a) Research, Development and Analysis Chemicals

New chemicals introduced for research, development and analysis purposes in quantities exceeding 50kg/12 months currently need to be notified and assessed by NICNAS for an assessment certificate or permit. There is little information available as to the value of the current volume limit for introduction. The category is an exemption, so NICNAS cannot accumulate notification statistics. In addition, given NICNAS finite resources for compliance activities, to date this area has necessarily been given low priority. Some introducers would have knowledge of their obligations to notify chemicals under NICNAS, especially those conducting R, D & A projects within the traditional chemical industry. Other introducers supplying chemicals to education or research institutions for example may not see themselves as falling under the auspices of the Act. NICNAS has no readily available figures on how many R, D and A chemicals are notified, but at least some of the chemicals notified in the Commercial Evaluation Permit (CEP) system or Low Volume Chemical (LVC) permit category would be R, D & A chemicals that were to be introduced above the 50kg/12 month threshold.

b) Transhipment

That is, where chemicals are off loaded at an Australian port of entry and remain in containment in the country for a short period. These new chemicals fall within the scope of NICNAS. Irrespective of the length of time the chemicals are off loaded and the fact that the risk to workers, the public and the environment would be low (except for accidental release), the importer is responsible for compliance with ICNA. Unless the chemical qualified for an exemption, the importer would need to apply for a NICNAS assessment certificate or permit prior to introduction. NICNAS has no information on the extent to which transhipment of new

chemicals occurs, having received few if any notifications and not having pursued compliance activity in this area.

c) Exemption for Low Volume Non-Cosmetic Chemicals

There is a current exemption for introduction of new industrial chemicals for volumes not exceeding 10kg per 12 months, unless the introducer knows that the chemical is of unreasonable risk to occupational health and safety, public health or the environment. NICNAS has incomplete statistics on industry use of this exemption, because notice of introduction is not mandatory. In addition, given NICNAS finite resources for compliance activities, to date this area has necessarily been given low priority. Volumes greater than 10kg need to be notified and assessed by NICNAS for a permit or certificate. This can be restrictive and costly if proposed introduction volumes are higher than 10kg. Introdurers are then required to notify the new chemical even if they are confident that the chemical is not of unreasonable risk.

d) Repeated applications for Low Volume Chemical Permit and Commercial Evaluation Category Permit

Currently applicants need to provide a new notification package and assessment fee, including a new application for exempt information, to renew an existing permit, irrespective of whether or not there has been a change in circumstances relevant to the original NICNAS risk assessment and the Permit Conditions for safe use of the chemical. This demonstrates inequity between industry resources to re-apply and NICNAS resources to re-process an application similar to the original.

Objectives

The objectives are to define conditions that would enable more efficient introduction of new industrial chemicals in these clearly defined low risk situations, facilitate industry compliance with NICNAS, while maintaining regulatory standards for OHS, public and environmental risk determination.

Options

Research, Development and Analysis Chemicals

Option 1a – No change to existing ICNA provisions, ie. exemption from notification and assessment by NICNAS for introduction of up to and including 50kg/12 months.

Option 2a – Increase allowable introduction volume to 100kg/12 months for an individual introducer without notification and assessment by NICNAS. In addition, introducers would be required to keep records of quantities for a period of five (5) years, to be produced for NICNAS upon request. This option would require legislative change.

Options for either complete exemption or larger volume thresholds are not proposed.

Impact Analysis

Parties affected include industry, chemical users, the Government (NICNAS), human volunteers, and the community.

Option 1a – Maintains the existing situation. This assumes that the risks to workers in industry and educational and research institutes, and the environment are effectively controlled for the specialist use and low volume involved. The public at large would not be exposed to R, D & A chemicals, with the exception of volunteers involved in human trials regulated by ethics committees. R, D & A introductions are unlikely to attract substantial NICNAS compliance investigations. While it is not known how many chemicals introduced for R, D & A successfully fall within the exemption, or how many introducers fail to notify if threshold is exceeded, we can assume that some chemicals notified in the CEP or LVC category are R, D & A chemicals. To notify in the either category for 51-100kg/12 months represents a high cost for introducers, in comparison with any increase in risk likely to be associated with chemical volumes above the current low threshold.

