

## **Low Regulatory Concern Chemicals (LRCC) Task Force** *Industry, Government and Community working together*

### ***Final Report and Recommendations for NICNAS Low Regulatory Concern Chemicals (LRCC) Reform Initiative***

<b>Executive Summary</b> .....	2
Recommendations.....	4
<b>Introduction</b> .....	10
<b>Background</b> .....	10
<b>Definition of LRCC</b> .....	11
<b>Consultation process</b> .....	12
<b>Summary of submissions</b> .....	13
<b>Findings and recommendations for LRCC reforms</b> .....	19
1. <i>Audited self-assessment</i> .....	21
2. <i>Modular assessment</i> .....	22
3. <i>Exemptions</i> .....	23
4. <i>Polymer regulation</i> .....	24
5. <i>Cosmetic chemicals regulation</i> .....	24
6. <i>Controlled use</i> .....	26
7. <i>Incentives for the introduction of new and safer technologies</i> .....	26
8. <i>International cooperation</i> .....	27
9. <i>Reducing the compliance burden</i> .....	28
10. <i>Safe use through compliance</i> .....	29
11. <i>Access to chemical safety information</i> .....	30
12. <i>Community participation</i> .....	30
<b>Implementation strategy</b> .....	31
<b>Attachments</b>	
1 List of LRCC Task Force members.....	33
2 List of submissions and TAG consultations .....	34

## Executive Summary

This is the final report of the Low Regulatory Concern Chemicals (LRCC) Task Force findings and recommendations for the LRCC reform initiative. The LRCC Task Force was charged to develop all recommendations in partnership with government, industry and the community. Hence extensive consultation has been undertaken.

Consultation was conducted in a variety of formats including: one on one meetings with NICNAS; focus groups; discussions with industry work groups; discussions with key community interest groups; NICNAS formal networks such as its Industry Government Consultative Committee (IGCC); the Memorandum of Understanding (MOU) Group for States and Territories; and NICNAS's Technical Advisory Group (TAG).

During the development of the reform options NICNAS and the LRCC Task Force met with over 90 companies, individuals and representatives of state and territory agencies and community groups including the ACTU and environmental groups.

Following the release of the *LRCC Public Discussion Paper – May 2003* comments were sought from 7 May to 6 June 2003. A total of 34 written submissions were received on or after the 6 June 2003.

The LRCC Task Force believes that the following recommendations offer an innovative approach to introduce flexibility into the current scheme. The LRCC reforms are not to be seen as a move towards deregulation of the industrial chemicals industry. Rather, it is focussed on regulatory efficiency and positive incentives to drive improvements in the safe and sustainable use of chemicals in Australia. The following recommendations reflect a balance between developing actions to reduce the compliance burden with actions to strengthen compliance, transparency and access to chemical safety information.

### Key Outcomes

A wide range of recommendations covering a number of elements within NICNAS have been identified. These recommendations can be broadly categorised into three areas: namely reforms that are:

- **new** innovative elements to the current scheme;
- **modifications to the existing scheme** to improve regulatory efficiency; and
- **consequential** to the above two categories and which are required to ensure the integrity of the regulatory process and an open and transparent system which maintains existing health and safety and environmental standards.

These are summarised briefly below.

## **NEW CONCEPTS / ELEMENTS**

### ***ASSESSMENT***

- Audited self-assessment against NICNAS criteria/guidelines
- Modular assessments
- Controlled/specified use

### ***EXEMPTIONS***

- Transshipment
- Export Only
- Non-hazardous Cosmetic Chemicals introduced in mixtures at concentrations of 1% or less.
- Non hazardous chemicals up to 100 kg

### ***STAKEHOLDER***

- Mandatory Company Registration for **all** chemical introducers
- Optional immediate AICS listing for industry
- Establish NICNAS community Consultative Forum

## **MODIFICATIONS/ IMPROVEMENTS**

### ***ASSESSMENT***

- Streamline CEC, LVC renewals (unless new data)
- increase bilateral agreements/foreign scheme recognition
- identify and clarify any cosmetic /drug interface issues

### ***EXEMPTIONS***

- increase general <10 kg exemption in volume for certain chemicals
- increase R&D volume

### ***DEFINITIONS***

- harmonise definition of cosmetic chemical
- clarify water extraction as it relates to naturally occurring chemicals

## **MAINTAINING CONFIDENCE IN THE SCHEME**

### ***STRENGTHEN COMPLIANCE PROGRAM:***

- audits, training, awareness raising, electronic tools and templates
- industry record keeping, annual reporting
- increased transparency through AICS
- increased penalties

### ***IMPROVED ACCESS TO CHEMICAL SAFETY INFORMATION:***

- consolidate on-line information to improve public and industry access
- with the Consultative Forum, explore options to expand NICNAS's public inquiry service to address aspects of community right-to-know

There are 12 key recommendations on LRCC:

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

Of these 12 key areas, many specific recommendations will require further development and consultation with all stakeholders to fully flesh out operational aspects.

Importantly, other recommendations such as audited self-assessment for polymers of low concern using existing criteria; aligning the cosmetic definition; the application of audited self assessment/modular assessment using the existing Early Introduction Permit (EIP) criteria as a basis for low risk/low hazard; compliance activities and industry training; the establishment of a community Consultative Forum; and improved access to chemical safety information are seen as priorities which can move forward quickly.

The overall success of delivering significant reform whilst maintaining, or improving health, safety and environmental standards is dependent upon implementation as a package. For example, compliance and information aspects are critical components of a number of recommendations and cannot be addressed in isolation. This will ensure that full community confidence is maintained in NICNAS and its operations while allowing industry to access the benefits of the reforms.

## **Recommendations**

### *Recommendation 1.1*

*NICNAS introduces a process of audited self-assessment for LRCC categories that involves:*

- *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.*

#### *Recommendation 1.2*

*Introduce an audited self-assessment permit for low hazard chemicals (introduced at low volumes 100-1000kg) against NICNAS criteria and/or guidelines developed by NICNAS, industry and the community. In addition, to align NICNAS's regulatory focus on areas of greatest risk, introduce audited self-assessment for low risk chemicals against NICNAS guidelines developed in consultation with industry and the community.*

#### *Recommendation 1.3*

*NICNAS enhance its compliance program to:*

- effectively audit the new self-assessment permits and certificates; and*
- have appropriate penalties to effectively deter non-compliance.*

#### *Recommendation 1.4*

*NICNAS facilitates industry compliance, including with audited self-assessment, by developing electronic tools and templates to assist with:*

- assessment, notification and permit applications;*
- tracking information for audited self-assessment processes; and*
- standardised application and reporting formats.*