Option 2a – increases the current introduction threshold to 100kg/12 months for an individual introducer and specifies that records of introduction are to be kept for five years for inspection by NICNAS upon request. The new threshold doubles introduction volumes under exemption from the current low base to an increased but still low level. The threshold is consistent with the R, D and A threshold currently in place in the European Union (noting that the EU chemicals regulation is under substantial review), and below that of Canada. The USA has a “not greater than necessary...” volume limit. By default the increased volume would increase industry compliance with ICNA. It would assist some introducers who would otherwise need to notify 51-100kg/12 months of low risk chemical through the CEP or LVC categories. The requirement for record keeping would make it easier for NICNAS to undertake targeted compliance investigations and reports on outcomes, since introducers would know to keep records and expect that NICNAS would ask to see them. There is little additional risk involved in doubling the R, D & A threshold to 100kg/12 months. The chemicals are generally contained in a controlled workplace, and the risks to workers in industry and educational and research institutes and environment are managed by the specialist and/or supervised use. In addition, the public at large would not be exposed to R, D & A chemicals. Human volunteers involved in research trials would operate under consent agreements.

Transshipment, ie. where chemicals are off loaded at an Australian port of entry for a short period

Option 1b – Status Quo. Unless covered by a current ICNA Act exemption, new industrial chemicals off-loaded from ships or planes are determined to be introduced and need to be notified and assessed by NICNAS.

Option 2b – Transshipment Exemption for new industrial chemicals off-loaded at an Australian port of entry for a period not exceeding thirty working days (or another as yet undetermined reasonable period) and where chemical is not processed in any way, including repackaging, prior to shipment from Australia. NICNAS would not need to receive a notice of introduction, or a notification and assessment package, and would not conduct a risk assessment.

Options for an exemption with no time limits, exemptions based on volume and/or time limits, or notice to NICNAS of transhipped chemicals are not proposed.

Impact Analysis

Parties affected include industry, transport and storage workers, the Government (NICNAS),

and the community.

Option 1b – Maintains the existing situation where importers responsibilities in this situation are not clearly defined within ICNA and the regulatory input for importers who do comply in notifying chemicals in this situation to NICNAS is not balanced by the risk to health and the environment posed by temporary introduction of chemicals retained in containers. Consequently, NICNAS currently receives very few if any notifications for chemicals in transit and NICNAS compliance activity is difficult to institute and is rarely if ever pursued. This option maintains the current impacts on industry, workers, the Government and the public. It is highly likely that industry is introducing new chemicals by transshipment without understanding that they need to comply with ICNA. Workers would be transporting and storing such chemicals under current regulations for transport, storage and handling of dangerous goods and control of workplace hazardous substances, the Government (ie. NICNAS) rarely if ever receives information on these chemicals, and the public is unaware of any impact.

Option 2b – seeks to regularise the regulatory environment under ICNA for new industrial chemicals in transshipment. It brings transshipment ICNA responsibilities to the attention of introducers, allows for short term introduction and re-export, noting that there are existing controls for labelling, transport, storage and handling of dangerous goods and workplace control of hazardous substances to deal with accidental release, and sets a boundary for the exemption timeframe, to overcome situations where chemicals may be left for long periods in storage. There is an impact on industry because ICNA will clearly state that NICNAS will need to be notified if the exemption timeframe is likely to be exceeded. There would be a positive impact on workers handling the chemicals because fewer chemicals should remain in long-term storage which involves an increasing risk of container damage or leakage and increased chance of a break in the chain of those responsible for the chemical (ie. changes in personnel, or company). The impact on Government is that NICNAS should expect an increase in notifications, though we have little information to gauge what this would be. The clearer industry responsibilities and timeframe for the exemption give a handle for NICNAS to commence basic compliance activity. There would be little direct public benefit in relation to exposure to off loaded chemicals. However there would be more information available on chemicals introduced to Australia through notifications and compliance activity.

Exemption for Low Volume Non-Cosmetic Chemicals

Option 1c – status quo under ICNA, where the current volume restriction for introduction of a new industrial non-cosmetic chemical under exemption is 10kg per 12 months.

Option 2c – to increase the volume allowable under the exemption for non-cosmetic chemicals to 100kg per 12 months, per individual introducer. The existing proviso for this category remains, namely that the introducer knows that the chemical does not pose an unreasonable risk to occupational health, public health or the environment. Include that introducers need to keep records of introduction and risk assessment for a period of five years, to be produced for NICNAS upon request. This option would require legislative change. The option is consistent with another new proposal to increase the allowable exemption volume for cosmetic chemicals to 100kg per 12 months.

Options for larger exemption volumes are not proposed.

Impact Analysis

Parties affected include industry, the Government (NICNAS), and the community.

Option 1c – To retain the exemption for non-cosmetic chemicals at 10kg per 12 months, unless the introducer knows that the chemical is of unreasonable risk to occupational health and safety, public health or the environment. The main impact with maintaining the existing volume threshold is on industry, because companies are obliged to incur the costs of notifying in another NICNAS category for volumes greater than 10kg. The most common category would be the Low Volume Chemical (LVC) category. In 2001-02, NICNAS issued 44 LVC permits, accounting for a total of \$114,400 in assessment fees. At least some of these permits would have been for chemicals of not unreasonable risk at proposed introduction volumes. There is little impact on the Government because it is not mandatory for introducers to give notice of chemicals that fit within this exemption and consequently little regulatory resources are expended in regulation. There is little impact on the public because cosmetic chemicals are not included. Should the chemicals be used in other consumer or domestic products, the low volume (up to 10kg) implies that the products either have limited distribution, or that the end use concentration would be low in products distributed widely.

Option 2c – increase the allowable introduction threshold to 100kg per 12 months and specifies that records of introduction and risk assessment are to be kept for five years for inspection by NICNAS upon request. There would be a positive impact on industry for chemicals known not to pose an unreasonable risk, because volumes from 10-100kg would not need to be notified and assessed by NICNAS. Previously these would have most likely been notified in the LVC category. The change would place a higher responsibility on NICNAS to confirm that introducers know the risk to workers, the public and the environment of the chemicals being introduced under exemption, and are effectively managing that risk. The requirement for industry record keeping would make it easier for NICNAS to conduct targeted compliance investigations and report on outcomes. There would be some community impact because the NICNAS risk assessment process currently conducted on chemicals introduced at volumes between 10 and 100kg would not take place. The impact would depend on the balance of industry assessment of risk and NICNAS compliance activity.

Repeated applications for Low Volume Chemical Permit and Commercial Evaluation Category Permit

Option 1d – status quo under ICNA, to require a new application package plus full fee to re-assess and process renewed applications for LVC permits and CEP. This is an anomaly when the re-application contains no new information relevant to the original risk assessment done by NICNAS and the existing permit conditions set by NICNAS

Option 2d – To institute a simplified, administrative process at NICNAS to deal with application for renewal for LVC permits and CEP. The simplified process would only apply if the applicant had not received any information indicating a change to the original risk assessment done by NICNAS and the existing permit conditions set by NICNAS.

Impact Analysis

Option 1d – maintains an inequitable situation. The anomaly has an adverse impact on industry resources needed to compile re-applications and pay another assessment fee. The

anomaly is of benefit for NICNAS in that fewer resources are needed to assess the re-application, as the same fee is provided. The anomaly is of no public benefit, because the original risk assessment and permit conditions remain relevant to the reapplication.

Option 2d – introduces a new administrative process. It would benefit industry because renewals would be faster and justify a lower NICNAS fee. If the circumstances have not changed, there would be no adverse impact on workers, the public or the environment. It is noted that this assumes the facility to use the quicker and cheaper administrative route does not act as a disincentive for applicants to provide new and relevant information at the time of re-application. Government (NICNAS) would benefit because an efficient administrative process would replace an assessment process. .

Data from NICNAS records indicate to date that 5% (31/616) of CEP applications and 14% (74/534) of LVC applications are renewals. This corresponds to a cost in assessment fees of \$273,000. This sum does not reflect the total cost to industry of renewals because it does not take into account industry resources in compiling applications, repeated applications for exempt information, or increased costs for introducers who opted to apply for an assessment certificate from the start, rather than a series of permits.

Conclusion and Preferred Options

The LRCC Task Force noted that in certain situations for the introduction and use of new industrial chemicals a balance between notification and assessment requirements under the Act and the anticipated low risk of introduction and handling of chemicals in such situations in Australia is not achieved. These situations can be clearly defined. There is a need to redress the imbalance between regulatory input and risk for these defined situations to better utilise regulatory resources.

Taking into account the views on the options from the public consultation, the focus groups and the views of the LRCC Task Force, the following preferred options are recommended as follows:

a) Research, Development and Analysis Chemicals

Increase the current exemption for Research, Development and Analysis from 50 to 100kg/12months, with new record-keeping requirements for 5 years. This option will increase industry flexibility to introduce new chemicals for R&D without notification and assessment costs and will bring Australian exemptions in line with EU volumes. By aligning Australian volume requirements with those of comparable overseas schemes, Australian industry to be more competitive in a global marketplace.

b) Transshipment

Introduce a Transshipment Exemption for instances when chemicals are off-loaded at an Australian port of entry and remain in containment unopened for a short period (30 days) before reshipment out of Australia. NICNAS would not need to be notified of introduction or conduct a risk assessment. The exemption will clarify obligations for introducers of chemicals in transshipment.