#### *Recommendation 2.1*

*NICNAS introduces modular assessment fees for low-hazardous and/or low risk chemicals and targeted assessment for chemicals where controls are in place such as:*

- situations where an assessment has been undertaken by another Australian regulatory authority;*
- substances of known hazard for which risks are specified and controlled;*
- analogue chemicals;*
- substances for which an international assessment has been conducted; and/or*
- polymers of low regulatory concern for which a potential risk is determined during screening (i.e. from the audited self-assessment process).*

#### *Recommendation 3.1*

*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.*

#### *Recommendation 3.2*

*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.*

### *Recommendation 3.3*

*Introduce an Exemption “without advice” for imported cosmetic chemicals introduced in mixtures at 1% or less, provided they are not determined to be hazardous. No volume threshold is proposed and the notifier is required to retain records that will be subject to compliance audits by NICNAS and provide an annual report to NICNAS of chemicals introduced under this exemption. The current additional safeguards excluding cosmetic chemicals that are colorants, preservatives and/or an ultra violet filter will apply to this new category.*

### *Recommendation 3.4*

*Increase the current exemption for Research, Development and Analysis from 50 to 100kg/12months, with new record-keeping requirements for 5 years.*

### *Recommendation 3.5*

*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 5 years and an annual report to NICNAS.*

### *Recommendation 4.1*

*Introduce an audited self-assessment certificate against existing NICNAS guidelines for polymers of low concern.*

### *Recommendation 4.2*

*Introduce a low hazard permit for polymers of low volume (1000kg/yr per introducer) for 3 years. Low hazard criteria appropriate for polymers would need to be developed in consultation with industry and the community.*

### *Recommendation 4.3*

*Introduce audited self-assessment for low regulatory concern polymers (ie polymers which do not meet the existing PLC criteria). New NICNAS criteria will need to be developed with industry and community involvement.*

### *Recommendation 5.1*

*Introduce audited self-assessment for all cosmetic ingredients with annual volumes of 10 kg 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 Commonwealth/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.*

#### *Recommendation 5.2*

*Require advice of introduction for low hazardous chemicals for cosmetic use of more than 10 kg and up to 100 kg per 12 months; similar to the current less than 10 kg exemption notice with self-assessment statements, declaration of compliance with current safeguards and submission of product label and MSDS. An audited self-assessment will be undertaken and an advice issued by NICNAS as an outcome.*

#### *Recommendation 5.3*

*To 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.*

#### *Recommendation 5.4*

*Recognising that negotiations are ongoing between industry and the Therapeutic Goods Administration (TGA), the LRCC Task Force recommends 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.*

#### *Recommendation 6.1*

*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.*

#### *Recommendation 6.2*

*Examine the introduction of an Export Only Permit.*

#### *Recommendation 7.1*

*Introduce to the standard certificate assessment category of a new low-hazardous chemical sub-category with appropriate criteria and modular assessment fee.*

#### *Recommendation 7.2*

*Expand access to Early Introduction Permit system to include low hazard and/or low risk chemicals based on appropriately developed criteria.*

#### *Recommendation 7.3*

*Introduce a low hazard permit for chemicals of low volume. These chemicals would be introduced in low volumes, 1000kg/yr per introducer for 3 years.*

*Recommendation 8.1*

*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.*

*Recommendation 9.1*

*Permit renewals for the current CEC, LVC permits to be administrative rather than assessment processes (unless new data is available or the conditions of introduction have significantly changed).*

*Recommendation 9.2*

*Introduce an option for industry to nominate an assessed chemical for immediate inclusion on the AICS (rather than a five year certificate period).*

*Recommendation 9.3*

*Review the definition of naturally occurring substances particularly in relation to steam distillation extraction for essential oils.*

*Recommendation 10.1*

*NICNAS introduces mandatory company registration of all chemical introducers currently below the current \$500,000 threshold. An administrative fee only should apply.*

*Recommendation 10.2*

*The costs, benefits and practicality of a mandatory registration number for chemical introducers be further investigated.*

*Recommendation 10.3*

*NICNAS, industry and the community investigate opportunities and the feasibility of introducing effective co-regulatory approaches where appropriate in relation to industrial chemicals regulation.*

*Recommendation 11.1*

*NICNAS consolidates its on-line information to improve public and industry access to industrial chemicals information by, for example:*

- *publishing the AICS on the web;*
- *making all NICNAS assessment decisions accessible to the public on the web;*
- *seamlessly link all permit and assessment decisions;*
- *making information about the assessment of chemicals accessible and uniform and timely;*
- *improving linkages within the NICNAS site and to other relevant sites and/or government information;*
- *linking assessment reports to the Chemical Gazette; and*
- *making controlled use restrictions of chemical certificates publicly available.*

### *Recommendation 12.1*

*NICNAS improve community participation in NICNAS's decision making processes through the establishment of a community based Consultative Forum.*

### *Recommendation 12.2*

*NICNAS and the IGCC, in consultation with the newly established community Consultative Forum, explore options to expand NICNAS's public inquiry service to address aspects of community right to know by considering options such as:*

- *regulatory alerts based on national or international information and/or concerns;*
- *improved linkages on the web site to chemical safety assessments and information from competent sources*
- *focussed information on chemical safety assessments/data on consumer chemicals monitoring information;*
- *NICNAS to provide a process for community access to chemicals information on the Scifinder database;*
- *mandatory reporting to NICNAS by industry of what chemicals are in active use (e.g. the US EPA currently require industry to report to Government every four years on their chemical inventories);*
- *removal from or flagging on AICS, of obsolete and/or nationally banned chemicals; and*
- *annotation of the public AICS to other regulatory lists eg for hazardous substances, scheduled poisons and environmental release data.*

### *Recommendation 12.3*

*That the open and inclusive consultation model adopted for LRCC reform processes be used by NICNAS in future reform processes.*

Further the LRCC Task Force notes that:

- *The implementation process of the reform initiative remains a partnership approach between government, industry and the community.*
- *That in its public report on LRCC, NICNAS identifies those areas that require further development processes of consultation and consideration and identifies options:*
  - *reforms that can be implemented administratively;*
  - *reforms that will require a change to regulations;*
  - *reforms that will require a change to the Act; and*
  - *reforms or suggestions that require a further process of consultation and consideration.*
- *To ensure that the reform benefits are passed onto industry, NICNAS and industry develop training programs to assist in the uptake of, and the compliance with, the new changes arising from the reform process.*

## Introduction

In announcing the Government response to the Chemicals and Plastics Action Agenda, the Government committed itself to, amongst other things, reducing unnecessary regulation. In particular, the Government gave a commitment 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 agreed to consider and develop options for access to adequately assessed and/or tested chemicals presenting low regulatory concern.