c) Exemption for Low Volume Non-Cosmetic Chemicals

Introduce an exemption for low-hazardous chemicals for volumes up to 100kg. Records would be required to be kept for audit purposes with annual reporting to NICNAS. In addition there should be an increase the general exemption for low volume non-cosmetic chemicals in line with EU volumes, from 10kg to 100kg/12 months/introducer, maintain existing conditions

and introduce new requirements for record keeping for five years and an annual report to NICNAS. These options will increase industry flexibility to introduce small amounts of new non-cosmetic chemicals without notification and assessment costs. These exemptions bring Australia in line with EU volumes. By aligning Australian volume requirements with those of comparable overseas schemes, Australian industry to be more competitive in a global marketplace. Guidelines for “low hazardous” will need to be developed with the industry, community and relevant government agencies.

d) Repeated applications for Low Volume Chemical Permit and Commercial Evaluation Category Permit

Permit renewals for the current Commercial Evaluation Category and Limited Volume Chemical permits to be administrative rather than assessment processes unless new data is available or the conditions of introduction have significantly changed. These administrative changes will save industry time and money. Currently a permit renewal process entails resubmitting an application including a data package and paying the full permit fee, currently set at \$2,831. An administrative renewal will mean that industry will not be required to resubmit a data package unless in exceptional circumstances and a lesser fee of approximately \$200 to \$500 will apply.

Cosmetics and personal care products

Background

The cosmetics industry is global, characterised by companies marketing branded products across international boundaries. Despite its size, Australia only accounts for about 1.2% of worldwide sales of cosmetic products. By the very nature of the mix of companies and their product lines, this industry is an extremely competitive one, with a high level of innovation, high product turnover and market driven style changes. Many cosmetics are imported as fully formulated and packaged products. The cosmetics industry, because of its competitive nature takes measures to ensure product safety above regulatory requirements. Market reality ensures that an unsafe product would destroy a brand and have a significant detrimental impact on a company.

At present, the regulatory requirements for “cosmetic products” are identical to other classes of industrial chemicals, with the following exceptions:

- (a) <10kg per 12-month (for cosmetic use) NICNAS exemption category, where additional safeguards are specified (ie. the chemical is not introduced as a UV filter, colouring agent or preservative in a cosmetic product, is not banned or restricted for use in cosmetics in Europe and/or the USA, complies with relevant state/territory law, and if present in a mixture at >1% concentration it is safe for use by sensitive subpopulations, consistent with the anticipated pattern of consumer exposure).
- (b) full ingredient disclosure on cosmetic product labels, under the *Trade Practices Act 1974* (TPA); and
- (c) cosmetic products that make therapeutic claims are regulated by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989*.

Problem

There appears to be two fundamental problems facing the cosmetics industry in Australia, within the parameters of the low regulatory concern chemicals reform initiative:

1. When products are defined as therapeutic goods in Australia, contrary to a cosmetic in some other countries, the TGA may require additional assessment beyond that which would be required if the product were regulated as a cosmetic.
2. Industry argues that the lack of cosmetic ingredients available for use in Australia compared to overseas chemical inventories prevents the timely introduction of safe and acceptable cosmetics (that are in use overseas) into Australia.

Objectives

Within the context of the overall objective of the LRCC, the specific objective of the Cosmetics Project is to develop a framework and criteria for identification of chemicals in cosmetic/personal care products as low regulatory concern and clarify the cosmetic/therapeutic interface, to assist the efficient introduction of these chemicals whilst maintaining regulatory standards for occupational health and safety, public health and environmental risk determination.

The following aims were identified to meet the specific objective of the Cosmetics Project to:

1. Broadly align with international cosmetic product classifications and permissible international cosmetic ingredient lists to minimise Australian specific data generation and/or assessment;
2. Review cosmetic definitions locally and internationally and adopt one singular definition for Australia (across all agencies); and
3. Increase the efficiency of inclusion and therefore the number of ingredients on the Australian Inventory of Chemical Substances (AICS) eligible for inclusion in cosmetic products.

Options

In order to meet the specific objectives listed above, the following issues are identified. Options are presented for each issue.

a) Cosmetics Definition

At present two definitions exist within the Australian regulatory system:

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) defines a cosmetic as: “A product applied to a person’s body for the purpose of its cleansing or care, colouring it, influencing its smell, or otherwise changing its appearance or smell, without affecting its structure or functions.”