This is the final report and recommendations of the Low Regulatory Concern Chemicals (LRCC) Task Force following seven months of collaborative effort on the part of government, industry and the community to introduce a new assessment approach into the existing assessment program of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for LRCC.

In implementing the Government response to the Chemicals and Plastics Action Agenda, both Government and industry have agreed that the following four principles apply:

- no “grand-fathering” or automatic listing of unassessed chemicals onto the Australian Inventory of Chemical Substances (AICS);
- cost-recovery is accepted Government policy;
- the new measures recognise the importance of regulation to protect occupational health and safety, public health and the environment but are aimed at reducing the compliance burden on industry; and
- industry recognises the need for a national approach to ecologically sustainable chemicals management and regulation.

## Background

The Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth, MP, announced the establishment of a Task Force to investigate the reform of the regulation of industrial chemicals of low regulatory concern on 19 November 2002. The LRCC Task Force, chaired by Dr Margaret Hartley, Director, NICNAS, was made up of individuals from government, industry and the community to oversee the LRCC initiative and provide expert input where needed (Attachment 1). 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.

Extensive consultation has been undertaken with the industry and community sectors including focus group discussions in Sydney, Melbourne and Brisbane. Advertisements seeking public comment on the *Low Regulatory Concern Chemicals Public Discussion Paper – May 2003* and its supplementary paper, *LRCC Draft Regulation Impact Assessments for Reform Options* were placed in the *Chemical Gazette* and *The Australian* on 6 May 2003 and the documents were placed on the NICNAS website on 7 May 2003. The Public Consultation period concluded on 30 May 2003, but at the request of industry was extended to close of business, 6 June 2003. NICNAS accepted all submissions including those lodged after 6 June 2003.

The LRCC Task Force is pleased to note that 34 submissions and comments were received. A list of submissions is at Attachment 2. In general, the submissions were highly supportive of the reform options presented in the Public Discussion Paper because of the benefits they would bring to industry through a more efficient and effective regulatory system:

*... a commendable job in proposing innovative and practical alternatives to the regulatory compliance of chemicals in Australia. ...The changes proposed can only improve business efficiency through a more streamlined approach.*

In particular, industry was highly complimentary of the way NICNAS undertook the consultation process:

*...NICNAS is to be commended for the consultative and open approach to the reform process and the manner in which the meeting recommendations were discussed and received.*

### **Is there a singular definition of low regulatory concern chemicals?**

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. The approach to date has been to identify case-by-case scenarios, which are then used to define or constitute a set of categories under the umbrella of “low regulatory concern” such as polymers of low concern (PLC) or early introduction permits for chemicals not classified as hazardous.

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. However, as will be identified in closer detail as the options are explored, a single definition of LRCC is not possible except in the most generic sense:

*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.*

In general, industry, government and the community have agreed that the LRCC reform initiative is aimed at introducing flexibility within the current notification, permit and 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.

Clear scientific rationale to adequately define acceptability criteria and guidelines will need to be developed to provide certainty and transparency to industry and the community. The introduction of new LRCC categories within the existing framework will optimise risk-resource allocation in the industrial chemicals assessment process.

## Consultation process

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 website 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.

A detailed draft options paper was provided to assist in the decision-making process to all the participants of the focus group consultations conducted in Sydney, Melbourne and Brisbane with industry and the community. 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.

Consultation provided an opportunity for all stakeholders to:

- comment on the definition of chemicals of low regulatory concern;
- identify problems or issues that may be addressed under chemicals of low regulatory concern;
- identify solutions to overcome the issues and problems and evaluate their strengths, weaknesses and impacts;
- suggest any additional work to improve the solutions; and
- suggest how solutions could be implemented.

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."

On 27 March 2003, TAG made available to NICNAS a Report and Recommendations arising from consultations held in 2002. Given the direct relevance of the report and a number of the recommendations, NICNAS incorporated into the discussion paper key

elements in relation to access to chemical safety information, community right to know issues and community consultation. The TAG consultation list is at Attachment 2.

## **Summary of 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 Commonwealth 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 its submission the Co-chair of the OECD New Chemicals Work Group noted that due to time constraints input had been limited to mainly industry members. However, the Chair believed that the comments provided were consistent with the mandate and objectives of the OECD Task Force.

The written submissions are consistent with the feedback given to the LRCC Task Force during its consultation processes, including the feedback provided by industry and community representatives at the eight focus group consultations.

### ***General comments***

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. 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.*

While there was overwhelming support from industry for the options presented in the Public Discussion Paper, it was recognised that positive benefits will only flow if implementation is undertaken effectively and in full consultation with industry. The general feeling is that the reforms will need to be implemented in a manner that leads to efficiencies, efficient risk-resource allocation and management and be based on 'sound science'. The reforms must also be consistent with the principles of regulatory best practice, reduce the compliance burden and must not restrict international trade. The majority of submissions indicated their willingness to work with NICNAS during the implementation phase, this included support not only from industry associations, but large and small businesses, government, worker and community representatives.

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.

### ***Specific comments***

#### *Treatment of low hazard and/or low risk chemicals*

There is strong support from industry for the proposals and concepts and the five category options for treatment of low hazard and/or low risk chemicals that provide for streamlining and efficiencies for NICNAS processes:

- *additional opportunities for Early Introduction;*
- *a simplified Low Volume Chemical Permit and Commercial Evaluation Category Permit for non-hazardous chemicals;*
- *LRCC Assessment Certificates - simplified assessment of non-hazardous chemicals and targeted assessment of chemicals where controls are in place; and*
- *a new category of LRCC Controlled Use Permit for defined situations (noting that NICNAS can set conditions for workplace use).*

Industry has offered strong support for involvement in the ongoing development of key criteria and guidelines to achieve the desired outcomes.

Industry, government and community submissions all raised issues around the definition of what may be considered to be low hazard and/or low risk chemicals and its relationship to the NOHSC Approved Criteria and the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS). Industry suggested that given the evolving status of these two developments, there may be a need for the following:

- decision on an interim definition; and
- finalisation of a definition once Australia’s consideration of GHS has been completed.

#### *Treatment of overseas assessment reports*

There was strong support for the acceptance of notifications and approvals from Australia's major trading partners, including those in North America, Japan and Europe. The extension of bilateral agreements is seen as a major step towards facilitating sharing of chemical assessment information between jurisdictions. Industry is highly supportive of the Australia-Canada Bilateral Agreement to date which includes:

- the signing of a formal agreement;
- comparison of notification data submitted to both schemes for selected chemicals;
- visits by NICNAS, Environment Canada (EC) and Health Canada (HC) to discuss at first-hand how the agencies work;
- identifying areas where agencies can build co-operation; and
- the similarities and gaps in their respective assessment processes.