The *Trade Practices Consumer Product Information Standards (Cosmetics) Regulations (1991)* defines a cosmetic product as “A substance or preparation intended for placement in contact with any external part of the human body, including: the mucous membranes of the oral cavity; the teeth; with a view to: altering the odours of the body; or changing its appearance; or cleansing it; or maintaining it in good condition; or perfuming it; or protecting it.”

Options

Option 1a - Identify one singular definition. Adoption of a singular definition brings with it the following advantages:

- avoids confusion and therefore increases industry’s understanding and compliance with a single definition;
- the potential to align with international definitions, thereby minimising Australian specific data generation and/or assessment;
- the potential to include an indicative list of cosmetic products as guidance for stakeholders; and
- all the above whilst maintaining current health, safety and environmental standards.

In identifying a single definition, it is prudent to broadly align with international cosmetic product classifications to minimise Australian specific data generation and/or assessment. The European regulatory scheme for industrial chemicals (with the exception of polymers) is identified as the closest fit to the NICNAS scheme and the definition of a cosmetic in the Cosmetics Directive aligns with the definition in the TPA.

The Cosmetics Directive 76/768/EEC definition: “A cosmetic product shall mean any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth

and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.”

Impact Analysis

The parties that may be directly affected by redefining a cosmetic are; industry, and government, whilst a change may have an indirect effect on the public, workers and the environment.

Industry

At present, cosmetic products are labelled in accordance with the TPA and cosmetics ingredients are regulated according to the Act. Therefore, industry is required to maintain awareness of and comply with two definitions. The TPA also includes an indicative list of product categories that serves as guidance to introducers of cosmetic products. Industry familiarity with the definition in the TPA and its guidelines potentially reduces the cost of compliance should the definition in the TPA be adopted by NICNAS. This definition aligns very closely with the European definition of a cosmetic. Alignment of Australian product categories with international (European) cosmetic product categories potentially minimizes Australian specific data generation and/or assessment.

Government

Revision of the current definition in the Act will require one-off legislative amendment. A change in the NICNAS definition will not impact on the TPA and associated regulations. The criteria for classification of a product as a cosmetic or therapeutic, which is predominantly based on product claims, will not be affected by a change in the NICNAS definition.

Community, workers and the environment

Currently, full ingredient disclosure is required on all cosmetic product labels, enabling the user to be aware of the composition of a given product and avoid ingredients to which they may be sensitive. Adoption of the TPA definition will not change existing labelling requirements.

Revision of the definition under the NICNAS Act will not influence current occupational health and safety standards or labelling requirements as per the National Model Regulations for the Control of Workplace Hazardous Substances.

A change in the definition of a cosmetic will not affect the NICNAS assessment process, which includes an environmental assessment and recommendations for safe use, as appropriate.

b) The Cosmetic/Therapeutic Goods Interface

When products are defined as therapeutic goods in Australia, the TGA may require additional assessment beyond that which would be required if the product were regulated as a cosmetic. Industry identifies the following product categories (currently regulated as therapeutic goods) as candidates for regulation as cosmetics:

- antiperspirants;
- mass market anti-dandruff shampoos;
- moisturisers with SPF;

- antibacterial skin washes; and
- anti-acne cleansers.

At present, the above product categories are subject to varying levels of regulatory control by the TGA. See Appendix 3, Low Regulatory Concern Chemicals, Public Discussion Paper (May 2003) for more information on the current regulatory status of the above mentioned product categories.

Options

Option 1b - Re-classify certain product categories as cosmetics. Any re-classification of product categories would need to be undertaken in partnership with the TGA. Product categories may be considered (on a case by case basis, if necessary) for reclassification as cosmetics, bringing them under NICNAS regulation and aligned with international (European) cosmetic definitions.

The reclassification would:

- (a) be based on transparent criteria (yet to be developed);
- (b) align with international definitions (in particular the European definition); and
- (c) ensure that all ingredients that remain in exempt therapeutic products as well as in cosmetic products are regulated by NICNAS.

Option 2b - Retain Therapeutic Goods as currently designated, with TGA to assess Exempt Therapeutic Goods excipients. Currently, new excipients in exempt medicines, such as antiperspirants and anti-dandruff shampoos, are not assessed by the TGA. This option would ensure that all excipient ingredients in medicines are considered by the TGA.

Option 3b - Regulate to create an Australian Cosmetic Directive. To introduce a specific cosmetic directive based on the EU Cosmetics Directive, Australia could adopt positive and negative lists for approved or restricted ingredients from EU Annexes. Currently, the concept of the negative list (prohibition) is maintained in Australia through poisons scheduling, where products that contain scheduled ingredients are required to be labelled CAUTION or POISON, thereby rendering marketing as a cosmetic generally unacceptable.

Impact Analysis

Options 1b and 2b

These options relate to the interface between regulatory agencies that administer separate legislation, therefore they should be considered within the context of current regulation, both therapeutic goods and cosmetics. These options will need to be progressed via a process that involves relevant regulatory agencies and in consultation with stakeholders, prior to any further impact analysis.

Option 3b

Creation of a cosmetic directive specifically for Australia would require regulatory intervention, thereby it will have an impact on NICNAS. The implications of such a directive on the current Australian poisons scheduling process will need to be investigated. A directive has the potential to introduce a cost and time burden to industry and as such is not supported by industry.

c) Volume/Concentration limits for exemptions

Current exemption thresholds for cosmetics are based on annual volumes. The general exemption threshold under NICNAS is 10kg per 12 months. However, it is a requirement that chemicals for cosmetic use under this category require advice of introduction to NICNAS. The advice of introduction requires the notifier to submit a summary self-assessment of the human health and environmental effects of the chemical (to demonstrate the lack of unreasonable risk) and a declaration that the introduction complies with specified safeguards. This exemption category does not attract a fee. NICNAS categories do not include exemptions based on concentration thresholds, at present.

Under current arrangements:

- a) Advice of Introduction at <10kg per 12 month for Cosmetic Use Exemption is checked (not assessed) by NICNAS;
- b) The volume limits requiring “action” in Australia are lower than those currently operating in Europe (ie. no advice of introduction required for <10kg per 12 month chemicals);
- c) Multiple <10kg exemption notifications for the same chemical may be submitted by different companies. This has the potential to result in a cumulative volume greater than the national limit for a single chemical of 100kg under a Low Volume Chemical (LVC) permit;
- d) There is no recognition of safe use history overseas of ingredients introduced as formulated products.

Options

Option 1c - Alignment with current European notification thresholds. At present, the European Directive has its lowest level requirement beginning at 10kg to below 100kg. It has an exemption for volumes under 10kg per 12 months and base set notification requirements for volumes between 10 to 100kg. Under the proposed EU Strategy for Future Chemicals Policy, it is proposed that notification will not be required for volumes of up to 1000kg and registration with basic information (chemical identity, physicochemical data, toxicological and ecotoxicological data with testing generally limited to *in-vitro* methods, use, exposure, hazard classification, Safety Data Sheet, preliminary risk assessment and proposed risk management measures) between 1 and 10 tonnes.

Under NICNAS, no consideration is given to chemicals introduced at low concentrations in mixtures. Notifiers are required to calculate the cumulative volume of each chemical across the full range of products. This may be disproportionate to the level of risk posed by these chemicals.

It is proposed that NICNAS exemption and lower notification thresholds align with current EU thresholds as follows:

- exempt all cosmetic ingredients with annual volumes of 10kg per 12 months or less from notification; notifier to undertake risk assessment and (a) determine that the chemical does not pose an undue risk to human health and the environment; and (b) that it meets existing safeguards. Notifier to retain this information that will be subject to NICNAS compliance “spot-checks”.
- require notification for more than 10kg up to 100kg per 12 months with Advice of Introduction; similar to the current less than 10kg exemption notice with self-assessment statements, declaration of compliance with current safeguards and submission of product label and MSDS. An assessment will be undertaken by NICNAS and a permit issued as an outcome.

- introduce an Exemption “without advice” for chemicals introduced in mixtures at 1% or less, provided they are not determined to be hazardous substances as defined by the NOHSC *Approved Criteria for Classifying Hazardous Substances* (including updates expected to be released mid-2003 which will include appendices that provide guidance criteria for classification based on physiochemical properties and environmental effects). No volume threshold is proposed and the notifier is required to retain records that will be subject to compliance audits by NICNAS.

Impact Analysis

The parties that may be directly affected are industry, and government, whilst a change may have an indirect effect on the public, workers and the environment.

Industry

Alignment with current European thresholds for notification will reduce industry compliance costs yet retain the accountability of the notifier to ensure that the chemicals do not pose an unreasonable risk to human health and the environment. Record keeping requirements will remain unchanged from the present position. Introduction of an exemption category for non-hazardous chemicals introduced at low concentrations in mixtures is expected to significantly reduce the cost incurred by industry introducing new chemicals into Australia.