Industry supports as the next step, drafting by NICNAS, EC and HC of specific notification guidelines that will assist industry in the preparation of data packages and facilitate the introduction of chemicals in both Australia and Canada.

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

There was overwhelming support from industry for the PLC and LRCP options. Streamlining polymer assessments is a high priority for industry. A number of industry submissions argued that all polymers should be exempt from assessment since they were of low risk and that this would be consistent with international practices. Worker representatives indicated the need for consultation on the development of guidelines and criteria.

#### *Modular assessments (eg analogue chemicals)*

There was overwhelming support from industry for modular assessments. From the responses to this section, there appears to have been some confusion on the part of industry in assuming that the options proposed in the Discussion Paper only referred to the treatment of analogues, whereas modular assessments were proposed for a suite of options. The following proposals were put forward by industry for inclusion under the modular assessment options:

- situations where an assessment has been undertaken by another Australian regulatory authority;
- substances of known hazard for which risks are specified and controlled;
- further clarification of substances for which an international assessment has been conducted. This may be under the current Transitional Arrangements or be as part of the process for acceptance of assessment outcomes under the OECD New Chemicals Taskforce work plan; and
- polymers of low regulatory concern for which a potential risk is determined during screening.

In addition, the OECD New Chemicals Task Force submission supports the continued development of concepts such as LRCP and analogue chemicals in conjunction with the OECD with a view to extending such concepts internationally.

While some submissions expressed concern about analogues in that detailed criteria will need to be developed, only one submission stated that the section on analogue chemicals should be removed from the LRCC process and regarded as a separate issue to be reviewed more thoroughly. Before a decision on the options for analogues can be made, "what constitutes an analogue" and what the "minimum data sets are", need to be defined. While the non-industry submissions gave in-principle support to

the concept of modular assessment, concerns were raised about the justification for the treatment of analogue chemicals in this way.

#### *Other alternative pathways for LRCC*

There was overwhelming support from industry for all options presented in this section as proposed:

- research, development and analysis chemicals – a small increase in the exemption from 50 to 100kg/12months, with a new record keeping requirements for 5 years;
- repeat applications for *Low Volume Chemical* and *Commercial Evaluation Permits*;
- transshipment exemption;
- increase in the general exemption for low volume non-cosmetic chemicals to 100kg/12months/introducer with existing conditions and a new requirement for record keeping for 5 years;
- intended for export only – proposed LRCC Controlled Use Permits and Certificates.

The OECD New Chemicals Work Group submission argued that the proposed R&D increases did not go far enough and that there should be no limitations on volume for this exemption category, noting trends in the USA and Canada in this area. There was some support from the industry for this view.

There was concern expressed that an export exemption could undermine Australia's reputation if it was thought that Australia was exporting unregulated chemicals to the rest of the world. Similarly, non-industry submissions expressed some reservations about the proposals.

#### *Cosmetics and personal care chemicals*

All the options proposed were supported by industry, including overwhelming support for the adoption of a single definition, with the preferred definition being that used in the *Trade Practices Act 1974* (TPA).

There was strong support for quick progress on the interface issues between cosmetics and therapeutic goods. In addition, it was suggested that, while the cosmetic/therapeutic goods interface has been identified as a priority, there are a number of other interfaces between Australian regulators that could also be improved.

The option for an Australian Directive did not receive universal support. While it was recognised that the idea had some merit, industry felt that the development of an Australian Directive was a longer-term reform goal.

There was overwhelming support from industry for the proposed volume/concentration limits for exemptions. In addition, the cosmetics industry supported the other LRCC options, as options such as the polymers and recognition of overseas assessments would also greatly assist this sector. Some concerns were raised in non-industry submissions about blanket increases and whether these would threaten existing health, safety and environmental standards.

#### *Compliance*

While there was no support for industry self-regulation, there was in-principle support given to co-regulation with the majority of submitters indicating further work should be undertaken to investigate the feasibility of a co-regulatory model. Concerns were

raised about possible cost shifting to industry under a co-regulatory approach. For this reason, it was suggested that full investigation of the costs and benefits which would arise to NICNAS, industry, and the community associated with a co-regulatory system was essential.

The process of audited self-assessment was recognised as an important development and is supported by industry. Industry has suggested that the process involves the following elements:

- 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; and
- NICNAS to conduct post-market audits to ensure robustness and integrity of the process.

Clear guidance and electronic tools to assist industry to comply were requested by industry. The OECD Work Group submission recognised that this was a particularly useful concept and should be recommended for further discussion within the OECD New Chemicals Task Force.

The concept of mandatory company registration for the industry sector was supported, but industry was divided on the need for a mandatory registration number. It was suggested that further work be undertaken to explore the feasibility of this proposal.

#### *Access to information*

This section was the most contentious of the sections in the Public Discussion Paper. While there was strong support for improved community consultation through the establishment of a community Consultative Forum, some industry felt such a forum should be representative of all stakeholders, including industry. Another proposal put forward was that NICNAS's Industry Government Consultative Committee (IGCC) be expanded to include community and worker representatives. An option for an interface and dialogue between the IGCC and the community Consultative Forum also exists.

Industry did not support any changes to the current confidentiality provisions. Many submitters stated that there should be no change to the current provisions and that if the AICS became annotated or there were other developments to improve public access to information, company confidentiality should be maintained. However, the idea that there be optional automatic AICS listing at the discretion of the company is supported by industry. Automatic AICS listing of all chemicals with confidentiality being provided by NICNAS only in exceptional circumstances is the preferred option put forward by one non-industry submission. In addition, the LRCC focus group consultations indicated that the industry was divided on this issue, while the community generally did not support confidential listing on the AICS. Access to the AICS online was welcomed, however the OECD Work Group argued that there should be no loss in confidentiality in doing so.

In general, the industry submissions supported the position:

*That, as a priority, given the importance of the issues of transparency and access to information, and the potential wide ranging ramifications to the entire NICNAS system (not just LRCC), a separate process be established to consider and make recommendations on stakeholder consensus positions.*

Annotating the inventory for those chemicals that had undergone audited self-assessed was not supported by industry as such annotation infers a “lesser standard” of regulatory oversight. However, annotation was supported by non-industry submissions and suggestions were put forward for the establishment of a process to remove chemicals deemed obsolete and/or banned from AICS.

### *Implementation*

Industry supported a speedy timeframe for the full development of proposals and implementation of the final agreed changes and sought assurances that the administrative and regulatory changes would be moved along quickly, followed as soon as possible by necessary changes to the Act and its regulations as appropriate.

A number of industry submissions stated that it is essential that the final outcome report and recommendations from the LRCC project clearly identify timeframes and processes for implementation as follows:

- reforms that can be implemented administratively;
- reforms that will require a change to regulations;
- reforms that will require a change to the Act; and
- reforms or suggestions that require a further process of consultation and consideration.

The timeframe for introduction of reforms also provides an important opportunity for both NICNAS and industry to participate in structured training and other implementation programs. Industry has identified training as a key element in:

- improving understanding of NICNAS requirements and processes;
- improving the quality of applications to NICNAS;
- assisting in improved communication between NICNAS and its clients, or persons who may be affected by NICNAS requirements, including those whose only dealings with NICNAS may be through company registration; and
- consolidating the image and perceptions of NICNAS as a respected and competent regulator.

Industry, the community and relevant government agencies have indicated willingness to engage in the ongoing reform program and to assist in the development of guidelines and criteria as well as in the implementation of the reforms. The LRCC Task Force welcomes the ongoing support for the reform processes. It is recognised by all parties that full consultation will need to occur as each recommendation is developed for implementation, to ensure that benefits flow onto industry through reduced compliance burden and costs whilst maintaining public health, worker safety and environmental standards. The OECD Work Group has indicated its willingness to work with the LRCC Task Force in the development of future legislation with a view to global harmonisation opportunities in the implementation of the LRCC options.

## Findings and recommendations for LRCC reforms

The LRCC Task Force believes that the following recommendations offer an innovative approach to introduce flexibility into the current scheme. The LRCC reforms are not to be seen as a move towards deregulation of the industrial chemicals industry. Rather, it is focussed on regulatory efficiency and positive incentives to drive improvement in the safe and sustainable use of chemicals in Australia. The following recommendations reflect a balance between actions to reduce the compliance burden with actions to strengthen compliance, transparency and access to chemical safety information.

### Key Outcomes

A wide range of recommendations covering a number of elements within NICNAS have been identified. These recommendations can be broadly categorised into three areas, namely reforms that are:

- **new** innovative elements to the current scheme;
- **modifications to the existing scheme** to improve regulatory efficiency; and
- **consequential** to the above two categories and which are required to ensure the integrity of the regulatory process and an open and transparent system which maintains existing health and safety and environmental standards.

The overall success of delivering significant reform whilst maintaining, or improving health, safety and environmental standards is dependant upon the implementation of these three elements as a package, not in isolation from each other. This will ensure continued full community confidence in NICNAS and its operations while allowing industry the benefits of the reforms. Throughout the review process, the LRCC Task Force was aware of the need to balance the needs of industry with those of government and the community.

The LRCC Task Force notes that the reforms themselves are consistent with international regulatory practices. The LRCC proposals also offer opportunities to stimulate greater international co-operation and harmonisation on chemical safety regulatory approaches, such as low regulatory concern polymers and analogue chemicals. Implementation of the proposed package will support harmonisation of the Australian notification and assessment scheme for new chemicals amongst comparable international schemes.

The LRCC Task Force makes these recommendations to Government, seeking in-principle support for further examination. In the development of each option prior to implementation, full consultation with industry and the community should occur, including the development of regulation impact analysis to take into account the costs and benefits for each recommendation.

These are detailed below.

## **NEW CONCEPTS / ELEMENTS**

### ***ASSESSMENT***

- Audited self assessment against NICNAS criteria/guidelines
- Modular assessments
- Controlled/specified use

### ***EXEMPTIONS***

- Transshipment
- Export Only
- Non-hazardous Cosmetic Chemicals introduced in mixtures at concentrations of 1% or less.
- Non hazardous chemicals up to 100 kg

### ***STAKEHOLDER***

- Mandatory Company Registration for **all** chemical introducers
- Optional immediate AICS listing for industry
- Establish NICNAS community Consultative Forum

## **MODIFICATIONS/ IMPROVEMENTS**

### ***ASSESSMENT***

- Streamline CEC, LVC renewals (unless new data)
- increase bilateral agreements/foreign scheme recognition
- identify and clarify any cosmetic /drug interface issues

### ***EXEMPTIONS***

- increase general <10 kg exemption in volume for certain chemicals
- increase R &D volume

### ***DEFINITIONS***

- harmonise definition of cosmetic chemical
- clarify water extraction as it relates to naturally occurring chemicals

## **MAINTAINING CONFIDENCE IN THE SCHEME**

### ***STRENGTHEN COMPLIANCE PROGRAM:***

- audits, training, awareness raising, electronic tools and templates
- industry record keeping, annual reporting
- increased transparency through AICS
- increased penalties

### ***IMPROVED ACCESS TO CHEMICAL SAFETY INFORMATION:***

- consolidate on-line information to improve public and industry access
- with the Consultative Forum, explore options to expand NICNAS's public inquiry service to address aspects of community right-to-know

## Recommendations

### *1 Audited self-assessment*

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.

#### *Recommendation 1.1*

*NICNAS introduces a process of audited self-assessment for LRCC categories that involves:*

- *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.*

#### *Recommendation 1.2*

*Introduce an audited self-assessment permit for low hazard chemicals (introduced at low volumes 100-1000kg) against NICNAS criteria and/or guidelines developed by NICNAS, industry and the community. In addition, to align NICNAS's regulatory focus on areas of greatest risk, introduce audited self-assessment for low risk chemicals against NICNAS guidelines developed in consultation with industry and the community.*

In introducing such a process, it needs to be recognised that audited self-assessment will only keep the public confidence if NICNAS has sufficient resources to undertake compliance and that the fines and penalties are strong enough to deter non-compliance.

### *Recommendation 1.3*

*NICNAS enhance its compliance program to:*

- *effectively audit the new self-assessment permits and certificates; and*
- *have appropriate penalties to effectively deter non-compliance.*

### *Recommendation 1.4*

*NICNAS facilitates industry compliance, including with audited self-assessment, by developing electronic tools and templates to assist with:*

- *assessment, notification and permit applications;*
- *tracking information for audited self-assessment processes; and*
- *standardised application and reporting formats.*

In enhancing NICNAS's compliance efforts, it is expected that NICNAS, States and Territories, industry, the unions and the community will work together to ensure that the most effective and efficient processes are put in place without undermining public confidence in the regulatory system.

## **2     *Modular assessment***

Under the current regulatory arrangements, NICNAS is unable to streamline its assessment processes to take account of information that may be available to form part of an assessment package or to specifically target assessments to areas of concern. For example, in many cases where the NICNAS electronic template is used by the notifier, the assessment of the submission is a modular process, with a reduced input of NICNAS resources in compiling the hazard and exposure assessment sections of the final report. It may be possible to take this into account under the LRCC modular assessment framework. NICNAS should explore streamlining its assessment processes and provide incentives for industry to provide assessment data.