Government

One-off amendment to the Act and associated regulations will be required. NICNAS assessment resources will be utilised to check advice of introduction notices for chemicals introduced at higher volumes than at present. However, the reliance on NICNAS compliance activity will be increased thereby shifting NICNAS resources from assessment to compliance activities.

Community, workers and the environment

The current requirement for a self-assessment by the notifier to ensure that these chemicals do not pose an unreasonable risk to human health and the environment and that existing additional safeguards are complied with remain unchanged. Record keeping requirements will be retained and such records will be subject to NICNAS audit.

d) Up-to-date access to information on assessed chemicals

Currently, information on chemicals assessed by NICNAS is made available to stakeholders via several mechanisms. All new chemicals assessment reports for certificate applications are published on the NICNAS web site and available on request from NICNAS. Information on permits is made available through the monthly *Chemicals Gazette*. Chemicals introduced under exemption categories are not publicised, at present. The public section of the AICS is available on CD-Rom and searches may be requested of NICNAS. The confidential section of the inventory is not publicly available. Chemicals granted NICNAS assessment certificates are listed on the inventory five years after the certificate is issued. The list of chemicals awaiting AICS listing (ie. those within the 5-year period) is currently retained in-house at NICNAS.

Options

Option 1d - Improved access to information through on-line search facility.

Institute an online facility, which would be regularly updated by NICNAS that includes:

- a list of assessed chemicals (permits and certificates). The list could be similar to the current *Chemicals Gazette* entries for permit applications, with a link to the public report for certificate chemicals; and
- the search facility to include chemical names, trade name under which the notification was submitted to NICNAS (only), alternate names, CAS number, and INCI nomenclature.

This search facility will enable all stakeholders to access information on assessed chemicals that is currently available via separate mechanisms.

Impact Analysis

The parties that may be directly affected are; industry, government, the public and workers.

Industry

Overall, the amount of information on assessed chemicals in the public domain will remain unchanged, however, ease of access to this information will be increased. This will be of benefit to industry.

Government

NICNAS will incur the cost of setting up and maintaining the search facility on the web site. The change would be administrative in nature therefore, will not require legislative changes.

Community, workers and the environment

The amount of information on assessed chemicals in the public domain will remain unchanged, however, ease of access to this information will be increased.

Conclusion and Preferred Options

Taking into account the views on the options from the public consultations, the focus groups and the LRCC Task Force, the following the preferred options are recommended.

a) *Cosmetics Definition*

Amend the definition of cosmetics currently used in the Act to that used in the *Trade Practices Act 1974* thus improving consistency in the Government's regulatory approach to cosmetics. This aligns the Australian definition with European definition and should increase stakeholder understanding and compliance with a single Australian definition. The impact is likely to be widespread for a high proportion of NICNAS notifiers (ie. >30%).

b) *The Cosmetic/Therapeutic Goods Interface*

Recognising that negotiations are ongoing between industry and the Therapeutic Goods Administration (TGA), it is recommended that the Parliamentary Secretary asks NICNAS and TGA to examine the reform options for addressing the interface issues dealing with:

- antiperspirants,
- mass market anti-dandruff shampoos,
- moisturisers with SPF,
- antibacterial skin washes; and
- anti-acne skin cleansers.

A report on options should be provided to the Parliamentary Secretary by December 2003. Addressing the interface issues between the regulatory agencies, ie. NICNAS and the TGA

have the potential to streamline regulatory requirements and reduce industry compliance burden. However, further work will be undertaken to determine the best way to proceed.

c) Volume/Concentration limits for exemptions

Introduce audited self-assessment for all cosmetic ingredients with annual volumes of 10kg per 12 months or less with the notifier to undertake risk assessment and (a) determine that the chemical does not pose an undue risk to human health and the environment; and (b) that it meets existing safeguards. Notifier to retain this information that will be subject to NICNAS compliance audits and “spot-checks” and an annual report to NICNAS.

Safeguards for cosmetics will continue to include that the chemical must not be used in the cosmetic as:

- a preservative; or
- a colouring agent; or
- an ultraviolet filter;
- *the chemical must not be prohibited or restricted for use as a cosmetic, or for use in cosmetics in the EU or USA under cosmetic legislation;*
- the chemical must comply with all relevant federal/state/territory regulations; and
- if the chemical is present in the cosmetic at a concentration of 1% or more, it must be safe for use by high-risk groups consistent with its anticipated use pattern.

These two options will reduce overall industry compliance costs, provides an incentive to introduce low risk chemicals on the Australian market and introduces reduced assessment time frames for low volume chemicals. The impact is likely to be widespread fro NICNAS notifiers (ie. >30%) with significant savings in time and cost. It is not possible at this stage to quantify potential cost savings at this time.

d) Up-to-date access to information on assessed chemicals

An improved search facility will enable all stakeholders to access information on assessed chemicals that is currently available via separate mechanisms. It will reduce the compliance burden on industry as there will be efficient access to timely information and this will also improve public access to chemical safety information. This will have widespread impact on NICNAS notifiers (ie. >30%) and should result in time saving for industry.

Introduce mandatory registration of all chemical introducers

Problem

Currently NICNAS does not engage directly with the broadest chemical industry as its focus is on introducers of chemicals (importers and/or manufacturers). Consultations have indicated that these current arrangements may be better extended to cover all of the industry. For example, company registration may be extended to cover those introducers below the current threshold and/or some form of engagement with industry beyond the introducer, ie the supply chain may need to be formalised with NICNAS. Industry members also want the assurance that its reputation is not harmed by the actions of those businesses who fail to comply with current regulatory requirements and importantly those who may not comply with new approaches to assessment.

Objectives

To improve compliance and industry knowledge of NICNAS and to maintain public confidence in the Scheme.

Options

Option 1 – Status quo for company registration requirements with increased education and awareness raising campaigns targeted at those introducers currently falling below the \$500,000 registration threshold.

Option 2 – A requirement for all importers/manufacturers as defined under the NICNAS legislation to register with NICNAS. Those businesses under the \$500,000 threshold would not be required to pay a registration fee, but would be required to notify NICNAS that they are entities that are importing, distributing and/or manufacturing relevant industrial chemicals. Companies falling under the current threshold would still remain exempt from Company Registration fees, however given that NICNAS is a fully cost recovered Scheme, and annual administrative fee would need to be imposed to cover costs.

Impact Analysis

Option 1

Industry

No additional cost burden on industry, but education and awareness raising may not reach all of the industry. It is a requirement of the Act that all chemical introducers be reasonably aware of their legal requirements whether they are registered or not with NICNAS.

Government

Likelihood of increased awareness and compliance by small companies is limited. The objects of the legislation require chemical introducers whether they are registered or not, to protect worker safety, public health and maintain environmental standards.

Community

Confidence in the Scheme may suffer since assurances that public health and environmental standards and worker safety are met across the industry may not be met by all industry

participants.

Option 2

Industry

To introduce mandatory registration can increase the compliance costs of those small businesses currently exempt from Company Registration requirements under the Scheme. The number of small businesses estimated to be exempt stands at 5,700, based on Customs data for the 2000-01 registration year. The LRCC Task Force is of the view however, that the benefits will outweigh the costs in the longer term and note that the only financial cost is likely to be a small annual administrative fee (currently \$300). The advantages of this option is that NICNAS and the community will have better information about companies falling under the scope of the legislation and NICNAS will be able to target its information and education activities towards this sector.

Industry, and in particular, small business compliance will improve since companies will be more aware of their regulatory obligations because of the requirement to engage directly with the NICNAS. In moving to full cost recovery in 1997, a tiered approach to charges for Company Registration was introduced, exempting small business under the \$500,000 threshold. The exemption from Company Registration does not exempt introducers from regulatory requirements. However, this may have inadvertently happened and the threshold exemption may have unwittingly exposed small business to compliance action.

The Register of Industrial Chemicals Companies in Australia is a public list. The inclusion of all businesses dealing with industrial chemicals on this list could open up business opportunities for smaller companies as many larger companies source suppliers from the Register. In addition, mandatory registration with a national regulatory agency can enhance industry credibility along the supply chain as well as with the general public.

Government

Additional administrative burden will be off set by recouping costs from industry. NICNAS has an activity based costing model which reflects time taken to perform the task. Administrative costs have been calculated to be a minimal impost of \$300 per annum. Mandatory registration will assist state and territory government agencies wanting to target users of particular chemicals.

Community

Community confidence in the integrity of the Scheme will be maintained in the knowledge that full coverage of industry is engaged in the regulatory process.

Consultation

Industry submissions to the Public Discussion Paper overwhelmingly supported the proposal to introduce mandatory registration of all introducers of industrial chemicals. This proposal was also welcomed by States and Territories and the community also supported this at focus group consultations.

Conclusion and Preferred Option

Taking into account the views on the options from the public consultations, the focus groups and the views of the LRCC Task Force, the preferred option is to introduce mandatory registration of all chemical introducers. The impact would be widespread affecting a potential 5,700 small businesses at a potential cost of \$1.7M per annum.