### *Recommendation 2.1*

*NICNAS introduces modular assessment fees for low-hazardous and/or low risk chemicals and targeted assessment for chemicals where controls are in place such as:*

- *situations where an assessment has been undertaken by another Australian regulatory authority;*
- *substances of known hazard for which risks are specified and controlled;*
- *analogue chemicals;*
- *substances for which an international assessment has been conducted; and/or*
- *polymers of low regulatory concern for which a potential risk is determined during screening (i.e. from the audited self-assessment process).*

NICNAS, industry and technical experts from academia and the community will be required to work together in the development of criteria and guidelines for modular assessment with appropriate input from the community.

### 3 Exemptions

A number of new exemptions from NICNAS have been recommended as well as modifications to existing exemptions. The majority of exemptions will either streamline administrative processes thereby saving industry time and money, or align Australian volume requirements with those of comparable overseas schemes. Harmonisation with international schemes enables Australian industry to be more competitive in a global marketplace.

#### *Recommendation 3.1*

*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.*

#### *Recommendation 3.2*

*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.*

#### *Recommendation 3.3*

*Introduce an Exemption “without advice” for imported cosmetic chemicals introduced in mixtures at 1% or less, provided they are not determined to be hazardous. No volume threshold is proposed and the notifier is required to retain records that will be subject to compliance audits by NICNAS and provide an annual report to NICNAS of chemicals introduced under this exemption. The current additional safeguards excluding cosmetic chemicals that are colorants, preservatives and/or an ultra violet filter will apply to this new category.*

The LRCC Task Force notes 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.

While the OECD Work Group submission recommends that there be no volume restriction for research and development, the LRCC Task Force has noted that comparable schemes require data for unlimited volumes. To accept the OECD Work Group proposal would be to introduce additional requirements from which Australian industry is currently exempt. The proposal for unlimited volumes for research and development under certain circumstances is an area which can be evaluated in future harmonisation considerations.

Modifications to the existing research, development and analysis provisions are recommended to increase the efficiency of the current regulatory scheme, to reduce the regulatory burden on industry, to promote research and development in Australia, to promote international harmonisation, improve internal business efficiencies, to streamline cosmetic regulation and to increase business efficiencies.

#### *Recommendation 3.4*

*Increase the current exemption for Research, Development and Analysis from 50 to 100kg/12months, with new record-keeping requirements for 5 years.*

#### *Recommendation 3.5*

*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 5 years and an annual report to NICNAS.*

### **4 Polymer regulation**

A range of options were considered which make it more attractive for industry to introduce new low hazard polymer chemicals by streamlining regulatory requirements and allowing industry to self-assess against agreed NICNAS criteria for low hazard or for polymers of low concern (PLC). Certain polymers are exempt from notification and assessment in overseas regulatory schemes. Under NICNAS, all new polymers must be notified and assessed, although currently the scheme provides for an abbreviated assessment for synthetic PLCs. 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 therefore 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 assessment categories provided for in the current scheme. NICNAS experience with polymers confirms that criteria can be used to categorise and classify low concern substances. The Task Force supports fast tracking the assessment of polymers of low concern and encourages mechanisms to be developed to promote the introduction of low-hazardous/low regulatory concern polymers.

#### *Recommendation 4.1*

*Introduce an audited self-assessment certificate against existing NICNAS guidelines for polymers of low concern.*

#### *Recommendation 4.2*

*Introduce a low hazard permit for polymers of low volume (1000kg/yr per introducer) for 3 years. Low hazard criteria appropriate for polymers would need to be developed in consultation with industry and the community.*

#### *Recommendation 4.3*

*Introduce audited self-assessment for low regulatory concern polymers (ie polymers which do not meet the existing PLC criteria). New NICNAS criteria will need to be developed with industry and community involvement.*

### **5 Cosmetic chemicals regulation**

Differences in regulatory requirements between countries can be critical in the optimisation of global product lines and lack of harmonisation can be very costly and restrictive. The unique regulatory requirements for Australian cosmetic

chemicals regulation can limit access by Australian consumers to the latest products and technology enjoyed by consumers in Europe or America.

Many cosmetic products are imported as fully formulated and packed products that have a safe history of sales around the world. The cosmetic industry, because of its competitive nature takes responsible steps to ensure product safety. Industry has advised that an unsafe product would destroy a brand and have significant impact on a company. Regulation of cosmetic chemicals in Australia is one of the most stringent in the world. Further specific safeguards are in place for certain classes of cosmetic chemicals. However, there are areas of reform for which consumer safety can still be maintained whilst reducing some elements of regulatory requirements. The harmonisation of definition issues are to be encouraged.

#### *Recommendation 5.1*

*Introduce audited self-assessment for all cosmetic ingredients with annual volumes of 10 kg 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 Commonwealth/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.*

#### *Recommendation 5.2*

*Require advice of introduction for low hazardous chemicals for cosmetic use of more than 10 kg and up to 100 kg per 12 months; similar to the current less than 10 kg exemption notice with self-assessment statements, declaration of compliance with current safeguards and submission of product label and MSDS. An audited self-assessment will be undertaken and an advice issued by NICNAS as an outcome.*

#### *Recommendation 5.3*

*To 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.*

#### *Recommendation 5.4*

*Recognising that negotiations are ongoing between industry and the Therapeutic Goods Administration (TGA), the LRCC Task Force recommends 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.*

## **6      *Controlled Use***

To enable industry to meet niche market demands, introduce controlled use permits based on history of use, limited exposure and in controlled environments or other defined parameters. Controlled use permits would be required to be developed with NICNAS, industry and community consultation. Chemicals approved under these conditions would be subject to public reporting.

A Controlled Use Permit for chemicals intended for export only may facilitate export opportunities for Australian business. Whether NICNAS would need to be notified for permit assessment or whether this could be conducted under an audited self-assessment process by industry needs to be explored. A self-assessment would involve a risk assessment, establishment of good work practices, responsible disposal and compliance with all relevant chemicals regulations. Any potential workplace exposure could be assessed and controlled with audited self-assessment processes and current state regulatory requirements for OHS.

Controlled use permits/certificates would need to have conditional use disclosure as an annotation to the public AICS to ensure industry compliance and hence safe use.

### *Recommendation 6.1*

*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.*

### *Recommendation 6.2*

*Examine the introduction of an Export Only Permit.*

## **7      *Incentives for the introduction of new and safer technologies***

A number of new options were considered for low regulatory concern certificates in order to encourage industry to introduce new chemicals to Australia which are considered to be of a low or non-hazardous nature. The new concept for audited self-assessment provides new scope for assessment of certain low regulatory concern chemicals.

Under current legislation, chemicals that may be of higher hazard but are overall of 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 Early Introduction permit (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 where the introduction is in the national interest and is not a routine option for 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/or 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. This would facilitate the introduction of many low hazardous chemicals currently assessed under limited or standard assessments.

*Recommendation 7.1*

*Introduce to the standard certificate assessment category of a new low-hazardous chemical sub-category with appropriate criteria and modular assessment fee.*

*Recommendation 7.2*

*Expand access to Early Introduction Permit system to include low hazard and/or low risk chemicals based on appropriately developed criteria.*

*Recommendation 7.3*

*Introduce a low hazard permit for chemicals of low volume. These chemicals would be introduced in low volumes, 1000kg/yr per introducer for 3 years.*

## **8 International cooperation**

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. As indicated in the summary of the submissions, industry is keen for Australia to commence negotiations with a number of other countries.

The LRCC Task Force notes that the 18<sup>th</sup> meeting of NICNAS's Industry Government Consultative Committee (IGCC) in May 2003, agreed to establish a working team to review countries of similar regulatory standards to consider for a future bilateral arrangement to work on. Given that this process is already underway, the LRCC Task Force is of a view that to make any firm recommendations along the lines proposed by industry would duplicate existing processes. The LRCC Task Force has agreed that instead, it will refer to the IGCC working team, a number of recommendations arising from industry submissions calling for additional work in this area such as:

- That a goal of achieving high levels of efficiencies, reduction in duplication, and acceptance of notifications and approvals from Australia's major trading partners, including those in North America, Japan and Europe, be established and that further objectives and strategies be developed in partnership with industry.
- That NICNAS, Environment Canada and Health Canada draft specific notification guidelines that will assist industry in the preparation of data packages and facilitate the introduction of chemicals in both Australia and Canada.
- That NICNAS actively co-opts the participation of willing Australian companies to participate in a pilot program between Australia and Canada, to facilitate the process of sharing information between the regulatory authorities and implement agreed processes to preserve confidential business information.

Recognising that the industrial chemicals business is global, the international regulatory community is working towards global approaches to drive improved health, worker safety and environmental outcomes through the promotion of national and international business competitiveness.

*Recommendation 8.1*

*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.*

## **9 Reducing the compliance burden**

Streamlining administrative processes, where appropriate to reduce the compliance burden on industry can be an effective way to introduce regulatory efficiency into NICNAS without compromising existing standards. Introducing administrative procedures for permit renewals rather than subjecting these renewals to full assessments will save industry time and money.

Discussions around access to information raised a number of issues which will be addressed later in this report. However, one of the proposals to come out of the discussion around access to chemical safety information and AICS listing, was a new initiative proposed by industry for optional nomination for automatic listing of a chemical once it was assessed. Currently this option does not exist and a five-year certificate period applies before AICS listing. Administrative efficiencies to industry and NICNAS could be gained by changing the permit renewal system in some cases and providing industry with an option for automatic AICS listing.

*Recommendation 9.1*

*Permit renewals for the current CEC, LVC permits to be administrative rather than assessment processes (unless new data is available or the conditions of introduction have significantly changed).*

*Recommendation 9.2*

*Introduce an option for industry to nominate an assessed chemical for immediate inclusion on the AICS (rather than a five year certificate period).*

The NICNAS arrangements have a number of exclusions from notification, including naturally occurring chemicals. A naturally occurring chemical is defined as follows:

“An unprocessed chemical occurring in a natural environment, or a chemical occurring in a natural environment, being a substance that is extracted by manual, mechanical, or gravitational means, dissolution in water, flotation, or a process of heating for the sole purpose of removing uncombined water, without a change in chemical substance.”

The above definition does not provide certainty to the essential oils industry, as currently steam distillation is not included as a means of extraction of water. NICNAS makes case-by-case decisions on whether an essential oil is naturally occurring or not based on examination of the extraction processes. Further NICNAS does not define the term essential oil. Internationally there are definitions for essential oil as well as definitions for naturally occurring substances.

*Recommendation 9.3*

*Review the definition of naturally occurring substances particularly in relation to steam distillation extraction for essential oils.*

## **10 Safe use through compliance**

An effective compliance program must underpin NICNAS’s activities in order to maintain industry and public confidence in NICNAS and the LRCC reforms. 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 who may not comply with new approaches to assessment.

The LRCC Task Force notes that in their submissions, industry 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.

The LRCC Task Force recognises that mandatory registration can increase the compliance burden of those small businesses currently exempt from the Scheme. 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).

Opportunities exist to further reduce the regulatory compliance burden on industry through a co-regulatory approach. Many industry members already comply with voluntary codes of conduct, which in some cases can require higher standards than the current regulatory requirements. The LRCC Task Force is aware of public concerns that co-regulation can undermine public confidence in the industry as well as the regulatory scheme.

*Recommendation 10.1*

*NICNAS introduces mandatory company registration of all chemical introducers currently below the current \$500,000 threshold. An administrative fee only should apply.*

### *Recommendation 10.2*

*The costs, benefits and practicality of a mandatory registration number for chemical introducers be further investigated.*

### *Recommendation 10.3*

*NICNAS, industry and the community investigate opportunities and the feasibility of introducing effective co-regulatory approaches where appropriate in relation to industrial chemicals regulation.*

## **11 Access to chemical safety information**

Increasing responsibility on industry through a risk management approach to audited self-assessment, places an increased requirement by government and industry to provide improved transparency and hence access to timely and comprehensible information to the public. The LRCC Task Force noted that in the submissions there was support for improved access to information, particularly suggestions such as improved on-line services, the consolidation of assessment information for easier access, and improved search facilities of chemical safety information held by NICNAS.

The issues of confidentiality and AICS annotation were not supported by industry to the degree that the industry submissions indicated that the entire issue of access to information and transparency should be dealt with outside the LRCC process due to the wide-ranging ramifications to the entire NICNAS scheme (not just LRCC).

The LRCC Task Force is of the view that many of the options for improving access to information and options for community right to know put forward for consideration in the Public Discussion Paper have support from the community, worker and government sectors. Access to information is an essential element in maintaining community trust and maintaining a balance between the needs and views of the various sectors.

### *Recommendation 11.1*

*NICNAS consolidates its on-line information to improve public and industry access to industrial chemicals information by, for example:*

- *publishing the AICS on the web;*
- *making all NICNAS assessment decisions accessible to the public on the web;*
- *seamlessly link all permit and assessment decisions;*
- *making information about the assessment of chemicals accessible and uniform and timely;*
- *improving linkages within the NICNAS site and to other relevant sites and/or government information;*
- *linking assessment reports to the Chemical Gazette; and*
- *making controlled use restrictions of chemical certificates publicly available.*

## **12 Community participation**

NICNAS is a cost recovered agency receiving a small amount of financial support from the Government to support its compliance activities. While industry has a voice

in the operations of NICNAS through membership of NICNAS's IGCC, there is no community involvement in NICNAS apart from consultation processes on a needs basis. To address this imbalance and to provide an opportunity for the community to have input into NICNAS's decision-making processes the LRCC Task Force recommends:

*Recommendation 12.1*

*NICNAS improve community participation in NICNAS's decision making processes through the establishment of a community based Consultative Forum.*

*Recommendation 12.2*

*NICNAS and the IGCC, in consultation with the newly established community Consultative Forum, explore options to expand NICNAS's public inquiry service to address aspects of community right to know by considering options such as:*

- *regulatory alerts based on national or international information and/or concerns;*
- *improved linkages on the web site to chemical safety assessments and information from competent sources*
- *focused information on chemical safety assessments/data on consumer chemicals monitoring information;*
- *NICNAS to provide a process for community access to chemicals information on the Scifinder database;*
- *mandatory reporting to NICNAS by industry of what chemicals are in active use (e.g. the US EPA currently require industry to report to Government every four years on their chemical inventories);*
- *removal from or flagging on AICS, of obsolete and/or nationally banned chemicals; and*
- *annotation of the public AICS to other regulatory lists eg for hazardous substances, scheduled poisons and environmental release data.*

*Recommendation 12.3*

*That the open and inclusive consultation model adopted for LRCC reform processes be used by NICNAS in future reform processes.*

## **Implementation Strategy**

Effective implementation is crucial if real and timely benefits are to flow to industry from improvements in the regulatory system. Unintended consequences of positive action by either government or the industry can at times have the opposite effect and lead to increases rather than decreases in the compliance burden. Therefore, to achieve effective outcomes, the implementation phase must fully engage with all stakeholders to deliver the anticipated outcomes expressed by industry in their submissions in support of the LRCC reform options.

Failure to deliver can be a major set back to NICNAS's reputation and to those involved in the reform process. To ensure that work is progressed, an effective strategy must be implemented.

The LRCC Task Force notes that:

- *The implementation process of the reform initiative remains a partnership approach between government, industry and the community.*
- *That in its public report on LRCC, NICNAS identifies those areas that require further development processes of consultation and consideration and identifies options:*
  - *reforms that can be implemented administratively;*
  - *reforms that will require a change to regulations;*
  - *reforms that will require a change to the Act; and*
  - *reforms or suggestions that require a further process of consultation and consideration.*
- *To ensure that the reform benefits are passed onto industry, NICNAS and industry develop training programs to assist in the uptake of, and the compliance with, the new changes arising from the reform process.*

***LRCC Task Force Members***

Dr Margaret Hartley (Chair)	Director, NICNAS
Dr David Grantham	Senior Principal Advisor (Health) Division of Workplace Health and Safety, Queensland Government, representing the interests of the States and Territories
Professor Neil Gunningham	School of Resources, Environment and Society, Australian National University, representing the public interest
Ms Margaret Donnan	Manager Regulatory Affairs, Plastics and Chemicals Industries Association (PACIA), representing the interests of industry
Ms Sylvia Kidziak	Managing Director of SL Engineering, representing the interests of industry.
Mr Geoff MacAlpine	Technical Manager, Australian Consumer & Specialty Products Association (ACSPA), representing the interests of industry
Ms Laurel Wolfram	Secretary, Botany & Eastern Regional Environmental Protection, representing the public interest

**Secretariat**

Dusanka Sabic, Project Leader  
Megan Smith, Technical Advisor

## Attachment 2

### List of Submitters provided in response to *LRCC Public Discussion Paper – 30 May 2003*

1. Huntsman Corporation Australia
2. WorkSafe Western Australia, Department of Consumer and Employment Protection
3. ATOFINA (Australia) Pty Ltd
4. Avon Australia
5. Estee Lauder Companies Australia
6. Plastral Fidene Pty Ltd
7. Innoxia Pty Ltd
8. Unilever Australasia
9. 3M Australia Pty Ltd
10. Amway of Australia
11. Nowra Chemical Manufacturers Pty Ltd
12. Beiersdorf Australia Ltd
13. Wella Australia
14. Cosmetics, Fragrances & Toiletries Association
15. DuPont (Australia) Ltd
16. Workplace Health and Safety Queensland, Department of Industrial Relations on behalf of NICNAS, State and Territory MOU Group
17. Bayer Australia New Zealand
18. ONDEO-Nalco Australia Pty Ltd
19. SICPA Australia Pty Ltd
20. Plastics and Chemicals Industries Association (PACIA)
21. Clariant (Australia) Pty Ltd
22. OECD New Chemicals Task Force
23. Dow Chemical (Australia) Ltd
24. Commodity Resources Pty Ltd
25. Australian Consumer & Specialty Products Association (ACSPA)
26. Faculty of Applied Science, RMIT University
27. Ciba Specialty Chemicals Pty Ltd
28. BASF Australia & New Zealand
29. Australian Council of Trade Unions (ACTU)
30. New South Wales Environment Protection Authority (NSW EPA)
31. Akzo Nobel Chemicals Pty Ltd
32. Australian Paint Manufacturers' Federation Inc (APMF)
33. Queensland Cosmetic Laboratories
34. Rural Industries Research & Development Corporation (RIRDC)

**Technical Advisory Group (TAG) Members:** Professor Graham Johnston, Dr Mariann Lloyd-Smith, Professor Ian Rae and Mr Jim Smith.

**List of participants on TAG consultations on NICNAS guidelines and confidential listing on the AICS**

***Community Melbourne and Sydney August and October 2002***

ACTU  
Victorian Environment Defender's Office  
Altona Complex Neighbourhood Consultative Group  
PACIA Community Advisory Panel  
Haztech  
Mariette Touhey  
Shop Well  
EPA Victoria National Pollutant Inventory  
Secretary Botany & Eastern Region Environmental Protection Agency Inc (BEREPA)  
The Allen Consulting Group  
Ms Barb Eldershaw  
Environmental Health Technologies Mosman  
Manly Environment Centre  
Total Environment Centre  
Lead Advisory Group Phonenumber  
Greenpeace Australia  
La Perouse Community Group  
Written Submission Ms Trixie Whitmore

***Industry Melbourne and Sydney March and May 2002***

Infineum Australia Pty Ltd  
Clariant (Australia) Pty Ltd  
Huntsman Chemical Company  
PACIA  
Orica SHE Shared Service  
Rohm and Haas Australia Pty Ltd  
Betzdearborn Australia  
Nalco Australia  
Lubrizol International Inc  
3M Australia Pty Ltd  
Johnson Wax Professional Australia Pty Ltd  
DuPont (Australia) Ltd  
Asia Pacific Specialty Chemicals Limited  
Pacific Resins Pty Ltd